Implementation of Community-Based Lifestyle Programs for Individuals with Type 2 Diabetes Mellitus in Southwest and Central Virginia: Formative and Process Evaluation

Kristina Ashleigh Jiles

PhD Candidate

Dissertation to be submitted to the faculty of the Virginia Polytechnic Institute and State University in partial fulfillment of the requirements for the degree of

Doctor of Philosophy

In

Human Nutrition, Foods, and Exercise

Carlin Rafie, *chair*

Kathryn Hosig

Samantha Harden

Elena Serrano

Thomas Archibald

October 30, 2019

Blacksburg, VA

Keywords: Type 2 Diabetes Mellitus, Balanced Living with Diabetes, Lifelong Improvements through Fitness Together, Social Cognitive Theory, RE-AIM Framework, Retention

Implementation of Community-Based Lifestyle Programs for Individuals with Type 2 Diabetes Mellitus in Southwest and Central Virginia: Formative and Process Evaluation

Kristina Ashleigh Jiles

Academic Abstract

Type 2 Diabetes Mellitus (T2D) is a major public health issue. Diabetes prevalence is growing and is the 7th leading cause of death in the US. Virginia has a slightly higher prevalence than the national average. Community-based diabetes lifestyle management programs that include a physical activity component are effective at improving glycemic control and influencing lifestyle behavior changes among people with T2D. The Balanced Living with Diabetes (BLD) program uses an active learning approach to improve glycemic control and healthful lifestyles. The Lifelong Improvements through Fitness Together (LIFT) program uses behavioral strategies to improve functional fitness, participant engagement, and program adherence. Participant retention is a challenge for community-based program. Participants may start the program, but then fail to complete the program and/or adhere to program recommendations. Two pilot studies were conducted to evaluate strategies for increasing participant retention and improving outcomes. The first evaluated the implementation and impact of a retention plan implemented in BLD programs conducted from 2015-2017. There were more participants returned to the reunion class session prior the development of the retention plan. There were improvements in some health behavior and self-efficacy indicators in programs that used the retention materials, however, impacts on outcomes were mixed. Preliminary findings showed that the retention plan could be a tool for providing additional support to participants, however strategies for dissemination of the retention plan needs to be reevaluated. The second study evaluated the impact on participant engagement and program outcomes when the LIFT

program is incorporated with the BLD program. There was an increase in participant retention, self-efficacy and one health behavior for physical activity and health behaviors related to diet in BLD+LIFT programs. Extension Agents are willing to implement the BLD+LIFT programs, however, clarity of program logistics is needed prior to implementation. Extension Agents indicated that implementation of these programs in locations with older adults that have greater disability may not be the best locations. Having larger studies on the effect of incorporation of LIFT with the BLD with older adult populations that have fewer co-morbidities are needed to determine the impact of addition of the LIFT program with the BLD program on program outcomes.

Implementation of Community-Based Lifestyle Programs for Individuals with Type 2 Diabetes Mellitus in Southwest and Central Virginia: Formative and Process Evaluation

Kristina Ashleigh Jiles

General Audience Abstract

Type 2 Diabetes is a chronic disease in which the body does not use insulin as it should or does not produce enough insulin. The Centers for Disease Control and Prevention (CDC) indicates that the prevalence of diabetes was 23.1 million among US adults in 2015. The prevalence of diabetes in Virginia is slightly higher than the national average. Community-based diabetes lifestyle management programs that include a physical activity component are effective in improving glycemic control and influencing lifestyle behavior changes among people with T2D. The Balanced Living with Diabetes (BLD) program uses an active learning approach to influence better glycemic control and healthful lifestyles. The Lifelong Improvements through Fitness Together (LIFT) program uses behavioral strategies to improve functional fitness, participant engagement, and program adherence. The challenge with implementing community-based programs is retention. Participants may initially agree to participate in a program, but then fail to complete the program and/or follow program recommendations. Two pilot studies were conducted to evaluate strategies for increasing participant retention and program outcomes. The first evaluated the implementation and impact of a retention plan implemented in BLD programs conducted from 2015-2017. There were more participants returned prior to the development of the retention plan. There were improvements in some health behavior and self-efficacy indicators in programs that used the retention materials, however, impacts on outcomes were mixed. Findings showed that the retention plan could be a useful tool for providing additional support to participants, however distribution of the retention plan needs to be reevaluated. The second study evaluated the impact of program outcomes when the LIFT program is combined with the BLD

program. There was an increase in participants' self-confidence to perform physical activity and making changes in their diet in BLD+LIFT groups. Extension Agents were enthusiastic about conducting more BLD+LIFT programs, however, program procedures and the time commitment needs to be understood before doing so. Expanding the conduct of BLD programs that incorporate the LIFT program can be effective in improving glycemic control and increasing physical activity, however, working with organizations that service people that have diabetes with fewer health conditions that limit physical activity may be more effective.

Dedication

I would like to dedicate this dissertation to Dr. Kathryn Hosig for introducing me to the field of public health. She has challenged, supported, and encouraged me in ways that have made me a better public health professional. She has provided me with multiple opportunities to work on-site in various communities to help address health disparities. She is one of the most kind-hearted, thoughtful, and sincerest people one will ever meet. I hope to reflect a fraction of her dedication and commitment to the field of public health.

Acknowledgements

I would like to express my deepest appreciation to my advisor, Dr. Carlin Rafie, for accepting me as a doctoral student and providing support and guidance during my tenure at Virginia Tech. Thank you for pushing me to think more critically, write more thoughtfully, and communicate more effectively.

I'm extremely grateful to my committee members, Drs. Archibald, Harden, Hosig, and Serrano for their support and assistance. Even with varying perspectives, there has been a distinctive sense of cohesion among my committee members. I thank them for sharing their expertise and willingness to guide me through the complexities of my research.

I would like to extend my deepest gratitude to Dr. Eleanor Schlenker for her insights into the public health field, invaluable advice, support, and being a great travel companion anytime I needed assistance with the BLD program.

I must also thank the late Professor Susan Marmagas for her support and bubbly personality during my time in the Master of Public Health program. The one thing that stood out the most was that she knew about me before I ever met her.

I would like to thank Dr. Michelle Penn-Marshall, Vice President for Research and Associate Provost at Hampton University, also a graduate of Virginia Tech's Human Nutrition, Foods, and Exercise program, for encouraging me to pursue a doctoral degree. She has such a positive energy that is remarkable in keeping students motivated to achieve greatness.

Special thanks to Dr. Karen Eley Sanders, Associate Vice Provost for College Access at Virginia Tech, for providing advice and counsel in helping me to maneuver and attain success at a predominately white institution.

I gratefully acknowledge the assistance of Tiange (Jennifer) Wu, Sarah Rothstein, and Azin Pourkhalili during my research project and being great early morning travel companions.

I am extremely grateful to my parents for their unconditional love, moral support, and continuous encouragement to follow my dreams and to achieve academic success. I am thankful to my brother, who has always been an inspiration and motivation to me.

Many thanks to my family and friends for their continued support throughout my academic journey.

Table of Contents

List of Appendices

List of Tables

Study 1

Study 2

Attributions

Study 1

Dr. Kathy Hosig is an Associate Professor and the Director of the Center for Public Health, Practice, and Research in the Department of Population Health Sciences at Virginia Tech. She assisted in conceptualizing, reviewing, and editing the manuscript for content.

Dr. Carlin Rafie is an Assistant Professor and Extension Specialist in the Department of Human Nutrition, Foods and Exercise at Virginia Tech. She assisted in conceptualizing, reviewing, and editing the manuscript for content.

Dr. Eleanor Schlenker is a Professor Emeritus in the Department of Human Nutrition, Food, and Exercise at Virginia. She assisted in developing, reviewing, and editing of the retention plan guide and retention plan materials.

Study 2

Dr. Kathy Hosig assisted in conceptualizing the research project and reviewing and editing the manuscript for content.

Dr. Samantha M. Harden is an Assistant Professor and Exercise Extension Specialist in the Department of Human Nutrition, Foods and Exercise at Virginia Tech. She assisted in the conceptualization of the research project and editing of the study.

Dr. Carlin Rafie assisted in conceptualizing the research project and reviewing and editing the manuscript for content.

Chapter 1

Introduction

The Centers for Disease Control and Prevention (CDC) indicates that diabetes mellitus (DM) is a chronic disease in which the body does not use insulin as it should or does not produce enough insulin [1,2,4]. Type 1 diabetes (T1D) is an autoimmune disorder causing the body to stop producing insulin which leads to insulin deficiency and hypoglycemia [2,5]. About 5% of diagnosed individuals has T1D [2,5]. Type 2 diabetes mellitus (T2D) is when cells do not respond well to insulin causing insulin levels to increase higher than normal which is known as hyperinsulinemia [1,3,4,5]. T2D accounts for 90-95% of patients who have diagnosed diabetes. Symptoms for T2D can develop over years without being noticed which is why many adults live with undiagnosed diabetes [1,3,4,5]. Symptoms of T2D can include frequent urination, excessive thirst, fatigue, and distorted vision.[1,2,3] Diagnosis of T2D by a doctor or health care professional can be determined by one of the following blood tests: fasting plasma glucose (FPG) test, hemoglobin A1C (A1C), or oral glucose tolerance test (OGTT). The most common diagnostic tests are the FPG and A1C [1,3,4]. For T2D diagnosis, an A1C test must read a blood glucose level of 6.5% (140 mg/dL) or greater and an FPG test must read a blood glucose level of 126 mg/dL or greater [1,3,4]. The OGTT test, however, is time dependent as the test checks the blood sugar before two hours after drinking a drink with a standard amount of glucose. After two hours, a test must read a blood glucose level of 200 mg/dL or greater for a T2D diagnosis. It is recommended that a second test is conducted to confirm the accuracy of results.

Risk for developing T2D increases when individuals have prediabetes, hypertension, and hyperlipidemia [4,5,7]. Additionally, risks for developing T2D also increase when individuals

are overweight or obese, are not physical active, and have poor dietary habits [4,5,7]. Not only do behavioral and medical risk factors play a role in developing T2D, but also nonmodifiable risk factors such as genetics, age, and ethnicity [4,5,7]. Individuals that are older in age, have a close family member with diabetes, and are either, Hispanic or Latino, African American or Black, Alaskan Native, or an American Indian are more at risk for developing T2D [4,5,7]. Ultimately, when cells stop producing insulin (insulin deficiency) or when the cells do not respond well to insulin (insulin resistance), this causes the glucose to remain in the bloodstream causing health complications such as vision impairment or loss, cardiovascular disease, lower-limb amputations, cerebrovascular disease, and kidney disease overtime [4,5,7].

Healthy People (HP) 2020 aims to "achieve greater health equity and eliminate disparities to improve the health for all" [8]. Regarding diabetes, HP 2020 lists specific goals and objectives to alleviate this public health issue [8]. The top 5 objectives for diabetes include: 1) reducing the annual incidence of diabetes in the US, 2) reducing the death rate among persons with diabetes, 3) reducing the rate of lower extremity amputations in persons with diabetes, 4) improving glycemic control in persons with diabetes, and 5) improving lipid control in persons with diabetes [8]. These objectives indicate how effective systems for the prevention and management of the major chronic health conditions such as diabetes impacting the population are needed. Using community-based strategies to increase use of preventive services by the adult population through linking community and clinical settings will improve health, particularly of those not linked to a regular healthcare provider.

This dissertation describes two studies conducted to improve the effectiveness of a community-based diabetes lifestyle management program, Balanced Living with Diabetes, which are presented in the following pages. The first study evaluated the impact of a tailored

retention plan on participant retention and outcomes in a diabetes lifestyle management program. The second study evaluated the impact of incorporating a physical activity program with the diabetes lifestyle management program on program outcomes. The specific aims and hypotheses of the two studies are provided below:

Specific Aims for Study 1

1. To determine if program retention rates improve from baseline to three-month follow-up in Balanced Living with Diabetes (BLD) programs conducted with a retention plan compared to BLD programs without a retention plan.
2. To determine if program outcomes (glycemic control, weight reduction, self-reported physical activity, self-reported dietary behaviors) show greater improvement from baseline to reunion class session in BLD programs conducted with a retention plan compared to BLD programs without a retention plan.
3. To determine FCS Extension Agents' adoption, implementation fidelity, adaptations, barriers, and facilitators to use of the retention plan.

Specific Aims for Study 2

1. To compare the change in glycemic control, patient engagement, self-reported physical activity, and self-reported dietary behaviors among participants in the BLD program conducted with and without the Lifelong Improvements through Fitness Together (LIFT) physical activity program.
2. To evaluate the implementation of the BLD program (fidelity, inner context, barriers/challenges, time, and acceptability) by FCS Extension with and without the LIFT physical activity program.

Research hypotheses for Study 1

1. The implementation of a tailored retention plan by FCS Extension Agents is feasible and will increase retention rates among participants that receive the retention plan compared to participants that do not receive the retention plan.
2. The implementation of a tailored retention plan FCS Extension Agents will improve participant outcomes (glycemic control, self-reported physical activity, and self-reported dietary behaviors) among participants that receive the retention plan compared to participants that do not receive the retention plan.

Research hypotheses for Study 2

1. Participants in the BLD + LIFT will demonstrate significantly greater reduction in A1C level (%) compared to patients in BLD (standard program)
2. Participants in the BLD + LIFT will demonstrate significantly greater patient engagement compared to patients in BLD (standard program).
3. Participants in the BLD + LIFT will demonstrate significantly greater increases of weekly leisure activity compared to patients in BLD.
4. Participants in the BLD + LIFT will demonstrate significantly greater increases of self-reported physical activity and self-reported dietary behaviors.
5. FCS Extension Agents will have positive experiences with the implementation process of incorporating the LIFT program with the BLD program.

References

1. American Diabetes Association. (2015, October 27). *Facts about Type 2*. Retrieved from American Diabetes Association: http://www.diabetes.org/diabetes-basics/type-2/facts-about-type-2.html

2. American Diabetes Association. (2018). 2. Classification and Diagnosis of Diabetes: Standards of Medical Care in Diabetes—2018. *Diabetes Care*, 13-27.
3. American Diabetes Association. (2018). *Type 2.* Retrieved from American Diabetes Association: http://www.diabetes.org/diabetes-basics/type-2/
4. Centers for Disease Control and Prevention. (2017, June 1). *About Diabetes*. Retrieved from Centers for Disease Control and Prevention: https://www.cdc.gov/diabetes/basics/diabetes.html
5. Centers for Disease Control and Prevention. (2017). *National Diabetes Statistics Report*. Retrieved from Centers for Disease Control and Prevention: https://www.cdc.gov/diabetes/pdfs/data/statistics/national-diabetes-statistics-report.pdf
6. Centers for Disease Control and Prevention. (2018, August 15). *Type 1 Diabetes*. Retrieved from Centers for Disease Control and Prevention: https://www.cdc.gov/diabetes/basics/type1.html
7. Centers for Disease Control and Prevention. (2018, August 15). *Type 2 Diabetes*. Retrieved from Centers for Disease Control and Prevention: https://www.cdc.gov/diabetes/basics/type2.html
8. Healthy People 2020. (2018, November 6). *Diabetes*. Retrieved from Healthy People 2020: https://www.healthypeople.gov/2020/topics-objectives/topic/diabetes/objectives

Chapter 2

Background and Literature Review

Burden of Diabetes (US and Virginia)

Type 2 diabetes (T2D) is a major public health issue, being the 7th leading cause of death in 2015 [1]. According to the National Diabetes Statistics Report, produced by the CDC, the prevalence of diagnosed diabetes has been estimated to be 23.1 million (7.2%) among US adults [1,2,3]. In addition, it has been estimated that 86 million US adults have prediabetes [4]. Statistics indicate that the highest prevalence of diagnosed T2D was among American Indians and Alaskan Natives (15.1%) followed by African Americans or Blacks (12.7%) and Hispanics or Latinos (12.1%) compared to Caucasians/Whites (7.4%) and Asians (8.0%). However, of 30.3 (9.4%) million people who were over the age of 18 with diabetes, 7.2 million (23.8%) of US adults were undiagnosed with diabetes [12,18,19 The incidence of adult diabetes increased to 1.5 million annually [5]. Statistics indicate that incidence was higher among adults between the ages of 45 and 64, and that age-adjusted incidence was higher among African Americans or Blacks and Hispanics or Latinos compared to Caucasians/Whites from 2013-2015 [1,5].

The prevalence of diabetes in Virginia is slightly higher than the national average (9.6% vs. 8.1%) in 2015, according to the American Diabetes Association (ADA) [6]. Recently, it has been estimated that approximately 837,000 (12.2%) residents in Virginia have diabetes according to the ADA [6]. The Diabetes Burden Report, produced by the Virginia Department of Health (VDH), indicates that the prevalence of diabetes in Virginia varies by socio-demographics [7,8]. Women tend to have higher rates of diabetes than men (9.8% vs. 9.6%) and African Americans/Blacks are more likely to have diabetes in Virginia (15.4%) compared to Hispanics/Latinos (5.4%) and Caucasians/Whites (9.1%) [7,8]. Those that live in eastern or

southern areas of Virginia tend to have higher rates of diabetes also [7,8]. Moreover, other social determinants such as having a lower socio-economic status and lower education level (less than a high school diploma) is associated with a higher prevalence of diabetes [7,8].

The ADA and CDC have estimated that direct and indirect costs related to diabetes were approximately $245 billion in 2012 and have increased to $327 billion in 2017 [9,10]. Medical expenditures averaged roughly $13,700 annually for individuals who were diagnosed with diabetes [9,10]. In 2014, there have been a total of 7.2 million hospital discharges due to diagnosis of diabetes among adults in the US [1]. Most hospital discharge complications consisted of cardiovascular diseases such as ischemic heart disease and stroke (1.5 million), lower limb amputations ($108,000) and diabetic ketoacidosis ($168,000) [1]. Costs due to diabetes and prediabetes, estimated by the ADA, were approximately $8.2 billion in Virginia in 2012 [6]. Over $6 billion were direct costs and $2 billion were indirect costs [6]. More recently, the costs due to diabetes in Virginia increased to $11 billion in 2013 [6]. Approximately $4.6 billion were direct costs and $6.4 billion were indirect costs according to the Virginia Department of Health in 2013 (VDH) [7,8]. Virginia residents spent an average of $15,000 annually in medical expenses attributed to diabetes in 2013. According to VDH, medical expenses among individuals that have diabetes are three times higher than those who do not have diabetes [7,8].

Statistics from the CDC indicate that some diabetes risk factors among Virginia residents were slightly higher than the US such as physical inactivity (40.3% vs. 36.4%), hypertension (65.1% vs. 59%), and smoking (21.6% vs. 20.8%) [11]. Commonly reported hospitalizations due to diabetes-associated complications in Virginia due to poor glycemic control consisted of diabetic ketoacidosis (16.1 per 1,000), congestive heart failure (10.5 per 1,000), cerebrovascular

disease (stroke) (7.0 per 1,000), myocardial infarction (6.1 per 1,000), lower extremity amputations (3.8 per 1,000), hypoglycemia (2.2 per 1,000), and hyperosmolar hyperglycemic nonketotic syndrome (1.6 per 1,000) [11]. Adults with diabetes who can control and sustain glucose levels close to normal levels will have reduced hospitalizations and medical costs [6,11]. The Diabetes Control and Complications Trial (DCCT) indicated that well controlled blood glucose levels in individuals with diabetes would lead to a reduction of end-stage renal disease (87%) and lower-extremity amputations (67%) [12,13]. The quality of life of Virginia residents is impacted among those who have diabetes and associated complications [7,8]. According to VDH, there have been approximately 2,000 deaths due to diabetes in Virginia since 2015 [7,8]. This suggests that death rates are three times higher than those without diabetes [7,8]. Healthy People 2020 indicates that complications due to diabetes are most common and severe among individuals whose diabetes is poorly controlled [14]. This makes diabetes an immense public health challenge [14].

Burden of Diabetes in Rural Communities

According to the Rural Healthy People (RHP) 2020 survey, diabetes was the second highest ranking health issue in rural communities after nutrition and weight status, and heart disease and stroke [15]. Access to quality health services was ranked the highest health issue and was correlated to increased rates of diabetes [15]. Self-reported diabetes among adults was 17% higher in rural communities (9%) compared to those living in more metropolitan or urban areas (7.7%) [15,16,17]. Diabetes rates in rural areas were highest among African American/Black residents and women [16,17]. In addition, residents living in rural areas reported lower educational attainment, lack of healthcare insurance, not seeing a physician due to increased medical costs, lack of access to healthcare facilities, and lack of engagement in diabetes self-

management (DSME) programs compared to those living in more urban areas [15,16]. Moreover, though there was no difference in insulin dependence among rural and urban residents, rural residents tended to be more overweight/obese (85.5%) and fewer reported good to excellent health (49.5%) compared to urban residents (83.4% and 53.5% respectively) [15,16]. It is imperative that increased efforts toward preventative and supportive care are made to improve diabetes care and self-management among residents living in rural areas and other health disparate populations so that health outcomes are improved [15,16].

Diabetes Self-Management Education (DSME) Programs

DSME programs have been developed to assist patients with actively managing their diabetes care [18-22]. Goals of the DSME programs are to change lifestyle behaviors, improve and control glycemic levels, and to prevent complications [18-22]. Similarly, community-based diabetes education programs are essential to helping people with type 2 diabetes better manage their diabetes to improve their glycemic control, however, community-based diabetes education programs are intended to promote behavioral lifestyle changes such as increasing physical activity and improving dietary behaviors [23-28].

Participant Retention in Diabetes Self-Management (DSME) Programs

A key component of DSME programs is the ongoing communication and assistance between the participants and those that are delivering DSME programs to assure consistent diabetes care by the participant [18-22]. High participation rates in DSME have been a challenge, as participants may initially agree to attend and participate in program sessions but then fail to adhere to the program by missing assigned sessions or may attend sessions sporadically [18-22]. Participants that drop out of DSME programs not only fail to adhere to recommended diabetes management activities, but also have poorer glycemic control, more diabetes-related

complications, and poorer health outcomes compared to those that continue with the program [18-22]. DSME programs have a small number of sessions and participants that fail to attend even a single session are unlikely to grasp the research knowledge and obtain the tools necessary for self-management and care of their diabetes [18-22]. There are studies that indicate, however, that greater engagement between educator and patient improves glycemic control [18-22].

It is important to identify strategies that increase patient engagement in health promotion programs [29,30]. Chambers and Norton describe the Adaptome, which evaluates adaptations made to an intervention or program to determine if the impact of the adaptations made will lead to better outcomes or will lead to program drift, hindering the effectiveness of the intervention or program [31]. The Adaptome evaluates several sources of intervention adaptations which include: 1) service setting, 2) target audience, 3) mode of delivery, 4) cultural adaptations, and 5) core components [31]. The idea of the Adaptome aligns with the Dynamic Sustainability Framework in which there will always be adaptions made to an intervention or program, creating different versions of the intervention or program overtime [31]. These adaptations will help to identify which version of the intervention or program is most appropriate for a certain population and whether the adaptations of an intervention or program benefits or hinders the population that receives it [31]. This is in-turn will lead to changes being made to the implementation process of an intervention or program in the future [31]. Unfortunately, adaptations made to an intervention or program are rarely evaluated [30].

Physical Activity Recommendations and Programs for Older Adults

The CDC indicates that adults and older adults ($\geq$ 65 years of age) should maintain regular should maintain regular physical activity for optimal health [32-36]. The 2nd edition Physical Activity Guidelines for Americans indicate that adults and older adults should engage in

at least 150 minutes to 300 minutes a week of moderately intense aerobic physical activity, 75 minutes to 150 minutes a week of vigorously intense aerobic physical activity, or a combination of moderately intense and vigorously intense aerobic exercise [32-36]. Additionally, adults and older adults should engage in muscle-strengthening exercises of moderate or greater intensity involving all major muscle groups on 2 or more days a week [32-36]. These guidelines suggest that by engaging in physical activity beyond the equivalent of 300 minutes of moderate-intensity physical activity a week will lead to greater health benefits and more independence for adults and older adults engage in daily activities [32-36].

Physical activity is an essential component in diabetes lifestyle management programs [36-45]. Clinical studies have shown significant improvement in insulin sensitivity with greater physical activity [36-45]. Several studies, systematic reviews, and meta-analyses have reported that increased physical activity and exercise in diabetes education and management programs produce a significant improvement in glycemic control in patients with type 2 diabetes, most studies reporting an A1C reduction of -0.4% to -0.6% [36-45].

There are many community-based physical activity programs and interventions, specifically those that contained a cognitive and/or a behavioral based strategy, have shown effective results in better strength and mobility in adults and older adults [46]. In a study conducted by Rejeski et al., participants that were randomized to receive a physical activity intervention and behavioral counseling engaged in more minutes of moderate exercise compared to participants randomized to the control group that only received educational counseling from baseline to follow-up ($p < 0.001$) [46,47]. In a study conducted by Morey et al. , male participants that were randomized to receive physical activity counseling were encouraged to walk or do lower extremity physical activity for 30 minutes 5 or more days each week and lower

extremity strength training 3 days each week. In addition, they received baseline and telephone counseling to assess physical activity goals and to provide support as well as tailored report to track progress. Participants randomized to the physical activity counseling group met the goal of 150 minutes of moderate to vigorous physical activity weekly from baseline (13%) to 12-month follow-up (32%) compared to participants that were randomized to the usual care group who were asked to continue daily activities ($p < 0.001$) [46,48].

Adults tend to lose muscle strength overtime with age and a sedentary lifestyle [32-36]. Loss of muscle strength or weakness tends to hinder the abilities of adults to perform daily tasks independently [32-36]. For example, adults with weakened muscles or who lack muscle strength tend to walk slower, have difficulty with walking up or down stairs, have issues standing for a longer duration of time, and have more accidental falls [32-36]. Adults and older adults that engage in recommended strength training have been shown to improve muscle mass and strength [32-36].

There have been effective community-based strength-training programs for older adults conducted by Extension that have shown that engaging in strength training exercises can improve muscle mass, strength, mobility, and bone density [46, 49-54]. The Better Bones and Balance^{TM} (BBB) program is an evidence-based strength-training program that has been shown to reduce the risk of hip fractures, bone loss, and falls in older adult women [49-51]. This fall and fracture reduction risk program consists of resistance training using weighted vests as well as balancing and impact exercises [49-51]. The program is delivered 3 times per week for 50-minutes [49-51]. The program has shown to improve strength and balance as well as maintain bone mineral density [49-51]. In a study conducted by McNamara and and Gunter, older adult women who were doing the BBB classes were compared to sedentary or inactive older adult

women [49]. Results indicated that no statistically significant differences in hip or spine bone mineral density or hip bone structures ($p > 0.05$) and both groups had higher total hip bone mass compared the national age average [49]. Though there were no significant differences, the BBB group had a lower BMI and body fat percentage as well as smaller hip bone mass compared to the control group, which indicates the positive impact of BBB on bone health and other health benefits [49]. In a more recent study conducted by McNamera, Pavol, Gunter, results indicated that adult and older adult post-menopausal women that attended weekly BBB classes with an increased dose and intensity of exercise was associated 126 $\pm$ 32 minutes a week spent doing moderate to vigorous physical activity [51]. Participants in this study, with the additional dose of physical activity, were obtaining an acceptable dose of aerobic physical activity, based upon the current recommended Physical Activity Guidelines for Americans, to improve optimal health [51].

The Stay Strong Stay Healthy (SSSH) program is a strength training program, implemented by Extension personnel, intended for older adults to prevent the risk of falls [39-41]. This program was adapted from Strong Women, Strong Bones program to appeal more to the male audience [39]. The program consisted of group strength, balancing, and flexibility training exercises for 1-2 weeks for 10 weeks [40, 41]. All sessions included a warm-up, two sets of 10 repetitions of the strength, balancing, and flexibility exercises, and a cool down, which consisted of stretching and balancing exercises [40,41]. In a study conducted by Ballet al. , results indicated significant improvement in each of the seven physical measures ($p < 0.001$) of the Senior Fitness Test used to assess strength and flexibility from pre to post assessment [41]. This study was intended to evaluate the effectiveness of this community-based program delivered by Extension professionals [41].

These studies indicated the effectiveness of these community-based programs for adults and older adults incorporating more physical activity into their daily lives, which leads to improvements in physical limitations such as mobility, lack of lower and upper extremity strength, osteoporosis, and musculoskeletal disorders, and would maximize health benefits long term and allow for greater independence [46, 49-56, 79].

Virginia Cooperative Extension

Community-based health and education programs play a pivotal role in prevention and/or management of chronic illnesses such as obesity, diabetes, cardiovascular disease, and some cancers [14]. Virginia Cooperative Extension (VCE) is an educational outreach network that conveys research findings from Virginia's land grant universities: Virginia Tech (VT) and Virginia State University (VSU) to the community [57,58,59]. VCE has established partnerships and collaboratives with several public and private organizations to provide the Commonwealth with scientific knowledge and research-based solutions to address the health issues identified within the Commonwealth [57,58,59]. Collaborations also allow for VCE Extension Agents to reach more diverse populations [57,58].

A goal of VCE is to improve the quality of life among the Commonwealth leading to greater productivity and better health in the communities served [57,58]. VCE is an educational leadership network for research-based Extension programs to address the needs identified by local communities[57,58,59]. Currently Extension-based programs are delivered by faculty at VT and VSU, 108 county and city offices, 11 agricultural research and Extension centers, and six 4-H educational centers [57,58]. The Local Extension Leadership Council assists with the design, implementation, and evaluation of these need-driven programs [57,58]. VCE's Family and Consumer Sciences (FCS) program strive to improve the quality of life of Virginia residents

by providing and implementing programs that will help increase residents' knowledge and address their needs [57,58].

Currently VCE provides educational programs related to chronic disease prevention as well as lifestyle modification and management which include the Balanced Living with Diabetes (BLD) Program and the Lifelong Improvements through Fitness Together (LIFT) Program [57,58].

Balanced Living with Diabetes (BLD) Program

The BLD Program, an evidence-based type 2 diabetes lifestyle self-management program, uses an active learning approach to influence behavior change that helps participants maintain a healthful weight and improve blood glucose control [60]. The BLD was adapted from the Dining with Diabetes (DWD) Program [61], which was an Extension program implemented in West Virginia [61,62]. It was developed through an iterative process of testing and modification in Virginia and has shown efficacy to modify dietary and physical activity behaviors that result in improved indicators of glucose control.

The BLD is guided by the Social Cognitive Theory (SCT), which is a health behavior theory that entails the interrelationship and social influences between the individual, the environment, and reciprocal determinism [63,64]. In addition to reciprocal determinism, other constructs of SCT include self-regulation, observational learning, behavioral capability, expectancies, outcome expectations, self-efficacy, and social norms [63,64]. This theory addresses how to change an individual's current behavior in which self-regulation is the driving factor. The BLD program strongly emphasizes SCT constructs such as self-efficacy, self-regulation through goal setting, and social support [63,64]. According to Bandura, self-efficacy refers to one's self-confidence in his or her own abilities to take on a specific action effectively.

Self-efficacy will enhance self-esteem for a patient to better manage his or her diabetes[63,64]. Self-regulation is the process of managing his or her own goal-directed behavior[63,64]. Self-regulation will allow for better self-management of diabetes improving glycemic control, physical activity, and dietary behaviors through goal setting. Social support is comfort received from family and close friends [63,64]. Social support will allow for greater interaction among the patients that also have diabetes. Addressing these constructs in the BLD program is designed to foster effective lifestyle change. The BLD program is an opportunity for individuals with T2D to be provided educational tools and resources to help better manage their diabetes.

The BLD consists of four weekly (two-hour) classes, a two-month hiatus, followed by a reunion class session to evaluate and reassess outcome measures. Outcome measures for the program are collected at baseline and include: 1) glycemic control (measured by A1C) 2) anthropometric measures (height and weight), and 3) measures related to dietary behaviors and physical activity using a validated questionnaire. The questionnaire for the BLD program was adapted from the Food's Beliefs Survey in which SCT constructs were used to evaluate nutrition behavior [62, 65-68]. The questionnaire was shown to be reliable and valid in various adult populations with programs related to nutrition, physical activity, and chronic diseases and illnesses using the SCT constructs [62, 65-68]. SCT constructs were measured in the questionnaire to obtain participants' knowledge regarding diabetes self-care and knowledge related to the BLD curriculum content. Questions related to nutrition and dietary behaviors include: 1) servings of fruits and vegetables, 2) servings of whole grains, 3) servings of dairy or foods high in calcium, 4) use of the Idaho Plate Method, and 5) eating regular meals. Questions related to physical activity include: 1) completing 30 minutes or more of physical activity, 2) making a plan to walk or exercise, 3) keeping tracking of walking and/or exercising, 4) walking

and or exercising, and 5) wearing and using a step-counter. Questions related to nutrition and dietary behaviors are looking back over the past 3 months.

The BLD program targets Virginia residents with diagnosed T2D or an A1C level of $\geq$ 5.7%. The interactive program is organized by a VCE Family and Consumer Science (FCS) Extension Agent and is taught by registered dietitian (RD) or Certified Diabetes Educator (CDE) located within the community. A Master Food Volunteer (MFV) and/or FCS Extension Agent provides a food demonstration that uses recipes appropriate for individuals with diabetes. Physical activity is a vital component of the program as participants are provided a pedometer to track their activity and are encouraged to increase their level of physical activity. Dietary recommendations are based upon the Idaho Plate method, a simple plate method used to control the amount of carbohydrates and increase more fruits and non-starchy vegetables through portion control [69, 70].

Studies funded by the National Institute of Health (NIH) and United States Department of Agriculture (USDA), to implement the BLD program across Virginia, have achieved significant A1C reduction and improvement in BLD program outcomes in patients with T2D. NIH study results indicated a clinically significant reduction in A1C level/ Mean A1C reduction for participants with baseline A1C over 7.0% was 0.68 ± 1.58 and 0.43 ± 1.36 (paired t-test, $p < 0.05$). for the two study groups.

USDA study results indicated a significant mean reduction in A1C level of 0.384 $\pm$ 1.182 (paired t-test $p = 0.014$). BLD program outcomes indicated significant improvement in all health behaviors (paired t-test $p < 0.05$), food knowledge (paired t-test $p = 0.019$), and self-efficacy (paired t-test $p = 0.001$).

Lifelong Improvements through Fitness Together (LIFT) Program

The Lifelong Improvements through Fitness Together (LIFT) program was adapted from Stay Strong Stay Healthy (SSSH) [54] and Activity for the Ages programs [73]. It is a strength training program for older adults consisting of 16 in-person strength training sessions (1-hour, twice a week for eight weeks) intended to increase physical activity and improve fitness capabilities to enhance strength, balance, and flexibility among older adult participants [71,72]. All sessions have a warm-up, followed by eight exercises, and finish with a cool-down [71,72]. Functional fitness tests, adapted from the Ricki and Jones functional fitness tests [74,75], are conducted prior to and after the LIFT program to evaluate improvement of upper and lower body strength and flexibility, balance, and endurance [71,72].

According to Wilson et al., evidence-based adaptations from SSSH and Activity for the Ages were made to develop the LIFT program and to make translation of the LIFT program more feasible within the context of the Cooperative Extension system [71,72]. Using the Chamber's Adaptome, adaptations [31] were made to SSSH that developed into LIFT which included: 1) group dynamics and behavioral change strategies were incorporated into the program, 2) addition of nutrition education as part of the program, 3) tracking and self-monitoring of fruits and vegetables intakes, 4) tracking and self-monitoring of physical activity, and 5) reduction of in-person time with the facilitator and participant by delivering the program for eight weeks versus ten weeks [71,72]. With these evidence-based adaptations, the LIFT program is intended to improve program adherence and to functional fitness [71,72].

Group dynamics strategies such as support and group goal setting are intended to increase group cohesiveness and interaction among participants [71,72]. Group dynamics strategies and behavioral change strategies embedded in the LIFT program were intended to improve self-

efficacy as well as improve self-monitoring and tracking of fruits and vegetables and physical activity, and accountability among participants [71,72]. In addition, having the LIFT class twice a week for 8-weeks would allow for participants to receive an acceptable quantity of strength training based upon the Physical Activity Guidelines for Americans recommendations without it being an onerous task. These adaptations made to the LIFT program were meant to lead to greater sustainability of increased physical activity and consistent long-term behavior change [71,72].

A study conducted by Wilson et al. that evaluated the reach and effect of the LIFT program compared to SSSH program indicated that functional fitness change scores were significant in all functional fitness measures in LIFT participants ($p < 0.05$) compared to SSSH participants, who were only able to significantly improve in 5 of the 7 functional fitness measures [72]. Results also indicated that though not statistically significant, LIFT had better retention rates and maintenance at the agent level to continue delivery of the LIFT program compared to the SSSH [72]. This study indicated that the LIFT program can have a significantly greater impact on balance, flexibility, endurance and other strength training exercises in older adults compared to the SSSH [72].

Implementation Research and Frameworks for Evaluation

Implementation science is known as "the scientific study of methods to promote the systematic uptake of research findings and other evidence-based practices into routine practice, and, hence, to improve the quality and effectiveness of health services" [76,77]. Implementation research aims to identify and address gaps in evidence-based programs that lack effectiveness and are underutilized [76,77]. Evaluation of implementation effectiveness of an intervention or program is important to determine if implementation was impactful [76,77]. Evaluating

components such as implementation fidelity is a vital component to the implementation process to determine if an intervention or program was delivered as intended [76,77]. If a program is implemented with fidelity and results did not indicate any overall impact, the researcher will want to understand whether that was due to the program being ineffective and/or lack of generalizability in a certain population setting, if there were pragmatic issues, or whether the implementation of the intervention or program was poor [76,77]. Implementation strategies can be developed to address barriers of the implementation process, enhance the implementation, as well as identify efforts to facilitate behavior change [76,77].

Evaluation of implementation of community-based health promotion programs that address chronic diseases such as T2D is imperative to determine their impact and reach in communities they serve [82]. One implementation framework is The Reach, Effectiveness, Adoption, Implementation, Maintenance (RE-AIM) Framework, which aims to evaluate the constructs relevant to real-world implementation of health programs to build capacity to reach individuals in need of such programs, and that lead to healthful behaviors [76-82]. The RE-AIM Framework aligns with the social ecological model, which highlights the impact of intrapersonal, organizational, community, and environmental influences and their feedback loop interactions on individual behavior change, and the importance of addressing these influences to develop sustainable solutions that will ultimately impact individual behavior change [76-82].

The reach dimension refers to the proportion and representativeness of individuals receiving the program/intervention [79-81]. The effectiveness dimension refers to the impact of the program/intervention on study outcomes [79-81]. The adoption dimension refers to the proportion and representativeness of settings and intervention agents/organizations who are willing to start and deliver a program/intervention [79-81]. The implementation dimension refers

to the intervention agents' delivering a program with fidelity to the program protocol, as well as the time and cost of the intervention [79-81]. The implementation dimension also evaluates the inner and outer context, adaptations and modifications, and acceptability of the program [79-81]. The maintenance dimension refers to long-term sustainability, which at the individual level is a long-term program/intervention effects and at the organizational level, continued implementation of the program/intervention [79-81].

The RE-AIM Framework was chosen as a theoretical framework in the first study because it evaluated the adoption and implementation of the retention plan among Extension Agents implementing BLD programs and it evaluated systems level maintenance of continued use of the retention plan in future BLD programs among Extension Agents. Additionally, the RE-AIM Framework evaluated reach to determine whether the retention plan impacted program retention in BLD programs with and without the retention plan and evaluated the effectiveness of program outcomes with and without the retention plan in BLD programs. The implementation dimension was used in the second study to evaluate implementation fidelity of Extension Agents implementing BLD programs with and without the LIFT program. The implementation constructs evaluated included the inner context, fidelity, adaptations and modifications, barriers and facilitators, time and acceptability.

Formative evaluation from previous BLD programs that have been conducted indicated a need for strategies to improve retention and to enhance participant engagement. In Study 1 of the doctoral line of research described in this dissertation evaluated the use and impact of a tailored retention plan implemented in BLD programs conducted from 2015-2017.

Formative evaluation from previous BLD programs that have been conducted also indicated incorporating more physical activity or adding a physical activity component with the

BLD program. The LIFT program, which is also a Cooperative Extension program, was incorporated with the BLD program. Study 2 of the doctoral line of research described in this doctoral dissertation evaluated the impact of program outcomes when the LIFT program is incorporated with the BLD program compared to when the LIFT program is not incorporated with the BLD program (standard program). The rationale for incorporating these two programs was that the BLD had a 2-month hiatus (8-weeks) between the last class and the reunion class and the LIFT program is an 8-week program. In addition, that both programs have overlapping constructs and strategies relative to improved health outcomes. The BLD program includes constructs such as self-efficacy, goal setting, tracking, and social support. The LIFT program includes behavioral strategies such as goal setting, monitoring, and group dynamics.

References

1. Centers for Disease Control and Prevention. (2017). *National Diabetes Statistics Report 2017.* CDC.
2. Centers for Disease Control and Prevention. (2018, February 2). *Prevalence of Both Diagnosed and Undiagnosed Diabetes*. Retrieved from Centers for Disease Control and Prevention: https://www.cdc.gov/diabetes/data/statistics-report/diagnosed-undiagnosed.html
3. Centers for Disease Control and Prevention. (2018, February 2). *Prevalence of Diagnosed Diabetes*. Retrieved from Centers for Disease Control and Prevention: https://www.cdc.gov/diabetes/data/statistics-report/diagnosed.html
4. Centers for Disease Control and Prevention. (2018, February 19). *Prevalence of Prediabetes*. Retrieved from Centers for Disease Control and Prevention: https://www.cdc.gov/diabetes/data/statistics-report/prevalence.html

5. Centers for Disease Control and Prevention. (2018, February 11). *Incidence of Diagnosed Diabetes*. Retrieved from Centers for Disease Control and Prevention: https://www.cdc.gov/diabetes/data/statistics-report/incidence-diabetes.html
6. American Diabetes Association. (2016). The Burden of Diabetes in Virginia . Retrieved from American Diabetes Association: http://main.diabetes.org/dorg/PDFs/Advocacy/burden-of-diabetes/virginia.pdf
7. Virginia Department of Health. (2015). Diabetes in Virginia.
8. Virginia Department of Health. (2017-2018). Diabetes Burden in Virginia Report.
9. American Diabetes Association. (2018). Economic Costs of Diabetes in the U.S. in 2017. Diabetes Care, 917-928.
10. American Diabetes Association. (2018, March 22). Statistics about Diabetes: Overall numbers, Diabetes, and Prediabetes. Retrieved from American Diabetes Association: http://www.diabetes.org/diabetes-basics/statistics/
11. Centers for Disease Control and Prevention. (2018). Diabetes State Burden Toolkit. Retrieved from Centers for Disease Control and Prevention: https://nccd.cdc.gov/Toolkit/DiabetesBurden/Home/Economic
12. Centers for Disease Control and Prevention. (2018, February 19). Risk Factors for Complications. Retrieved from Centers for Disease Control and Prevention: https://www.cdc.gov/diabetes/data/statistics-report/risks-complications.html
13. Nathan, D. (2014). The Diabetes Control and Complications Trial/Epidemiology of Diabetes Interventions and Complications Study at 30 Years: Overview. *Diabetes Care*, 9-16.

14. Healthy People 2020. (2018, November 6). Diabetes. Retrieved from Healthy People 2020: https://www.healthypeople.gov/2020/topics-objectives/topic/diabetes/objectives
15. Bolin, J., & Bellamy, G. (2017). Rural Healthy People 2020.
16. Hale, N., Bennett, K., & Probst, J. (2010). Diabetes Care and Outcomes: Disparities Across Rural America. *Community Health*, 365-374.
17. Massey , C., Appel, S., Buchanan, K., & Cherrington, A. (2010). Improving Diabetes Care in Rural Communities: An Overview of Current Initiatives and a Call for Renewed Efforts. *Clinical Diabetes*, 20-27.
18. Gucciardi, E., DeMelo, M., Offenhiem, A., & Steward, D. (2008). Factors contributing to attrition behavior in diabetes self-management programs: A mixed method approach. *BMC Health Services Research*, 1-11.
19. Gucciardi , E., DeMelo , M., Booth, G., Tomlinson , G., & Stewart, D. E. (2009). Individual and contextual factors associated with follow-up use of diabetes self-management education programmes: a multisite prospective analysis. *Diabetic Medicine*, 510-517.
20. Gucciardi, E., Smith, T. & DeMelo, M. (2006) Use of diabetes resources in adults attending a self-management education program. *Patient Education and Counselling*, 64 (1–3), 322–330.
21. Gucciardi, E., DeMelo, M., Offenheim , A., Grace, S., & Stewart, D. (2007). Patient factors associated with attrition from a self-management education programme. *Journal of Evaluation in Clinical Practice*, 914-91.

22. Rutledge, S., Masalovich, S., Blacher, R., & Saunders, M. (2017). Diabetes Self-Management Education Programs in Nonmetropolitan Counties-United States 2016. Centers for Disease Control and Prevention.
23. Shellberg et.al. (2013) Lifestyle interventions for patients with and at risk for type 2 diabetes: a systematic review and meta-analysis, Annals Internal Medicine, 159, 543-551
24. M.K. Baker, K. Simpson, B. Lloyd, A.E. Bauman, M.A. Singh. (2011) Behavioral strategies in diabetes prevention programs: a systematic review of randomized controlled trials, Diabetes Research and Clinical Practice, 91 (1), 1-12
25. Chen et.al. (2015). Effect of lifestyle intervention in patients with type 2 diabetes: a meta-analysis, Metabolism, 64 (2), 338-347
26. Gillies CL, Abrams KR, Lambert PC, Cooper NJ, Sutton AJ, Hsu RT, Khunti K. (2007). Pharmacological and lifestyle interventions to prevent or delay type 2 diabetes in people with impaired glucose tolerance: systematic review and meta-analysis. Br Med J 334, 299– 308.
27. Strine TW, Okoro CA, Chapman DP, Beckles GL, Balluz L, Mokdad AH. (2005). The impact of formal diabetes education on the preventive health practices and behaviors of persons with type 2 diabetes. Preventative Medicine. 41(1),79–84.
28. Boulé NG, Haddad E, Kenny GP, Wells GA, Sigal RJ. (2001). Effects of exercise on glycemic control and body mass in type 2 diabetes mellitus: a meta-analysis of controlled clinical trials. The Journal of the American Medical Association. 286, 1218–1227
29. Deakin University. (2012). Identifying effective strategies to increase recruitment and retention in community-based promotion programs.

30. McCann, J., Ridgers, N., Thorton, L., & Teychenne, M. (2013). Effective recruitment and retention strategies in community health programs. Health Promotion Journal Australia, 104-110.
31. Chambers, D., Phil, D., & Norton, W. (2016). The Adaptome-Advancing the Science of Intervention Adaptation. American Journal of Preventive Medicine , 124-131
32. U.S. Department of Health and Human Services. (2018) Physical Activity Guidelines for Americans, 2nd edition. Washington, DC
33. Centers for Disease Control and Prevention. (2015, June 4). How much physical activity do older adults need? Retrieved from Centers for Disease Control and Prevention: https://www.cdc.gov/physicalactivity/basics/older_adults/index.htm
34. Centers for Disease Control and Prevention. (2018, July 16). Cancer Prevention and Control. Retrieved from Centers for Disease Control and Prevention: https://www.cdc.gov/cancer/dcpc/prevention/policies_practices/physical_activity/guidelines.htm
35. Centers for Disease Control and Prevention. (2018, October 31). How much physical activity do you need? Retrieved from Centers for Disease Control and Prevention: https://www.cdc.gov/physicalactivity/basics/adults/index.htm
36. Centers for Disease Control and Prevention. (2018, February 13). Physical Activity and Health. Retrieved from Centers for Disease Control and Prevention: https://www.cdc.gov/physicalactivity/basics/pa-health/index.htm
37. Avery, L., Flynn, D., van Wersch, A., Sniehotta, F., Trenell, M. (2012) Changing physical activity behavior in type 2 diabetes: a systematic review and meta-analysis of behavioral interventions. *Diabetes Care*, 35, 2681-2689;

38. Brand,T., Pischke, C.R., Steenbock, B., Schoenbach, J., Poettgen, S., Samkange-Zeeb, F. et al. (2014) What works in community-based interventions promoting physical activity and healthy eating? A review of reviews. *International Journal of Environmental Research and Public Health*, 11 (6), 5866-5888.

39. Yang, Z., Scott, C.A., Mao, C., Tang, J., (2014). Resistance exercise versus aerobic exercise for type 2 diabetes: a systematic review and meta-analysis *Sports Medicine*, 44 (4), 487-499

40. Colberg SR, Albright AL, Blissmer BJ, Braun B, Chasan-Taber L, Fernhall B, Regensteiner JG, Rubin RR, Sigal RJ American College of Sports Medicine; American Diabetes Association. (2010). Exercise and type 2 diabetes: American College of Sports Medicine and the American Diabetes Association: joint position statement. Exercise and type 2 diabetes. *Med Sci Sports Exerc*. 42, 2282–2303

41. Zhao G, Ford ES, Li C, Balluz LS. (2011). Physical activity in U.S. older adults with diabetes mellitus: prevalence and correlates of meeting physical activity recommendations. *Journal of the American Geriatrics Society*. 59, 132–137.

42. Nelson ME, Rejeski WJ, Blair SN, Duncan PW, Judge JO, King AC, Macera CA, Castaneda-Sceppa C American College of Sports Medicine; American Heart Association. (2007). Physical activity and public health in older adults: recommendation from the American College of Sports Medicine and the American Heart Association. *Circulation*. 116, 1094–1105.

43. Sigal RJ, Kenny GP, Wasserman DH, Castaneda-Sceppa C. Physical activity/exercise and type 2 diabetes. (2004) *Diabetes Care*. 27,2518–2539

44. Zanuso S, Jimenez A, Pugliese G, Corigliano G, Balducci S. (2010) Exercise for the management of type 2 diabetes: a review of the evidence. Acta Diabetol, 47, 15–22.
45. Balducci, S., Zanuso, S., Nicolucci, A., et.al (2010). Anti-inflammatory effect of exercise training in subjects with type 2 diabetes and the metabolic syndrome is dependent on exercise modalities and independent of weight loss. Nutrition Metabolism and Cardiovascular Diseases. 20, 608-617.
46. Chase, J. (2013). Physical Activity Interventions Among Older Adults: A Literature Review. *Research and Theory for Nursing Practice*, 53-80.
47. Rejeski et al. (2009) Lifestyle Interventions and Independence for Elders Pilot (LIFE-P): 2-year follow-up. *Journal of Gerontology Series A Biological Science and Medical Science*. 462–467
48. Morey et.al (2009). The Veterans LIFE Study: A Randomized Trial of Primary Care Based Physical Activity Counseling for Older Men. *Journal of the American Geriatrics Society*, 1166-1174.
49. McNamara, A., Gunter, K. (2012). The influence of participation in Better Bones and BalanceTM on skeletal health: evaluation of a community-based exercise program to reduce fall and fracture. *Journal of Osteoporosis International*, 1813-22
50. Gunter, K. (2010). Successful Translation of Better Bones and Balance: a community-based fall and fracture risk reduction exercise program for older adults. Medicine & Science in Sports & Exercise Volume: 42 Issue 5
51. McNamara, A., Pavol, M., Gunter, K. (2013). Meeting Physical Activity Guidelines Through Community-Based Group Exercise: "Better Bones and Balance". *Journal of Aging and Physical Activity*, 155-166

52. Nelson, M. E., Fiatarone, M. A., Morganti, C. M., Trice, I., Greenberg, R. A., & Evans, W. J. (1994). Effects of high-intensity strength training on multiple risk factors for osteoporotic fractures. *The Journal of the American Medical Association*, 272, 1909-1914

53. Seguin et.al. (2013) Design and national dissemination of the Strong Women Community Strength Training Program. *Preventing Chronic Disease*. A25

54. Ball, S. (2013). Outcomes of Stay Strong, Stay Healthy in Community Settings. *Journal of Aging and Health*, 1388-1397

55. Korkiakangas EE, Alahuhta MA, Laitinen JH.(2009) Barriers to regular exercise among adults at high risk or diagnosed with type 2 diabetes: a systematic review. *Health Promotion International*. 24, 416–427.

56. Thomas N, Alder E, Leese GP. (2004). Barriers to physical activity in patients with diabetes. *Postgrad Medical Journal*. 80, 287–291.

57. Virginia Cooperative Extension. (2018). About Virginia Cooperative Extension. Retrieved from Virginia Cooperative Extension: https://ext.vt.edu/about.html

58. Virginia Cooperative Extension. (2018). Chronic Disease Prevention and Control Programs. Retrieved from Virginia Cooperative Extension: https://ext.vt.edu/food-health/chronic-disease.html

59. Franz, N., Towson, L., (2008). The Nature of Complex Organizations: The Case of Cooperative Extension. *New Directions for Evaluation*, 120, 5–14

60. Chapman-Novakofski, K., & Karduck, J. (2005). Improvements of knowledge, social cognitive variables, and movement through stages of change after a community-based diabetes education program. *American Dietetic Association*, 1613-1616.

61. WVU Extension . (2012, June 12). Dining with Diabetes. Retrieved from WV Extension Service: https://extension.wvu.edu/harrison/family-community/dining-with-diabetes
62. Winett, R., Anderson, E., Wojcik, J., Winett, S., & Bowden, T. (2007). Nutrition and Physical Activity outcomes of a group-randomized trial of an internet-based intervention in churches. Annals of Behavioral Medicine, 251-261.
63. Bandura, A. (1977). Self-efficacy: toward a unifying theory of behavior change. Psychological review, 191-215.
64. Bandura, A. (2001). Social Cognitive Theory of Mass Communication. Psychology, 265-299.
65. Anderson, E., Winett, R., & Wojcik, J. (2007). Self-regulation, self-efficacy, outcome expectations, and social support: Social cognitive theory and nutrition behavior. Annals of Behavioral Medicine, 304-312.
66. Anderson, E., Winett, R., & Wojcik, J. (n.d.). Social cognitive mediators of change in a group randomized nutrition and physical activity intervention: social support, self-efficacy, outcome expectations, and self-regulation in the Guide-to-Health Trial. Journal of Health Psychology.
67. Anderson, E., Winett, R., Wojcik, J., Winett, S., & Bowden, T. (2001). A computerized social cognitive intervention for nutrition behavior: Direct and mediated effects of fat, fiber, fruits, and vegetables, self-efficacy and outcome expectations among food shoppers. Annals of Behavioral Medicine, 88-100.
68. Anderson ES, Winett RA, Wojcik JR, Winett SG, Bowden T (2006): Social-cognitive determinants of physical activity: the influence of social support, self-efficacy, outcome

expectations, and self-regulation among participants in a church-based health promotion study. Journal of Health Psychology, 510-20.

69. Rizor H., Smith M., Thomas K., Harker J., Rich M., (1996). "Have you tried The Idaho Plate Method?" American Dietetic Association. Diabetes Care and Education Practice Group. DCE Newsflash. 17,18-20.
70. Rizor H., Smith M., Thomas K., Harker J., Rich M., (1998) "Practical Nutrition: The Idaho Plate Method," Practical *Diabetology.* 17, 42-45.
71. Wilson, M., Strayer, T., Davis, R., & Harden, S. (2018). Informed Adaptations of a Strength-Training Program through a Research–Practice Partnership. *Frontiers in Public Health*, 1-9.
72. Wilson, M., Strayer, T., Davis, R., & Harden, S. (2018). Use of an Integrated Research-Practice Partnership to Improve Outcomes of a Community-Based Strength-Training Program for Older Adults: Reach and Effect of Lifelong Improvements through Fitness Together (LIFT). *Int Journal Environment Res Public Health*, 1-15.
73. Estabrooks et al. (2016) Move More: Translating an efficacious group dynamics physical activity intervention into effective clinical practice. PsycINFO Database Record (c), American Psychological Association.
74. Rikli R.E., Jones C.J. (1999) Development and validation of a functional fitness test for community-residing older adults. *Journal of Aging Physical Activity*, 129–161
75. Rikli RE. (2000) Reliability, validity, and methodological issues in assessing physical activity in older adults. Research Quarterly for Exercise and Sport. S89–96
76. Bauer, M., Damschroder, L., Hagedorn, H., Smith, J., & Kilbourne, A. (2015). An introduction to implementation science for the non-specialist. *BMC Psychology*, 1-12.

77. Eccles, M., & Mittman, B. (2006). Welcome to Implementation Science. Implementation Science, 1-3.

78. Sweet et.al. (2014) Operationalizing the RE-AIM framework to evaluate the impact of multi-sector partnerships. *Implementation Science*, 74.

79. Gaglio, B., Shoup, J., Glasgow, R. (2013) The RE-AIM Framework: A Systematic Review of Use Over Time. *American Journal of Public Health*, e38–e46

80. Glasgow, R., McKay, H., Piette, J., & Reynolds, K. (2001). The RE-AIM framework for evaluating interventions: what can it tell us about approaches to chronic illness management? Patient Education and Counseling, 119-127.

81. Glasgow, R., Vogt, T., & Boles, S. (1999). Evaluating the public health impact of health promotion interventions: the RE-AIM framework. American Journal of Public Health, 1322-1327.

82. Harden et al. (2015). Fidelity to and comparative results across behavioral interventions evaluated through the RE-AIM framework: a systematic review. Systematic Reviews, 155.

Chapter 3

Formative and process evaluation of a participant retention plan in a community-based diabetes lifestyle management program using the RE-AIM Framework

Abstract

Purpose Statement: The Virginia Cooperative Extension Balanced Living with Diabetes (BLD) Program uses an active learning approach to influence behavior change by helping participants maintain healthy lifestyles and improve blood glucose control. A vital component of diabetes self-management (DSME) programs is ongoing communication, however, high attrition rates for DSME programs is a major challenge. The purpose of this study was to conduct formative and process evaluation during implementation of a new participant retention plan for BLD programs conducted from 2015-2017.

Methods: Qualitative data gathered though interviews with Agents who had access to the retention plan was used to evaluate retention plan implementation using domains of the RE-AIM Framework. Quantitative comparisons of retention and program outcomes for BLD programs delivered by the same Agents before and after the retention plan was available were conducted.

Results Six Agents conducted a BLD program both prior to and after the development of the retention plan. Three confirmed use of the retention plan (RP) two confirmed non-use of the retention plan (NRP). Themes from interviews included ineffective retention plan dissemination and reinforcement of lifestyle changes by the retention plan. A higher percentage of NRP participants returned for the reunion class. No significant differences were observed for health behavior or self-efficacy.

Conclusions: Agents found the retention plan to be useful for ongoing communication with participants. Low awareness of the retention plan resulted in low adoption, indicating the need

for better dissemination. An appropriately powered prospective study is needed to determine whether the retention plan improves retention and program outcomes.

Introduction

According to the Centers for Disease Control and Prevention (CDC), the prevalence of diagnosed diabetes was estimated to be 23.1 million (7.2%) among US adults in 2015.[1-3] The prevalence of type 2 diabetes (T2D) is higher in patients with excessive body weight and sedentary lifestyles, and patients that develop T2D are at increased risk for developing other comorbidities such as cardiovascular disease, metabolic syndrome, and blindness.[4-5] Lifestyle interventions that include dietary change behaviors and increased physical activity have been shown to prevent and delay the onset of T2D in populations at risk for developing the disease.[6]

Diabetes self-management education (DSME) programs can aid patients in effectively managing their diabetes.[7-9] A key component of these programs is ongoing communication and assistance for the participants from facilitators who are delivering DSME programs to assure that diabetes care is consistently being managed by the patient.[7-9] However, participant retention in DSME programs is a major challenge.[7-19] Reasons for attrition in DSME include patients' lack of readiness to begin a DSME program and lack of communication by the facilitator delivering the program and/or participant.[7-19] Patients that drop out of a DSME program early or fail to adhere to self-management program activities are more likely to have poor glycemic control and are at higher risk for other health complications compared to those who continue with the program and attend follow-up sessions.[7-19] According to a systematic review by Gucciardi, there is lack of information in the literature on attrition in diabetes education programs despite the high rates of attrition across programs reviewed.[8] Identifying effective strategies to sustain patients' engagement in community programs would assist in achieving higher retention rates in DSME programs.[20,21]

Community-based programs are an alternative to traditional programs within healthcare settings as these programs are low or no cost and allow for better access and reach to low-income populations to improve their health and support maintenance of healthy lifestyles.[6,12-17] They are also more likely to emphasize lifestyle changes such as diet, physical activity, and other health behaviors in addition to diabetes self-management.[12-17] The Cooperative Extension System is an educational network funded by federal, state, and county government funds, that brings research-based knowledge and education to the population through community-based programs.[22,23]

The Balanced Living with Diabetes (BLD) Program, an evidence-based diabetes lifestyle management program, is offered in community settings through the Virginia Cooperative Extension (VCE) Service. BLD is guided by Social Cognitive Theory (SCT) and uses an active learning approach to influence behavior change that helps patients improve blood glucose control.[24-26] SCT constructs that are heavily emphasized in BLD include self-efficacy, self-regulation (goal setting and tracking), and social support to encourage improvement in self-management of diabetes and foster lifestyle change including increased physical activity, and better dietary choices.[25,26] BLD is designed to serve patients with T2D who may not have access to, or who cannot afford, health programs offered through hospitals or local DSME programs. Extension Agents, in collaboration with a registered dietitian nutritionist (RDN) or certified diabetes educator (CDE) facilitate BLD. BLD consists of four (2-hour) weekly classes with an 8-week hiatus, followed by a reunion session that reinforces class materials and reassesses outcome measures.

Participant retention was a challenge in BLD implementation in rural communities in 2015 and 2016. McCann and colleagues conducted interviews with key informants from various community health promotion organizations that delivered programs aimed at promoting healthy

eating and/or physical activity within a community setting.[20] Strategies that were frequently reported for retention included printed materials, media outlets, referrals, a retention leader, and making social connections. The evidence-based Rural Health Promotion and Disease Prevention Toolkit includes flyers, newsletters, advertisements, and community presentations as strategies to retain rural participants; materials should convey enthusiasm to engage participants and provide incentives to motivate participants.[21] Moreover, retention materials should be tailored to low literacy, culturally relevant to the target population, and use more than one type of material.[21]

To improve retention rates for BLD programs in rural Virginia counties, a retention plan with associated materials was developed and introduced to Extension Agents in August 2017. The materials were to be used during the two-month (eight-week) hiatus . The purpose of this study was to evaluate implementation and effectiveness of the retention plan used with BLD programs conducted between 2015-2017 using the Reach, Effectiveness, Implementation, Maintenance (RE-AIM) Framework.[27,28]

Methods

Research Design

Formative, process and outcome data were used to assess implementation fidelity and impact of the retention plan on participant retention and BLD program outcomes using the RE-AIM Framework. The RE-AIM Framework can be used to plan and evaluate public health interventions. It assesses five domains to determine the public health or population-based impact of the intervention.[26-30] According to Harden et al., measuring RE-AIM pragmatically can be done by "leveraging data already collected within the organizational setting" and "engaging delivery personnel for guiding pragmatic evaluations". Quantitative comparisons of program outcomes and retention rates between programs with and without the retention plan implemented

by Extension Agents were conducted. Only BLD programs conducted by Extension Agents that used the retention plan for their second program were included in this study. Qualitative data gathered through interviews with Extension agents who had access to the retention plan was used to evaluate the fidelity and barriers and facilitators to use of the retention plan.

The research protocol was approved by the Virginia Tech Institutional Review Board (IRB #18-1091) (see Appendix A).

Development of the Retention Plan

The BLD retention plan was developed in June 2017. Information from participating Extension Agents and a review of the literature was used to develop a retention plan with associated materials. The research team determined the guiding framework for the retention plan and materials based on recommendations from the literature.[20,21] The framework included: 1) materials for weekly distribution; 2) reinforcement of key messages from the four BLD sessions; 3) two newsletters to provide recipes from a cookbook that participants would receive at the reunion session; and 4) recommendations for physical activity in all materials to compensate for a perceived deficit in specific instruction in this area during the BLD sessions. Three members of the research team created an initial draft of the retention materials, and an iterative process of feedback from all team members was used to create the final retention plan and materials.

The final version of the retention plan included an implementation guide and associated materials(see Table 1, Appendix B and C). The guide detailed when and how the retention materials were to be distributed to participants. Materials included two newsletters to be distributed in weeks two and six that reinforced information taught in BLD and included diabetes friendly recipes. For the other six weeks, short reminders about key lifestyle recommendations were provided. The final correspondence included a reminder about the reunion session.

Retention materials were provided to participants through multiple communication channels (i.e. telephone, email, social media outlets, etc.).

Table 1.
Description of the Content in BLD Retention Plan Materials

Week 1	A reminder about working towards physical activity goals. Description of how to stretch before exercise[1]. Reminder to get permission from physician prior to physical activity if at risk.
Week 2	Newsletter 1: Information on the health benefits of being active and tips for eating less sugar, a recipe from the Diabetes by the Plate cookbook, and reminder that they would receive the cookbook at the reunion class session.
Week 3	Benefits of a heart healthy diet and exercise for people with diabetes. Foods to add to the diet to lower blood pressure and cholesterol (based on DASH recommendations)[2].
Week 4	A recipe from the BLD program manual to make at home[3].
Week 5	A reminder about working towards physical activity goals. Description of how to do bicep curls. Reminder to get permission from MD prior to physical activity if at risk[4].
Week 6	Newsletter 2: Information on the health benefits of setting goals and tracking, a recipe from the Diabetes by the Plate cookbook, and reminder that they would receive the cookbook at the reunion class session.
Week 7	Information about hidden salts in foods, ways to cut back on sodium, and trying other herbs and spices when preparing foods (based on ADA recommendations)[5].
Week 8	Reminder of BLD reunion class session

Sources: Strength Training for Older Adults: Growing Stronger-CDC[1]; The DASH Eating Plan as Part of a Heart-Healthy Lifestyle[2]; Heart Healthy Cooking African American Style, National Heart, Lung, and Blood Institute, 2008, page 12[3]; Exercise and Physical Activity-National Institute on Aging[4]; Cutting Back on Sodium: American Diabetes Association[5]

The retention plan was introduced to 12 Extension Agents delivering BLD for a USDA-funded study through a virtual webinar in August 2017. Each agent had conducted BLD at least once. A follow-up email reviewed the retention plan, the retention plan guide, the associated

retention materials, and where the plan and materials could be accessed. All retention plan materials were accessible to Extension Agents through the university's online learning management platform.

Study Sample

BLD programs associated with the USDA-funded study were delivered by 12 Family and Consumer Science (FCS) Extension Agents to 27 separate BLD programs (representing 158 participants) from January 2015- December 2017. FCS Extension Agents who had delivered one BLD program prior to development of the retention plan and one after the development of the retention plan were eligible for this study and were approached for participation. Extension Agents who used the retention plan for the second program are categorized as *retention plan* (RP). Extension Agents who did not use the retention plan for their second program were categorized as *non-retention plan* (NRP).

Data Collection

Qualitative

Semi-structured interviews were conducted with Agents that implemented two BLD programs in their respective county/city, one before and one after the existence of the retention plan. An email was sent to eligible Agents that included details about the study(Appendix D). For Agents that responded to the e-mail and agreed to participate, a follow-up email was sent to schedule a telephone interview at their convenience. For agents who did not respond to the initial e-mail, a second email was sent, and two follow up phone call attempts were made.

At the start of the interview, Agents were given a detailed description of the study and questions about the study were answered and asked to provide verbal consent (Appendix E). . Interview questions addressed three categories (see Appendix F): 1) use and implementation

fidelity; 2) mode of delivery and dose; and 3) barriers and facilitators for use of the retention plan.

Interviews were recorded using a digital sound recorder and then transcribed, and field notes were taken. Transcriptions and recordings were reviewed at least two times to ensure accuracy of the transcription.

Quantitative

Data were compared between BLD programs delivered prior to the development of the retention plan and after the development of the retention plan available and for which at least some part of the retention plan was used. Comparisons included: 1) participant retention rate; and 2) BLD program outcomes (glycemic control, diet/physical activity behaviors and SCT constructs). Glycemic control was assessed via glycosylated hemoglobin (A1C). A fingerstick was used to obtain the blood sample for analysis using the A1C Now + A1C system. Self-reported physical activity and dietary behavior changes were measured using questions assessing diet and physical activity behaviors and related SCT constructs(see Appendix G and H). Questions were adapted from the Health Belief's Questionnaire which has been validated in a variety of populations[31] All items in the health behavior section of the BLD questionnaire began with the root "In the past 3 months, how many days a week did you…" and participants selected a number from 0-7. All items in the self-efficacy section of the BLD questionnaire began with the root "How sure are you that on most days you can…" and questions were on a 5-point Likert scale (1= very unsure , 5= very sure).

Analysis

Extension Agent Semi-Structured Interviews

Thematic analysis was conducted to identify, analyze, and report major themes and subthemes from semi-structured interviews.[32,33] A deductive approach was used, in which major themes and subthemes were driven by the RE-AIM framework and associated with specific research questions included in the interviews.. Braun and Clarke's multidirectional six-phase guide[32,33] was used to conduct the thematic analysis, which includes: 1) becoming familiar with the data (including transcription), 2) generating initial codes, 3) searching for themes, 4) reviewing themes, 5) defining and naming themes, and 6) writing up the report. The thematic analysis was conducted using ©QSR International NVivo qualitative analysis software.[34]

Initial notes and ideas of the data corpus were written to assist in prepare the coding process, along with careful review of transcripts.(Phase 1). Coding was conducted to highlight specific segments of the transcripts into specific thematic categories that were relevant to the specific interview questions, and the main research question, including the organizational constructs (adoption, implementation, maintenance) of the RE-AIM Framework. This was used as a guide to assist with organizing and collating the data set in preparation of developing themes (Phase 2). An iterative process of collating data extracts and sorting codes was conducted to develop prospective themes (see Appendix I, figure 2). Themes correlated to the specific interview questions were driven by the RE-AIM Framework (Phase 3). Themes that were identified during phase 3 were reviewed and refined to make sure that they were distinctive and coherent. During the iterative process, the data corpus was re-read carefully to make sure that there were no contradictions among themes, and themes were addressing the specific research

questions (Phase 4). Themes that were identified in phase 3 and 4 were then refined and renamed (Phase 5).

BLD Program Outcomes

Data used for outcomes analyses included only participants from programs conducted by Agents that delivered a second BLD program after the development of the retention plan. Retention rates were computed for BLD programs within each condition. Chi-square analysis ($p < 0.05$) was used to compare the percentage of participants that began BLD and returned for the reunion session between NRP and RP programs. Independent samples t-tests were used to compare mean differences in program outcome measures at baseline and reunion for NRP and RP programs. Statistical analyses were performed using the Statistical Package for the Social Sciences (SPSS version 23.0 for Windows, IBM Corporation, Armonk, NY USA).[35]

Results

Extension Agent Interviews

Six Extension Agents representing seven counties/cities conducted a BLD program prior to and after the development of the retention plan. Of those, five responded to the email consenting to be part of the study. One Agent did not respond after two emails and two phone call attempts. Two Extension Agents collaborated for BLD delivery in one county while one Extension Agent delivered the BLD in two counties. Of the five Extension Agents that consented to be in the study, three used the retention plan (RP) and two did not (NRP).

Major themes associated with RE-AIM constructs initially identified at phase 3 included: 1) lack of dissemination of the retention plan (adoption), 2) reminders to use the retention plan (implementation), 3) contact with use of the retention plan (implementation), and 4) benefits of using the retention plan with the BLD program (maintenance). Three subthemes were discovered

in re-reading the data corpus during phase 4: 1) reinforcement 2) engagement, and 3) feedback from participants. The first subtheme fell under the reminders theme and the second and third subthemes fell under the contact theme. In refining the themes, contact was determined to be too specific, as it was a matter of Agents speaking with participants and vice-versa, so it was broadened to 'ongoing communication'. Reinforcement became the overarching theme as the retention plan was not just simply reminding participants of the content in the BLD curriculum, but also reinforcing and applying what they had learned to make better lifestyle changes. Reminders, ongoing communication, engagement and feedback with participants were changed to subthemes for the reinforcement theme. Moreover, the benefits of the retention plan were removed as the reinforcement theme addressed how the retention plan is beneficial to participants and the BLD program. Major themes that were identified in the final analysis were 1) ineffective dissemination of the retention plan by Extension Agents to participants (adoption) and 2) reinforcement of making lifestyle changes using the retention plan with reminders, ongoing communication, engagement, and feedback as subthemes (implementation and maintenance) (See Table 2 and Appendix I, figure 3).

Table 2. *Semi-structured interviews with Extension Agents*

RE-AIM Framework Domains	Themes and Subthemes	Content Analysis	Qualitative Feedback Responses
Adoption	Ineffective dissemination	Three Extension Agents confirmed that they used the retention plan (i.e., responded yes to a close ended item asking if they used it) and two agents who did not. The two agents did not use the plan said: they forgot about the retention plan and that they did not have enough information about the retention plan.	***Extension Agent #4***: "I knew we had it and then kind of slipped my mind that we had that as a resource until you reached out to me." ***Extension Agent #5***: "I am not sure. I guess I didn't have the information about it."
Implementation	Reinforcement of making lifestyle changes using the retention plan Subthemes: reminders, ongoing communication, engagement, and feedback	Extension Agents indicated how the retention plan was used and discussed implementation fidelity. One Extension Agent said she followed the retention plan when distributing the retention materials to her participants. The other Extension Agent said that she only distributed newsletters to her participants, as that was the only documentation related to the retention plan that she received.	***Extension Agent #3***: "The necessary document that went with that particular week, yes." ***Extension Agent #1***: "It's like whenever I got one...I wasn't following the plan. I wasn't aware of the entire plan but if I got one, I sent it".
		Distribution of retention materials to participants was mentioned. One Extension Agent provided all the retention materials to participants while the other Extension Agent only sent out the newsletters and was not intentionally following the retention plan but did communicate weekly with her participants through personal email.	***Extension Agent #1:*** "I did send emails to folks pretty much every week just reminding them, okay next week, same place, same time…but it wasn't intentionally following your plan." ***Extension Agent #3:*** "I provided all that was provided to me that associated with links."
		Extension Agents indicated that they sent their participants retention materials primarily in email or by mail depending on what	***Extension Agent #1***: "I had several older folks, so I printed them off and then sent them regular mail if they didn't have an

	participants suggested.	email address." ***Extension Agent #3***: "I sent it (retention materials) out either email or mail. Some preferred email and some preferred mail so that's why we implemented it both ways."
	One Extension Agent did not indicate any barriers or challenges with use and distribution of the retention materials; however, the other Extension Agent (with the co-facilitator) mentioned that distributing the retention materials was not the same as one-on-one interaction and could potentially impact participant accountability.	***Extension Agent #3***: "Via email and mail you know getting out the educational materials that's wonderful but the interaction, some of the participants really liked hearing from others in the class…I think they liked being a part of the group and face-to face." ***Extension Agent #3***: "I think with the motivation to actually come to class vs. having that long gap, that could maybe with issues following through because of the accountability piece…maybe for some that need that extra motivation than just the retention materials we sent them."
	The impact the retention materials had on participants coming back to the reunion session and making lifestyle changes was mentioned. Extension Agents said that participants engaged with the retention materials and they made an impact when it came to healthy lifestyle changes. This related to the ongoing communication and feedback subtheme.	***Extension Agent #1:*** "When folks got the newsletters that I sent out, they read them I know because they would mention I tried that recipe. There was conversation about it, and I think they appreciated and did use the information." ***Extension Agent #2***: "It kept it on their mind on what they were supposed to be focused on...and they were pleased with it most of them reported getting something in the mail, a reminder, then the newsletter, and the sheet that was sent and so they were aware of what came and so that kept them

			committed to the program." ***Extension Agent #3***: "Some of the participants even said that they even made some of those recipes in addition to the binder that they received."
Maintenance	Reinforcement of making lifestyle changes using the retention plan Subthemes: reminders, ongoing communication, engagement, and feedback	One Extension Agent that used the retention plan thought providing additional information beyond that provided during the BLD sessions related to healthy eating and physical activity would be beneficial. This related to the reinforcement theme.	***Extension Agent #3***: "Maybe adding to repertoire, like if you have additional recipes that we can include, that would be great…I don't know if there are any exercise videos that maybe we can include for them (the participants) or additional handouts on exercise that we can send to them."
		When asked about their plans for future BLD program and whether they planned to use the retention plan, agents indicated they would use the retention plan moving forward; however, one Extension Agent thought that having a support group would be an additional benefit to the BLD program.	***Extension Agent #1***: "I think it would be great just as a continuous reminder, not only for here is this upcoming meeting but hey don't forget you're supposed to tracking, you're supposed to be exercising, here is what to try…I can see where it would be a great benefit." ***Extension Agent #3***: "Maybe a support group…I think you were at the LIFT training and I am really excited about that and I think that is a great opportunity to support the BLD program and knowing that they will get the physical activity. I think that would be very very beneficial and be able to see improvements."

		Extension Agents that did not use the retention plan were asked their perspectives on the retention plan and if the retention plan was something that they would like to implement in their BLD programs moving forward. One Extension Agent indicated that she would use the retention plan and that it would be useful in her BLD programs. The other Extension Agent is no longer conducting BLD programs, but she would have liked to have used the retention plan in her previous programs.	***Extension Agent #4***: "I will definitely make sure I use the retention plan because like last year with me not using this or than like a phone, our attendance dropped off at the reunion." ***Extension Agent #5***: "I could have used something like this retention with every one of my programs. It would have been helpful to have them come to the reunion.

BLD Program Outcomes

Twenty-seven BLD programs, delivered by 12 Agents, were conducted during the study from January 2015- December 2017. Of the 27 BLD programs, there were only 14 BLD programs delivered by Agents who conducted programs both before and after the retention plan was available. Table 3 provides the retention rates for the 14 BLD programs delivered by the six Extension Agents either prior to or after the development of the retention plan by county. Qualitative feedback from Agents about whether they used the retention plan is also included (see Appendix J).

Reach and Adoption

Of the six Agents that delivered a BLD program after development of the retention plan, only three agents representing three counties confirmed use of the retention plan materials (RP) with a combined total of 26 participants in their post retention plan programs. Prior to the release of the retention plan, these three agents delivered the BLD to 27 participants. Two agents representing three counties confirmed that they did not use the retention plan (NRP) with a combined total of 18 participants in their post retention plan programs. Prior to the release of the retention plan, these two agents delivered the BLD to 45 participants. One agent representing one county did not respond to multiple email and phone call attempts (unknown) and was not included in the data analysis. This agent had five participants in the program prior to the development of the retention plan and six participants in the program after the development of the retention plan. Retention rates prior to and after the development of the retention plan are shown in Table 3.

Table 3.
Average Retention Rates Before and After the Retention Plan was Available for RP and NRP BLD programs

		BLD Programs Before the Retention Plan (Program #1)		BLD Programs After the Retention Plan (Program #2)	
Dimension	**Measure**	RP[a]	NRP[b]	RP	NRP
Reach, N	Number of programs	3 programs	3 programs	3 programs	3 programs
	Number of participants at baseline	27	45	26	18
Retention %	Percentage of participants retained	70%	69%	58%	67%

[a]Retention Plan. The Extension Agent used the retention plan for their second BLD program.

[b]Non-retention Plan. The Extension Agent did not use the retention plan for their second BLD program.

Effectiveness

The proportion of participants that began the program compared to participants that returned for the reunion class session in RP and NRP program was compared using the Pearson Chi-Square test ($p < 0.05$). More participants returned for the reunion class sessions in BLD programs prior to the development of the retention plan compared to BLD programs after the retention plan as reflected in the retention rates (see Table 3). This was true for both RP and NRP programs. Due to the exploratory nature of this study, it was not powered to detect statistical significance because of the small sample size.

A1C decreased in both RP and NRP programs. (see Table 4, Appendix J). RP programs showed greater improvement in four (two dietary behavior and two physical activity) of the eight health behaviors after the development of the retention plan. These included: increased use of the Plate Method, eating regular meals, tracking of walking and exercising, and walking or exercising. The other four health behaviors, eating five servings of fruits and vegetables, eating three servings of whole grains, eating three servings of milk, dairy or foods high in calcium, and planning to walk or exercise showed less improvement. RP programs with the retention plan showed greater improvement in self-efficacy for two dietary behaviors and one physical activity behavior compared to RP programs without the retention plan condition. These included: use of the Plate Method, choosing healthy foods when eating out, and keeping track of walking and exercising. Self-efficacy for the other four health behaviors, keeping track of eating, eating meals at regular times, using the nutrition facts label, and walking or exercise when other things need to be done, moved in a negative direction (see Table 4, Appendix J).

NRP programs only showed improvement in two dietary behaviors after the the retention plan was available. These included: eating three servings of whole grains and eating three servings of milk, dairy or foods high in calcium. The other six health behaviors, eating five servings of fruits and vegetables, using the Plate Method, eating meals at regular times, planning to walk or exercise, track of walking or exercising, and walking or exercising showed the opposite trend. NRP programs showed improvement in three (two dietary behavior and one physical activity) of the eight self-efficacy questions. These included: eating meals at regular times, choosing healthy foods when eating out, and keeping track of walking and exercising. The other five, keeping track of eating, using the Plate Method, using the nutrition facts label to

choose healthy foods, walking or exercising, and walking or exercise when other things need to be done, moved in a negative direction (see Table 4, Appendix J).

Independent samples t-tests did not show any significant differences in changes in health behaviors and self-efficacy between RP and NRP programs (see Appendix J).

Table 4.

Change in Program Outcomes between RP and NRP BLD programs before and after the development of the Retention Plan

			RP Programs		**NRP Programs**	
Dimension	**Measure**	**Tool**	Before Retention Plan (Program #1)	After Retention Plan (Program #2)	Before Retention Plan (Program #1)	After Retention Plan (Program #2)
Effectiveness						
A1C	Change in M(SD)	A1C Now+ Multi-test A1C System	-0.05 (1.14) [a]n = 17	-0.39 (0.63) [a]n = 15	-0.69 (1.01) [a]n = 31	-0.19 (0.34) [a]n = 12
Health Behavior	Change in M(SD)	BLD Questionnaire				
		In the past 3 months, how many days a week did you usually eat 5 servings of fruits and vegetables?	1.64 (2.02) [b]n = 14	0.47 (2.03) [b]n = 15	1.33 (2.62) [b]n = 24	0.91 (1.38) [b]n = 11
		In the past 3 months, how many days a week did you eat 3 servings of whole grains?	1.41 (1.68) [b]n = 12	0.46 (2.57) [b]n = 13	-0.17 (2.67) [b]n = 23	1.00 (1.79) [b]n = 11
		In the past 3 months, how	0.82 (1.40)	0.46 (2.57)	-0.04 (2.39)	0.00 (1.34)

	many days a week did you eat 3 servings of milk, dairy, or foods high in calcium?	[b]n = 9	[b]n = 13	[b]n = 24	[b]n = 11
	In the past 3 months, how many days a week did you use the Plate Method?	1.33 (2.55) [b]n = 11	1.69 (2.36) [b]n= 13	2.75 (2.55) [b]n = 20	1.00 (2.36) [b]n = 10
	In the past 3 months, how many days a week did you eat meals at regular times?	0.00 (2.70) [b]n = 12	0.85 (2.12) [b]n = 13	0.78 (2.90) [b]n= 23	0.60 (2.07) [b]n = 10
	In the past 3 months, how many days a week did you make a plan to walk or exercise?	1.50 (2.79) [b]n = 14	1.07 (2.09) [b]n = 14	2.40 (2.19) [b]n = 20	1.20 (1.55) [b]n = 10
	In the past 3 months, how many days a week did you keep track of how much you walked or exercised?	1.14 (2.68) [b]n = 14	1.86 (1.75) [b]n = 14	2.20 (2.42) [b]n= 20	0.78 (1.64) [b]n = 9
	In the past 3 months, how	0.50 (1.40)	0.86 (2.57)	1.80 (1.94)	1.27 (2.15)

		many days a week did you walk or exercise?	[b]n = 14	[b]n = 14	[b]n = 20	[b]n = 11
Self-efficacy	Change in M(SD)	BLD Questionnaire				
		How sure are you that on most days you can keep track of what you eat?	0.21 (1.12) [b]n = 14	0.00 (1.36) [b]n = 14	0.52 (1.16) [b]n = 25	0.30 (0.48) [b]n = 10
		How sure are you that on most days you can use the Plate Method?	0.21 (1.19) [b]n = 14	0.42 (1.88) [b]n = 12	0.27 (1.08) [b]n= 22	0.11 (0.78) [b]n = 9
		How sure are you that on most days you can eat meals at regular times?	-0.07 (1.07) [b]n = 14	-0.07 (1.07) [b]n= 14	0.00 (1.22) [b]n = 24	0.44 (1.33) [b]n = 9
		How sure are you that on most days you can choose healthy foods when you eat out?	0.67 (0.98) [b]n = 15	0.85 (1.28) [b]n = 13	0.05 (1.00) [b]n = 22	0.30 (0.67) [b]n = 10
		How sure are you that on most days you can use the nutrition facts label to choose healthy foods?	0.57 (1.22) [b]n = 14	0.21 (1.12) [b]n = 14	0.38 (0.86) [b]n = 21	0.30 (0.48) [b]n = 10

	How sure are you that on most days you can walk or exercise?	0.53 (1.19) [b]n = 15	-0.71 (0.83) [b]n = 14	0.41 (0.96) [b]n= 22	0.40 (0.84) [b]n = 10
	How sure are you that on most days you can walk or exercise when you have other things to do?	0.40 (1.35) [b]n = 15	0.33 (1.23) [b]n= 12	0.00 (0.82) [b]n= 22	-0.30 (1.06) [b]n= 10
	How sure are you that on most days you can keep track of how much you walked or exercised?	0.00 (1.71) [b]n = 14	0.36 (1.50) [b]n = 14	0.09 (1.00) [b]n= 23	0.20 (1.32) [b]n = 10

M(SD) = mean and standard deviation

[a]n= number of participants that provided an A1C

[b]n = number of participants that responded to the question pre and post.

Conclusions

Overall, the retention plan was valued by Agents as a useful tool that allowed them to be in ongoing communication with their participants. Use and dissemination of the retention plan by Agents varied and was lower than anticipated (low adoption).

Two major themes that arose from interviews with Agents were ineffective dissemination and reinforcement. Of the six agents who conducted a second BLD program after the retention plan was introduced, only three remembered to use it. Of those, not all used it in its entirety. This was unexpected, as the retention materials were produced in response to a need identified by the Agents themselves. Despite the retention plan being provided to Extension Agents with guidance on use and distribution of associated materials, as well as accessibility on the online instructional technology site, some Agents were still unaware of the retention plan.

Lack of fidelity could explain why some of the health behavior and self-efficacy indicators in programs where the Agent used the retention plan did not show greater improvement. Despite this, in programs that used the retention plan, participants slightly improved glycemic control and some health behaviors, specifically: increased use of the Plate Method, eating regular meals, tracking of walking and exercising, and walking or exercising.

Self-efficacy also improved slightly for using the Plate Method, choosing healthy foods when eating out, and keeping track of walking and exercising. In a randomized weight management trial for people with diabetes, positive reinforcement, social support, and monitoring progress were key retention strategies to retain participants in the program and to keep them on track with program goals.[43] Ongoing use of the retention plan could keep

participants engaged with the BLD program and encourage them to utilize aspects of the BLD program that would lead to greater health benefits.

Reinforcement was an overarching theme from the agent interviews. The retention plan would provide additional support to participants to continue making lifestyle changes. Agents thought the retention plan was helped to keep participants motivated and reminded to continue tracking and setting goals. This corroborates a study by Carroll and colleagues[42] that indicated that having contact with study participants and having a positive caring attitude towards participants were effective retention strategies mentioned in community-based programs.

Agents thought that ongoing communication with participants would allow for more feedback and engagement. This is consistent with a study by McCann and colleagues[20], in which key informants of community health promotion organizations indicated that participants' enabling social connections, promoting participant input and support were effective retention strategies. Some participants in RP programs told Agents of their use of recipes included in retention materials and about their lifestyle changes. The literature indicates that a vital component of DSME programs is continued assistance and follow-up with participants.[6,7-19] . One of the three RP Agents suggested that in addition to the retention plan, having a support group and having more physical activity would assist BLD participants. Agents that did not use the retention plan indicated that they would use it in the future.

The small number of Agents that used the retention plan makes it difficult to draw definitive conclusions. This low adoption rate among the agents who could have used the retention plan highlighted a need to evaluate the way it was disseminated. According to Franz et al., Extension educators have many responsibilities in their workspace such as forming and serving on committees and task forces, building long term relationships with community

members and addressing needs of the community, serving as facilitators for educational settings to provide research-based knowledge to the community through media outlets and conducting public forms to address those community-based issues.[36] Obtaining input from Extension Agents who plan to implement BLD program on ways they can most efficiently and effectively receive retention plan materials needs to be addressed.

This study had several limitations. First, there was a small sample size in both RP and NRP programs because there were not many BLD programs conducted after introduction of the retention plan during the USDA-funded study Second, the retrospective nature of this study made it difficult to assess whether the retention plan itself influenced participants in RP programs to return to the reunion class session. In addition, interviews with Extension Agents were conducted two years after the end of the USDA study. This could have introduced recall bias. Although recall bias is common in retrospective studies, recall bias due to the long gap may have led to underreporting of awareness and use of the retention plan. Third, there was only one coder for the thematic analysis, which could have introduced coder biases. To compensate for this, the thematic analysis procedures were strictly followed, with methodical documentation presented in detail in this study. Efforts to reduce bias included taking additional notes, repeating the data coding, and re-reading the data corpus multiple times to ensure accuracy of the thematic analysis processes.

The retention plan was an adaptation to the BLD program, made in response to a practical need to address low retention rates. It was intended to improve retention rates and maintain ongoing communication and support between the Extension Agents and their participants. Chambers and Norton's Adaptome identifies adaptations made to programs/interventions as an ongoing process to determine which version of the program is most appropriate, and if it helps or

hinders the population that receives the adapted program.[37] Though the literature suggests that finding effective strategies to improving retention in community-based programs is an important area of research, there are very few studies that address attrition or retention rates in DSME programs.[8,9, 38-40] In addition, there is no standard method for evaluating attrition in DSME programs.[41] This study retrospectively evaluated the implementation and effects of a retention plan developed as a preliminary strategy to improve retention rates. Preliminary findings indicate that retention materials are well received by Extension Agents, who felt that they increased ongoing communication with participants in their programs, although methods of disseminating information about the retention materials need to be improved to assure broad awareness of their existence.

Future research should include studies with a larger number of BLD programs that use the retention plan. This would allow for greater power to determine whether the retention plan improves program outcomes. Our findings suggest that the retention plan should be disseminated more effectively to Extension Agents prior to the start of their programs, which will allow for greater accessibility and understanding of the utilization of the retention plan. It is essential that the retention materials be used with fidelity in order to determine its their effects on participant retention and program outcomes.

Follow-up interviews with participants may be helpful to obtain their input regarding the retention plan, and gain insight on factors that motivated them to attend weekly BLD sessions and the reunion class session. Additionally, studies to understand the underlying psychosocial factors that influence attrition rates, and that can be addressed to enhance readiness in DSME programs would be valuable as most studies only evaluate program attrition based upon clinical factors.[7-19]

References

1. Centers for Disease Control and Prevention. (2017). *National Diabetes Statistics Report 2017.* CDC.
2. Centers for Disease Control and Prevention. (2018, February 2). *Prevalence of Both Diagnosed and Undiagnosed Diabetes*. Retrieved from Centers for Disease Control and Prevention: https://www.cdc.gov/diabetes/data/statistics-report/diagnosed-undiagnosed.html
3. Centers for Disease Control and Prevention. (2018, February 2). *Prevalence of Diagnosed Diabetes*. Retrieved from Centers for Disease Control and Prevention: https://www.cdc.gov/diabetes/data/statistics-report/diagnosed.html
4. American Diabetes Association. (2016). *The Burden of Diabetes in Virginia* . Retrieved from American Diabetes Association: http://main.diabetes.org/dorg/PDFs/Advocacy/burden-of-diabetes/virginia.pdf
5. CDC National Center for Chronic Disease Prevention and Health Promotion Division of Diabetes Translation. National diabetes statistics report. http://www.cdc.gov/diabeteS/pubs/statsreport14/national-diabetes-report-web.pdf.
6. Chapman-Novakofski, K., & Karduck, J. (2005). Improvements of knowledge, social cognitive variables, and movement through stages of change after a community-based diabetes education program. *American Dietetic Association*, 1613-1616.
7. Gucciardi, E., DeMelo, M., Offenhiem, A., & Steward, D. (2008). Factors contributing to attrition behavior in diabetes self-management programs: A mixed method approach. *BMC Health Services Research*, 1-11.

8. Gucciardi, E. (2008). A Systematic Review of Attrition from Diabetes Education Services: Strategies to Improve Attrition and Retention Research. *Canadian Journal of Diabetes*, 53-65.
9. Powers et al. (2015). Diabetes Self-management Education and Support in Type 2 Diabetes: A Joint Position Statement of the American Diabetes Association, the American Association of Diabetes Educators, and the Academy of Nutrition and Dietetics. *The Diabetes Educator*, 1-14.
10. Rutledge, S., Masalovich, S., Blacher, R., & Saunders, M. (2017). Diabetes Self-Management Education Programs in Nonmetropolitan Counties-United States 2016, *Centers for Disease Control and Prevention.*
11. Norris SL, Engelgau MM, Narayan KM. Effectiveness of self-management training in type 2 diabetes: a systematic review of randomized controlled trials. *Diabetes Care*. 2001;24:561-587.
12. Norris SL, Nichols PJ, Caspersen CJ, et al. Increasing diabetes self-management education in community settings. A systematic review. *Am J Prev Med.* 2002;22(4 suppl):39-66.
13. Norris SL, Lau J, Smith SJ, et al. Self-management education for adults with type 2 diabetes: a meta-analysis of the effect on glycemic control. *Diabetes Care*. 2002; 25:1159-1171.
14. Renders CM, Valk GD, Griffin S, et al. Interventions to improve the management of diabetes mellitus in primary care, outpatient and community settings. *Cochrane Database Syst Rev*. 2001;(1):CD001481.

15. Vermeire E, Wens J, Van Royen P, et al. Interventions for improving adherence to treatment recommendations in people with type 2 diabetes mellitus. *Cochrane Database Syst Rev*. 2005;(2):CD003638.
16. Gary TL, Genkinger JM, Guallar E, et al. Meta-analysis of randomized educational and behavioral interventions in type 2 diabetes. *Diabetes Educ*. 2003;29:488-501.
17. Strine, T. W., Okoro, C. A., Chapman, D. P., et al. (2005) The impact of formal diabetes education on the preventive health practices and behaviors of persons with type 2 diabetes. *Preventive Medicine*, 41 (1), 79–84.
18. Rhee MK., Slocum W., Ziemer DC., et al. Patient adherence improves glycemic control. *Diabetes Educ*. 2005;31:240-250.
19. Mensing C., Boucher J., Cypress M., et al. National standards for diabetes self-management education. *Diabetes Care*. 2004;27(suppl 1):S143-S150.
20. McCann, J., Ridgers, N., Thorton, L., & Teychenne, M. (2013). Effective recruitment and retention strategies in community health programs. *Health Promotion Journal Australia*, 104-110.
21. Health Resources and Services Administration . (2019). *Recruiting and Retaining Program Participants*. Retrieved from Rural Health Information Hub: https://www.ruralhealthinfo.org/toolkits/health-promotion/3/recruiting-and-maintaining
22. U.S. Department of Agriculture. (n.d.-a). Extension. Retrieved November 11, 2019, from https://nifa.usda.gov/extension
23. U.S. Department of Agriculture. (n.d.-a). Economic Research Service. Retrieved November 11, 2019, from https://www.ers.usda.gov/agricultural-act-of-2014-highlights-and-implications/

24. Bandura, A. (1977). Self-efficacy: toward a unifying theory of behavior change. *Psychological review*, 191-215.

25. Bandura, A. (2001). Social Cognitive Theory of Mass Communication. *Psychology*, 265-299.

26. Glasgow RE. Outcomes of and for diabetes education research. *Diabetes Educ.* 1999;25(6 suppl):74-88.

27. Glasgow RE, Vogt TM, Boles SM. Evaluating the public health impact of health promotion interventions: the RE-AIM framework. *Am J Public Health.* 1999;89(9):1322–1327

28. Glasgow, R.E., Nelson, C.C., Strycker, L.A., King, D.K. Using RE-AIM Metrics to Evaluate Diabetes Self-Management Support Interventions. 2006;(30): 67-73

29. Gaglio, B., Shoup, J., & Glasgow, R. E. (2013). The RE-AIM Framework: A Systematic Review of Use Over Time. *American Journal of Public Health*, 38-46.

30. Sweet, S. N., Martin Ginis, K. A., Estabrooks , P. A., & Latimer-Cheung , A. E. (2014). Operationalizing the RE-AIM framework to evaluate the impact of multi-sector partnerships. *Implementation Science*, 1-10.

31. Harden et al. (2018). RE-AIM in Clinical, Community, and Corporate Settings: Perspectives, Strategies, and Recommendations to Enhance Public Health Impact. *Frontiers in Public Health*, 71, 1-10

32. Anderson ES, Winett RA, Wojcik JR, Winett SG, Bowden T (2006): Social-cognitive determinants of physical activity: the influence of social support, self-efficacy, outcome expectations, and self-regulation among participants in a church-based health promotion study. *Journal of Health Psychology*, 510-20.

33. Bruan V., & Clarke, V. (2006). Using thematic analysis in psychology. *Qualitative Research in Psychology*, 77-101

34. Bruan, V., & Clarke, V. (2012). Thematic Analysis. In I. H. Cooper, P.M. Camic, L. Long, D. Panter, D. Rindskopf, & K. J. Sher, *APA Handbook of Research Methods in Psychology Vol. 2 Research designs: Quantitative, qualitative, neuropsychological, and biological* (pp. 55-71).

35. QSR International NVivo [Computer software]. (2019). Retrieved from https://www.qsrinternational.com/nvivo/

36. IBM Corp. Released (2018). IBM SPSS Statistics for Windows, Version 26.0. Armonk, NY: IBM Corp.

37. Franz, N., Towson, L., (2008). The Nature of Complex Organizations: The Case of Cooperative Extension. *New Directions for Evaluation*, 120, 5–14

38. Chambers, D., Phil, D., & Norton, W. (2016). The Adaptome-Advancing the Science of Intervention Adaptation. *American Journal of Preventive Medicine* , 124-131.

39. Gucciardi , E., DeMelo , M., Booth, G., Tomlinson , G., & Stewart, D. E. (2009). Individual and contextual factors associated with follow-up use of diabetes self-management education programmes: a multisite prospective analysis. *Diabetic Medicine* , how510-517.

40. Gucciardi, E., Smith, T. & DeMelo, M. (2006) Use of diabetes resources in adults attending a self-management education program. *Patient Education and Counselling*, 64 (1–3), 322–330.

41. Gucciardi, E., DeMelo, M., Offenheim , A., Grace, S., & Stewart, D. (2007). Patient factors associated with attrition from a self management education programme. *Journal of Evaluation in Clinical Practice,* 914-91.

42. McCallugh, Marjorie, Sanon, Marie-Anne., Cohen, Michael. (2014) Strategies to enhance participant recruitment and retention in research involving a community-based population. *Journal of Applied Nursing Research*, 27(4): 249–253.

43. Parra-Medina D., D'Antonio A., Smith SM., Levin S., Kirkner G., Mayer-Davis E. (2004) Successful recruitment and retention strategies for a randomized weight management trial for people with diabetes living in rural, medically underserved counties of South Carolina: the POWER study. Journal of the American Dietetic Association. 104(1):70–75

Chapter 4

The effects of the incorporation of a physical activity program (LIFT) into a diabetes lifestyle management (BLD) program on implementation and outcomes: A pilot multi-methods study

Abstract

Introduction: The prevalence of diagnosed diabetes was estimated to be 23.1 million adults in the U.S. in 2015. It was estimated that approximately 837,000 residents in Virginia have diabetes. Physical activity in older adults is essential to managing chronic illnesses such as diabetes and cardiovascular disease. Community-based health and education programs such as the Balanced Living with Diabetes (BLD) program and the Lifelong Improvements through Fitness Together (LIFT) program play a pivotal role in establishing healthy lifestyle changes such as increased physical activity and improved dietary behaviors.

Methods: The purpose of this randomized control pilot study was to evaluate the effects of incorporating LIFT program with the BLD program on outcomes. Quantitative evaluation methods included comparative analysis of glycemic control measured by A1C, retention, patient engagement using the Patient Activation Measure, weekly leisure activity using the Godin Leisure Exercise Time Questionnaire, self-reported physical activity and dietary behaviors using the BLD questionnaire, and functional fitness using an adapted functional fitness test. Qualitative evaluation methods included conducting interviews with Extension Agents that implemented BLD and BLD+LIFT programs.

Results: More participants returned for the reunion class session in BLD+LIFT programs. A1C values increased for both programs. PAM activation scores and levels declined in BLD+LIFT programs. Total weekly leisure activity scores declined in both programs. There were improvements in one health behavior and three self-efficacy indicators for physical activity, and

two health behavior indicators for diet in BLD+LIFT programs. Themes from Extension Agents interviews included modifications to BLD and LIFT programs, use of the retention plan, time commitment of BLD and LIFT programs, program logistics of BLD and LIFT programs, and benefits of implementing the BLD+LIFT.

Discussion/Conclusion: This pilot study indicated that participation in the LIFT program may have impacted self-efficacy for physical activity and some dietary health behaviors in BLD+LIFT programs. Extension Agents are interested to implement BLD+LIFT programs however, clarity of program logistics is needed. Implementation at locations with older adults having greater disabilities may not be the best locations. A fully powered randomized trial with BLD and BLD+LIFT programs would allow for a greater effect size to determine the impact of addition of the LIFT program with the BLD program on program outcomes.

Introduction

According to the Centers for Disease Control and Prevention (CDC), the National Diabetes Statistics Report indicated that the prevalence of diagnosed diabetes was estimated to be 23.1 million (7.2%) adults in the U.S. in 2015 [1]. The Virginia Department of Health (VDH) and the CDC indicate the prevalence of diabetes in Virginia is higher than the national average (9.6 vs. 8.1) and it is estimated that approximately 837,000 (12.2%) residents in Virginia has diabetes [2,3]. Risk for developing type 2 diabetes increases when patients have prediabetes, hypertension and hyperlipidemia [1,4,5]. Additionally, risks for developing type 2 diabetes increases when individuals are overweight or obese, are not physically active, and have poor dietary habits [1,4,5]. Adults that develop type 2 diabetes are at increased risk for developing other health comorbidities such as cardiovascular disease, kidney disease, metabolic syndrome, and nerve damage [1,4,5]. In Virginia, women tend to have higher rates of diabetes than men (9.8% vs. 9.6%) and African Americans/Blacks are more likely to have diabetes in Virginia (15.4%) compared to Hispanics/Latinos (5.4%) and Caucasians/Whites (9.1%) [2,3].

Physical activity in adults and older adults is essential to managing chronic illnesses such as diabetes, arthritis, and cardiovascular disease [6,7]. Older adults who are physically active are more likely to be able to perform activities of daily living such as getting out of bed, getting dressed, taking a bath, and being mobile within or outside the home, which are important for independent living [6,7]. The benefits of being physically active for older adults is a decreased risk for falls or injuries [6,7]. In addition, it improves physical function and mobility, and helps delay or prevent other major disabilities [7]. According to the Physical Activity Guidelines for Americans 2nd edition, older adults should do from 150 minutes (2 hours and 30 minutes) to 300 minutes (5 hours) of moderate-intensity, or 75 minutes (1 hour and 15 minutes) to 150 minutes

(2 hours and 30 minutes) of vigorous-intensity aerobic physical activity a week [8,9]. In addition, it recommends adults should do muscle-strengthening activities of moderate or greater intensity on 2 or more days a week [8,9]. According to the American Diabetes Association, adults 65 years or older are sedentary and do not engage in physical activity, so interventions that increase physical activity in the older adult population are important to promote health and prevent chronic disease [8,9].

Healthy People 2020 indicates that community-based health and education programs play a pivotal role in establishing wellness and promoting healthy lifestyle changes such as increased physical activity and improved dietary behaviors in adults [10]. The Cooperative Extension System (CES) is a nationwide education network that provides research-based information and programs in nearly all of the 3,000 counties in the U.S. The Extension System is associated with the land-grant universities in each state and conducts outreach and educational programs in the communities they serve through partnerships and collaborations with public and private organizations. [11]. The Extension System offers educational evidence-based programs and information in the areas of agriculture, community development, natural resources, and food and nutrition [11]. Recently, objectives to incorporate physical activity programming to Extension activities was added to the U.S. Agricultural Act of 2014 (also known as the Farm Act) which "authorizes physical activity promotion in addition to promotion of healthy food choices as part of this nutrition education and obesity prevention program" [12]. Physical activity was also included in the 2014 strategic plan of the National Institute of Food and Agriculture [13]. Virginia Cooperative Extension (VCE) specifically, provides scientific knowledge and research-based solutions through community-based educational programs that address chronic disease prevention and control to improve health issues in the Commonwealth [14,15]. Among these are

the Balanced Living with Diabetes (BLD) Program, and the Lifelong Improvements through Fitness Together (LIFT) Program [14,15].

The BLD program, an evidence-based diabetes lifestyle self-management program, uses an active learning approach to influence behavior change to help participants improve glucose control and maintain a healthful lifestyle. Guided by the Social Cognitive Theory (SCT), the BLD program emphasizes self-efficacy, goal setting, self-regulation, and social support to encourage improvement in self-management of diabetes [16,17]. The program consists of four (two hour) weekly classes, a 2-month (8-week) hiatus, followed by a reunion class session to reevaluate program outcome measures. The interactive program is organized by a VCE Family and Consumer Science (FCS) Agent and is co-facilitated by a registered dietitian nutritionist (RDN) or a certified diabetes educator (CDE) located within the community. Studies funded by the National Institute of Health (NIH) and United States Department of Agriculture (USDA) on the implementation and effectiveness of the BLD program have shown significant A1C reduction [18] among participants. The NIH study showed a clinically significant reduction in A1C level of 0.5%. Mean A1C reduction for participants with baseline A1C over 7.0% was 0.57 ± 1.43. USDA study results indicated significant mean A1C reduction for all participants with diabetes; with a mean reduction in participants with baseline A1C over 7.0% of 0.384 ± 1.182 (paired t-test $p = 0.014$) (K. Hosig, personal communication, September 1, 2018).

LIFT is a groups dynamics-based strength training program for older adults. LIFT offers 16 in person strength training sessions (one-hour, twice a week for eight weeks) intended to increase physical activity and improve fitness capabilities to enhance strength, balance, and flexibility among older adult participants [19,20]. Functional fitness assessments are conducted before and after the LIFT program to measure upper and lower body strength as well as

flexibility, balance, and endurance to assess level of activity [19,20]. Adapted from Stay Strong Stay Healthy (SSSH) [21] and Activity for the Ages [22], this program uses group dynamics, nutrition education, self-monitoring and tracking to enhance self-efficacy [19,20]. Extension Agents work with participants in the LIFT program to 1) monitor their dietary behaviors, 2) monitor physical activity and increase functional fitness behaviors, and 3) generate participant engagement and group cohesion so that participants maintain ongoing communication and interaction with one another. Participants can also create friendly competition so that they are more likely to hold themselves accountable when tracking and setting goals [19,20]. A study conducted by Wilson and colleagues to evaluate the reach and effect of the LIFT program compared to the SSSH program indicated that functional fitness change scores were significant in all seven of the functional fitness measures in LIFT participants ($p < 0.05$) compared to SSSH participants, who were only able to significantly improve in five of the seven functional fitness measures. Overall the study indicated that both the LIFT and SSSH are feasible programs and although not significant ($p = 0.138$), the LIFT program has better retention compared to SSSH program (75% vs. 58%) [20].

The benefit of integrating the BLD and LIFT programs is that participants would receive diabetes and nutrition education, as well as a structured physical activity program, enhancing the opportunity for participants to make lifestyle changes. Studies have shown that incorporating physical activity in diabetes education programs for patients that have type 2 diabetes improves glycemic control [23-28]. Since the BLD program has a 2-month hiatus (an 8-week time period between the last or the 4th BLD class session and the reunion class session) and the LIFT program is an 8-week program, the LIFT program could easily be incorporated with the BLD. Adding LIFT as part of the BLD would increase the duration and intensity of the BLD program.

This could potentially lead to a greater impact on glycemic control and increase the dose of physical activity needed to achieve behavior change. In addition, the BLD and LIFT programs have overlapping constructs and strategies relative to improved health outcomes. Incorporating both programs would help participants reinforce the content learned, develop individual goals, and increase self-efficacy. It would also increase fitness activity as well as participant engagement and social support. The purpose of this pilot study was to evaluate the impact of incorporation of the LIFT program with the BLD program on program outcomes and evaluate the implementation of the BLD and BLD+LIFT programs by Extension Agents.

Methods

Study locations

Three Extension Agents, two of whom were working together in the same county, were recruited. They agreed to implement BLD and BLD+LIFT programs. The programs were conducted in three counties. These Extension Agents collaborated with two community organizations: Piedmont Senior Resources (PSR) Area Agency on Aging (AAA) [29] and Program for All-Inclusive Care for the Elderly (PACE) [30]. PSR AAA serviced Lunenburg County (Victoria, VA) and Charlotte County (Keysville, VA), PACE serviced Roanoke County (Roanoke, VA). Each site was randomized to receive the BLD (control) or the BLD+LIFT (intervention) program.

Descriptive statistics of study locations indicate that Lunenburg and Charlotte County have similar population sizes (12,369 and 12,176) as well as similar median ages (45.4 years and 45.2 years) and household income ($39,537 and $38,350) [31]. Roanoke County has a larger population size (93,419), greater household income ($62,134), and slightly lower median age

(43.7 years) [31]. Lunenburg and Charlotte County have greater racial diversity and poverty rates compared to Roanoke County [31] (see Table 1).

Table 1.
Sociodemographic data of standard BLD and BLD+LIFT study locations

	Roanoke County (Roanoke, VA)	**Lunenburg County (Victoria, VA)**	**Charlotte County (Keysville, VA)**
Population Size	93,419 residents	12,369 residents	12,176 residents
Median Age	43.7 years	45.4 years	45.2 years
Total Population	93,419 residents	12,369 residents	12,176 residents
Population 60+	20,026 residents	3,504 residents	3,668 residents
Race/Ethnicity	Caucasian/White: 86.5% African American/Black: 5.8%% Hispanic/Latino: not reported	Caucasian/White: 59.9% African American/Black: 30.8% Hispanic/Latino: 4.28%	Caucasian/White: 67.5% African American/Black: 29.6% Hispanic/Latino: not reported
Median Household Income	$62,134	$39,537	$38,350
Overall Poverty Rates	7.98%	18.6%	22.7%
Poverty Rates by Race	Caucasian/White: 80% African American/Black: 8.93% Hispanic/Latino: 2.78%	Caucasian/White: 41.6% African American/Black: 46.8% Hispanic/Latino: 5.99%	Caucasian/White: 57.7% African American/Black: 38.2% Hispanic/Latino: 1.88%

Source: United States Census Bureau (2018). Retrieved from American Community Survey (ACS) 5-year estimate.

Research design

Four groups were pair-matched by geographical location and randomized within pairs to receive the standard program (BLD) or BLD with the eight-week LIFT strength-training program BLD+LIFT. This randomized controlled pilot study evaluated the effects of incorporating LIFT program with the BLD program on program outcomes, which included glycemic control, participant retention, participant engagement, self-reported physical activity, self-reported

dietary behaviors, and functional fitness. It also evaluated aspects of implementation of the BLD and BLD+LIFT by Extension Agents which included 1) inner context, 2) fidelity, 3) barriers and facilitators 4) time, and 5) acceptability.

Interventions

The BLD program consisted of four (two-hour) weekly BLD class sessions, a 2-month (8-week) hiatus, and the BLD reunion class session. During the hiatus, 8-weeks between the last BLD class session and the reunion class session, participants received retention materials that reinforced BLD content taught during the sessions. The retention plan and associated materials are described elsewhere (Chapter 3).

The BLD+LIFT program consisted of four (two-hour) weekly BLD class sessions, the 8-week LIFT class sessions, and the BLD reunion class session. Agents received materials designed to foster participant retention to use when delivering BLD+LIFT program during the time LIFT was being implemented. Prior to the implementation of LIFT, participants were required to complete a Physical Activity Readiness Questionnaire+ (PARQ+) (see Appendix R). The PARQ+ is a self-administered exercise screening measure used to identify individuals for which physical activity may be inadvisable [32,33]. The PARQ+ was used for program participants to evaluate their physical abilities before engaging in any physical activity and if it was necessary to seek medical advice from a physician or healthcare professional before becoming more physically active [32,33]. If program participants answered yes to any of the questions, participants were required to obtain written physician authorization (via a physician authorization form) prior to participation in the LIFT program (see Appendix R).

To compare level of change in functional fitness between the standard BLD (control group) and BLD+LIFT (intervention group) program participants, functional fitness tests were

conducted with participants in both groups the week after the fourth BLD session (pre), and the week before the reunion class session (post).

Approval of the study was obtained from the Virginia Tech Institutional Review Board (IRB #18-1130) prior to engaging in any research activities. (see Appendix K).

Participant recruitment

Recruitment for the program was conducted by the Extension Agents in their respective counties and by their community partners (PSR AAA and PACE) which included posting flyers and brochures and having verbal communication with people that attended the sites. Extension Agents that collaborated with the AAA recruited participants for the study by posting flyers at their local Extension office and in local healthcare facilities where they receive referrals from local physicians. PSR also advertised the program among their clientele. The flyers and brochures provided general information about a diabetes lifestyle management program (BLD) and being part of a research study (see Appendix M). For prospective participants that were interested in the program, the program directors at the PSR AAA and PACE sites obtained their names.

An informational session was conducted by the research team for interested participants at each site prior to the start of the programs. Researchers introduced the BLD program, the opportunity to receive strength training classes in addition to the BLD (LIFT). Researchers also introduced being part of a research study, which included participants' responsibilities and data collection procedures. Groups at the locations were told that they may receive the BLD+LIFT or the BLD program, however, it would not be until after baseline data collection until they knew. Those that did not want to be part of the study could still participate in the BLD or BLD+LIFT sessions. Informed consent was acquired prior to baseline data collection for those who agreed to

participate in the research study (see Appendix L). To avoid experimenter bias, a simple randomization method was used to randomly assign each group by location to either the BLD program or BLD+LIFT program. LIFT was offered to the group that was not randomized to receive LIFT after completion of the study. Baseline data collection was held a week after the information session.

Data collection

Participant Outcomes

Participant outcome measures were used to compare the BLD and BLD+LIFT programs. The primary outcome was glycemic control. The secondary outcomes were program retention rates, changes in participant engagement, self-reported physical activity, self-reported dietary behaviors, and functional fitness. Primary and secondary outcomes were measured at baseline and at the reunion class session two months later.

Glycemic control was measured using glycosylated A1C (A1C). Approximately five µl of blood was acquired via fingerstick and analyzed for A1C via an A1C kit (A1C Now+ Multi-test A1C System). Two tests were conducted, with an additional third test conducted if the first two test results were more than 0.4 A1C units (%) apart. Average A1C, from the two tests that were the closest in range, was the unit of analysis.

Patient engagement was measured using the validated Patient Activation Measure (PAM) from Insignia Health (see Appendix P) [33,34]. Responses on hard copy questionnaires were entered into the online PAM scoring system. PAM is a 13-item survey used to measure a patient's self-management abilities, more specifically, a patient's knowledge, skills, and confidence to manage his or her health and healthcare [34,35]. This 13-item tool also contains valid and reliable psychometric measures intended to assess activation in four stages: 1)

believing the patient role is important, 2) having the confidence and knowledge necessary to take action, 3) taking action to maintain and improve one's health, and 4) staying the course even under stress [34,35]. The PAM survey provided two metrics: activation score and activation level [33,34]. The activation score is based on a 0-100-point scale [34,35]. The activation level is determined from the activation score. The activation level is an indicator of a patient's competency to tackle new behaviors [34,35]. Levels of patient activation consisted of: Level 1- disengaged and overwhelmed; Level 2- becoming aware but still struggling; Level 3- taking action; Level 4- maintaining behaviors and pushing forward [34,35]. The level is an indicator of an individual's competency to tackle new behaviors, so patients that receive a high activation score have a higher activation level thus indicating increased patient engagement and better diabetes self-management capabilities [34,35]. The online PAM scoring system automatically adjusts activation score and activation level for response patterns with higher than typical rates of agreement or disagreement (see Appendix Q).

Self-reported physical activity was measured using the Godin Leisure-Time Exercise Questionnaire (GLTEQ) (see Appendix O) [36,37]. The GLTEQ is a self-administered validated tool that asks participants to recall the amount of time spent in strenuous, moderate, and mild leisure time physical activity for each day over seven days [36,37]. This 4-item questionnaire measures weekly frequencies in strenuous, moderate, or mild leisure time physical activities of at least 15 minutes during a 7-day period [36,37]. The frequency scores are multiplied by 9 (strenuous), 5 (moderate), and 3 (mild) metabolic equivalents respectively and summed to form a measure of total weekly leisure activity score expressed in arbitrary units [36,37].

Self-reported physical activity and dietary behavior changes were measured using health behavior and self-efficacy questions within the BLD questionnaire provided to participants at baseline and the reunion class session (see Appendix G and H). The questionnaire was adapted from the Foods Beliefs Survey, a valid and reliable tool for measuring nutrition behavior using SCT constructs [38-41]. It was tailored to also measure physical activity using SCT constructs. All items in the health behavior section of the BLD questionnaire began with the root "In the past 3 months, how many days a week did you…" and participants selected a number from 0-7. All items in the self-efficacy section of the BLD questionnaire began with the root "How sure are you that on most days you can…and questions were on a 5-point Likert scale, 1= very unsure , 5= very sure. Reasons for evaluating the health behavior and self-efficacy sections of the questionnaire were to see if participants made changes to their dietary and physical activity behaviors during the time between the start of the BLD program and the end BLD program (reunion class session), and to see if self-efficacy to make changes to their dietary and physical activity behaviors improved.

Functional fitness tests were used to measure functional fitness outcomes of BLD and BLD+LIFT programs as mentioned previously (see Appendix R). Adapted from the functional fitness tests by Rikli and Jones [42], this validated and reliable tool measured upper and lower body strength, aerobic endurance, upper and lower body flexibility, agility, and balance. The assessment includes a balance station of six balance challenges to be completed for 10 seconds. If a participant, at any juncture, could not complete the balance movement for the full 10 seconds, the participant did not move on to the next balance movement. A composite balance score was computed based on the total number of balance movements participants were able to complete.

At baseline data collection, A1C and anthropometric measurements were obtained from program participants in the BLD and BLD+LIFT programs, and they were provided the BLD questionnaire, PAM Survey, the GLTEQ, and the PARQ+ for completion (see Appendices G, H, P, Q, and R). Program participants requiring assistance to complete the questionnaires were assisted with their paperwork by a researcher, which included reading the questions and providing oral guidance when needed. A1C, anthropometric measurements, and paperwork data was collected by the researchers and Extension Agents from program participants on the same day as the first BLD session. Similarly, at the reunion session, A1C and anthropometric measurements were obtained from program participants, and they were provided the BLD questionnaire, PAM survey, and the GLTEQ for completion. As with the baseline data collection, program participants requiring assistance to complete the questionnaires were assisted with their paperwork.

Retention rates were calculated by obtaining the proportion of BLD and BLD+LIFT program participants that began the BLD program and returned for the BLD reunion class session.

Program Implementation

Program implementation of BLD and BLD+LIFT programs by Extension Agents were evaluated from information gathered via semi-structured interviews. Extension Agents provided verbal consent prior to participating in the interview. An initial email was sent to Extension Agents after completion of both BLD and BLD+LIFT programs that included details about the interview process and asking if they were willing to participate (see Appendix S). For Extension Agents that initially agreed to participate, a follow-up email was sent to schedule a telephone interview at their convenience. At the start of the telephone interview, Extension Agents were

given a detailed description of the study, contact information of the principal investigator and co-investigators, and asked to provide verbal consent (Appendix T). Interviews were conducted with Extension Agents that provided verbal consent.

Interview questions queried three areas of implementation (see Appendix U):

1. The Extension Agents' delivery process and implementation strategies used with BLD with and without LIFT.
2. The Extension Agents' perceptions (i.e. attitudes) about implementation of BLD with and without LIFT.
3. The Extension Agents' experiences (i.e. benefits, barriers/challenges, feasibility) with implementation of BLD+LIFT.

Semi-structured interviews were conducted by telephone for a duration of approximately 20 minutes. Interviews were recorded using a digital sound recorder, and additional notes taken during the interview. Once all semi-structured interviews were conducted, they were transcribed and analyzed. Transcribed data and recordings were read by the researcher several times to ensure accuracy of the transcription.

Analysis

Participant Outcomes

Descriptive statistics were calculated. Means and standard deviations of continuous variables and frequencies and proportions of nominal variables were calculated for BLD and BLD+LIFT programs. Participant retention rates were computed for BLD and BLD+LIFT programs. Chi-square analysis was used to compare the proportion of program participants that began the BLD program and returned for the reunion class session in BLD versus BLD+LIFT programs. Independent samples t-tests using an intention to treat (ITT) analysis [43] were used to

compare mean differences in primary and secondary program outcome measures (glycemic control, patient engagement, self-reported physical activity, self-reported dietary behaviors, and functional fitness) from pre (baseline) and post (reunion session) data in BLD and BLD+LIFT programs. ITT analysis includes all the participants that were randomized to their randomization assignment and disregards noncompliance, withdrawal, and any other event that resulted in lack of data or continuation in the study after randomization process [43]. It also preserves the sample size because if participants are noncompliant or dropout and are excluded from the final analysis, sample size may be significantly reduced [43]. The strategy used with the ITT analysis was the last observation carried forward (LOCF), in which baseline (pre) data was also used for follow-up (post) data for program outcomes if the participant was not in attendance at the reunion class session [43]. Statistical analyses were performed using the Statistical Package for the Social Sciences (SPSS version 23.0 for Windows, IBM Corporation, Armonk, NY USA) [44].

Program Implementation

A thematic analysis was conducted to identify, analyze, and report major themes and subthemes in audio-recorded semi-structured interviews. The thematic analysis was conducted using a deductive approach, in which major themes and subthemes were identified using specific questions developed by the PI and co-investigators to ask to Extension Agents. Braun and Clarke's multidirectional six-phase guide [45,46] was used to conduct the thematic analysis which included: 1) becoming familiar with the data (including transcription of verbal data), 2) generating initial codes, 3) searching for themes, 4) reviewing themes, 5) defining and naming themes, and 6) writing up the report. The thematic analysis was conducted manually by one coder.

Results

Participant Outcomes

Sociodemographic characteristics for participants in BLD and BLD+LIFT are shown in Table 2. There were no significant differences in age, gender, race, ethnicity, educational level, and household income for participants in BLD and BLD+LIFT.

Table 2.
Sociodemographics of BLD and BLD+LIFT Programs

	BLD	**BLD+LIFT**	**Total**	***p* value**
Number of participants, N	16	19	35	
Age, M (SD)	71.6 (7.4)	76.0 (9.9)	73.8 (8.7)	0.20
N (%)				
50-59	1 (5.3)	0 (0)	1 (2.6)	
60-69	3 (18.8)	5 (26.5)	8 (22.7)	
70-79	8 (50.2)	3 (15.9)	11 (33.1)	
80-89	2 (12.6)	6 (31.7)	8 (22.2)	
Not reported	2 (12.5)	5 (26.3)	7 (19.4)	
Gender, N (%)				1.00
Male	2 (12.5)	2 (10.5)	4 (11.5)	
Female	13 (81.3)	13 (68.4)	28 (74.9)	
Not reported	1 (6.3)	4 (21.1)	5 (13.7)	
Race, N (%)				0.23
Caucasian/white	3 (18.8)	6 (31.6)	9 (25.2)	
African American/black	12 (75)	9 (47.4)	21 (61.2)	
Not reported	1 (6.3)	4 (21.1)	5 (13.7)	
Ethnicity, N (%)				**-
Hispanic	0 (0)	0 (0)	0 (0)	
Non-Hispanic	13 (81.3)	14 (73.7)	27 (77.5)	
Not reported	3 (18.8)	5 (26.3)	8 (22.6)	
Education Level, M (SD)	11.4 (1.31)	11.3 (2.05)		0.36
N (%)				
7-8 years	0 (0)	2 (10.6)	1 (5.3)	
9-12 years	11 (87.6)	9 (47.4)	20 (67.5)	
Some college	1 (6.3)	3 (15.8)	4 (11.1)	
College graduate	1 (6.3)	1 (5.3)	2 (5.8)	
Not reported		4 (21.1)	4 (10.6)	
Household Income, N (%)				0.80
$10,000 or less	3 (18.8)	4 (21.1)	7 (20)	
$10,001- $30,000	5 (31.3)	3 (15.8)	8 (23.6)	
$30,001- $60,000	1 (6.3)	2 (10.6)	3 (8.5)	
Not reported	7 (43.8)	10 (52.6)	17 (48.2)	

M (SD) = mean and standard deviation; N (%) = number and percentage of participants; Inferential statistics (chi-square tests) were used to determine significant differences between BLD and BLD+LIFT programs (*$p < 0.05$ and represents differences between BLD and BLD+LIFT programs). **Ethnicity was coded as a categorical variable and the p value could not be generated.

Retention rates for participants in the BLD was 62.5% and retention rates for participants in the BLD+LIFT program was 89% (see Table 3, Appendix V). Chi-square analysis did not show a significant difference in participant retention rate [X^2 (1, N =35), p = 0.058].

Table 3.
Average Retention Rates in BLD and BLD+LIFT programs

Measure	BLD	BLD+LIFT	Significance (p*)
Number of participants at baseline	16	19	
Percentage of participants retained	62.5%	89.5%	p = 0.058

Inferential statistics (chi-square tests) were used to determine significant differences between BLD and BLD+LIFT programs (*p < 0.05 and represents differences between BLD and BLD+LIFT programs).

Independent samples t-tests were conducted to compare participant outcomes (A1C, patient engagement, self-reported physical activity, self-reported dietary behaviors, and functional fitness) between the BLD and BLD+LIFT programs (see Appendix V). Mean A1C increased for both the BLD and the BLD+LIFT programs (t(30)=1.06, p = 0.30) (see Table 4).

Table 4.
Change in A1C in BLD and BLD+LIFT programs

	BLD Programs	**BLD+LIFT Programs**	***p* value***
A1C	0.64 (1.44)	0.24 (0.64)	0.30
	[a]N = 13	[a]N = 19	

M (SD) = mean and standard deviation

[a]N= the number of participants in BLD and BLD+LIFT programs that had an A1C test completed.

**p* value < 0.05

Patient activation scores and activation levels declined in BLD+LIFT programs and increased in BLD programs ($t(27)= 0.65$, $p = 0.52$), ($t(27) = 0.85$, $p = 0.41$) (see Table 5).

Table 5.
Change in patient engagement in BLD and BLD+LIFT programs

	Standard BLD Programs	**BLD+LIFT Programs**	***p* value***
PAM Score	0.37 (8.42)	-2.77 (16.91)	0.52
	[a]N =16	[a]N = 13	
PAM Level	0.06 (0.77)	-0.23 (1.09)	0.41
	[a]N = 16	[a]N = 13	

M(SD) = mean and standard deviation

[a]N= the number of participants in BLD and BLD+LIFT programs that completed a PAM survey.

**p* value < 0.05

Total weekly leisure activity scores declined in both the BLD and BLD+LIFT programs, however, there was a greater decline in the BLD programs compared to participants in the BLD+LIFT programs ($t(17)= -0.05$, $p = 0.96$) (see Table 6).

Table 6.
Change in total weekly leisure activity in BLD and BLD+LIFT programs

	BLD Programs	**BLD+LIFT Programs**	***p* value***
Self-reported physical activity	-5.43 (20.76) [a]N = 7	-4.83 (28.82) [a]N = 12	0.96

M(SD) = mean and standard deviation

[a]N= the number of participants in BLD and BLD+LIFT programs that completed a GLETQ.

*p value < 0.05

Self-reported physical activity was also measured using two health behavior questions (tracking walking and exercising, and days a week walking or exercise) and three self-efficacy questions (confidence in walking or exercising, confidence in walking or exercising when doing it with others, and confidence in tracking walking or exercising) from the BLD questionnaire. There were no statistically significant differences in health behavior or self-efficacy between BLD and BLD+ LIFT programs (see Table 7).

Table 7.
Change in health behavior and self-efficacy in BLD and BLD+LIFT programs

		BLD	BLD+LIFT	Mean Difference	*p* value*
Health Behavior (self-reported physical activity)	In the past 3 months, how many days a week did you usually track how much you walked or exercised?	0.71 (2.13) [a]N = 14	1.20 (2.82) [a]N = 10	-0.49[b]	0.64
	In the past 3 months, how many days a week did you usually walk or exercise?	0.67 (3.31) [a]N = 15	0.43 (2.06) [a]N = 14	0.24	0.82
Self-efficacy (self-reported physical activity)	How sure are you that on most days you can walk or exercise?	0.08 (0.86) [a]N =13	0.33 (1.07) [a]N = 12	-0.26[b]	0.52
	How sure are you that on most days you can walk or exercise when you have other things to do?	0.07 (0.83) [a]N = 14	0.40 (0.70) [a]N = 10	-0.33[b]	0.32
	How sure are you that on most days you can keep track of how much you walk or exercise?	-0.15 (1.46) [a]N = 13	0.27 (1.10) [a]N = 11	-0.43[b]	0.44

M(SD) = mean and standard deviation
[a]N= the number of participants in BLD and BLD+LIFT programs that completed a BLD questionnaire.
[b]Negative mean difference = increase in health behavior or self-efficacy
**p* value < 0.05

Dietary behaviors were measured using five health behavior questions from the BLD questionnaire. There were no statistically significant differences in dietary health behaviors between BLD and BLD+LIFT programs (see Table 8).

Table 8.
Change in health behavior and self-efficacy in BLD and BLD+LIFT programs

		Standard	BLD+LIFT	Mean Difference	*p* value*
Health Behavior (self-reported dietary behaviors)	In the past 3 months, how many days a week did you usually track what you ate?	0.21 (3.24) [a]N = 14	0.50 (3.09) [a]N = 12	-0.28[b]	0.82
	In the past 3 months, how many days a week did you usually eat 5 servings of fruits and vegetables?	0.80 (2.24) [a]N = 15	0.25 (2.77) [a]N = 12	0.55	0.57
	In the past 3 months, how many days a week did you usually eat 3 servings of whole grains?	1.00 (3.74) [a]N = 13	0.91 (3.14) [a]N = 11	0.09	0.95
	In the past 3 months, how many days a week did you usually eat 3 servings of milk or dairy or other foods high in calcium?	0.46 (2.47) [a]N = 13	0.00 (1.94) [a]N = 11	0.46	0.62
	In the past 3 months, how many days a week did you usually use the Plate Method?	0.93 (2.09) [a]N = 14	2.40 (3.24) [a]N = 10	-1.47[b]	0.19

M(SD) = mean and standard deviation

[a]N= the number of participants in BLD and BLD+LIFT programs that completed a BLD questionnaire.

[b]Negative mean difference = increase in health behavior

**p* value < 0.05

Change in two functional fitness measures was statistically significant between BLD and BLD+LIFT programs. Improvement in the two-minute step test was greater for BLD+LIFT. Increase in number of arm curls was greater for BLD. There were no other statistically significant differences in functional fitness measures between BLD and BLD+LIFT programs. (see Table 9).

Table 9.
Change in functional fitness in BLD and BLD+LIFT programs

		BLD	**BLD+LIFT**	**Mean Change**	***p* value***
Functional Fitness	Number of balance exercises completed, out of six stations[b]	0.20 (0.42) [a]N = 10	0.17 (0.83) [a]N = 12	0.03	0.91
	Max Number of Arm Curls in 30 seconds[c]	1.80 (1.87) [a]N = 10	-0.82 (2.32) [a]N = 11	2.62	0.01*
	Number of Steps: 2-minute step test[d]	-14.57 (22.82) [a]N = 7	13.50 (27.65) [a]N = 12	-28.07	0.04*
	Max Distance of Lower Leg Flex (in inches)[e]	1.56 (2.47) [a]N = 9	2.75 (4.76) [a]N = 12	-1.19	0.50
	Max Distance of Upper Arm Flex (in inches)[e]	4.72 (5.84) [a]N = 9	0.64 (6.11) [a]N = 11	4.09	0.15
	Time completion of 8 ft up and go (in seconds)[f]	1.33 (3.87) [a]N = 9	1.13 (2.91) [a]N = 11	0.21	0.89

M (SD) = mean and standard deviation
Independent Samples t-test (ITT) (* $p < 0.05$), one participant in the BLD+LIFT program was removed from the data analysis because a dramatic decline in change score
[a]N= the number of participants in BLD and BLD+LIFT programs that completed a functional fitness test.
[b]Balance Station: Number of stations completed out of 6 progressive balance stations. Participants must complete 10 seconds to move on to the next station.
[c]Repetitions completed in 30 seconds
[d]Number of steps taken in 2 minutes
[e]Flexibility reported in inches
[f]Time (in seconds)

Program Implementation

Familiarizing and Transcribing the data corpus

Semi-structured interviews were transcribed and reviewed against the original audio recording to ensure accuracy. Initial notes and ideas of the data corpus were written to prepare for the coding process.

Generating Initial Codes

Coding was conducted manually to highlight specific segments of the transcripts into specific thematic categories that were relevant to the specific questions and to address the main research question. Figure 1 shows how codes were developed and applied to specific segments of the data set using implementation constructs (see Appendix W, Table 1).

Searching for Themes

Once the codes were identified across the data set, an iterative process of collating data extracts and sorting codes was conducted to develop prospective themes (Appendix W, figure 1). Major themes initially identified included: 1) group cohesion (barriers and facilitators), 2) lack of autonomy (barriers and facilitators), 3) modifications/adaptations to BLD+LIFT (fidelity) 4) participants' attitudes toward LIFT (barriers and facilitators and acceptability), 5) retention plan (fidelity), 6) resources (fidelity and barriers and facilitators), 6) time commitment (time), 7) program logistics (time and barriers and facilitators), and 8) benefits of BLD+LIFT (acceptability).

Reviewing Themes

Themes that were identified during phase 3 were reviewed to make sure that they were distinctive and coherent. During the iterative process, the data corpus was re-read carefully to make sure that there were no contradictions among themes, and themes were addressing the

specific research questions. In reviewing the themes and re-reading the data corpus, modifications and adaptations to BLD+LIFT were separated into their own themes since BLD+LIFT are separate programs.

Refining and Naming Themes

Prospective themes that were identified in phase 3 and phase 4 included: 1) group cohesion, 2) lack of autonomy, 3) modifications to BLD, 4) modifications to LIFT, 5) participants' attitudes toward LIFT, 5) retention plan, 6) time commitment, 7) program logistics, and 8) benefits of BLD+LIFT. In refining the themes, participants' attitudes toward LIFT was removed as the data set identified to support that theme could be embedded into benefits of BLD+LIFT theme and the group cohesion them. In addition, group cohesion and lack of autonomy were embedded into the modifications to BLD and modifications to LIFT as subthemes as they were the main reasons why there were modifications to the programs. Moreover, group cohesion and lack of autonomy were embedded into the program logistics themes as these subthemes were related to logistics and were causing issues during the programs.

Final Thematic Analysis

Major themes that were identified in the final analysis were 1) modifications to BLD with group cohesion and lack of autonomy as subthemes (fidelity) 2) modifications to LIFT with group cohesion and lack of autonomy as subthemes (fidelity) 3) retention plan (fidelity) 4) time commitment (time), 5) program logistics with group cohesion, and autonomy as subthemes (barriers and facilitators, inner context, and fidelity), and 6) benefits of BLD+LIFT (acceptability) (see Appendix W, figure 2).

The two Extension Agents that worked collaboratively at PSR indicated that the location for the BLD + LIFT (intervention) program was a great space for the BLD+LIFT programs. The

location for the BLD program (control) experienced audio difficulties that affected participants' ability to hear. The Extension Agent conducting the program at PACE indicated that the BLD and BLD+LIFT programs were conducted in the same space. This space was a common space used at that location for other activities, which at times conflicted with the BLD class sessions.

> ***Extension Agent #1***: "It (the location) was easily accessible, a nice space, very comfortable."
>
> ***Extension Agent #1:*** "Because it was an older church building or recreation room, sometimes the audio was a problem with their hearing the Balanced Living with Diabetes classes."
>
> ***Extension Agent #2:*** "I think it was an ideal place to have it, working with our seniors to prevent falls."
>
> ***Extension Agent #3:*** "…because this was the one common area that they used for other things which made it difficult to start and end on time."

Fidelity

Modifications to the two BLD programs and one BLD+LIFT program were mentioned. One Extension Agent (with a co-facilitator) who conducted the BLD programs at PSR nutrition sites indicated that the BLD program had to be shortened due to lunch schedules at that location. In addition, during one of the sessions they did not conduct a food demonstration because the other Extension Agent was not in attendance. The Extension Agent that worked at PACE indicated that she had to shorten the BLD sessions in both the BLD and BLD+LIFT programs due to participants not arriving on time, and participants having other things to do during the time of BLD sessions. In addition, she did not spend as much time doing the food

demonstrations because the majority of participants at this site were not able to cook for themselves or make their own food decisions.

Extension Agent #1: "I know with the Keysville one, we may have had to shorten it maybe about 20 to 30 minutes just because they started lunch earlier than the other program."

Extension Agent #1: "We did have an occasion where it did not offer the sample and that was because there was only one of us there."

Extension Agent #3: "…the biggest change was that we definitely had to shorten it right? Because the time that people go there kept being later and the time, we needed to be out...so we definitely had to abbreviate things."

Extension Agent #3: "But again, this group, a lot of them told me "I don't cook for myself"…so a lot of folks in our group were not necessarily making a lot of their own food decisions."

Extension Agent #3: "We didn't spend as much time showing the food demo…we just didn't have enough time to dedicate to it."

Extension Agent #3: "We were doing the food demo as "here try this food" rather than, "here's how you can make it at home."

Extension Agent #3: "..so if our class fell during the time that they happen to be at a doctor's appointment or be able to get taken to the eye doctor or something like that, then they certainly were going to take those opportunities, because that was their only opportunity to do that…and even things not medical related like going to the grocery store."

Modifications to the LIFT program were mentioned. One Extension Agent that worked at PSR indicated that she had to modify the exercises for one of the participants that was in a wheelchair and that the program ran slightly longer due to a lot of discussion. The Extension Agent that worked at PACE indicated that there were schedule changes during the time in which the BLD+LIFT group was transitioning to the LIFT program, which caused confusion. The LIFT was shortened due to lack of attendance on this occasion. In addition, due to participant health issues, she had to modify the exercises.

Extension Agent #1: "We used weights and I did have to modify some of the exercises for a client, a participant that was wheelchair bound."

Extension Agent #1: "We probably had maybe an hour and 15 minutes because we had a lot of conversation."

Extension Agent #3: "...right around the beginning of LIFT was also when schedules changed because the days that we had LIFT was not necessarily the days that all of our participants were normally at the center."

Extension Agent #3: "So maybe they normally came on Tuesdays and then we had moved them to coming on Mondays and they were like "I don't want to be here on Mondays…I have other things that I like to do on Mondays."

Extension Agent #3: "The (LIFT class) usually ran shorter because they were more like 45 minutes and the reason for that was because we didn't have more than one or two people...it's hard to facilitate discussion when it's just you and one other person, right?"

Extension Agent #3: "There were some of them towards the end that were just like "I don't want to come today."

Extension Agent #3: "Because you don't have people attending, so then the people who are attending, you're not getting that group cohesion because you don't really have a group."

Extension Agent #3: "But also, they struggled to do a lot of things that we were asking them to do, even if we were doing adaptations and stuff…we had people with really bad shoulders or who needed a walker to be able to stand."

Extension Agent #3: "LIFT itself, I mean, I tried to stick pretty close to the recommendations…again a lot of people had mobility issues…these folks, we sat down to do arm curls and that kind of stuff just because a lot of people weren't real steady on their feet."

Barriers and Facilitators

Facilitators to the BLD and BLD+LIFT programs were identified. One Extension Agent that worked at PSR indicated that having another Extension Agent as a co-facilitator was helpful in distributing the retention plan materials, and with doing the food demonstrations. The Extension Agent that worked at PACE indicated having staff at the site to help identify people that needed the BLD was helpful.

Extension Agent #1: "It was helpful to have her (the other Extension Agent) do distribute the materials to the location that was not part of the site because they met on the same day that I was teaching LIFT.

Extension Agent #2: "She (the other Extension Agent) was in Lunenburg and on that Thursday, I went to Charlotte County."

Extension Agent #3: "...they had a dietitian, doctors, nurses on staff that could really identify people in the program that needed the BLD."

No barriers were mentioned about the BLD and BLD+LIFT programs specifically. Extension Agents did, however, indicate barriers to the overall program logistics such as Extension Agents' lack of understanding of project roles and responsibilities, participants not having autonomy to complete data collection materials themselves, and making their own health and food decisions. Extension Agents working as co-facilitators at PSR suggested obtaining information related to the BLD and BLD+LIFT programs from participants prior to the start of the program (i.e. physician authorization) as well as having assistance when it comes to LIFT. The Extension Agent at PACE suggested having family and/or caregivers coming to the BLD sessions and providing support.

> ***Extension Agent #1:*** "But I definitely would suggest that if they're doing the LIFT together with the BLD that maybe they have another either volunteer or another agent to assist."
>
> ***Extension Agent #2:*** "Starting (LIFT) directly after BLD I think was a good cause, but it does take some planning and preparation for that extended class."
>
> ***Extension Agent #2:*** "…it seemed like there was ongoing confusion about when they were supposed to be there when they weren't so that was a challenge."
>
> ***Extension Agent #2:*** "There were some challenges trying to get the paperwork back and the information that we needed, and the authorization of the doctor."
>
> ***Extension Agent #2:*** "They had power of attorney or something like that and they wanted their children to read over the information before they could sign."
>
> ***Extension Agent #3:*** "I'm not sure that they had as much control over their lives to make decisions about their behavior change."

Extension Agent #3: "But again, this group, a lot of them told me "I don't cook for myself"…so a lot of folks in our group were not necessarily making a lot of their own food decisions."

Extension Agent #3: "I really wish, especially for this type of senior group, that there would've been a way to bring in family members to BLD with them because I just got the impression that, like I said, so many of them weren't really making their own food choices."

No barriers were mentioned to the use of the retention plan for BLD and BLD+LIFT programs, however, the Extension Agent that worked at PSR and the Extension Agent that worked at PACE indicated that having the retention materials done ahead of time facilitated distribution to participants.

Extension Agent #1: "I think I may have started a little bit sooner than I was supposed to."

Extension Agent #3: "...at the end of BLD and beginning of LIFT, I just sat down and I made all the copies. And then I put them in envelopes and labeled them with each person's name and then put them together...."

Extension Agent #3: So, I did all the work up front so that I didn't have to think about that each week.

Distribution of the retention plan materials for BLD and BLD+LIFT programs was done in person, and if participants were not in attendance at the PSR and PACE sites, they left it with the staff to provide to the participants. The Extension Agent (with a co-facilitator) that worked at PSR indicated having additional copies if participants were not in attendance at the session.

Extension Agent #1: "It's (LIFT) face-to face so I handed it out."

Extension Agent #1: "If they weren't there on that particular day, I did have additional copies for the next class session."

Extension Agent #2: "I went to the site to deliver (the retention materials)."

Extension Agent #3: "So retention materials, it really wasn't bad, because both groups were in the same place, so I just took the things each week labeled for each participant and then they were going home in the bags with the participants."

Extension Agent #3: I mean there was staff there who put them with the coat and their stuff that they were taking home."

The retention plan was followed according to the plan instructions and no modifications were made; however, the Extension Agents (with a co-facilitator) that worked at PSR and delivered the LIFT program, and the Extension Agent that worked at PACE, indicated they did not follow-up with participants about the retention materials. The other Extension Agent that worked at PSR indicated she talked to participants about the retention materials they were receiving.

Extension Agent #1: "They got all the retention materials."

Extension Agent #1: "I did put reminder dates on the ones that had the space for reminder states for the reunion, but I did not change anything on the materials themselves, no."

Extension Agent #1: "…any retention materials outside of that (BLD), I'm not sure if they are actually reading them, because there's really no way to tell unless you pick up the phone and call them if you have their number…"

Extension Agent #2: "I went the way it (retention materials) was designed to be done."

Extension Agent #2: "...have face to face conversation with participants and went over if they had questions about what they were receiving and just made that connection."

Extension Agent #3: "No I kept them (retention materials) as they were."

Extension Agent #3: "And I really didn't follow-up and ask them too much about it (retention materials).

Extension Agent #3: "I don't know if they were read. I don't know how much they were being utilized."

Extension Agents indicated that the retention plan was not redundant to the LIFT program, but rather the retention plan was a helpful reminder.

Extension Agent #1: "No...I think it reminded them that some of the materials that they had in their folder."

Extension Agent #3: "No I don't think so...I felt like it was still a good touch point."

Time Commitment

The time required to prepare BLD sessions for BLD and BLD+LIFT programs was mentioned. The Extension Agents that worked collaboratively at PSR indicated that it took them an hour to prepare, while the Extension Agent at PACE indicated that it took about three hours due to driving to pick up produce to provide to the participants. The Extension Agent at PACE had the opportunity to partner with the Fresh Foods Rx program through United Way funding to provide fresh foods and produce to participants in BLD and BLD+LIFT programs.

Extension Agent #1: "Because I've done them before, it would probably take me up to on the generous side up to an hour just to make sure I had copies if I needed to have copies made for people, just to make sure that the information hadn't changed.

Extension Agent #2:"...but I know going and getting food and stuff like that, printing off whatever we needed, I would say about an hour, hour and a half."

Extension Agent #3: "So to just prep for the class itself I would say was maybe two hours as week...and then you have to add another hour for the produce thing because I had to drive to get the produce…"

One of the two Extension Agents that worked at PSR indicated that they had the other to assist with BLD session preparation for BLD and BLD+LIFT programs. The Extension Agent at PACE indicated that she had Master Food Volunteers and dietetic interns to assist at times.

Extension Agent #1: "She worked on the food demonstration and I worked on the presentation component."

Extension Agent #3: "So, I had Master Food Volunteers help me during the class (BLD) and then for some weeks, I had the dietetic interns."

The Extension Agent that worked at PSR and delivered the LIFT program indicated that it took an hour to prepare for the LIFT sessions. The Extension Agent at PACE indicated that it took her 2 hours initially and then it only took an hour.

Extension Agent #1: "Again it was probably about an hour with copying time and make sure that was familiar with the exercises and the process and that was on the generous side."

Extension Agent #3: "I mean in the beginning, it probably took me closer to two hours just to, because I was still getting used to it. I would say by the end, it was more just like an hour."

Extension Agents did not have to work after hours and on weekends in preparation for the BLD+LIFT sessions, however, one Extension Agent that worked at PSR mentioned time

travel as a barrier due to not being in proximity to the site receiving LIFT. The other Extension Agent that worked at PSR indicated that she had to put other programs aside while delivering the BLD and BLD+LIFT programs.

> ***Extension Agent #1:*** "...the restrictions for time travel probably, they wouldn't be as restrictive because it took me about 45 minutes to get to that particular site, whereas if it was at a closer location, I might be more willing to do it on a long term basis."
>
> ***Extension Agent #2:*** "It was little time-consuming for me because I had to kind of put some programs on hold, and to work with this program because it was certain dates."

Acceptability

Extension Agents indicated that they would like to continue implementing the LIFT program with the BLD program. In addition, two Extension Agents, one that worked at PSR and the other that worked at PACE, provided insights from participants about their experiences with LIFT.

> ***Extension Agent #1:*** "That's something I would like to do in the future."
>
> ***Extension Agent #1:*** "I just felt that the benefits of doing the BLD with the LIFT, my particular participants were very engaged, and I felt that it was an enhancement to it."
>
> ***Extension Agent #1:*** "The girl in the wheelchair said she had fallen but she didn't hurt herself so I'm thinking by having more movement, being a little more flexible, that she was able to pick herself back up out of the chair...she said "because I was working out, I didn't hurt myself."
>
> ***Extension Agent #2:*** "I think it's a good idea to put both of them together, especially working with our seniors."

Extension Agent #2: "Going through the Balanced Living with Diabetes Program, is it's such a good program for communities…but with seniors, the LIFT program is also important because they need to eliminate a lot of falls and things like that to strengthen them."

Extension Agent #3: "Yeah I would definitely, if participants thought that they would be willing to do it, I definitely start there and try and encourage that, to do the two together."

Extension Agent #3: "So one of the early weeks of LIFT, we were talking about why exercise is important to you and his (BLD + LIFT participant) comment was that he has to stay healthy because he wants to be able to walk and go see his wife every day."

Extension Agent #3: "When we got up to being able to do 12 reps and stuff, you could tell she (BLD + LIFT participant) was proud of herself …she was like oh in the beginning, I remember we did six and now I can do 12."

Discussion

The purpose of this pilot multi-methods study was to evaluate the impact and implementation of incorporating an existing physical activity promotion program (LIFT) with an existing community-based diabetes lifestyle management program (BLD) conducted by Extension Agents. Findings of this study indicate programs that incorporate LIFT could improve retention, self-efficacy, and health behavior for older adults with type 2 diabetes that want to be physically active. Additionally, programs that incorporate LIFT could impact certain dietary health behaviors for older adults with type 2 diabetes. Extension Agents expressed enthusiasm for incorporating the LIFT program with the BLD program and indicated that they would be willing to implement more BLD+LIFT programs however, addressing program logistics is vital.

Comparison of the BLD and BLD+LIFT program outcomes showed greater improvement in tracking behaviors, specifically for walking or exercising, and improvements in self-efficacy to conduct and track walking or exercising in participants of the BLD+LIFT programs. According to Costello et al., efforts to promote physical activity in older adults with T2D should focus on improving their self-efficacy [47]. This suggested that addition of the LIFT program may be a good implementation strategy to increase participant's self-efficacy and put additional emphasis on tracking and goal setting when becoming more physically active. There were also greater improvements in dietary behaviors in participants of the BLD+LIFT programs including tracking of food intake and use of the Plate Method. The LIFT program may impact those specific dietary behaviors, particularly among those that cook for themselves, and are involved in meal planning. Since encouragement of the consumption of more fruits and vegetables is part of the LIFT program, this may have supported these specific diet related behaviors promoted in the BLD.

An unexpected finding was an increase in A1C in both BLD and BLD+LIFT programs, as that is not usually what happens in the BLD program. The BLD program targets people that have diabetes or an A1C above 7%, and it is in these participants that the greatest improvements in glycemic control are seen. Although there was an increase in A1C from pre to post, it was much lower in BLD+LIFT programs compared to BLD programs. An additional unexpected finding was that total weekly leisure activity declined in both BLD and BLD+LIFT programs. Again, this decline was greater in BLD programs compared to BLD+LIFT programs. It is important to note that there were not a lot of participants in the BLD programs that completed the GLETQ which may have impacted these findings.

According to the American Diabetes Association (ADA), there is a correlation between sedentary behaviors and higher glycemic levels in adults with T2D [48,49]. That is why the ADA recommends that after 90 minutes of sedentary activity, that patients with T2D should do some physical activity like aerobic exercise training, resistance and strength training, flexibility training, and balance training exercises to improve blood glucose [48,49]. The BLD and LIFT both promote this recommendation, with LIFT providing an opportunity for actively applying this recommendation.

An unexpected finding was that there was no increase in patient engagement in BLD+LIFT programs when compared to those in the BLD programs. This was not anticipated given that the BLD+LIFT programs have social support and group dynamic components intended to increase ongoing communication and group cohesiveness among participants so that they are able to better manage their own health. Participants particularly at the PACE site used the services provided to them at the site which assisted them with their daily living activities. This posed barriers to regular participation for participants at this site, as they often chose to do alternate activities rather than attend BLD and/or LIFT sessions. The Extension Agent indicated that doing exercise was low on the priority list for most participants and availability of other activities is why some of them were unable or unwilling to attend LIFT sessions. In addition, participants at the PACE site had greater physical impairments, which according to the Extension Agent, is why there were modifications made to the LIFT program. Despite these modifications, the Extension Agent indicated that they were still struggling to do the exercises asked of them. This may also have influenced low attendance to the LIFT sessions at this site. Studies have shown that type 2 diabetes and other related health complications in older adults are associated with a high risk of physical disabilities, which may result in a lower level of physical activity

participation [50,51]. Additionally, exercise contraindications and a patient's beliefs, attitudes, and motivation toward managing their diabetes could affect physical activity participation [50,52]. Implications of these findings are that the LIFT program may not be appropriate at sites like PACE, and perhaps alternative low to moderate exercise activities with ongoing support by program staff are a better option for older adults with greater health and physical disabilities.

It was mentioned by the Extension Agent at PACE that providing family and/or caregiver support to participants is important, especially for those participants that do not live independently and/or are unable to make food and health decisions on their own. This would provide family and/or caregivers of these participants a better understanding of diabetes and the health benefits of making lifestyle changes. This might also help to enhance patient engagement in BLD and BLD+LIFT programs. Studies have shown that the impact of family support in diabetes self-management education programs is to improve A1C levels [53,54] and have a positive effect on self-efficacy [55], dietary and exercise behaviors [56], perceived support [57], medical adherence [58], and quality of life among patients with type 2 diabetes [58]. Participants in the BLD+LIFT programs were slightly older and may need additional social support to help maintain their diabetes self-management capabilities and staying physically active.

Functional fitness tests indicated statistically significant improvement in only two of six fitness measures, in participants in the BLD+LIFT programs compared to the BLD program. No differences were observed between groups for balancing exercises. . Complicating interpretation of these outcomes was the situation that most of the participants at the PACE site, and some from the PSR sites, had significant co-morbidities in addition to their diabetes. Participants had walkers or canes to help assist them with mobility and some of the participants were on portable breathing machines. This became more apparent when participants did the LIFT functional

fitness test before and after LIFT, as some participants could not do most of the exercises asked of them. This brings into question the the fit for the LIFT program in more debilitated older adult populations.

In 2011, statistics from the CDC indicated that 61.6% of adults aged 45-64, 68.9% of older adults aged 65-74 and 81.4% of older adults aged 75 and older reported limited mobility [59]. Other physical limitations of patients with T2D include visual impairment, osteoporosis, musculoskeletal disorders, neuropathy, arthritis, and lower extremity vascular disease [59,60]. A diabetes care and education program study indicated that pain was a barrier reported most often by patients that exercised less frequently and for a shorter duration [61]. These physical limitations are associated with poor glycemic control and inactivity [49]. Costello et al. indicates that promoting physical activity in older adults should address perceived barriers towards being more active and include more positive beliefs towards the health benefits of being more active to increase adherence [47]. The real barriers to physical activity, including pain, must also be addressed in older adults with disabilities. This would lead to greater adoption of exercise and long-term maintenance of being physically active and functionally fit [48].

Extension Agents indicated that they are willing and interested to implement BLD+LIFT programs, however, addressing program logistics is imperative. That would include making sure Extension Agent roles are understood and that they are cognizant of the time commitment required when implementing BLD+LIFT programs, communicating more frequently and clearly with sites implementing BLD+LIFT programs regarding participants' schedules, and that expectations of participants regarding the time commitment of BLD+LIFT is clear. In addition, Extension Agents indicated that implementation of these programs at PACE or comparable sites with older adults that have greater disability and dependency may not be the best locations.

PACE is associated with the integrated care delivery that combines delivery and management services related to diagnosis, treatment, care, and rehabilitation [32]. PACE is a federal and state funded program that provides healthcare and patient engagement opportunities for older adults 55 years or older [32]. PACE is an alternative to nursing facilities for low-income older adults with significant disabilities so that they do not have to be put into long-term care facilities [32]. PACE is a coordinated healthcare umbrella that offers services such as nutrition services, in-home assistance, medication management, physical, occupational, and speech therapy, transportation, among others to assist seniors with living independent lives [32].

It was unanticipated that many of the participants at the PACE site were too debilitated to participate in the LIFT program or to actively change their dietary habits due to dependency on others. Although working with the PACE site reduced the ability to detect the impact of LIFT on program outcomes, it provided valuable information about locations where BLD+LIFT programs would be most appropriate. Other opportunities were identified however with one Extension Agent mentioning the local health clinic or YMCA as more feasible locations.

Limitations of this study primarily included a sample size smaller than projected for the study. The small sample size was due to programs recruiting fewer participants into the programs than anticipated. In addition, some attrition occurred towards the end of BLD and BLD+LIFT programs. Using the intention to treat approach assisted in preserving the sample size for the data analyses.

One coder was used to evaluate and summarize the agent interviews due to the small number of interviews and pilot nature of the study. This does present coder biases, however. To compensate for this, the thematic analysis procedures were strictly followed and were documented and presented in detail in this study. Additional notes were taken, data coding was

repeated , the data corpus was read multiple times to ensure accuracy of the thematic analysis processes. The thematic analysis was helpful in addressing the data in the quantitative analysis; In future, more appropriately powered studies, the thematic analysis should be conducted again with an additional coder.

Overall, older adult participants were able to engage in the educational sessions and the food demonstrations in the BLD and BLD+LIFT programs to learn more about how they can better manage their diabetes and to make better food choices. There is some indication from these preliminary findings that addition of the LIFT program resulted in greater improvement in self-efficacy of participants to track their physical activity and diets, engage in physical activity, and to monitor their dietary pattern using the Plate Method. On a cautionary note, results also suggest that addition of LIFT to the BLD may have a negative impact on participant engagement in some populations, perhaps due to the added required commitment. In addition, BLD+LIFT participants indicated that they enjoyed the LIFT program. Despite some of the BLD+LIFT participants having physical limitations, they mentioned to Extension Agents that they are stronger and have better mobility than before. Extension Agents also indicated that they would continue conducting the BLD+LIFT. Moreover, and most importantly, BLD and BLD+LIFT participants have the tools to continue making lifestyle changes by eating healthier and incorporating physical activity into their daily lives.

Conclusion

Older adults aged 65 years and older make up roughly 15% of the population and are projected to increase by 2030 [62]. The prevalence of diabetes in this population varies from 22 to 33% [63]. The American Diabetes Association (ADA) suggests that even if the incidence rates of diabetes levels off, that the prevalence would still double in the next 15-20 years due partly to

the aging of the population [63]. In addition, it is projected that the number of diagnosed diabetes cases in adults age 65 years or older will increase [63,64], and adults age 65 years and older are at an increased risk of health comorbidities such as myocardial infarction, visual impairment, and lower-extremity amputations [63,64].

It is imperative that older adults that have type 2 diabetes take an active role in managing their diabetes and become more physically active in their daily lives. Co-morbidities in older adults with type 2 diabetes may impact glycemic control efforts and be a barrier to the recommended dose of physical activity needed to receive the overall health benefit. This may require more social support and physical assistance. Older adult participation in diabetes education programs and group physical activity programs that include aerobic and strength training exercises, would help to address these barriers.

Future research should include a more fully powered randomized control trial with BLD and BLD+LIFT programs delivered in appropriate settings with participants who are physically able to participate in LIFT to better estimate effect size. In addition, our study findings suggest that AAA sites are good avenues for reaching a target population for the BLD+LIFT programs but testing the program with other types of organizations that service people that have diabetes with fewer co-morbidities that limit physical activity would provide important information. AAA is a membership organization intended to build capacity in the community, and to provide information, services, and assistance to older adults and those who care for them [65,66]. AAA's have the funds to implement evidence-based healthy lifestyle programs but limited human resources to deliver the programs. Collaboration between the AAA and Cooperative Extension allow for these program costs to be covered and for Extensions Agents, who have the expertise, to deliver programs efficiently. Moreover, conducting follow-up interviews with participants

may be helpful to obtain their input about the BLD and BLD+LIFT programs and gain insight into factors that motivate them to attend BLD sessions, LIFT sessions, and the reunion class session. Of particular interest from this study is to evaluate the impact of the required commitment by participants to additional sessions with addition of LIFT on participant engagement. Finally, implications suggest that conducting more BLD+LIFT programs could be a potential approach for increasing physical activity among patients with T2D.

References

1. Centers for Disease Control and Prevention. (2017). *National Diabetes Statistics Report 2017.* CDC
2. Virginia Department of Health. (2015). *Diabetes in Virginia.*
3. Virginia Department of Health. (2017-2018). Diabetes Burden in Virginia Report.
4. Centers for Disease Control and Prevention. (2017, June 1). *About Diabetes*. Retrieved from Centers for Disease Control and Prevention: https://www.cdc.gov/diabetes/basics/diabetes.html
5. Centers for Disease Control and Prevention. (2018, August 15). *Type 2 Diabetes*. Retrieved from Centers for Disease Control and Prevention: https://www.cdc.gov/diabetes/basics/type2.html
6. Edemekong, P., Bomgaars, D., Levy, S. (2019). *Activities of Daily Living (ADLs)*. StatPearls Publishing LLC.
7. Kemmis, K. (2016). Exercise with Diabetes and Physical Limitations. *Diabetes Care*, 8-14.
8. U.S. Department of Health and Human Services (2018). Physical Activity Guidelines for Americans 2nd Edition, Washington, DC.

9. U.S. Department of Health and Human Services (2018). Physical Activity Guidelines for Americans 2nd Edition Executive Summary, Washington, DC.
10. Healthy People 2020. (2018, November 6). *Diabetes.* Retrieved from Healthy People 2020: https://www.healthypeople.gov/2020/topics-objectives/topic/diabetes/objectives
11. U.S. Department of Agriculture. (n.d.-a). Extension. Retrieved November 11, 2019, from https://nifa.usda.gov/extension
12. Congress.gov. H.R.2642 - Agricultural Act of 2014. Retrieved November 23, 2019, from https://www.congress.gov/bill/113th-congress/house-bill/2642
13. U.S. Department of Agriculture. (n.d.-a). Economic Research Service. Retrieved November 11, 2019, from https://www.ers.usda.gov/agricultural-act-of-2014-highlights-and-implications/
14. Virginia Cooperative Extension. (2018). *About Virginia Cooperative Extension*. Retrieved from Virginia Cooperative Extension: https://ext.vt.edu/about.html
15. Virginia Cooperative Extension. (2018). *Chronic Disease Prevention and Control Programs.* Retrieved from Virginia Cooperative Extension: https://ext.vt.edu/food-health/chronic-disease.html
16. Bandura, A. (1977). Self-efficacy: toward a unifying theory of behavior change. *Psychological review*, 191-215.
17. Bandura, A. (2001). Social Cognitive Theory of Mass Communication. *Psychology*, 265-299.
18. Little RR, Rohlfing C. The long and winding road to optimal HbA1c measurement. *Clin Chim Acta*. 2013;418:63-71.

19. Wilson, M., Strayer, T., Davis, R., & Harden, S. (2018). Informed Adaptations of a Strength-Training Program through a Research–Practice Partnership. *Frontiers in Public Health*, 1-9.
20. Wilson, M., Strayer, T., Davis, R., & Harden, S. (2018). Use of an Integrated Research-Practice Partnership to Improve Outcomes of a Community-Based Strength-Training Program for Older Adults: Reach and Effect of Lifelong Improvements through Fitness Together (LIFT). *Int Journal Environment Res Public Health*, 1-15.
21. Ball, S. (2013). Outcomes of Stay Strong, Stay Healthy in Community Settings. *Journal of Aging and Health*, 1388-1397.
22. Estabrooks et al. (2016) Move More: Translating an efficacious group dynamics physical activity intervention into effective clinical practice. *PsycINFO Database Record (c)*, American Psychological Association.
23. Dube et al. (2012). Exercise Dose and Insulin Sensitivity: Relevance for Diabetes Prevention. *Medicine Sci Sports Exercise*, 793-799.
24. Amati F, Dube JJ, Coen PM, Stefanovic-Racic M, Toledo FG, Goodpaster BH. (2009) Physical inactivity and obesity underlie the insulin resistance of aging. *Diabetes Care*, 1547–9.
25. Colberg et.a1. (2010) Exercise and Type 2. Diabetes Care. 2009, 147–167.
26. Araiza P, Hewes H, Gashetewa C, Vella CA, Burge MR. (2006). Efficacy of a pedometer-based physical activity program on parameters of diabetes control in type 2 diabetes mellitus. *Metabolism*, 1382–7.

27. Bweir S, Al-Jarrah M, Almalty AM, et al. (2009). Resistance exercise training lowers HbA_{1c} more than aerobic training in adults with type 2 diabetes. Diabetol Metabolic Syndrome, 1-27.
28. Dutton, G., Lewis, C. (2009). The Look AHEAD Trial: Implications for Lifestyle Intervention in Type 2 Diabetes Mellitus. Progress in Cardiovascular Diseases, 69-75.
29. Piedmont Senior Resources Area Agencies on Aging Inc. Retrieved on October 1, 2019. https://www.psraaa.org/about.html
30. Innovage PACE. Retrieved on October 2019. https://www.myinnovage.com/about-pace/pace-overview
31. United States Census Bureau (2018). Retrieved from American Community Survey (ACS) 5- year estimate: https://www.census.gov/programs-surveys/acs/
32. Cardinal, B., Esters, J., Cardinal M. (1996) Evaluation of the Revised Physical Activity Readiness Questionnaire in older adults. *Medicine & Science in Sports & Exercise.* 28: 468-472.
33. Chisholm, D. M., M. L. Collis, L. L. Kulak, W. (1975) Davenport, and N. Gruber. Physical activity readiness. *British Columbia Medical Journal*. 17:375-378.
34. Hibbard et al. (2004). Development of the Patient Activation Measure (PAM): Conceptualizing and Measuring Activation in Patients and Consumers. *Health Services Research Journal*, 1005–1026.
35. Hibbard et al. (2005). Development and testing of a short form of the patient activation measure. *Health Services Research Journal*, 1918-30.
36. Godin, G. (2011) The Godin Shephard Leisure Time Physical Activity Questionnaire. *Health & Fitness Journal of Canada*, 18-22.

37. Godin, G. (2015) The Godin-Shepard Leisure-Time Physical Activity Questionnaire: Validity Evidence Supporting It's Use for Classifying Healthy Adults into Active and Insufficiently Active Categories. *Perceptual & Motor Skills: Physical Development & Measurement*, 1-9.

38. Anderson, E., Winett, R., & Wojcik, J. (2007). Self-regulation, self-efficacy, outcome expectations, and social support: Social cognitive theory and nutrition behavior. *Annals of Behavioral Medicine*, 304-312.

39. Anderson, E., Winett, R., & Wojcik, J. (2003). Social cognitive mediators of change in a group randomized nutrition and physical activity intervention: social support, self-efficacy, outcome expectations, and self-regulation in the Guide-to-Health Trial. *Journal of Health Psychology*.

40. Anderson, E., Winett, R., Wojcik, J., Winett, S., & Bowden, T. (2001). A computerized social cognitive intervention for nutrition behavior: Direct and mediated effects of fat, fiber, fruits, and vegetables, self-efficacy and outcome expectations among food shoppers. *Annals of Behavioral Medicine*, 88-100.

41. Anderson ES, Winett RA, Wojcik JR, Winett SG, Bowden T (2006): Social-cognitive determinants of physical activity: the influence of social support, self-efficacy, outcome expectations, and self-regulation among participants in a church-based health promotion study. *Journal of Health Psychology*, 510-20.

42. Rikli R.E., Jones C.J. (1999) Development and validation of a functional fitness test for community-residing older adults. *J. Aging Phys. Act*. 7:129–161.

43. Gupta, S. (2011) Intention-to-treat concept: A review. Perspectives in Clinical Research. 2(3): 109–112.

44. IBM Corp. Released (2018). IBM SPSS Statistics for Windows, Version 26.0. Armonk, NY: IBM Corp.

45. Bruan V., & Clarke, V. (2006). Using thematic analysis in psychology. *Qualitative Research in Psychology*, 77-101

46. Bruan, V., & Clarke, V. (2012). Thematic Analysis. In I. H. Cooper, P.M. Camic, L. Long, D. Panter, D. Rindskopf, & K. J. Sher, *APA Handbook of Research Methods in Psychology Vol. 2 Research designs: Quantitative, qualitative, neuropsychological, and biological* (pp. 55-71).

47. Costello E, Kafchinski M, Vrazel J, Sullivan P, (2011). Motivators, barriers, and beliefs regarding physical activity in an older adult population. *Journal of Geriatric Physical Therapy*, 138-147.

48. American Diabetes Association (2015). Foundations of care: education, nutrition, physical activity, smoking cessation, psychosocial care, and immunization. *Diabetes Care*, S20-30.

49. American Diabetes Association (2016). Physical Activity/Exercise and Diabetes: A Position Statement of the American Diabetes Association. *Diabetes Care*, 2065-2079.

50. Zhao G, Balluz, L.(2011). Physical Activity in U.S. Older Adults with Diabetes Mellitus: Prevalence and Correlates of Meeting Physical Activity Recommendations. *American Geriatrics Society*; 59 (1),132-137.

51. Zhao G, Ford ES, Li C et al. (2009). Disability and its correlates with chronic morbidities among U.S. adults aged 50–<65 years. *Preventative Medicine*; 48:117–121.

52. Korkiakangas EE, Alahuhta MA, Laitinen JH. (2009) Barriers to regular exercise among adults at high risk or diagnosed with type 2 diabetes: A systematic review. *Health Promotion International*; 24:416–427.

53. Baig A.A., Benitez A., Quinn M.T., Burnet D.L. (2015) Family interventions to improve diabetes outcomes for adults. *Annals of the New York Academy of Sciences*.;1353:89–112.

54. Keogh K.M., Smith S.M., White P., McGilloway S., Kelly A., Gibney J., O'Dowd T. Psychological Family Intervention for Poorly Controlled Type 2 Diabetes. (2011) *The American Journal of Managed Care*; 17:105–113.

55. Kluding P.M., Singh R., Goetz J., Rucker J., Bracciano S., Curry N. (2010) Feasibility and effectiveness of a pilot health promotion program for adults with type 2 diabetes: Lessons learned. *Diabetes Educator*; 36:595–602.

56. Fall E., Roche B., Izaute M., Batisse M., Tauveron I., Chakroun N. (2013) A brief psychological intervention to improve adherence in type 2 diabetes. *Diabetes Metabolism*; 39:432–438.

57. Miller T.A., Dimatteo M.R. (2013)Importance of family/social support and impact on adherence to diabetic therapy. *Diabetes, Metabolic Syndrome and Obesity*: Targets and Therapy; 6:421–426.

58. Tang T.S., Funnell M.M., Sinco B., Spencer M.S., Heisler M. (2015) Peer-Led, Empowerment-Based Approach to Self-Management Efforts in Diabetes (PLEASED): A Randomized Controlled Trial in an African American Community. *Annals of. Family Medicine*; 1:27–35

59. Centers for Disease Control and Prevention. (2014). Percentage of Adults with Diagnosed Diabetes Reporting Any Mobility Limitation, by Age, United States, 1997-2011: https://www.cdc.gov/diabetes/statistics/mobility/health_status/fig3.htm.

60. Yau et.al. (2013). Diabetes and risk of hospitalized fall injury among older adults. *Diabetes Care*, 3985-91.

61. Wanko NS, Brazier CW, Young-Rogers, D et.al. (2004). Exercise preferences and barriers in urban African Americans with type 2 diabetes. *The Diabetes Educator*, 502-513.

62. United States Census Bureau. (2010). *The Older Population in the United States: 2010 to 2050.*

63. Kirkman et. al. (2012) Diabetes in Older Adults. *Diabetes Care*, 2650-2664.

64. Selvin E, Coresh J, Brancati FL. (2006). The burden and treatment of diabetes in elderly individuals in the U.S. *Diabetes Care*, 2415–2419

65. Area Agency on Aging (2017). Retrieved from Administration for Community Living: https://acl.gov/programs/aging-and-disability-networks/area-agencies-aging

66. Area Agency on Aging: Local Leaders in Aging and Community Living (2017).

Chapter 5

Summary, Conclusions, and Implications

The burden of diabetes in the U.S. has risen exponentially as the prevalence of the disease continues to increase [1]. Community-based diabetes education and management programs are practical, low-resource and are vital in lowering the prevalence and incidence of type 2 diabetes [2]. Community-based diabetes education and management programs are effective and have aided in diabetes care and the improvement of glycemic control in patients with type 2 diabetes [2-5]. This dissertation study looked at a community-based diabetes lifestyle management program, and in two separate pilot studies, evaluated the impact of a retention plan and the incorporation of a community-based physical activity program on improving program outcomes.

Though community-based diabetes education and management programs are effective, reach, attrition, and adherence in such programs are still a concern [6,7]. Participants that fail to adhere to the recommended diabetes management activities are unable to effectively manage their diabetes therefore have poorer glycemic control [6,7]. The literature suggests that patient engagement and ongoing communication with the patient and the facilitator are correlated to improved glycemic control [6,7]. In addition, community-based diabetes education and management programs that have a theoretical basis and include behavioral strategies provide an understanding of the factors that influence adherence to lifestyle modification behaviors [8]. Moreover, effective recruitment and retention strategies are needed to maintain active engagement in such programs [9,10]. Study 1 evaluated the implementation of a retention plan developed for the Balanced Living with Diabetes (BLD) programs conducted from 2015-2017

using the RE-AIM Framework. The retention plan was a modification made to the BLD program that was intended to improve retention rates and maintain ongoing communication and support between the Extension Agents and their participants. The results from this pilot mixed methods study indicate that the retention plan was valued by Extension Agents who found it to be a useful tool that allowed them to be in ongoing communication with their participants. The method used for dissemination of the retention plan was not effective, however, as evidenced by the low level of adoption. Preliminary findings of the impact of the retention plan on outcomes of the BLD program indicate that it may improve effects on glycemic control. It also indicated it may improve health behaviors with use of the Plate Method, eating meals at regular times, tracking walking or exercising, and walking or exercising, and self-efficacy with use of the Plate Method, choosing healthier foods when eating out, and tracking walking or exercising. The small number of Extension Agents that used the retention plan makes it difficult to draw definitive conclusions on the impact of the retention plan. This low adoption rate among the agents who could have used the retention plan highlighted a need to evaluate the way it was disseminated. Dissemination efforts need to be improved to inform Extension Agents working with the BLD program of the retention plan in a way that they are aware of and utilize the retention plan for their programs.

Implications from study 1 suggest that follow-up on these preliminary findings should include studies with a larger sample size of BLD programs that use the retention plan. This would allow for a greater effect size in determining whether the retention plan makes an impact on program outcomes. Our findings suggest that the retention plan should be disseminated more effectively to Extension Agents prior to the start of their programs, which will allow for greater accessibility and understanding of the utilization of the retention plan.

Physical activity in community-based diabetes and management programs are vital for overall glycemic control through improved insulin sensitivity and blood glucose tolerance [11-14]. Older adults in general tend to be sedentary and this can cause issues with managing their blood glucose levels that could lead to other health complications especially in those with type 2 diabetes [12,16]. Physical activity not only improves glycemic control but if adopted as a lifestyle practice, it is effective in maintaining or improving physical functioning among older adults with type 2 diabetes [11-14, 17-19]. Studies have shown that older adults that engage in regular physical activity such as aerobic and strength training have better physical function, mobility, balance, and strength to help with completing daily activities and maintaining independence [17-19].

Study 2 described in this dissertation was a randomized controlled pilot study that evaluated the effects of an existing physical activity program (LIFT) with an existing community-based diabetes lifestyle management program (BLD) conducted by Extension Agents. Study locations of participants for this study were in southwest Virginia (Roanoke County) and central Virginia (Lunenburg County and Charlotte County). Three Extension Agents (two of whom were working together in central Virginia and one working in southwest Virginia) were recruited for and obtained BLD and LIFT training to deliver BLD and BLD+LIFT programs. These agents had established local community collaborations with an Area Agency on Aging (AAA) and Program of All-inclusive Care for the Elderly (PACE) for program implementation for this study. Preliminary findings indicate that comparison of the BLD and BLD+LIFT program outcomes showed greater improvement in tracking behaviors, specifically for walking or exercising, and improvements in self-efficacy to conduct and track walking or exercising in participants of the BLD+LIFT programs. This suggested that addition of

the LIFT program may be a good implementation strategy to increase participant's self-efficacy and put additional emphasis on tracking and goal setting when becoming more physically active. There were also greater improvements in diet behaviors in participants of the BLD and LIFT programs including tracking of food intake and use of the Plate Method. This suggested that the LIFT program may impact those specific dietary behaviors and that with the LIFT having a nutritional component may support these specific diet related behaviors promoted in the BLD.

Unexpected findings from this study included an increase in mean A1C values in BLD and BLD+LIFT programs, however, the increase was much lower in BLD+LIFT programs. There was also a decrease in total weekly leisure activity in BLD and BLD+LIFT programs, however, the decline was much greater in BLD programs. Finally, there was a decrease in participants engagement in BLD+LIFT programs. A possible explanation for the decline of engagement with the combined programs may relate to the expanded participation required with the LIFT program, and the need for participants to access other essential services offered at the sites. Participants particularly at the PACE site used additional services provided to them at the site, which assisted them with their daily living activities. This posed barriers to regular participation by participants at this site, as they often chose to do alternate activities rather than attend BLD and/or LIFT sessions.

Functional fitness tests indicated improvements in two of six fitness measures in the BLD+LIFT programs compared to the BLD program, which included the maximum distance of the lower leg flex (in inches) and the number of steps during the two-minute step test reaching statistical significance. The other three fitness measures, number of arm curls, maximum distance of the upper arm flex, and time completion of 8 ft up and go improvements in the BLD program. The balancing exercises showed minimal difference between the two groups.

Complicating interpretation of these outcomes was the situation that most of the participants at the PACE site, and some from the AAA sites, had significant health issues in addition to their diabetes which impacted their ability to participate fully in the LIFT program.

Overarching themes from Extension Agents interviews included modifications that Extension Agents made to the BLD and LIFT programs to make them accommodable to participants and the sites at which the programs were conducted, use of the retention plan in conjunction with the program, the impact of the time commitment on Agents schedules, understanding program logistics with implementing both BLD and LIFT programs, and the benefits of implementing the BLD program with the LIFT program. Extension Agents indicated that they are willing and interested to implement BLD+LIFT programs, however, addressing program logistics by communicating more frequently and clearly with sites implementing BLD+LIFT programs regarding participants' schedules and being more cognizant of the time commitment of implementing BLD+LIFT programs is important. Extension Agents also indicated that implementation of these programs at PACE or comparable sites with older adults that have greater disability and dependency may not be the best locations.

Findings from study 2 indicate that retention was greater in BLD+LIFT programs compared to BLD programs which suggests that additional support and assistance from Extension Agents was helpful in keeping participants on track with program goals. This study also suggests that that the LIFT program could enhance certain health behaviors and self-efficacy for people with type 2 diabetes that want to be more physically active. The LIFT programs' nutrition component may support these specific diet related behaviors promoted in the BLD, thereby impacting participants' making recommended dietary behavior changes.

A study of larger sample size in BLD programs that incorporate the LIFT program would allow for a greater effect size to determine whether the LIFT program makes an impact on program outcomes. In addition, AAA sites are great avenues for reaching a target population for the BLD and LIFT programs, however, reaching the target population at PACE site was a challenge, as participants were too debilitated to participate in the LIFT program or to actively change their dietary habits due to dependency on others. Perhaps, working with and expanding sites used in future studies to include locations where older adults who have fewer co-morbidities could be recruited, like YMCA's, churches, etc. should be considered. People that have greater co-morbidities need additional support and assistance beyond what the BLD and LIFT programs could provide.

It is important that older adults that have type 2 diabetes are able to take an active role in managing their diabetes and become more physically active in their daily lives. Findings from the two pilot studies found that BLD and BLD+LIFT programs conducted by Cooperative Extension could address this need. The programs are highly acceptable to Extension Agents, and the retention materials developed in support of the program show promise to increase participant engagement and behavior change. Combining the two programs together is feasible, and may increase participant retention, self-efficacy, and behavior change, however further study is required to make definitive conclusions. Additional co-morbidities in older adults with type 2 diabetes may impact glycemic control efforts and be a barrier to the recommended dose of physical activity needed to receive the overall health benefit. This may require more support and physical assistance and should be a factor in deciding locations for the combined programs. Older adult participation in accessible diabetes education programs and group physical activity

programs that include aerobic and strength training exercises, is important to improving outcomes for the growing number of adults with diabetes.

References

1. Centers for Disease Control and Prevention. (2018, February 2). *Prevalence of Diagnosed Diabetes*. Retrieved from Centers for Disease Control and Prevention: https://www.cdc.gov/diabetes/data/statistics-report/diagnosed.html
2. Shellberg et.al. (2013) Lifestyle interventions for patients with and at risk for type 2 diabetes: a systematic review and meta-analysis, Annals Internal Medicine, 159, 543-551
3. M.K. Baker, K. Simpson, B. Lloyd, A.E. Bauman, M.A. Singh. (2011) Behavioral strategies in diabetes prevention programs: a systematic review of randomized controlled trials, Diabetes Research and Clinical Practice, 91 (1), 1-12
4. Chen et.al. (2015). Effect of lifestyle intervention in patients with type 2 diabetes: a meta-analysis, Metabolism, 64 (2), 338-347
5. Strine TW, Okoro CA, Chapman DP, Beckles GL, Balluz L, Mokdad AH. (2005). The impact of formal diabetes education on the preventive health practices and behaviors of persons with type 2 diabetes. Preventative Medicine. 41(1),79–84.
6. Gucciardi, E., DeMelo, M., Offenhiem, A., & Steward, D. (2008). Factors contributing to attrition behavior in diabetes self-management programs: A mixed method approach. *BMC Health Services Research*, 1-11.
7. Gucciardi, E., DeMelo, M., Offenheim , A., Grace, S., & Stewart, D. (2007). Patient factors associated with attrition from a self management education programme. *Journal of Evaluation in Clinical Practice*, 914-91.

8. M.K. Baker, K. Simpson, B. Lloyd, A.E. Bauman, M.A. Singh. (2011) Behavioral strategies in diabetes prevention programs: a systematic review of randomized controlled trials, Diabetes Research and Clinical Practice, 91 (1), 1-12
9. Deakin University. (2012). Identifying effective strategies to increase recruitment and retention in community-based promotion programs.
10. McCann, J., Ridgers, N., Thorton, L., & Teychenne, M. (2013). Effective recruitment and retention strategies in community health programs. *Health Promotion Journal Australia*, 104-110.
11. Colberg SR, Albright AL, Blissmer BJ, Braun B, Chasan-Taber L, Fernhall B, Regensteiner JG, Rubin RR, Sigal RJ American College of Sports Medicine; American Diabetes Association. (2010). Exercise and type 2 diabetes: American College of Sports Medicine and the American Diabetes Association: joint position statement. Exercise and type 2 diabetes. Med Sci Sports Exerc. 42, 2282–2303
12. Zhao G, Ford ES, Li C, Balluz LS. (2011). Physical activity in U.S. older adults with diabetes mellitus: prevalence and correlates of meeting physical activity recommendations. Journal of the American Geriatrics Society. 59, 132–137.
13. Sigal RJ, Kenny GP, Wasserman DH, Castaneda-Sceppa C. Physical activity/exercise and type 2 diabetes. (2004) Diabetes Care. 27, 2518–2539
14. Zanuso S, Jimenez A, Pugliese G, Corigliano G, Balducci S. (2010) Exercise for the management of type 2 diabetes: a review of the evidence. Acta Diabetol, 47, 15–22.
15. Balducci, S., Zanuso, S., Nicolucci, A., et.al (2010). Anti-inflammatory effect of exercise training in subjects with type 2 diabetes and the metabolic syndrome is dependent on

exercise modalities and independent of weight loss. Nutrition Metabolism and Cardiovascular Diseases. 20, 608-617.

16. Centers for Disease Control and Prevention. (2015, June 4). *How much physical activity do older adults need?* Retrieved from Centers for Disease Control and Prevention: https://www.cdc.gov/physicalactivity/basics/older_adults/index.htm
17. Yang, Z., Scott, C.A., Mao, C., Tang, J., (2014). Resistance exercise versus aerobic exercise for type 2 diabetes: a systematic review and meta-analysis Sports Med, 44 (4), 487-499
18. Ball, S. (2013). Outcomes of Stay Strong, Stay Healthy in Community Settings. Journal of Aging and Health, 1388-1397
19. McNamara, A., Gunter, K. (2012). The influence of participation in Better Bones and Balance™ on skeletal health: evaluation of a community-based exercise program to reduce fall and fracture. *Journal of Osteoporosis International*, 1813-20

Appendices

Appendix A. Institutional Review Board Approval Letter

Office of Research Compliance
Institutional Review Board
North End Center, Suite 4120
300 Turner Street NW
Blacksburg, Virginia 24061
540/231-3732 Fax 540/231-0959
email irb@vt.edu
website http://www.irb.vt.edu

MEMORANDUM

DATE: January 9, 2019

TO: Carlin Rafie, Kristina Ashleigh Jiles, Kathy Hosig

FROM: Virginia Tech Institutional Review Board (FWA00000572, expires January 29, 2021)

PROTOCOL TITLE: The implementation of a retention plan in a VCE community-based diabetes lifestyle management program (BLD) using the RE-AIM Framework: A retrospective mixed methods study

IRB NUMBER: **18-1091**

Effective January 9, 2019, the Virginia Tech Institution Review Board (IRB) approved the New Application request for the above-mentioned research protocol.

This approval provides permission to begin the human subject activities outlined in the IRB-approved protocol and supporting documents.

Plans to deviate from the approved protocol and/or supporting documents must be submitted to the IRB as an amendment request and approved by the IRB prior to the implementation of any changes, regardless of how minor, except where necessary to eliminate apparent immediate hazards to the subjects. Report within 5 business days to the IRB any injuries or other unanticipated or adverse events involving risks or harms to human research subjects or others.

All investigators (listed above) are required to comply with the researcher requirements outlined at:

https://secure.research.vt.edu/external/irb/responsibilities.htm

(Please review responsibilities before the commencement of your research.)

PROTOCOL INFORMATION:

Approved As:	**Expedited, under 45 CFR 46.110 category(ies) 5,6,7**
Protocol Approval Date:	**January 9, 2019**
Protocol Expiration Date:	**January 8, 2020**
Continuing Review Due Date*:	**December 25, 2019**

*Date a Continuing Review application is due to the IRB office if human subject activities covered under this protocol, including data analysis, are to continue beyond the Protocol Expiration Date.

FEDERALLY FUNDED RESEARCH REQUIREMENTS:

Per federal regulations, 45 CFR 46.103(f), the IRB is required to compare all federally funded grant proposals/work statements to the IRB protocol(s) which cover the human research activities included in the proposal / work statement before funds are released. Note that this requirement does not apply to Exempt and Interim IRB protocols, or grants for which VT is not the primary awardee.

The table on the following page indicates whether grant proposals are related to this IRB protocol, and which of the listed proposals, if any, have been compared to this IRB protocol, if required.

Date*	OSP Number	Sponsor	Grant Comparison Conducted?

* Date this proposal number was compared, assessed as not requiring comparison, or comparison information was revised.

If this IRB protocol is to cover any other grant proposals, please contact the IRB office (irb@vt.edu) immediately.

Balanced Living with Diabetes Retention Plan

Week 1 - 4: Sessions #1**- 3**

- Extension Agent and/or Master Food Volunteer to send reminder message about upcoming sessions to participants a day prior to the session.

Week 5: Exercise Activity **(Sent by Extension Agent via email, text, or social media platform)-provide visual**

Hi BLD participant(s)! We hope that you are tracking your physical activity goals. Here is an exercise that you can incorporate into your daily activities and that can do right at home! Chair Squats can help strengthen your legs and abdomen! Here is how to do it:

It's a good idea before and after walks or strength exercises to stretch. Here is how to do it:

- Gently stretch out the muscles you are using
- Hold the stretch for 15 seconds or 3-5 deep breaths
    - Remember, do NOT bounce when you stretch – you could injure your muscles that way

Week 6: Newsletter #1 **(Sent by Extension Agent and/or Master Food Volunteer via email or mail)**

Week 7: Fact regarding health **(Sent by Extension Agent and/or Master Food Volunteer via email, text, or social media platform)**

- Fact: It is important to have a heart healthy diet and get as much exercise as your health will allow, because people who have diabetes have twice the risk of heart attacks.
- To help control your blood pressure and cholesterol, here are some foods to incorporate into your daily diet:
    - Fruits and vegetables
    - Whole Grains
    - Lean-cut meats
    - Low-fat dairy

Week 8: Recipe (**Sent by Master Food Volunteer via email, text, or social media platform)**

Take Home Recipe: Autumn Salad

Ingredients:

• 1 medium Granny Smith apple, sliced thinly (with skin)

• 2 tablespoons lemon juice

• 1 bag (about 5 cups) mixed lettuce greens (or your favorite lettuce)

• ½ cup dried cranberries

• ¼ cup walnuts, chopped

• ¼ cup unsalted sunflower seeds

• ⅓ cup low-fat raspberry vinaigrette dressing

Directions

1. Sprinkle lemon juice on the apple slices.

2. Mix the lettuce, cranberries, apple, walnuts,

and sunflower seeds in a bowl.

3. Toss with ⅓ cup of raspberry vinaigrette dressing,

to lightly cover the salad.

Nutritional Content

Yield: 6 servings

Serving size: 1 cup

Calories 138

Total Fat 7 g

Saturated Fat 1 g

Cholesterol 0 mg

Sodium 41 mg

Total Fiber 3 g

Protein 3 g

Carbohydrates 19 g

Potassium 230 mg

Source: This recipe was taken from Heart Healthy Cooking African American Style, National Heart, Lung, and Blood Institute, 2008, page 12

Week 9: Exercise Activity **(Sent by Extension Agent via email, text, or social media platform)-provide visual!**

Hi BLD participant(s)! We hope that you are tracking your physical activity goals. Here is an exercise that you can incorporate into your daily activities and that can do right at home! **Bicep curls** can help strengthen your lower arms! Here is how to do it:

- Get a small weight or use a bottle of bottled water or small bottle of soda.
- Stand up straight or sit up straight in a chair, hold your stomach in
- Hold a weight in each hand with your arms at your sides
- Bending your arms at the elbows, lift the weights to your shoulders and then lower them to your sides

Week 10: Newsletter #2 **(Sent by Extension Agent and/or Master Food Volunteer via email or mail)**

Week 11: Fact and Reminder about the Reunion Class **(Sent by the Extension Agent and/or Master Food Volunteer via email, text, social media platform)**

- Fact: According to the American Diabetes Association, “hidden salt” may be the biggest source of sodium in our meal plans! Preparing food at home is one of the best ways to begin cutting back on sodium. Here are some suggestions:
    - Try using small amounts of fresh or dried herbs, like basil, rosemary, oregano, cumin, curry, among others to learn these new tastes when salt must be reduced
    - Read labels carefully for sodium content when you buy pre-packaged foods and seasoning mixtures
    - Choose food products that indicate they are reduced in sodium
- **Reunion Class Reminder (date, time location, etc.)**

Week 12: Reunion Class **(Follow-up)**

Retention Plan Materials

Stretching: Exercise Activity 1

Hi BLD participant(s)! We hope that you are meeting your physical activity goals. Here is an exercise that you can incorporate into your daily activities and that you can do right at home!

It's a good idea before and after walks or strength exercises to **stretch**. Here is how to do it:

- Gently stretch out the muscles you are using
- Hold the stretch for 15 seconds or 3-5 deep breaths
- Repeat 3-5 times

Remember, do NOT bounce when you stretch – you could injure your muscles that way

If you haven't been exercising regularly, check with your doctor first and refer to the PAR-Q

Contact us: (Extension Agent name)
(Extension Agent phone number
(Extension Agent office)

Virginia Tech
Center for Public Health
Practice and Research

Virginia Cooperative Extension
Virginia Tech • Virginia State University

Balanced Living with Diabetes

For People with Diabetes and Their Families

Newsletter #1

Hello fellow participants! We have missed you since the last Balanced Living with Diabetes session! We hope that you are taking the information that you have learned from the sessions and putting them into practice in your daily lives! Here are some health tips and a healthy recipe to keep you on track!

Get ACTIVE!

Being active with diabetes allows you body cells to take up more sugar, which keeps your blood sugar lower! Here are some benefits:

- Controls and lowers blood sugar
- Burns calories
- Controls blood pressure and cholesterol
- Relieves stress

Eat LESS sugar!

Remember it is easier to avoid added sugars to control the amount of carbohydrate you eat! Here are some tips:

- Drink fewer sugar sweetened beverages
- Buy foods with less sugar added
- Eat more fruits and vegetables with natural sugars
- Use less sugar when cooking or adding to foods

Southern Pork Plate

Source: *Diabetes Meals by the Plate* cookbook (pg 120– 121)

Servings: 4 (1 pork chop each)
Prep: 5 minutes
Bake: 30 minutes
Ingredients:
Four-4 ounce boneless pork loin chops
2 tablespoons of Dijon mustard
Black Pepper

Baked Honey Dijon Pork Chops

Preheat oven to 425 degrees F. Place pork chops in a baking dish. Brush pork chops evenly with mustard and sprinkle with pepper. Bake, covered, about 30 minutes or until done (145 degrees F). Cover with foil and let stand for 3 minutes. Place one chop on each of four serving plates.

Per serving: 167 cal., 5 g total fat (2 g sat. fat), 63 mg chol., 114 mg sodium, 2 g carb (0 g fiber, 1 g sugar), 25 g pro.

Exchanges: 3.5 lean meat

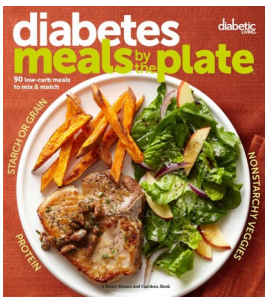
Sautéed Kale

In two batches, in a large skillet cook 12 cups chopped kale and 2 cloves garlic, minced in 2 teaspoons of hot oil over medium heat fir 8 to 10 minutes or until kale is tender, stirring frequently.

Divide among plates. Makes 4 servings (1 cup each).

Per serving: 121 cal., 4g total fat (0g sat fat), 0 mg chol., 77 mg sodium, 18g carb. (4g fiber, 4 g sugars), 9 g pro.

Exchanges: 3.5 vegetable, 1 fat



You will get this Cookbook at the Reunion Class!!

Reunion Class Date/Time:
Reunion Class Location:

Virginia Tech
Center for Public Health
Practice and Research

Virginia Cooperative Extension
Virginia Tech • Virginia State University

Fun Fact About Your Health

Hi BLD participant(s)! It is important to have a heart healthy diet and get as much exercise as your health will allow, because people who have diabetes have twice the risk of heart attacks.

To help control your blood pressure and cholesterol, here are some foods to incorporate into your daily diet:

- Fruits and vegetables
- Whole grains
- Lean-cut meats
- Low-fat dairy foods

Contact us: (Extension Agent name)
(Extension Agent phone number
(Extension Agent office)

Virginia Tech
Center for Public Health
Practice and Research

Virginia Cooperative Extension
Virginia Tech • Virginia State University

Do you remember this recipe?
Autumn Salad

You will need:

- 1 medium Granny Smith apple, sliced thinly (with skin)
- 2 tablespoons lemon juice
- 1 bag (about 5 cups) mixed lettuce greens (or your favorite lettuce)
- ½ cup dried cranberries
- ¼ cup walnuts, chopped
- ¼ cup unsalted sunflower seeds
- ⅓ cup low-fat raspberry vinaigrette dressing

1. Sprinkle lemon juice on the apple slices.
2. Mix the lettuce, cranberries, apple, walnuts, and sunflower seeds in a bowl.
3. Toss with ⅓ cup of raspberry vinaigrette dressing, to lightly cover the salad.

Yield: 6 servings
Serving size: 1 cup
Calories 138
Total Fat 7 g
Saturated Fat 1 g
Cholesterol 0 mg
Sodium 41 mg
Total Fiber 3 g
Protein 3 g
Carbohydrates 19 g
Potassium 230 mg

Source: This recipe was taken from Heart Healthy Cooking African American Style, National Heart, Lung, and Blood Institute, 2008, page 12

Virginia Tech Center for Public Health Practice and Research
Virginia Cooperative Extension
Virginia Tech • Virginia State University
www.ext.vt.edu

Bicep Curls: Exercise Activity 2

Hi BLD participant(s)! We hope that you are meeting your physical activity goals. Here is an exercise that you can incorporate into your daily activities and that you can do right at home!

Bicep curls can help strengthen your arms! Here is how to do it:

1. Get a small weight or use a bottle of water or a small bottle of soda
2. Stand up straight or sit up straight in a chair,
3. Hold your stomach in
4. Hold a weight in each hand with your arms at your sides
5. Bending your arms at the elbows, lift the weights to your shoulders and then lower them to your sides
6. Repeat 8-10 times, after resting a minute between each set.

If you haven't been exercising regularly, check with your doctor first and refer to the PAR-Q

Contact us: (Extension Agent name)
(Extension Agent phone number
(Extension Agent office)

Virginia Tech
Center for Public Health
Practice and Research

Virginia Cooperative Extension
Virginia Tech • Virginia State University
www.ext.vt.edu

Balanced Living with Diabetes

For People with Diabetes and their Families

Newsletter #2

Hello fellow participants! The Balanced Living with Diabetes Reunion session is coming up in just a few weeks! We hope that you are keeping track of your diet and setting physical activity goals! Here are some health tips and a healthy recipe to try!

Keeping Track and Setting Goals!

The best way to make changes that you can stick to is to set realistic goals and to keep track of your food intake and physical activity. Here are some tips:

- Use your food diary to write down what you eat at meals and snacks.
- Use the Idaho Plate Method to control portion sizes, carbohydrates, and to focus on healthy foods.
- Spread out food during the day to prevent overeating and help maintain a healthy weight.
- Use your pedometer to keep track of your steps.
- Try to obtain 30 minutes of moderate exercise like brisk walking, 5 days a week.

Virginia Cooperative Extension

Virginia Tech • Virginia State University

www.ext.vt.edu

Fun Fact About Your Health

According to the American Diabetes Association, “hidden salt” may be the biggest source of sodium in our meal plans! Here are some suggestions:

- Read labels carefully for sodium content when you buy pre-packaged foods and seasoning mixtures
- Choose food products that indicate they are reduced in sodium
- Preparing food at home is one of the best ways to begin cutting back on sodium
- Try using small amounts of fresh or dried herbs, like basil, rosemary, oregano, cumin, curry, among others to learn these new tastes when salt must be reduced

Remember, the BLD class reunion is (enter date, time, location, etc.)

Contact us: (Extension Agent name)
(Extension Agent phone number
(Extension Agent office)

Weekend Brunch

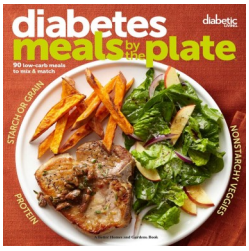
Source: *Diabetes Meals by the Plate* cookbook (pg 37– 38)

Servings: 8 (1/8 wedge of quiche' each)
Prep: 5 minutes
Bake: 30 minutes
Ingredients: Half of a 15 - ounce package rolled refrigerated unbaked piecrust (1 piecrust); Nonstick cooking spray; 6 ounces skinless, boneless chicken breast cut into 3/4-inch chunks; 2 cups shredded fresh spinach (about 2 ounces); 2 cups refrigerated or frozen egg product, thawed, or 8 eggs, lightly beaten; 3/4 cup shredded Gruyere or Swiss cheese (3 ounces); 1/2 cup fat-free milk; 1/3 cup chopped bottled roasted red sweet peppers

Chicken-Spinach Quiche'

1. Preheat oven to 425 degrees F. Let piecrust stand at room temperature according to package directions. Line a 9-inch pie plate with piecrust. Crimp edge as desired. Line unpricked piecrust with a double thickness of foil. Bake for 8 minutes. Remove foil. Bake for 4 to 5 minutes more or until piecrust is set and dry. Remove from oven. Reduce oven temperature to 350 degrees F.
2. Coat an unheated medium skillet with cooking spray. Heat over medium heat. Add chicken to skillet. Cook and stir for 6 to 8 minutes or until chicken is done and no longer pink. Remove chicken from skillet. Return skillet to heat. Add spinach and cook over medium heat for 1 to 2 minutes or until wilted, turning frequently.
3. In a large bowl whisk together the eggs, chicken, spinach, cheese, milk, roasted peppers, thyme, salt, and pepper. Pour egg mixture into baked piecrust.
4. Bake for 40 minutes. If necessary to prevent overbrowning, cover edge of quiche with foil. Bake for 5 to 10 minutes more or until a knife inserted near center comes out clean. Let stand on a wire rack for 10 minutes before serving. Cut into wedges and place one wedge of each of four serving plates. See tip for storing the remaining wedges.

PER SERVING: 209 cal., 10 g total fat (5 g sat. fat), 28 mg chol., 396 mg sodium, 15 g carb. (1 g fiber, 1 g sugars), 15 g pro.



You will get this Cookbook at the Reunion Class!!

Reunion Class Date/Time:
Reunion Class Location:

Virginia Tech
Center for Public Health
Practice and Research

Virginia Cooperative Extension
Virginia Tech • Virginia State University
www.ext.vt.edu

Appendix D: Email Script to Extension Agents

Email Script

Hello, my name is Kristina Jiles, a doctoral candidate in the Department of Human Nutrition, Foods, and Exercise at Virginia Tech under the advisement of Extension Specialist, Dr. Carlin Rafie. You were identified as an Extension Agent involved with the Balanced Living with Diabetes (BLD) Program study in 2015-2017. The study indicates that you had conducted at least one BLD Program after the development of a retention plan for the BLD Program, and I am inviting you to participate in a telephone interview for a study that I am conducting on the retention plan.

In the telephone interview, you will be asked a series of questions about the retention plan used in your BLD program. This will include the usage, implementation processes, and barriers and facilitators of the retention plan. Should you agree to participate in this interview, your total time commitment for the interview will be 15-20 minutes.

If you would like to participate in this study and if you have any questions, please email me at krist14@vt.edu to confirm your interest to participate and for further information about this project.

Thank you,

Kristina Jiles

VIRGINIA POLYTECHNIC INSTITUTE AND STATE UNIVERSITY

Verbal Informed Consent for Participants in Research Projects Involving Human Subjects

Title of Project: The implementation of a retention plan in a VCE community-based diabetes lifestyle management program (BLD) using the RE-AIM Framework: A retrospective mixed methods study

Investigator(s):	Carlin Rafie, PhD, RD	PI	crafie@vt.edu	540-231-3163
	Kristina Jiles, MS, MPH, CHES®	Co-I	krist14@vt.edu	
	Kathy Hosig, PhD, MPH, RD	Co-I	khosig@vt.edu	540-231-6637

Institutional Affiliation: Dr. Rafie is a faculty member in the Department of Human Nutrition, Foods and Exercise; and Kristina Jiles is a PhD Candidate in the Department of Human Nutrition, Foods and Exercise at Virginia Tech.

I. Purpose of this Research Project

The purpose of this study is to evaluate the adoption and implementation of the Balanced Living with Diabetes (BLD) retention plan among Family and Consumer Science (FCS) Extension Agents. The interview will include a discussion of your experiences with the retention plan. Study results will be used for Kristina Jiles' dissertation project and may be published in educational journals or presented at educational meetings.

II. Procedures

You are invited to participate in this study. You are eligible to participate because you have been identified as an FCS Extension Agent that was involved with the BLD study conducted in 2015-2017 by Dr. Carlin Rafie, and that you conducted at least one BLD program during the development of a retention plan for the BLD. The following information is provided to help you make an informed decision whether or not to participate. If you have any questions, please do not hesitate to ask.

Should you agree to participate, you will be asked to participate in a 15-20-minute audio-recorded interview. You will be asked questions about the retention plan used in your BLD program. This will include the usage, implementation processes, and barriers and facilitators of the retention plan.

III. Risks

Your participation poses minimal risk to you. In order to protect your identity, you will be assigned a study number, which will be used on all notes from the interview so that your name is not associated with these materials. Transcriptions of the audio recordings will also be labeled with your participant number, and the recordings will be destroyed after the transcriptions are made.

IV. Benefits

Information from this study will allow researchers to understand your experiences with the retention plan and how it affected participant retention in the BLD programs. This will allow us to make improvements to the plan and inform its future use in BLD programs. No promise or guarantee of these benefits is being made to encourage you to participate.

V. Extent of Anonymity and Confidentiality

Any information obtained during this study that could identify you will be kept strictly confidential. Any identifiable information will be stored separately on a password-protected computer on the VT campus of the Principal Investigator. As mentioned previously, you will be assigned a participant number and all notes and transcripts will be identified with this number. We may publish the combined results of this study in educational journals or present them at educational meetings, but your identity will be kept strictly confidential.

The Virginia Tech (VT) Institutional Review Board (IRB) may view the study's data for auditing purposes. The IRB is responsible for the oversight of the protection of human subjects involved in research.

VI. Compensation

There will be no compensation for your participation in this telephone interview.

VII. Freedom to Withdraw

It is important for you to know that you are free to withdraw from this study at any time without penalty. You are free not to answer any questions that you choose without penalty.

Please note that there may be circumstances under which the investigator may determine that a subject should not continue as a subject.

VIII. Questions or Concerns

Should you have any questions about this study, you may contact one of the research investigators whose contact information is included at the beginning of this document.

Should you have any questions or concerns about the study's conduct or your rights as a research subject, or need to report a research-related injury or event, you may contact the Virginia Tech Institutional Review Board at irb@vt.edu or (540) 231-3732.

IX. Subject's Consent

Do you understand the information that I have gone over? Do you have any questions?

Do you agree to participate in this study?

_____ Date_____
Subject name

_____ Date_____
Co-investigator signature

Appendix F: Semi-Structured Interview Questions

Study #1: Semi-structured interview questions with Extension Agents with use of the retention plan.

ADOPTION

1. Did you use the retention plan? (yes/no)
    a. If no, why didn't you use the retention plan?

IMPLEMENTATION

FIDELITY

1. Describe how you used the retention plan.
    a. Did you follow the retention plan accordingly when distributing retention materials to participants? (yes/no)
2. What modifications, if any, were made to the retention plan?
    a. Why did you make those modifications?
    b. How did you make those modifications?
    c. How did those modifications differ from the original retention plan?

DOSE

3. How many retention materials did you provide to participants?
    a. Why did you provide only these retention materials to participants?
4. How were the retention materials distributed to participants? (Email, mail, verbal-telephone, text messages with attachments)
    a. Why did you choose to distribute the retention materials in this format?
    b. Did all the participants receive the retention materials? (yes/no)

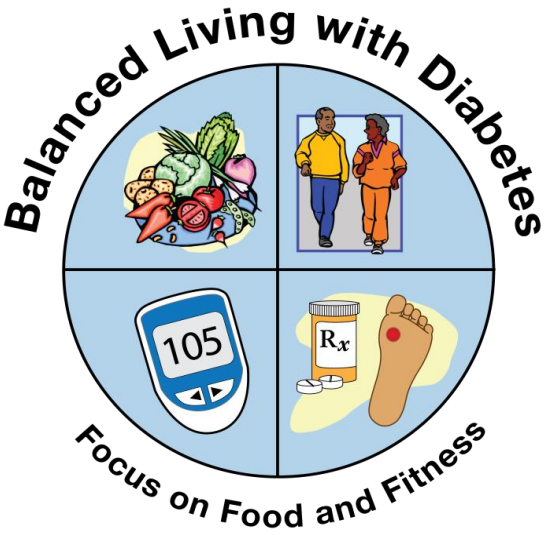
BARRIERS AND FACILITATORS

5. What barriers or challenges, if any, did you face using the retention plan?
6. What barriers or challenges, if any, did you face distributing retention materials participants?
7. What helped you to distribute the retention materials to participants?

SYSTEMS LEVEL MAINTENANCE

8. What impact do you think the retention materials had on participants coming to the reunion session? On lifestyle changes made by the participants?
9. Do you have any recommendations on improving the retention materials?
10. What are your plans for the BLD program in the future?
    a. Do you plan to use the retention materials?

DATE_____ PARTICIPANT NUMBER_____



BALANCED LIVING WITH DIABETES

Participant Information

First Class

Virginia Cooperative Extension
Virginia Tech • Virginia State University

Virginia Tech
Center for Public Health
Practice and Research

Welcome to Balanced Living with Diabetes! We hope this program will help you manage your diabetes. The information you share will help us make our program better. Feel free to skip any question and remember that all of your information will be kept confidential.

1. Do you smoke or use tobacco products such as dip or snuff?

   _____ Yes _____ No

2. Do you have diabetes?

   _____ Yes, type 2 diabetes

   _____ Yes, type 1 diabetes

   _____ No, my doctor told me that I am pre-diabetic (borderline)

   _____ No, but a family member has diabetes

   _____ No, and none of my family has diabetes

3. In the past year, did you see a doctor for diabetes?

   _____ Yes _____ No

4. Do you take diabetes pills to control your blood sugar?

   _____ Yes _____ No

5. Do you take insulin (shots) to control your blood sugar?

   _____ Yes _____ No

6. What complications, if any, have you experienced with your diabetes?

   ____ bladder control problems
   ____ nerve damage
   ____ eye disease
   ____ sexual problems
   ____ foot problems
   ____ low blood sugar
   ____ kidney disease
   ____ stomach problems

The next questions ask about managing your diabetes.

7. People with diabetes should try to have an A1c number of less than ____%.

8. People with diabetes should have their A1c checked at least ____ time(s) each year.

9. How often should people with type 2 diabetes check their blood sugar?

   ____ every day ____ every week ____ every month

10. How often should people with diabetes get a flu shot?

    ____ every year ____ every 2 years ____ every 3 years

11. How often should people with diabetes get a dilated eye exam?

    ____ every year ____ every 2 years ____ every 3 years

12. How often should people with diabetes have a complete foot exam?

    ____ every doctor's visit
    ____ every 6 months
    ____ every year
    ____ every 2 years

13. Which of these foods are healthy fats? (you can check more than one)

    ____ canola oil ____ tub margarine ____ bacon ____ corn oil

14. Which of the following foods does NOT contain carbohydrate?

    ____ milk ____ green beans ____ sugar ____ hamburger patty

15. Which of the following foods has the lowest amount of fiber?

    ____ raisin bran cereal ____ apples ____ white bread ____ beans

16. How much of your diabetes supplies and medications are covered by insurance?

    ____ None

    ____ A little bit

    ____ About half

    ____ Most of it

    ____ All of it

    ____ I do not need supplies and medications

17. Have you ever participated in a diabetes education or support group besides this class (Balanced Living with Diabetes)?

    _____ Yes _____ No

    If yes, please list the name, location and dates for the class:

    _____

    How many times did the class meet? _____

<u>In the past week</u>, how many days did you (circle the number):

18. Take your diabetes medications as directed by your doctor?

    0 1 2 3 4 5 6 7

19. Check your blood sugar at least once?

    0 1 2 3 4 5 6 7

20. Do a total of 30 minutes or more of physical activity that was enough to make you breathe harder?

    0 1 2 3 4 5 6 7

21. Use the Plate Method to control your portion sizes for at least one meal?

    0 1 2 3 4 5 6 7

22. Skip checking your blood sugar or taking your diabetes medicines due to cost?

    0 1 2 3 4 5 6 7

Circle the number that best describes how often you USUALLY did these things:

In the past 3 months, **how many days a week** did you usually …	Days a week							
23. Keep track of what you ate?	0	1	2	3	4	5	6	7
24. Eat 5 servings of fruits and vegetables?	0	1	2	3	4	5	6	7
25. Eat 3 servings of whole grains?	0	1	2	3	4	5	6	7
26. Eat 3 servings of milk or dairy or other foods high in calcium?	0	1	2	3	4	5	6	7
27. Use the Plate Method?	0	1	2	3	4	5	6	7
28. Eat meals at regular times?	0	1	2	3	4	5	6	7
29. Make a plan to walk or exercise?	0	1	2	3	4	5	6	7
30. Keep track of how much you walked or exercised?	0	1	2	3	4	5	6	7
31. Walk or exercise?	0	1	2	3	4	5	6	7

How confident are you that you can do these things to manage your diabetes?

How sure are you that on most days you can …	Very Unsure	Unsure	Neither Sure or Unsure	Sure	Very Sure
32. Keep track of what you eat?	Very Unsure	Unsure	Neither	Sure	Very Sure
33. Use the Plate Method?	Very Unsure	Unsure	Neither	Sure	Very Sure
34. Eat meals at regular times?	Very Unsure	Unsure	Neither	Sure	Very Sure
35. Choose healthy foods when you eat out?	Very Unsure	Unsure	Neither	Sure	Very Sure
36. Use the nutrition facts label to choose healthy foods?	Very Unsure	Unsure	Neither	Sure	Very Sure
37. Walk or exercise?	Very Unsure	Unsure	Neither	Sure	Very Sure
38. Walk or exercise when you have other things to do?	Very Unsure	Unsure	Neither	Sure	Very Sure
39. Keep track of how much you walk or exercise?	Very Unsure	Unsure	Neither	Sure	Very Sure

40. Do you wear your step counter?

____ Yes, on most days
____ Yes, on some days
____ No

41. If you do wear your step counter, about how many steps do you walk on a:

_____ typical day when you do not make a special effort to walk

_____ typical day when you make a special effort to walk

The last questions are about you. Please remember that your name is not on this form and you can skip any questions that make you uncomfortable.

42. What is your age? _____ years

43. What is your gender? ____ Male ____ Female

44. Which of the following best describes you? (check all that apply)

_____ Caucasian/white
_____ African American
_____ Asian/ Pacific Islander
_____ Other (please list) _____

45. Are you Hispanic?

_____ Yes _____ No

46. How many years of school have you completed?

1 2 3 4 5 6 7 8 9 10 11 12 Some College College Graduate

47. What is the annual income of your household? (include all working adults)

_____ $10,000 or less

_____ $10,001 - $20,000

_____ $20,001 - $30,000

_____ $30,001 - $40,000

_____ $40,001 - $50,000

_____ $50,001 - $60,000

_____ $60,001 - $70,000

_____ $70,001 - $80,000

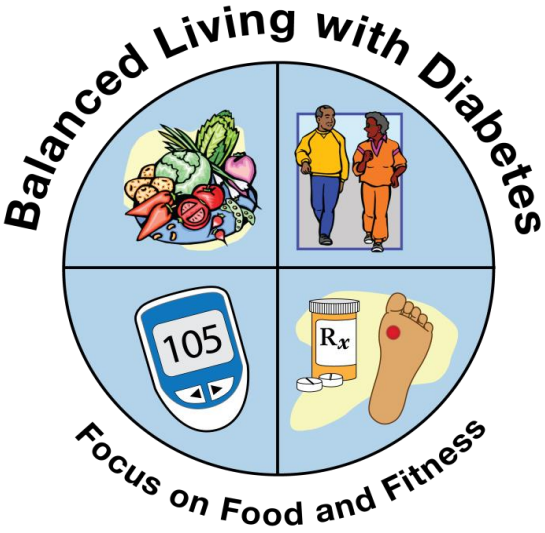
_____ $80,001 - $90,000

_____ Greater than $90,000

Thank You for Completing this Questionnaire!

Balanced Living with Diabetes
Center for Public Health Practice and Research
Virginia Cooperative Extension
Virginia Tech
Blacksburg, Virginia

DATE_____ PARTICIPANT NUMBER_____



BALANCED LIVING WITH DIABETES

Participant Information

Reunion Class

Virginia Cooperative Extension
Virginia Tech • Virginia State University

Virginia Tech
Center for Public Health
Practice and Research

Welcome to Balanced Living with Diabetes! We hope this program will help you manage your diabetes. The information you share will help us make our program better. Feel free to skip any question and remember that all of your information will be kept confidential.

1. Do you smoke or use tobacco products such as dip or snuff?

   _____ Yes _____ No

2. Do you have diabetes?

   _____ Yes, type 2 diabetes

   _____ Yes, type 1 diabetes

   _____ No, my doctor told me that I am pre-diabetic (borderline)

   _____ No, but a family member has diabetes

   _____ No, and none of my family has diabetes

3. In the past year, did you see a doctor for diabetes?

   _____ Yes _____ No

4. Do you take diabetes pills to control your blood sugar?

   _____ Yes _____ No

5. Do you take insulin (shots) to control your blood sugar?

   _____ Yes _____ No

6. What complications, if any, have you experienced with your diabetes?

   ____ bladder control problems
   ____ nerve damage
   ____ eye disease
   ____ sexual problems
   ____ foot problems
   ____ low blood sugar
   ____ kidney disease
   ____ stomach problems

The next questions ask about managing your diabetes.

7. People with diabetes should try to have an A1c number of less than ____%.

8. People with diabetes should have their A1c checked at least ____ time(s) each year.

9. How often should people with type 2 diabetes check their blood sugar?

   ____ every day ____ every week ____ every month

10. How often should people with diabetes get a flu shot?

    ____ every year ____ every 2 years ____ every 3 years

11. How often should people with diabetes get a dilated eye exam?

    ____ every year ____ every 2 years ____ every 3 years

12. How often should people with diabetes have a complete foot exam?

    ____ every doctor's visit
    ____ every 6 months
    ____ every year
    ____ every 2 years

13. Which of these foods are healthy fats? (you can check more than one)

    ____ canola oil ____ tub margarine ____ bacon ____ corn oil

14. Which of the following foods does NOT contain carbohydrate?

    ____ milk ____ green beans ____ sugar ____ hamburger patty

15. Which of the following foods has the lowest amount of fiber?

    ____ raisin bran cereal ____ apples ____ white bread ____ beans

16. How much of your diabetes supplies and medications are covered by insurance?

    ____ None

    ____ A little bit

    ____ About half

    ____ Most of it

    ____ All of it

    ____ I do not need supplies and medications

17. Have you ever participated in a diabetes education or support group besides this class (Balanced Living with Diabetes)?

    _____ Yes _____ No

    If yes, please list the name, location and dates for the class:

    _____

    How many times did the class meet? _____

<u>In the past week</u>, how many days did you (circle the number):

18. Take your diabetes medications as directed by your doctor?

    0 1 2 3 4 5 6 7

19. Check your blood sugar at least once?

    0 1 2 3 4 5 6 7

20. Do a total of 30 minutes or more of physical activity that was enough to make you breathe harder?

    0 1 2 3 4 5 6 7

21. Use the Plate Method to control your portion sizes for at least one meal?

    0 1 2 3 4 5 6 7

22. Skip checking your blood sugar or taking your diabetes medicines due to cost?

    0 1 2 3 4 5 6 7

Circle the number that best describes how often you USUALLY did these things:

In the past 3 months, **how many days a week** did you usually …	Days a week							
23. Keep track of what you ate?	0	1	2	3	4	5	6	7
24. Eat 5 servings of fruits and vegetables?	0	1	2	3	4	5	6	7
25. Eat 3 servings of whole grains?	0	1	2	3	4	5	6	7
26. Eat 3 servings of milk or dairy or other foods high in calcium?	0	1	2	3	4	5	6	7
27. Use the Plate Method?	0	1	2	3	4	5	6	7
28. Eat meals at regular times?	0	1	2	3	4	5	6	7
29. Make a plan to walk or exercise?	0	1	2	3	4	5	6	7
30. Keep track of how much you walked or exercised?	0	1	2	3	4	5	6	7
31. Walk or exercise?	0	1	2	3	4	5	6	7

How confident are you that you can do these things to manage your diabetes?

How sure are you that on most days you can …	Very Unsure	Unsure	Neither Sure or Unsure	Sure	Very Sure
32. Keep track of what you eat?	Very Unsure	Unsure	Neither	Sure	Very Sure
33. Use the Plate Method?	Very Unsure	Unsure	Neither	Sure	Very Sure
34. Eat meals at regular times?	Very Unsure	Unsure	Neither	Sure	Very Sure
35. Choose healthy foods when you eat out?	Very Unsure	Unsure	Neither	Sure	Very Sure
36. Use the nutrition facts label to choose healthy foods?	Very Unsure	Unsure	Neither	Sure	Very Sure
37. Walk or exercise?	Very Unsure	Unsure	Neither	Sure	Very Sure
38. Walk or exercise when you have other things to do?	Very Unsure	Unsure	Neither	Sure	Very Sure
39. Keep track of how much you walk or exercise?	Very Unsure	Unsure	Neither	Sure	Very Sure

40. Do you wear your step counter?

____ Yes, on most days
____ Yes, on some days
____ No

41. If you do wear your step counter, about how many steps do you walk on a:

_____ typical day when you do not make a special effort to walk

_____ typical day when you make a special effort to walk

The last questions are about you. Please remember that your name is not on this form and you can skip any questions that make you uncomfortable.

42. What is your age? _____ years

43. What is your gender? ____ Male ____ Female

44. Which of the following best describes you? (check all that apply)

_____ Caucasian/white
_____ African American
_____ Asian/ Pacific Islander
_____ Other (please list) _____

45. Are you Hispanic?

_____ Yes _____ No

46. How many years of school have you completed?

1 2 3 4 5 6 7 8 9 10 11 12 Some College College Graduate

47. What is the annual income of your household? (include all working adults)

_____ $10,000 or less
_____ $10,001 - $20,000
_____ $20,001 - $30,000
_____ $30,001 - $40,000
_____ $40,001 - $50,000
_____ $50,001 - $60,000
_____ $60,001 - $70,000
_____ $70,001 - $80,000
_____ $80,001 - $90,000
_____ Greater than $90,000

48. Did your doctor change your diabetes medication since you started this class?

_____ Yes _____ No

If yes, please tell us how your medication changed (check all that apply):

_____ I started taking pills to control my blood sugar
_____ I stopped taking pills to control my blood sugar
_____ My doctor increased the dose of my diabetes pills
_____ My doctor decreased the dose of my diabetes pills
_____ I started taking insulin (shots or pump) to control my blood sugar
_____ I stopped taking insulin (shots or pump) to control my blood sugar
_____ My doctor increased my insulin dose
_____ My doctor decreased my insulin dose

Thank You for Completing this Questionnaire!

Balanced Living with Diabetes
Center for Public Health Practice and Research
Virginia Cooperative Extension
Virginia Tech
Blacksburg, Virginia

Appendix I: Qualitative Supplementary Documents

Table 1.

Data extracts with codes applied

Data Extract	Coded for
"Yes. With the specific dates that it aligned with." "I provided all that was basically provided to me that associated with the week's post."	**Adoption/Implementation**: Following the retention plan.
"I am not even aware of what the retention plan is" "I didn't know what the plan was." "I'm not sure when that was, or I guess I just didn't have the information about it" "If I was aware of this retention program that you're doing, probably I might've used it with this group at some point." "Honestly, I knew we had it and then it kind of slipped my mind that we kind of had that as a resource."	**Adoption:** Unaware of the retention plan
"I wasn't following the plan. I wasn't aware of the entire plan, but if I got one, I sent it." "I did a little of that, but I wasn't intentionally following your plan."	**Adoption:** Not following the retention plan

"But in between that time, there was nothing about "remember to exercise", and that sort of thing, none of that kind of conversation." "I guess I was just kind of going with what I had been doing in previous years and everything, which was basically just the telephone reminders and everything."	
"I did send out emails to folks pretty much every week reminding them okay next week same place same time." "Well, just before they left every time and see you next week, that sort of deal." "A few days or maybe even a week before, I would contact them all or at least have leaders of the group contact each one of them."	**Implementation:** Retention approaches aside from retention plan
"I printed them off and then sent them regular mail. They didn't have email access." "Most of them reported getting something in the mail, the reminders and the newsletter." "Because some preferred email, some preferred mail and so that's why I chose, that's why we implemented it both ways."	**Implementation**: Format of retention materials
"Everyone needs a reminder."	**Implementation**: The

"And I think it would be just as that continuous reminder not only of here's our next upcoming meeting but hey don't forget you're supposed to be tracking, you're supposed to be exercising." "So yeah, I think it would've reminded them constantly about the overall program and how they needed to keep in practice in their daily lives to make a lifestyle changing group." "...reminding them the handouts and information, just constantly reminding them about healthy eating and making sure the snacks and things that they were getting were okay." "Keeps them reminded of what they should be doing." "It kept it on their mind, what they should be focused on." "So a good reminder and just reinforcement from the lessons." "And like I said, having that weekly reminder, I think helped a few of them when they spoke to me one-on-one."	retention plan as a reminder
"It seemed more like just an extra meeting for them rather than kind of a follow-up...it was just a touch base with..at the end after so much time had lapsed." "That two or three months of not having any contact, people soon forget." "You don't know those things if you don't continuously touch base with	**Implementation**: Lack of contact with participants during 2-month hiatus

folks." "It's hard to work with folks like that and then they're gone and you don't know unless you see them around or something like that...you don't know how they're doing." "It wasn't face to face interaction unless they came into the office." "Some of the participants really liked hearing from others in the class…I think they liked being a part of the group and face-to face."	
"And so they were aware of what came and so that kept them connected to the program." "Having the modification piece was probably one of the reasons why I keep in contact with them." "I think it (the retention plan) really does help to stay in contact and keeps them connected." "Anytime you can stay in contact, the longer, the better." "I talked to the individuals on the phone too when I called or they called."	**Implementation**: Contact with the participants
"I'm wondering if I could get some of my Master Food Volunteers involved to help out." "She (in collaboration with an Extension Agent) had sent the cards,	**Implementation**: Assistance with the BLD program with the retention plan

reminders to them to follow through and keep in contact with them."	
"I think that (the retention plan) would've definitely, definitely been a benefit." "And any program where you have that lag time would be good." "So even just sending the recipe and getting the newsletter, it's just something to let them know that we're still there." "But I think when you have this reinforcement of the materials from the classes, to hear again maybe via the newsletter or a text or whatever the little hint, I think it's really useful." "Because we have additional information coming their way and we don't want them to miss out because this is going to be very important on their journey, you know?" "When folks got the newsletters that I sent out, they read them I know because they would say "I tried that recipe that was in it" or there was conversation about it." "One of them did come by the office and we talked and this individual was telling me all the things that…she was making lifestyle changes." "Some participants even said that they even made some of those recipes in addition to their binder that they received."	**Systems-Level Maintenance**: Benefits of the retention plan

“And we’re just thinking about doing another program soon.” “And if we do it down there, we definitely would, definitely would include it into any program.” “So (an Extension Agent) and I are planning to do another BLD program.” “I just think that everything’s great, and I think that if we can get the LIFT in conjunction with BLD, I think that it would make the program even stronger.” “I would definitely make sure I use the retention plan because like last year with me not using this, other than like a phone call or whatever, our attendance dropped off at the reunion.”	**Systems-Level Maintenance**: Conducting another BLD program including the retention plan

Figure 1: Initial Thematic Map

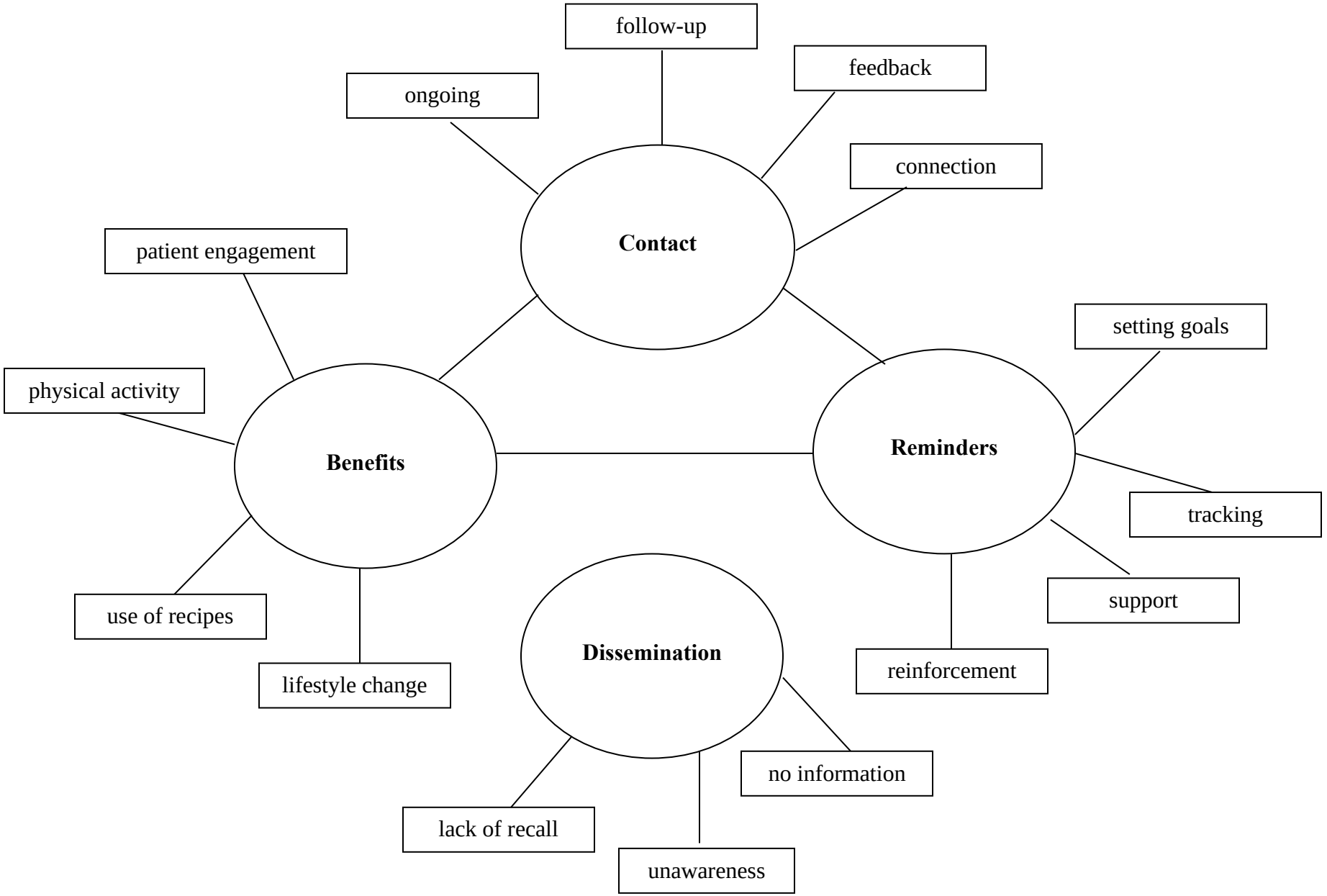
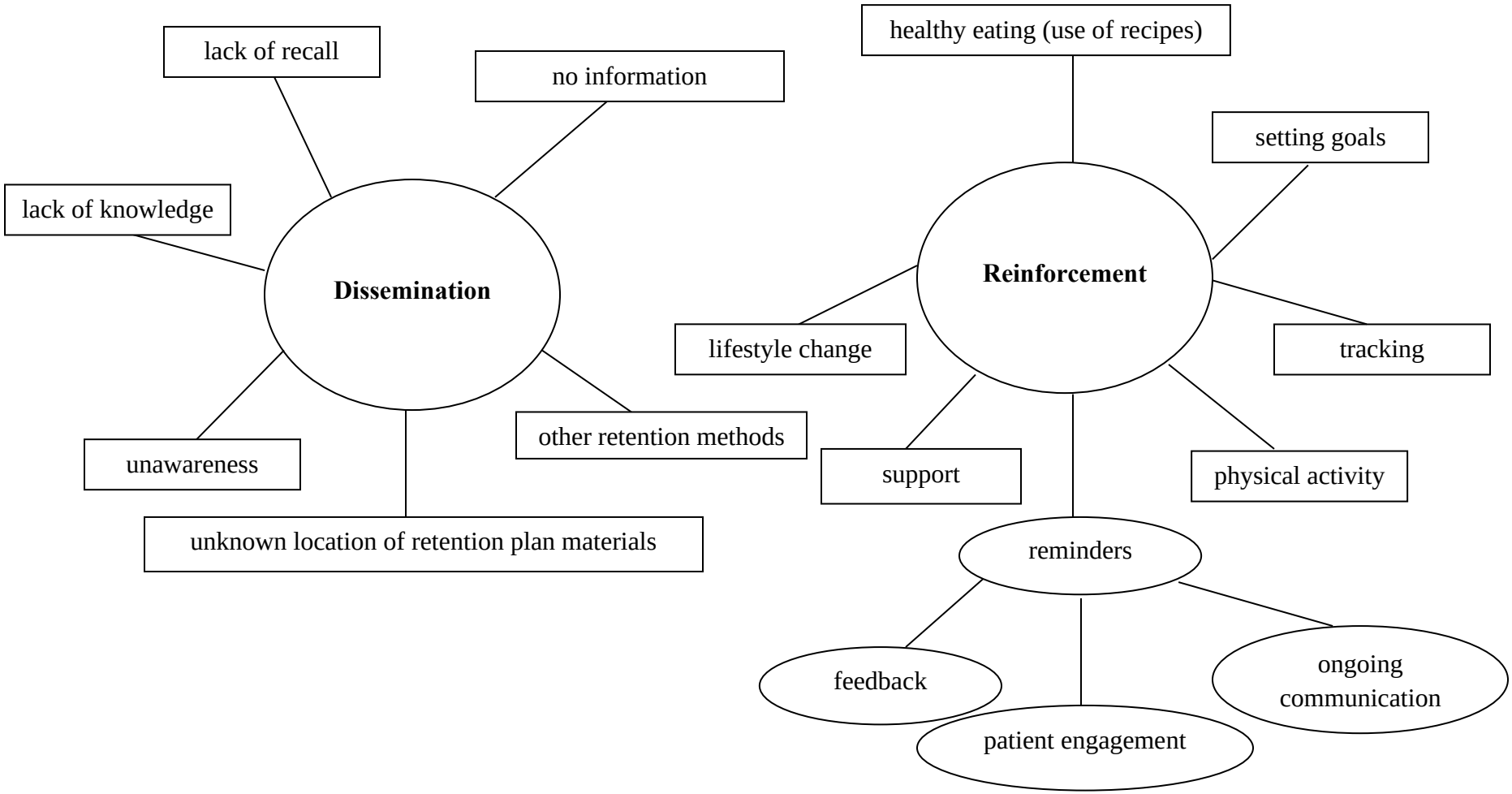


Figure 2: Final Thematic Map



Appendix J. Quantitative Data Analysis

1. Retention Rates

Table 1.
Retention Rates Before and After the Development of the Retention Plan in BLD Programs by County

Agent	County	Programs Before the Retention Plan	Programs After the Retention Plan			Qualitative Feedback about the Retention Plan
		Program Retention Rate %	Program Retention Rate %			
			Retention Plan Used			
			Yes	**No**	**Unknown**	
1 & 2[a]	County 1	100% (7/7)	67% (4/6)			"I provided all that was provided to me that associated with links."
3	County 2	80% (12/15)	75% (6/8)			"It's like whenever I got one...I wasn't following the plan. I wasn't aware of the entire plan but if I got one, I sent it".
4	County 3	37.5% (3/8)		50% (6/12)		"I knew we had it and then kind of slipped my mind that we had that as a resource until you reached out to me."
3	County 4	0% (0/5)	42% (5/12)			*
5	County 5	100% (19/19)		75% (6/8)		"I am not sure. I guess I didn't have the information about it."
6	County 6	40% (2/5)			67% (4/6)	No qualitative feedback provided because Agent was non-responsive.
5	County 7	50% (9/18)		71% (5/7)		**

Retention Plan (RP)

2. Chi-Square Tests

Table 1.
*Returned * Retention Plan Chi-Square Crosstabulation*

			Retention Plan		
			no	yes	Total
Returned	no	Count	8	11	19
		Expected Count	9.7	9.3	19.0
	yes	Count	19	15	34

	Expected Count	17.3	16.7	34.0
Total	Count	27	26	53
	Expected Count	27.0	26.0	53.0

Table 2.

Chi-Square Tests of non-user programs

	Value	df	Asymptotic Significance (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	.926[a]	1	.336		
Continuity Correction[b]	.457	1	.499		
Likelihood Ratio	.928	1	.335		
Fisher's Exact Test				.398	.250
Linear-by-Linear Association	.908	1	.341		
N of Valid Cases	53				

a. 0 cells (0.0%) have expected count less than 5. The minimum expected count is 9.32.

b. Computed only for a 2x2 table

3. Independent Samples T-tests

Table 3.

Group Descriptive Statistics of change in A1c in user programs

	RetPlan	N	Mean	Std. Deviation	Std. Error Mean
A1c	no	17	-.0529	1.13997	.27648
	yes	15	-.3933	.63270	.16336

Table 4.

Independent Samples Test of change in A1c in user programs

Levene's Test for Equality of Variances		t-test for Equality of Means						
							95% Confidence Interval of the Difference	
F	Sig.	t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	Lower	Upper

A1c	Equal variances assumed	.667	.420	1.024	30	.314	.34039	.33229	-.33824	1.01902
	Equal variances not assumed			1.060	25.561	.299	.34039	.32114	-.32027	1.00105

*Statistical significance $p < 0.05$

Table 5.

Group Descriptive Statistics of change in health behavior in user programs

	RetPlan	N	Mean	Std. Deviation	Std. Error Mean
In the past 3 months, how many days a week did you usually eat 5 servings of fruits and vegetables?	no	14	1.6429	2.02322	.54073
	yes	15	.4667	2.03072	.52433
In the past 3 months, how many days a week did you eat 3 servings of whole grains?	no	12	1.4167	1.67649	.48396
	yes	13	.4615	2.56955	.71266
In the past 3 months, how many days a week did you eat 3 servings of milk, dairy, or foods high in calcium?	no	11	.8182	1.40130	.42251
	yes	13	.4615	2.56955	.71266
In the past 3 months, how many days a week did you use the Plate Method?	no	9	1.3333	2.54951	.84984
	yes	13	1.6923	2.35884	.65422
In the past 3 months, how many days a week did you eat meals at regular times?	no	12	.0000	2.69680	.77850
	yes	13	.8462	2.11527	.58667
In the past 3 months, how many days a week did you make a plan to walk or exercise?	no	14	1.5000	2.79422	.74679
	yes	14	1.0714	2.09263	.55928
In the past 3 months, how many days a week did you keep track of how much you walked or exercised?	no	14	1.1429	2.68492	.71757
	yes	14	1.8571	1.74784	.46713
In the past 3 months, how many days a week did you walk or exercise?	no	14	.5000	1.60528	.42903
	yes	14	.8571	1.79131	.47875

Table 6.

Independent Samples Test of change in health behavior of user programs

		Levene's Test for Equality of Variances		t-test for Equality of Means						
									95% Confidence Interval of the Difference	
		F	Sig.	t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	Lower	Upper
In the past 3 months, how many days a week did you usually eat 5 servings of fruits and vegetables?	Equal variances assumed	.052	.821	1.561	27	.130	1.17619	.75330	-.36945	2.72183
	Equal variances not assumed			1.562	26.876	.130	1.17619	.75320	-.36958	2.72196
In the past 3 months, how many days a week did you usually eat 3 servings of whole grains?	Equal variances assumed	.419	.524	1.090	23	.287	.95513	.87605	-.85713	2.76738
	Equal variances not assumed			1.109	20.795	.280	.95513	.86146	-.83744	2.74770
In the past 3 months, how many days a week did you milk or dairy or other foods high in calcium?	Equal variances assumed	3.583	.072	.411	22	.685	.35664	.86846	-1.44444	2.15773
	Equal variances not assumed			.430	19.088	.672	.35664	.82849	-1.37687	2.09016
In the past 3 months, how many days a week did you use the Plate Method?	Equal variances assumed	.259	.616	-.340	20	.738	-.35897	1.05671	-2.56323	1.84528
	Equal variances not assumed			-.335	16.442	.742	-.35897	1.07249	-2.62759	1.90964

In the past 3 months, how many days a week did you eat meals at regular times?	Equal variances assumed	.533	.473	-.877	23	.390	-.84615	.96515	-2.84273	1.15042
	Equal variances not assumed			-.868	20.871	.395	-.84615	.97480	-2.87413	1.18182
In the past 3 months, how many days a week did you make a plan to walk or exercise?	Equal variances assumed	.530	.473	.459	26	.650	.42857	.93300	-1.48923	2.34638
	Equal variances not assumed			.459	24.093	.650	.42857	.93300	-1.49665	2.35379
In the past 3 months, how many days a week did you track how much you walked or exercised?	Equal variances assumed	.463	.502	-.834	26	.412	-.71429	.85623	-2.47428	1.04571
	Equal variances not assumed			-.834	22.341	.413	-.71429	.85623	-2.48842	1.05985
In the past 3 months, how many days a week did you walk or exercise?	Equal variances assumed	.524	.476	-.556	26	.583	-.35714	.64286	-1.67855	.96427
	Equal variances not assumed			-.556	25.694	.583	-.35714	.64286	-1.67932	.96504

*Statistical significance $p < 0.05$

Table 7.

Group Descriptive Statistics of change in self-efficacy in user programs

	RetPlan	N	Mean	Std. Deviation	Std. Error Mean
How sure are you that on most days you can keep track of what you eat?	no	14	.2143	1.12171	.29979
	yes	14	.0000	1.35873	.36314
How sure are you that on most days you can use the Plate Method?	no	14	.2143	1.18831	.31759
	yes	12	.4167	1.88092	.54298

How sure are you that on most days you can eat meals at regular times?	no	14	-.0714	1.07161	.28640
	yes	14	-.0714	1.07161	.28640
How sure are you that on most days you can choose healthy foods when you eat out?	no	15	.6667	.97590	.25198
	yes	13	.8462	1.28103	.35529
How sure are you that on most days you can use the nutrition facts label to choose healthy foods?	no	14	.5714	1.22250	.32673
	yes	14	.2143	1.12171	.29979
How sure are you that on most days you can walk or exercise?	no	15	.5333	1.18723	.30654
	yes	14	-.0714	.82874	.22149
How sure are you that on most days you can walk or exercise when you have other things to do?	no	15	.4000	1.35225	.34915
	yes	12	.3333	1.23091	.35533
How sure are you that on most days you can keep track of how much you walked or exercised?	no	14	.0000	1.70970	.45694
	yes	14	.3571	1.49908	.40065

Table 8.

Independent Samples Tests of change in self-efficacy in user programs

		Levene's Test for Equality of Variances		t-test for Equality of Means						
									95% Confidence Interval of the Difference	
		F	Sig.	t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	Lower	Upper
How sure are you that on most days you can keep track of what you eat?	Equal variances assumed	.025	.875	.455	26	.653	.21429	.47090	-.75365	1.18223
	Equal variances not assumed			.455	25.100	.653	.21429	.47090	-.75535	1.18392
How sure are you that on most days	Equal variances assumed	1.201	.284	-.333	24	.742	-.20238	.60772	-1.45666	1.05189

you can use the Plate Method?	Equal variances not assumed			-.322	18.029	.751	-.20238	.62904	-1.52379	1.11903
How sure are you that on most days you can eat meals at regular times?	Equal variances assumed	.192	.665	.000	26	1.000	.00000	.40503	-.83255	.83255
	Equal variances not assumed			.000	26.000	1.000	.00000	.40503	-.83255	.83255
How sure are you that on most days you can choose healthy foods when you eat out?	Equal variances assumed	.781	.385	-.420	26	.678	-.17949	.42707	-1.05735	.69837
	Equal variances not assumed			-.412	22.277	.684	-.17949	.43557	-1.08216	.72319
How sure are you that on most days you can use the nutrition facts label to choose healthy foods?	Equal variances assumed	.100	.754	.805	26	.428	.35714	.44342	-.55433	1.26861
	Equal variances not assumed			.805	25.810	.428	.35714	.44342	-.55466	1.26894
How sure are you that on most days you can walk or exercise?	Equal variances assumed	1.299	.264	1.580	27	.126	.60476	.38288	-.18084	1.39036
	Equal variances not assumed			1.599	25.074	.122	.60476	.37819	-.17401	1.38354
How sure are you that on most days	Equal variances assumed	.002	.962	.132	25	.896	.06667	.50359	-.97049	1.10382

you can walk or exercise when you have other things to do?	Equal variances not assumed			.134	24.529		.895	.06667	.49816	-.96032	1.09365
How sure are you that on most days	Equal variances assumed	.017	.898	-.588	26		.562	-.35714	.60771	-1.60630	.89202
you can keep track of how much you walked or exercised?	Equal variances not assumed			-.588	25.563		.562	-.35714	.60771	-1.60734	.89306

*Statistical significance $p < 0.05$

Non-retention plan (NRP)

4. Chi-Square Tests

Table 9.

*Returned * RetPlan Crosstabulation*

			RetPlan		
			no	yes	Total
Returned	no	Count	14	6	20
		Expected Count	14.3	5.7	20.0
	yes	Count	31	12	43
		Expected Count	30.7	12.3	43.0
Total		Count	45	18	63
		Expected Count	45.0	18.0	63.0

Table 10.

Chi-Square Tests in non-user programs

	Value	df	Asymptotic Significance (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	.029[a]	1	.864		
Continuity Correction[b]	.000	1	1.000		
Likelihood Ratio	.029	1	.864		

Fisher's Exact Test				1.000	.545
Linear-by-Linear Association	.029	1	.865		
N of Valid Cases	63				

a. 0 cells (.0%) have expected count less than 5. The minimum expected count is 5.71.

b. Computed only for a 2x2 table

5. Independent Samples T-tests

Table 11.

Group Statistics of change in A1c in non-user programs

	RetPlan	N	Mean	Std. Deviation	Std. Error Mean
C_A1C	no	31	-.6919	1.01440	.18219
	yes	12	-.1875	.33920	.09792

Table 12.

Independent Samples Tests of change in A1c in non-user programs

		Levene's Test for Equality of Variances		t-test for Equality of Means						
									95% Confidence Interval of the Difference	
		F	Sig.	t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	Lower	Upper
C_A1C	Equal variances assumed	3.476	.069	-1.676	41	.101	-.50444	.30100	-1.11232	.10345
	Equal variances not assumed			-2.439	40.596	.019	-.50444	.20684	-.92228	-.08659

*Statistical significance $p < 0.05$

Table 13.

Group Statistics of change in health behavior in non-user programs

	RetPlan	N	Mean	Std. Deviation	Std. Error Mean

In the past 3 months, how many days a week did you usually eat 5 servings of fruits and vegetables?	no	24	1.3333	2.61545	.53388
	yes	11	.9091	1.37510	.41461
In the past 3 months, how many days a week did you eat 3 servings of whole grains?	no	23	-.1739	2.67399	.55756
	yes	11	1.0000	1.78885	.53936
In the past 3 months, how many days a week did you eat 3 servings of milk, dairy, or foods high in calcium?	no	24	-.0417	2.38618	.48708
	yes	11	.0000	1.34164	.40452
In the past 3 months, how many days a week did you use the Plate Method?	no	20	2.7500	2.55209	.57066
	yes	10	1.0000	2.35702	.74536
In the past 3 months, how many days a week did you eat meals at regular times?	no	23	.7826	2.90699	.60615
	yes	10	.6000	2.06559	.65320
In the past 3 months, how many days a week did you make a plan to walk or exercise?	no	20	2.4000	2.18608	.48882
	yes	10	1.2000	1.54919	.48990
In the past 3 months, how many days a week did you keep track of how much you walked or exercised?	no	20	2.2000	2.41922	.54095
	yes	9	.7778	1.64148	.54716
In the past 3 months, how many days a week did you walk or exercise?	no	20	1.8000	1.93581	.43286
	yes	11	1.2727	2.14900	.64795

Table 14.
Independent Samples Tests of change in health behavior in non-user programs

		Levene's Test for Equality of Variances		t-test for Equality of Means						
									95% Confidence Interval of the Difference	
		F	Sig.	t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	Lower	Upper
In the past 3 months, how many days a week did you usually eat 5 servings of fruits and vegetables?	Equal variances assumed	5.628	.024	.504	33	.617	.42424	.84145	-1.28771	2.13619
	Equal variances not assumed			.628	32.184	.535	.42424	.67596	-.95234	1.80082
In the past 3 months, how many days a week did you usually eat 3 servings of whole grains?	Equal variances assumed	2.151	.152	-1.317	32	.197	-1.17391	.89163	-2.99010	.64228
	Equal variances not assumed			-1.513	28.170	.141	-1.17391	.77575	-2.76253	.41471
In the past 3 months, how many days a week did you milk or dairy or other foods high in calcium?	Equal variances assumed	1.534	.224	-.054	33	.957	-.04167	.77358	-1.61554	1.53220
	Equal variances not assumed			-.066	31.358	.948	-.04167	.63315	-1.33239	1.24906
In the past 3 months, how many days a	Equal variances assumed	.316	.578	1.814	28	.080	1.75000	.96478	-.22627	3.72627

week did you use the Plate Method?	Equal variances not assumed			1.864	19.474	.077	1.75000	.93873	-.21155	3.71155
In the past 3 months, how many days a week did you eat meals at regular times?	Equal variances assumed	1.928	.175	.179	31	.859	.18261	1.01892	-1.89549	2.26071
	Equal variances not assumed			.205	23.918	.839	.18261	.89111	-1.65689	2.02211
In the past 3 months, how many days a week did you make a plan to walk or exercise?	Equal variances assumed	.365	.551	1.546	28	.133	1.20000	.77598	-.38952	2.78952
	Equal variances not assumed			1.734	24.390	.096	1.20000	.69206	-.22713	2.62713
In the past 3 months, how many days a week did you track how much you walked or exercised?	Equal variances assumed	2.898	.100	1.598	27	.122	1.42222	.89004	-.40398	3.24842
	Equal variances not assumed			1.848	22.308	.078	1.42222	.76942	-.17219	3.01663
In the past 3 months, how many days a week did you walk or exercise?	Equal variances assumed	.256	.617	.698	29	.491	.52727	.75522	-1.01732	2.07186
	Equal variances not assumed			.677	18.933	.507	.52727	.77923	-1.10407	2.15862

*Statistical significance $p < 0.05$

Table 15.

Group Statistics of change in self-efficacy in non-user programs

	RetPlan	N	Mean	Std. Deviation	Std. Error Mean
How sure are you that on most days you can keep track of what you eat?	no	25	.5200	1.15902	.23180
	yes	10	.3000	.48305	.15275
How sure are you that on most days you can use the Plate Method?	no	22	.2727	1.07711	.22964
	yes	9	.1111	.78174	.26058
How sure are you that on most days you can eat meals at regular times?	no	24	.0000	1.21584	.24818
	yes	9	.4444	1.33333	.44444
How sure are you that on most days you can choose healthy foods when you eat out?	no	22	.0455	.99892	.21297
	yes	10	.3000	.67495	.21344
How sure are you that on most days you can use the nutrition facts label to choose healthy foods?	no	21	.3810	.86465	.18868
	yes	10	.3000	.48305	.15275
How sure are you that on most days you can walk or exercise?	no	22	.4091	.95912	.20449
	yes	10	.4000	.84327	.26667
How sure are you that on most days you can walk or exercise when you have other things to do?	no	22	.0000	.81650	.17408
	yes	10	-.3000	1.05935	.33500
How sure are you that on most days you can keep track of how much you walked or exercised?	no	23	.0870	.99604	.20769
	yes	10	.2000	1.31656	.41633

Table 16.

Independent Samples Tests of change in self-efficacy in non-user programs

	Levene's Test for Equality of Variances	t-test for Equality of Means

									95% Confidence Interval of the Difference	
		F	Sig.	t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	Lower	Upper
How sure are you that on most days you can keep track of what you eat?	Equal variances assumed	8.825	.006	.576	33	.568	.22000	.38169	-.55655	.99655
	Equal variances not assumed			.792	32.851	.434	.22000	.27761	-.34490	.78490
How sure are you that on most days you can use the Plate Method?	Equal variances assumed	.677	.417	.407	29	.687	.16162	.39740	-.65116	.97440
	Equal variances not assumed			.465	20.534	.647	.16162	.34733	-.56169	.88492
How sure are you that on most days you can eat meals at regular times?	Equal variances assumed	.095	.761	-.912	31	.369	-.44444	.48750	-1.43870	.54981
	Equal variances not assumed			-.873	13.317	.398	-.44444	.50904	-1.54151	.65262
How sure are you that on most days you can choose healthy foods when you eat out?	Equal variances assumed	.378	.543	-.730	30	.471	-.25455	.34853	-.96635	.45726
	Equal variances not assumed			-.844	25.156	.407	-.25455	.30152	-.87533	.36624
How sure are you that on most days you can use the nutrition	Equal variances assumed	4.076	.053	.275	29	.785	.08095	.29462	-.52162	.68352

facts label to choose healthy foods?	Equal variances not assumed			.333	28.041	.741	.08095	.24276	-.41629	.57820
How sure are you that on most days you can walk or exercise?	Equal variances assumed	.141	.710	.026	30	.980	.00909	.35312	-.71208	.73026
	Equal variances not assumed			.027	19.767	.979	.00909	.33604	-.69241	.71060
How sure are you that on most days you can walk or exercise when you have other things to do?	Equal variances assumed	.806	.376	.878	30	.387	.30000	.34183	-.39811	.99811
	Equal variances not assumed			.795	14.077	.440	.30000	.37753	-.50930	1.10930
How sure are you that on most days you can keep track of how much you walked or exercised?	Equal variances assumed	.280	.600	-.272	31	.788	-.11304	.41620	-.96188	.73580
	Equal variances not assumed			-.243	13.690	.812	-.11304	.46526	-1.11305	.88697

*Statistical significance $p < 0.05$

Investigator Name: Carlin Rafie, PhD, RD	**Board Action Date:** 02/08/2019
Investigator Address: 295 West Campus Drive, 321 Wallace Hall Blacksburg, VA 24060, United States	**Approval Expires:** 01/24/2020 **Continuing Review Frequency:** No CR Required
Sponsor: Virginia Tech **Institution Tracking Number:** 18-1130	**Sponsor Protocol Number:** 18-1130 **Amended Sponsor Protocol Number:**
Study Number: 1253619	**IRB Tracking Number:** 20190154
Work Order Number: 1-1154069-1	**Panel:** 5
Protocol Title: The effects of incorporation of a physical activity program (LIFT) into a diabetes lifestyle management (BLD) program on implementation and outcomes: A mixed methods study	

THE FOLLOWING ITEMS ARE APPROVED:
BLD Program and Evaluation Materials #23648436.1 - As Submitted
LIFT Program and Evaluation Materials #23648434.1 - As Submitted
Revised Protocol
Consent Form [IN1]

Please note the following information:
Under the revised common rule (effective 1-21-2019), continuing review by the Board of the above referenced research is not required; however, the IRB will maintain our records and continue responsibility for exercising administrative and regulatory oversight of this research. The IRB will automatically charge a maintenance fee for this administrative effort unless we are notified the research is closing. To avoid unnecessary fees due to closure, a closure form must be submitted for each site 30 days prior to expiration.

Please have all future subjects sign the Consent Form(s) specified in this approval.

THE IRB HAS APPROVED THE FOLLOWING LOCATIONS TO BE USED IN THE RESEARCH:
Virginia Polytechnic Institute and State University, 295 West Campus Drive, 321 Wallace Hall, Blacksburg, Virginia 24061-0430

ALL IRB APPROVED INVESTIGATORS MUST COMPLY WITH THE FOLLOWING:
As a requirement of IRB approval, the investigators conducting this research will:

- Comply with all requirements and determinations of the IRB.
- Protect the rights, safety, and welfare of subjects involved in the research.
- Personally conduct or supervise the research.
- Conduct the research in accordance with the relevant current protocol approved by the IRB.
- Ensure that there are adequate resources to carry out the research safely.
- Ensure that research staff are qualified to perform procedures and duties assigned to them during the research.
- Submit proposed modifications to the IRB prior to their implementation.
    - Not make modifications to the research without prior IRB review and approval unless necessary to eliminate apparent immediate hazards to subjects.
- Submit continuing review reports when requested by the IRB.
- Submit a closure form to close research (end the IRB's oversight) when:
    - The protocol is permanently closed to enrollment
    - All subjects have completed all protocol related interventions and interactions

This is to certify that the information contained herein is true and correct as reflected in the records of this IRB. WE CERTIFY THAT THIS IRB IS IN FULL COMPLIANCE WITH GOOD CLINICAL PRACTICES AS DEFINED UNDER THE U.S. FOOD AND DRUG ADMINISTRATION (FDA) REGULATIONS, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES (HHS) REGULATIONS, AND THE INTERNATIONAL CONFERENCE ON HARMONISATION (ICH) GUIDELINES.

    - For research subject to federal oversight other than FDA:
        - No additional identifiable private information about the subjects is being obtained
        - Analysis of private identifiable information is completed
- If research approval expires, stop all research activities and immediately contact the IRB.
- Promptly report to the IRB the information items listed in the IRB's "Prompt Reporting Requirements" available on the IRB's Web site.
- Not accept or provide payments to professionals in exchange for referrals of potential subjects ("finder's fees.")
- Not accept payments designed to accelerate recruitment that are tied to the rate or timing of enrollment ("bonus payments") without prior IRB approval.
- When required by the IRB ensure that consent, permission, and assent are obtained and documented in accordance with the relevant current protocol as approved by the IRB.
- Promptly notify the IRB of any change to information provided on your initial submission form.

Consistent with AAHRPP's requirements in connection with its accreditation of IRBs, the individual and/or organization shall promptly communicate or provide, the following information relevant to the protection of human subjects to the IRB in a timely manner:

- Upon request of the IRB, a copy of the written plan between sponsor or CRO and site that addresses whether expenses for medical care incurred by human subject research subjects who experience research related injury will be reimbursed, and if so, who is responsible in order to determine consistency with the language in the consent document.
- Any site monitoring report that directly and materially affects subject safety or their willingness to continue participation. Such reports will be provided to the IRB within 5 days.
- Reports from any data monitoring committee, data and safety monitoring board, or data and safety monitoring committee in accordance with the time frame specified in the research protocol.
- Any findings from a closed research when those findings materially affect the safety and medical care of past subjects. Findings will be reported for 2 years after the closure of the research.

For Investigator's Brochures, an approval action indicates that the IRB has the document on file for the research.

If the board approves a change of Principal Investigator - Once approved, the new Principal Investigator is authorized by the IRB to carry out the study as previously approved for the prior Principal Investigator (unless the Board provides alternate instructions to the new Principal Investigator). This includes continued use of the previously approved study materials. The IRB considers the approval of the new PI a continuation of the original approval, so the identifying information about the study remains the same.

If your research site is a HIPAA covered entity, the HIPAA Privacy Rule requires you to obtain written authorization from each research subject for any use or disclosure of protected health information for research. If your IRB-approved consent form does not include such HIPAA authorization language, the HIPAA Privacy Rule requires you to have each research subject sign a separate authorization agreement. "

Federal regulations require that the IRB conduct continuing review of approved research. You will receive Continuing Review Report forms from this IRB when the expiration date is approaching.

Thank you for using this WCG IRB to provide oversight for your research project.

DISTRIBUTION OF COPIES:
Contact, Company
Jennifer Farmer, Virginia Tech
VA Tech WIRB, Virginia Polytechnic Institute and State University (Virginia Tech)
Carlin Rafie, PhD, RD, Virginia Tech
Kristina A Jiles, Virginia Tech

Appendix L: Participant Informed Consent Form

RESEARCH SUBJECT CONSENT FORM

Title:	The effects of incorporation of a physical activity program (LIFT) into a diabetes lifestyle management (BLD) program on implementation and outcomes: A mixed methods study.
Protocol No.:	18-1130 WIRB® Protocol #20190154 IRB 18-1130
Sponsor:	Virginia Tech
Investigator:	Carlin Rafie, PhD, RD 321 Wallace Hall 295 West Campus Drive Blacksburg, VA 24061-0430 USA
Daytime Phone Number:	540-231-3163

You are being invited to take part in a research study. A person who takes part in a research study is called a research subject, or research participant.

What should I know about this research?
Someone will explain this research to you. This form sums up that explanation. Taking part in this research is voluntary. Whether you take part is up to you. You can choose not to take part, or you can agree to take part and later change your mind, and there will be no penalty or loss of benefits to which you are otherwise entitled. If you don't understand, ask questions. Ask all the questions you want before you decide.

Why is this research being done?
The purpose of this study is to determine the impact of conducting the Lifelong Improvements through Fitness Together program (LIFT) with the Balanced Living with Diabetes program (BLD), and if combining the programs improves the health of people with diabetes in Virginia. There will be approximately 15-20 subjects per location will take part in this research.

How long will I be in this research?
We expect that your taking part in this research will last approximately 12-20 weeks.

What happens to me if I agree to take part in this research?
Balanced Living with Diabetes is a series of four classes held once a week followed by a class reunion three months later. Each class will last about 2 1/2 hours. The classes are team taught by your local county Extension Agent and a health care professional. Classes will include a lecture on healthy food choices. The Lifelong Improvements for Fitness Together is a series of strength training sessions held twice a week for eight weeks. Each strength training session will last about

1 hour. You will be randomized to receive either the Balanced Living with Diabetes program alone, or the Balanced Living with Diabetes program with the Lifelong Improvements through Fitness Together program conducted between the 4th and 3-month session of the Balanced Living with Diabetes program. We will offer those individuals who are randomized to receive the Balanced Living with Diabetes program alone the opportunity to participate in the Lifelong Improvements through Fitness Together program after they complete the study activities.

What are my responsibilities if I take part in this research?
If you decide to join the study, you will be asked to complete a demographic questionnaire, a survey of what foods you eat and how you usually manage your diabetes, and a Godin Leisure-Time Exercise Questionnaire to assess how physically active you are. We will repeat the questionnaire about your food, activity and diabetes management practices again at the reunion to see if you have made any changes. These forms should not take more than 25 minutes each time. You may see these forms before agreeing to participate and you do not have to answer any question that you feel uncomfortable about. We will measure your height and weight, and take a finger stick blood sample to measure your hemoglobin A1c level at the first class and the reunion class. The A1c test tells what your average blood sugar level has been for the past 2 to 3 months and shows how good your blood sugar control has been. In addition, you will take a functional fitness test after the fourth BLD session and at the reunion session. Finally, you will be asked to take the functional fitness test and complete a survey 6 months after the program. All of this information will be made available to you.

Could being in this research hurt me?
There is mild discomfort of the finger prick for the A1c blood test. Although we will make recommendations regarding follow-up or immediate health care when A1c values are extremely elevated, we will not directly provide this care. Completing the data collection forms may be frustrating or cause a feeling of discomfort as you do them.

Regular physical exercise is fun and healthy, and being more active is very safe for most people. Physical exercise will be encouraged in the Balanced Living with Diabetes, and the Lifelong Improvements through Fitness Together program includes strength training sessions twice a week for 8 weeks. Some people should check with their doctor before they start becoming more physically active. You will be required to complete a Physical Activity Readiness Questionnaire Plus (PAR-Q+) and if you answer "yes" to any of the questions, you must obtain a physical authorization letter from your physician prior to participating in the Lifelong Improvements through Fitness Together program. You will learn about the benefits of physical activity and how to safely increase your activity level. Today you will receive a checklist to help you see if you should talk to your doctor before becoming more active. Although increasing your physical activity can have great benefits, you may also get tired or have sore muscles or joints. It is also possible that you could fall or be injured. Finally, exercising at very, very hard levels has been known to cause heart attack and sudden death related to heart problems, although moderate intensity exercise such as walking carries less risk of such complications. Nevertheless, you need to be aware of these cautions.

In the event a researcher or other staff person is improperly exposed to your blood, your blood will be tested for the presence of HIV, the Hepatitis B Virus, and the Hepatitis C Virus. There will not be any cost to you for this test. The research team will follow proper procedures for testing and reporting as outlined by Virginia State Law, which includes sending the sample to a certified laboratory. Please note that, should your blood require testing, you will be informed of your test results and provided with the opportunity to receive appropriate and timely counseling. In addition, your results will be sent to the local health department.

Will it cost me money to take part in this research?
There is no cost to you for taking part in this diabetes research study. The blood hemoglobin A1c measurements are provided without charge.

Will being in this research benefit me?
By participating in the Balanced Living with Diabetes/ Lifelong Improvements through Fitness Together research study you will learn more about diabetes and how to select and prepare healthy foods. You will learn what your blood A1c levels are now and three months from now when the classes have been completed. You will also see to what extent you have increased your physical activity. We will provide you with an information sheet that you can use to record your A1c for your own use or to give to your doctor at your next visit. Your participation in this diabetes research study will help us learn how we can improve and expand this program to reach more people with diabetes and their families. No promise or guarantee of benefits has been made to encourage you to participate.

What other choices do I have besides taking part in this research?
If you choose not to participate in the Balanced Living with Diabetes/Lifelong Improvements through Fitness Together research study, you are still welcome to attend all classes and receive all class handouts, we will not measure your blood hemoglobin A1c.

What happens to the information collected for this research?
The research plans to disseminate the study findings to the Center for Business Intelligence and Analytics (CBIA) in partnership with Leidos in final report that will not contain any identifiable data after the completion of the study. In addition, dissemination of study findings will be presented to VCE and FCS Extension Agents. Moreover, study findings will be used in Kristina Jiles' dissertation and for journal publication. Information collected for this research which may identify you and the consent form signed by you may also be looked at and/or copied for research or regulatory purposes by: The institution where the research is being done, and Western Institutional Review Board® (WIRB®).

Absolute confidentiality cannot be guaranteed because of the need to give information that identifies you to these parties. The results of this research study may be presented at meetings or in publications. Your identity will not be disclosed in those presentations.

Who can answer my questions about this research?
If you have questions, concerns, or complaints, or think this research has hurt you or made you sick, talk to the research team at the phone number listed above on the first page.

This research is being overseen by an Institutional Review Board ("IRB"). An IRB is a group of people who perform independent review of research studies. You may talk to them at (800) 562-4789, help@wirb.com if: You have questions, concerns, or complaints that are not being answered by the research team. You are not getting answers from the research team. You cannot reach the research team. You want to talk to someone else about the research. You have questions about your rights as a research subject.

What if I am injured because of taking part in this research?
If you are injured or get sick because of being in this research, no payment is available from the study sponsor. Please notify study staff immediately if you feel you have been injured because of being in this research study. For serious injuries, you can fill out an accident/incident report to be mailed and faxed to the Virginia Tech office of Risk Management. If you are injured as a result of this study, you do not give up your right to pursue a claim through the legal system.

Can I be removed from this research without my approval?
The person in charge of this research can remove you from this research without your approval. Possible reasons for removal include: It is in your best interest, or you are unable to continue performing the tasks required as a community research team member.

What happens if I agree to be in this research, but I change my mind later?
Taking part in this study is completely voluntary. You are free to withdraw your consent to participate at any time, and all materials collected from you will be destroyed. If you choose not to participate or withdraw from the study you will still have the opportunity to attend all classes, ask questions, join in food tasting, and receive all class materials.

Will I be paid for taking part in this research?
You will not be paid for taking part in this research.

Statement of Consent:
I have read the Consent Form and I was given the opportunity to ask questions about the research and anything that I did not understand. I have had all of my questions answered. I agree to participate in this diabetes research study. I will receive a copy of this consent form to keep for my records.

Your signature documents your consent to take part in this research.

Signature of adult subject capable of consent	**Date**

Signature of person obtaining consent	**Date**

Have Type 2 diabetes?

Want to lower your blood sugar and prevent complications?

Join ***Balanced Living with Diabetes***, a 12 week program, where you get support to eat healthier, be more active, and take control of your diabetes.

You will:

- ✓ learn how your lifestyle impacts your diabetes
- ✓ manage your diet using a simple plate method
- ✓ set and track activity goals using a step counter
- ✓ get hands on experience preparing and tasting delicious recipes

For more information, contact your local Extension Office to register:

Extension contact name -

Phone -

E-mail -

Virginia Tech Center for Public Health Practice and Research

Virginia Cooperative Extension
Virginia Tech • Virginia State University

There is an opportunity for eligible individuals to participate in a study to evaluate the impact of this program. If you are a person with a disability and require assistance or accommodation to participate in this program, please call (Extension Agent Name at phone number between the hours of 8 a.m. and 5 p.m.)

Information Session Guide (Agenda)

Date:_____ Time:_____ Location: _____

1. Participant Attendance
2. Brief introduction of the information session
    a. Provide information about the Balanced Living with Diabetes (BLD) Program and the Lifelong Improvements through Fitness Together (LIFT) Program.
3. Distribute the informed consent forms
4. Review the informed consent form with prospective participants.
    a. Use Facilitator script
5. Acquire informed consent
6. Provide date/time/location of the first Balanced Living with Diabetes Program class session
    a. Discuss the assessments that will be take prior to the first BLD class.
        i. HbA1c
        ii. Anthropometric measurements (height and weight)
        iii. Godin Leisure Time Exercise Questionnaire
        iv. Physical Activity Readiness Questionnaire (PAR-Q)
        v. Pre-Survey

Godin Leisure-Time Exercise Questionnaire

INSTRUCTIONS

In this excerpt from the Godin Leisure-Time Exercise Questionnaire, the individual is asked to complete a self-explanatory, brief four-item query of usual leisure-time exercise habits.

CALCULATIONS

For the first question, weekly frequencies of strenuous, moderate, and light activities are multiplied by nine, five, and three, respectively. Total weekly leisure activity is calculated in arbitrary units by summing the products of the separate components, as shown in the following formula:

Weekly leisure activity score = (9 × Strenuous) + (5 × Moderate) + (3 × Light)

The second question is used to calculate the frequency of weekly leisure-time activities pursued "long enough to work up a sweat" (see questionnaire).

EXAMPLE

Strenuous = 3 times/wk

Moderate = 6 times/wk

Light = 14 times/wk

Total leisure activity score = (9 × 3) + (5 × 6) + (3 × 14) = 27 + 30 + 42 = 99

Godin Leisure-Time Exercise Questionnaire

1. During a typical **7-Day period** (a week), how many times on the average do you do the following kinds of exercise for **more than 15 minutes** during your free time (write on each line the appropriate number).

Times Per Week

a) STRENUOUS EXERCISE
(HEART BEATS RAPIDLY) _____
(e.g., running, jogging, hockey, football, soccer,
squash, basketball, cross country skiing, judo,
roller skating, vigorous swimming,
vigorous long distance bicycling)

MODERATE EXERCISE

(NOT EXHAUSTING) _____

(e.g., fast walking, baseball, tennis, easy bicycling, volleyball, badminton, easy swimming, alpine skiing, popular and folk dancing)

b) MILD EXERCISE

(MINIMAL EFFORT) _____

(e.g., yoga, archery, fishing from river bank, bowling, horseshoes, golf, snow-mobiling, easy walking)

2. During a typical **7-Day period** (a week), in your leisure time, how often do you engage in any regular activity **long enough to work up a sweat** (heart beats rapidly)?

OFTEN	SOMETIMES	NEVER/RARELY
1. |_|	2. |_|	3. |_|

Appendix P: Patient Activation Measure Survey

Below are statements people sometimes make when they talk about their health. Please indicate how much you agree or disagree with each statement as it applies to you personally.

Circle the answer that is most true for you today. If the statement does not apply, select N/A.

1.	When all is said and done, I am the person who is responsible for taking care of my health.	Strongly Disagree	Disagree	Agree	Strongly Agree	N/A
2.	Taking an active role in my own health care is the most important thing that affects my health.	Strongly Disagree	Disagree	Agree	Strongly Agree	N/A
3.	I am confident I can help prevent or reduce problems associated with my health.	Strongly Disagree	Disagree	Agree	Strongly Agree	N/A
4.	I know what each of my prescribed medications do.	Strongly Disagree	Disagree	Agree	Strongly Agree	N/A
5.	I am confident that I can tell whether I need to go to the doctor or whether I can take care of a health problem myself.	Strongly Disagree	Disagree	Agree	Strongly Agree	N/A
6.	I am confident that I can tell a doctor concerns I have even when he or she does not ask.	Strongly Disagree	Disagree	Agree	Strongly Agree	N/A
7.	I am confident that I can follow through on medical treatments I may need to do at home.	Strongly Disagree	Disagree	Agree	Strongly Agree	N/A
8.	I understand my health problems and what causes them.	Strongly Disagree	Disagree	Agree	Strongly Agree	N/A
9.	I know what treatments are available for my health problems.	Strongly Disagree	Disagree	Agree	Strongly Agree	N/A
10.	I have been able to maintain (keep up with) lifestyle changes, like eating right or exercising.	Strongly Disagree	Disagree	Agree	Strongly Agree	N/A
11.	I know how to prevent problems with my health.	Strongly Disagree	Disagree	Agree	Strongly Agree	N/A
12.	I am confident I can figure out solutions when new problems arise with my health.	Strongly Disagree	Disagree	Agree	Strongly Agree	N/A
13.	I am confident that I can maintain lifestyle changes, like eating right and exercising, even during times of stress.	Strongly Disagree	Disagree	Agree	Strongly Agree	N/A

Preventing & Addressing Unreliable PAM® Response Patterns

Twelve years of research and use in programmes in more than 30 countries consistently shows that the Patient Activation Measure® (PAM®) reliably and accurately measures activation, or an individual's self-management ability. However, accurate measurement does require that individuals fully participate and answer PAM statements truthfully. Though it is unusual, some individuals may not participate in a reliable manner when taking PAM.

Inaccurate response is a challenge for any survey assessment. Fortunately, the rate of poor response with PAM is quite low. Moreover, PAM statements have a known difficulty structure which allows unreliable response patterns to be quickly identified and addressed.

The difficulty structure represents how much activation it takes to be able to agree to a PAM statement. Some statements see a high rate of agreement – 'agree' and 'strongly agree,' while others see a higher rate of 'disagree' and 'strongly disagree' responses. These varied rates of agreement for PAM statements creates a Guttmann-like scale which is characterized by a higher rate of difficulty as the survey progresses. An example of the difficulty structure of PAM 13 is shown below.

Participants whose response patterns differ significantly from the known difficulty structure of PAM are to be treated with caution, and in many cases, should not be considered usable or reliable data. Examples of unreliable data from respondents who do not reliably participate when taking the assessment includes:

- Individuals who respond with all 'strongly disagrees.' This pattern consistently accounts for **less than 0.3%** of completed assessments.
- Individuals who respond with all 'agrees.' This pattern typically accounts for **4% to 6%** of completed PAM assessments.
- Individuals who respond with all 'strongly agrees.' A perfect score does not indicate a legitimate response pattern. This pattern accounts for **3% to 5%** of completed PAM assessments.
- Individuals who respond with a high rate of 'not applicable.' NA is used infrequently in populations managing a long-term health condition. Less than **1%** of PAM surveys have three or more NAs.

On average, 90% of individuals provide reliable and truthful responses to PAM statements in client programmes. They 'fully participate,' which is quite high for any survey. PAM benefits from its brevity, and from statements that are not threatening or which require difficult recall.

How Insignia's Scoring Resources Address Unreliable Data

Insignia's scoring resources (connected spreadsheet, Browser App, iPad App, online site, scoring Web service) adjust some unreliable scores to ensure support does not push an individual beyond their true self-management ability.

- Surveys with all strongly disagrees are rare. These surveys are left as is at Level 1. If possible, it is recommended to re-administer PAM for these individuals (see *PAM administration primer*).
- Surveys with all agrees (score of 56, Level 3) are defaulted to a Level 2 and a score of 52 by Insignia's scoring resources. This ensures that coaching and support does not exceed a person's self-care ability.
- Survey with all strongly agrees are left as is at Level 4. Most of these individuals are likely Level 4 given the large scoring range (74 to 100). If possible, it is recommended to re-administer PAM for these individuals (see *PAM administration primer*).

Addressing Unreliable Responses

Factors that can diminish the reliability of PAM responses, and ways to address these situations, include:

Challenge	Solution
"Not another survey -- I know my patients.' A coach or provider administering PAM does not believe they will gain any new insight. This coach/provider may simply circle responses such as all 'agrees,' or bias an individual taking PAM by introducing the survey with the notion, 'I have to complete this survey with you.'	Individuals administering PAM must know that it should take only a few minutes to complete, and that most individuals can take PAM without needing the questions posed to them verbally. Help the coach/provider understand how a PAM score/level can help him or her be more successful with the individuals they support. With a PAM score/level they: • Know immediately which individuals need more of their time, or can benefit from signposting • Can more effectively tailor their support to an individual's self-management ability • Can track the impact of their support well in advance of traditional outcome measures
Individual believes --'Not worth my time:' The survey respondent does not feel that completing the assessment is worth their time or serious consideration. As such, they answer with all 'agrees' to get through the assessment quickly and without much thought.	When introducing PAM, share that the assessment will take less than 5 minutes, and that the individual's responses will help you provide more personalized support. Indicate that the brief assessment is important to developing the best possible support relationship. If the first seven PAM statements (five with PAM 10) are all answered with agree, start over, including the introduction. Indicate that most individuals vary in how they respond to the survey questions, and that you'd like to make sure that their responses truly reflect how they view their health.
Individual wants to look good**.** With pride at stake, an individual may answer with all 'strongly agrees.' ***Individual believes their access to care or support will be positively influenced by responding with all 'strongly agrees.'***	When introducing PAM, emphasize that there are no right or wrong answers, just what is true for the individual. If the first seven PAM statements are all answered with strongly agree (five with PAM 10), start over. Repeat the intro and indicate that most people vary in how they respond to the survey questions, and that you'd like to make sure that the individual's responses truly reflect how they view their health.
'I want my coach/provider to look good.' The individual may answer with all 'strongly agrees.'	Administer PAM when the relationship first begins and early in the first interaction. The lack of a relationship will help with reliable responses. If a relationship exists and PAM is administered verbally, consider having someone other than the coach/provider administer PAM. See discussion above re: the use of all 'strongly agrees.'
Cognitive impairment**.** An individual with early onset dementia, Alzheimer's, or other serious mental impairment may struggle with any health survey.	In these recognized situations, use Caregiver PAM. If this impairment involves a child, Parent PAM should be used. Individuals with depression, schizophrenia, and bipolar disorder have shown to take PAM with high reliability.
Language understanding difficulty	Use one of the 35+ translations if a person's English is not proficient.

LIFT Program and Evaluation Materials

2019 PAR-Q+

The Physical Activity Readiness Questionnaire for Everyone

The health benefits of regular physical activity are clear; more people should engage in physical activity every day of the week. Participating in physical activity is very safe for MOST people. This questionnaire will tell you whether it is necessary for you to seek further advice from your doctor OR a qualified exercise professional before becoming more physically active.

GENERAL HEALTH QUESTIONS

Please read the 7 questions below carefully and answer each one honestly: check YES or NO.	YES	NO
1) Has your doctor ever said that you have a heart condition ☐ OR high blood pressure ☐?	☐	☐
2) Do you feel pain in your chest at rest, during your daily activities of living, **OR** when you do physical activity?	☐	☐
3) Do you lose balance because of dizziness **OR** have you lost consciousness in the last 12 months? Please answer **NO** if your dizziness was associated with over-breathing (including during vigorous exercise).	☐	☐
4) Have you ever been diagnosed with another chronic medical condition (other than heart disease or high blood pressure)? **PLEASE LIST CONDITION(S) HERE:** _____	☐	☐
5) Are you currently taking prescribed medications for a chronic medical condition? **PLEASE LIST CONDITION(S) AND MEDICATIONS HERE:** _____	☐	☐
6) Do you currently have (or have had within the past 12 months) a bone, joint, or soft tissue (muscle, ligament, or tendon) problem that could be made worse by becoming more physically active? Please answer **NO** if you had a problem in the past, but it **does not limit your current ability** to be physically active. **PLEASE LIST CONDITION(S) HERE:** _____	☐	☐
7) Has your doctor ever said that you should only do medically supervised physical activity?	☐	☐

If you answered NO to all of the questions above, you are cleared for physical activity.
Please sign the PARTICIPANT DECLARATION. You do not need to complete Pages 2 and 3.

- Start becoming much more physically active – start slowly and build up gradually.
- Follow International Physical Activity Guidelines for your age (www.who.int/dietphysicalactivity/en/).
- You may take part in a health and fitness appraisal.
- If you are over the age of 45 yr and NOT accustomed to regular vigorous to maximal effort exercise, consult a qualified exercise professional before engaging in this intensity of exercise.
- If you have any further questions, contact a qualified exercise professional.

PARTICIPANT DECLARATION

If you are less than the legal age required for consent or require the assent of a care provider, your parent, guardian or care provider must also sign this form.

I, the undersigned, have read, understood to my full satisfaction and completed this questionnaire. I acknowledge that this physical activity clearance is valid for a maximum of 12 months from the date it is completed and becomes invalid if my condition changes. I also acknowledge that the community/fitness center may retain a copy of this form for its records. In these instances, it will maintain the confidentiality of the same, complying with applicable law.

NAME _____ DATE _____

SIGNATURE _____ WITNESS _____

SIGNATURE OF PARENT/GUARDIAN/CARE PROVIDER _____

If you answered YES to one or more of the questions above, COMPLETE PAGES 2 AND 3.

Delay becoming more active if:

- You have a temporary illness such as a cold or fever; it is best to wait until you feel better.
- You are pregnant - talk to your health care practitioner, your physician, a qualified exercise professional, and/or complete the ePARmed-X+ at **www.eparmedx.com** before becoming more physically active.
- Your health changes - answer the questions on Pages 2 and 3 of this document and/or talk to your doctor or a qualified exercise professional before continuing with any physical activity program.

2019 PAR-Q+

FOLLOW-UP QUESTIONS ABOUT YOUR MEDICAL CONDITION(S)

1. Do you have Arthritis, Osteoporosis, or Back Problems?

If the above condition(s) is/are present, answer questions 1a-1c If **NO** ☐ go to question 2

1a.	Do you have difficulty controlling your condition with medications or other physician-prescribed therapies? (Answer **NO** if you are not currently taking medications or other treatments)	YES ☐ NO ☐
1b.	Do you have joint problems causing pain, a recent fracture or fracture caused by osteoporosis or cancer, displaced vertebra (e.g., spondylolisthesis), and/or spondylolysis/pars defect (a crack in the bony ring on the back of the spinal column)?	YES ☐ NO ☐
1c.	Have you had steroid injections or taken steroid tablets regularly for more than 3 months?	YES ☐ NO ☐

2. Do you currently have Cancer of any kind?

If the above condition(s) is/are present, answer questions 2a-2b If **NO** ☐ go to question 3

2a.	Does your cancer diagnosis include any of the following types: lung/bronchogenic, multiple myeloma (cancer of plasma cells), head, and/or neck?	YES ☐ NO ☐
2b.	Are you currently receiving cancer therapy (such as chemotheraphy or radiotherapy)?	YES ☐ NO ☐

3. Do you have a Heart or Cardiovascular Condition? This includes Coronary Artery Disease, Heart Failure, Diagnosed Abnormality of Heart Rhythm

If the above condition(s) is/are present, answer questions 3a-3d If **NO** ☐ go to question 4

3a.	Do you have difficulty controlling your condition with medications or other physician-prescribed therapies? (Answer **NO** if you are not currently taking medications or other treatments)	YES ☐ NO ☐
3b.	Do you have an irregular heart beat that requires medical management? (e.g., atrial fibrillation, premature ventricular contraction)	YES ☐ NO ☐
3c.	Do you have chronic heart failure?	YES ☐ NO ☐
3d.	Do you have diagnosed coronary artery (cardiovascular) disease and have not participated in regular physical activity in the last 2 months?	YES ☐ NO ☐

4. Do you have High Blood Pressure?

If the above condition(s) is/are present, answer questions 4a-4b If **NO** ☐ go to question 5

4a.	Do you have difficulty controlling your condition with medications or other physician-prescribed therapies? (Answer **NO** if you are not currently taking medications or other treatments)	YES ☐ NO ☐
4b.	Do you have a resting blood pressure equal to or greater than 160/90 mmHg with or without medication? (Answer **YES** if you do not know your resting blood pressure)	YES ☐ NO ☐

5. Do you have any Metabolic Conditions? This includes Type 1 Diabetes, Type 2 Diabetes, Pre-Diabetes

If the above condition(s) is/are present, answer questions 5a-5e If **NO** ☐ go to question 6

5a.	Do you often have difficulty controlling your blood sugar levels with foods, medications, or other physician-prescribed therapies?	YES ☐ NO ☐
5b.	Do you often suffer from signs and symptoms of low blood sugar (hypoglycemia) following exercise and/or during activities of daily living? Signs of hypoglycemia may include shakiness, nervousness, unusual irritability, abnormal sweating, dizziness or light-headedness, mental confusion, difficulty speaking, weakness, or sleepiness.	YES ☐ NO ☐
5c.	Do you have any signs or symptoms of diabetes complications such as heart or vascular disease and/or complications affecting your eyes, kidneys, **OR** the sensation in your toes and feet?	YES ☐ NO ☐
5d.	Do you have other metabolic conditions (such as current pregnancy-related diabetes, chronic kidney disease, or liver problems)?	YES ☐ NO ☐
5e.	Are you planning to engage in what for you is unusually high (or vigorous) intensity exercise in the near future?	YES ☐ NO ☐

2019 PAR-Q+

6. **Do you have any Mental Health Problems or Learning Difficulties?** This includes Alzheimer's, Dementia, Depression, Anxiety Disorder, Eating Disorder, Psychotic Disorder, Intellectual Disability, Down Syndrome

If the above condition(s) is/are present, answer questions 6a-6b If **NO** ☐ go to question 7

6a.	Do you have difficulty controlling your condition with medications or other physician-prescribed therapies? (Answer **NO** if you are not currently taking medications or other treatments)	YES ☐ NO ☐
6b.	Do you have Down Syndrome **AND** back problems affecting nerves or muscles?	YES ☐ NO ☐

7. **Do you have a Respiratory Disease?** This includes Chronic Obstructive Pulmonary Disease, Asthma, Pulmonary High Blood Pressure

If the above condition(s) is/are present, answer questions 7a-7d If **NO** ☐ go to question 8

7a.	Do you have difficulty controlling your condition with medications or other physician-prescribed therapies? (Answer **NO** if you are not currently taking medications or other treatments)	YES ☐ NO ☐
7b.	Has your doctor ever said your blood oxygen level is low at rest or during exercise and/or that you require supplemental oxygen therapy?	YES ☐ NO ☐
7c.	If asthmatic, do you currently have symptoms of chest tightness, wheezing, laboured breathing, consistent cough (more than 2 days/week), or have you used your rescue medication more than twice in the last week?	YES ☐ NO ☐
7d.	Has your doctor ever said you have high blood pressure in the blood vessels of your lungs?	YES ☐ NO ☐

8. **Do you have a Spinal Cord Injury?** This includes Tetraplegia and Paraplegia

If the above condition(s) is/are present, answer questions 8a-8c If **NO** ☐ go to question 9

8a.	Do you have difficulty controlling your condition with medications or other physician-prescribed therapies? (Answer **NO** if you are not currently taking medications or other treatments)	YES ☐ NO ☐
8b.	Do you commonly exhibit low resting blood pressure significant enough to cause dizziness, light-headedness, and/or fainting?	YES ☐ NO ☐
8c.	Has your physician indicated that you exhibit sudden bouts of high blood pressure (known as Autonomic Dysreflexia)?	YES ☐ NO ☐

9. **Have you had a Stroke?** This includes Transient Ischemic Attack (TIA) or Cerebrovascular Event

If the above condition(s) is/are present, answer questions 9a-9c If **NO** ☐ go to question 10

9a.	Do you have difficulty controlling your condition with medications or other physician-prescribed therapies? (Answer NO if you are not currently taking medications or other treatments)	YES ☐ NO ☐
9b.	Do you have any impairment in walking or mobility?	YES ☐ NO ☐
9c.	Have you experienced a stroke or impairment in nerves or muscles in the past 6 months?	YES ☐ NO ☐

10. **Do you have any other medical condition not listed above or do you have two or more medical conditions?**

If you have other medical conditions, answer questions 10a-10c If **NO** ☐ read the Page 4 recommendations

10a.	Have you experienced a blackout, fainted, or lost consciousness as a result of a head injury within the last 12 months **OR** have you had a diagnosed concussion within the last 12 months?	YES ☐ NO ☐
10b.	Do you have a medical condition that is not listed (such as epilepsy, neurological conditions, kidney problems)?	YES ☐ NO ☐
10c.	Do you currently live with two or more medical conditions?	YES ☐ NO ☐

PLEASE LIST YOUR MEDICAL CONDITION(S) AND ANY RELATED MEDICATIONS HERE: _____

_____

GO to Page 4 for recommendations about your current medical condition(s) and sign the PARTICIPANT DECLARATION.

2019 PAR-Q+

If you answered NO to all of the FOLLOW-UP questions (pgs. 2-3) about your medical condition, you are ready to become more physically active - sign the PARTICIPANT DECLARATION below:

- It is advised that you consult a qualified exercise professional to help you develop a safe and effective physical activity plan to meet your health needs.
- You are encouraged to start slowly and build up gradually - 20 to 60 minutes of low to moderate intensity exercise, 3-5 days per week including aerobic and muscle strengthening exercises.
- As you progress, you should aim to accumulate 150 minutes or more of moderate intensity physical activity per week.
- If you are over the age of 45 yr and **NOT** accustomed to regular vigorous to maximal effort exercise, consult a qualified exercise professional before engaging in this intensity of exercise.

If you answered **YES** to **one or more of the follow-up questions** about your medical condition:

You should seek further information before becoming more physically active or engaging in a fitness appraisal. You should complete the specially designed online screening and exercise recommendations program - the **ePARmed-X+ at www.eparmedx.com** and/or visit a qualified exercise professional to work through the ePARmed-X+ and for further information.

Delay becoming more active if:

- You have a temporary illness such as a cold or fever; it is best to wait until you feel better.
- You are pregnant - talk to your health care practitioner, your physician, a qualified exercise professional, and/or complete the ePARmed-X+ **at www.eparmedx.com** before becoming more physically active.
- Your health changes - talk to your doctor or qualified exercise professional before continuing with any physical activity program.

- You are encouraged to photocopy the PAR-Q+. You must use the entire questionnaire and NO changes are permitted.
- The authors, the PAR-Q+ Collaboration, partner organizations, and their agents assume no liability for persons who undertake physical activity and/or make use of the PAR-Q+ or ePARmed-X+. If in doubt after completing the questionnaire, consult your doctor prior to physical activity.

PARTICIPANT DECLARATION

- All persons who have completed the PAR-Q+ please read and sign the declaration below.
- If you are less than the legal age required for consent or require the assent of a care provider, your parent, guardian or care provider must also sign this form.

I, the undersigned, have read, understood to my full satisfaction and completed this questionnaire. I acknowledge that this physical activity clearance is valid for a maximum of 12 months from the date it is completed and becomes invalid if my condition changes. I also acknowledge that the community/fitness center may retain a copy of this form for records. In these instances, it will maintain the confidentiality of the same, complying with applicable law.

NAME _____ DATE _____

SIGNATURE _____ WITNESS _____

SIGNATURE OF PARENT/GUARDIAN/CARE PROVIDER _____

For more information, please contact

www.eparmedx.com

Email: eparmedx@gmail.com

Citation for PAR-Q+

Warburton DER, Jamnik VK, Bredin SSD, and Gledhill N on behalf of the PAR-Q+ Collaboration. The Physical Activity Readiness Questionnaire for Everyone (PAR-Q+) and Electronic Physical Activity Readiness Medical Examination (ePARmed-X+). Health & Fitness Journal of Canada 4(2):3-23, 2011.

The PAR-Q+ was created using the evidence-based AGREE process (1) by the PAR-Q+ Collaboration chaired by Dr. Darren E. R. Warburton with Dr. Norman Gledhill, Dr. Veronica Jamnik, and Dr. Donald C. McKenzie (2). Production of this document has been made possible through financial contributions from the Public Health Agency of Canada and the BC Ministry of Health Services. The views expressed herein do not necessarily represent the views of the Public Health Agency of Canada or the BC Ministry of Health Services.

Key References

1. Jamnik VK, Warburton DER, Makarski J, McKenzie DC, Shephard RJ, Stone J, and Gledhill N. Enhancing the effectiveness of clearance for physical activity participation; background and overall process. APNM 36(S1):S3-S13, 2011.

2. Warburton DER, Gledhill N, Jamnik VK, Bredin SSD, McKenzie DC, Stone J, Charlesworth S, and Shephard RJ. Evidence-based risk assessment and recommendations for physical activity clearance; Consensus Document. APNM 36(S1):S266-s298, 2011.

3. Chisholm DM, Collis ML, Kulak LL, Davenport W, and Gruber N. Physical activity readiness. British Columbia Medical Journal. 1975;17:375-378.

4. Thomas S, Reading J, and Shephard RJ. Revision of the Physical Activity Readiness Questionnaire (PAR-Q). Canadian Journal of Sport Science 1992;17:4 338-345.

PHYSICIAN AUTHORIZATION FORM

(Highlight indicates areas to be completed by VCE personnel: remove this statement before printing/sending)	
Physician / practice	
Address	
Phone number	
Fax number	
Patient Name	
Program	
	Yes, my patient can participate.
	Yes, my patient can participate with the following limitations:
	No, my patient cannot participate at this time due to his/her medical conditions and health status.
Physician signature:	
Printed name:	

This form may be faxed to_____, given to patient, or mailed to: INSERT ADDRESS HERE

Please return this form by:_____(Date) _____

Return Contact Information Here

Date

Dear Dr._____,

Your patient,_____, would like to participate in a Virginia Cooperative Extension (VCE) program that involves physical activity.

Part of the mission of VCE is to “put scientific knowledge to work through learning experiences that improve economic, environmental, and social well-being.” Through a partnership of the land-grant universities of Virginia and community-based faculty and staff, these programs are developed and delivered through best practices and evidence and aim to improve health behaviors.

To determine if a participant may have a contraindication to physical activity, we have participants complete the Physical Activity Readiness Questionnaire before engaging in this particular program. Your patient has indicated an answer that requires us to obtain physician approval before he/she engages in the program, which includes moderate intensity physical activity (tailor as needed).

Please complete and sign the enclosed authorization form. If you have any further questions about this program, please call me at _____.

Sincerely,

Name
Position
Location

FITNESS ASSESSMENT PROTOCOL & MATERIALS NEEDED

EXERCISE	EQUIPMENT	PROCEDURE	SCORING
Beginning Station	Pens Clipboard Informed consent Pre-program survey Demographics	Complete Forms	
Balance Station	Stopwatch Chair with armrests Chair without armrests, OR space near a wall	1. Mountain Pose: Stand behind a chair with your feet side by side and touching without using hands for support (10 sec) 2. Tandem Stand: Stand behind a chair using one hand for support. Place one foot directly in front of the other. The heel of front foot should be touching the toes of the back foot. Let go of chair and hold for 10 sec 3. One-legged Stand: Stand behind a chair and shift weight to one foot and bend the knee of the other leg. Let go of chair and hold for 10 sec 4. Tandem Stand w/ Eyes Closed: (spotter needed) Position same as #2 except w/ eyes closed (10 sec) 5. Tandem Stand w/ Eyes Closed and Head Turning: (spotter needed) Same as #4 except turn head slowly to the left, slowly to the right, and return to center (10 sec) 6. One-Legged Stand w/ Eyes Closed: (spotter needed) Same position as #2, except you will close your eyes (10 sec)	If at any point the participant cannot complete 10 seconds of one position, DO NOT move on to the next move. Write down the number of seconds they completed and move directly into 30 sec chair stands.
30-second Chair stand	Stopwatch Chair 2 research assistants (1 for counting, 1 for support)	1. Place chair against wall (17 in) 2. “In this exercise you will stand and sit as many times as you can in 30s. I will signal you with the word go.” 3. Demonstrate for participant 4. Starting position: Sit in the middle of the chair; feet flat on floor; arms crossed 5. On “go,” the timer will run for 30 seconds, Complete as many as possible in 30 seconds. 6. Allow a 30 second break between each trial.	Count the total number of stand and sits in 30 seconds; more than half way up counts as a full stand.

FITNESS ASSESSMENT PROTOCOL & MATERIALS NEEDED

EXERCISE	EQUIPMENT	PROCEDURE	SCORING
30-sec Arm Curl	Stopwatch Chair without armrests Dumbbell	1. Participant should be seated with back against the chair, feet flat on floor, dominant side of the body close to edge of the chair; RA hand on elbow for guidance 2. In this exercise participant will do an arm curl, starting with hand in 'handshake' position. 3. Bring the dumbbell up in full motion. Demonstrate for the participant and then they can practice once before beginning. 4. On "go," the timer will run for 30 seconds. Complete as many arm curls as you can. 5. 30 second break between each trial.	Count the total number of curls; if the arm is more than halfway up at the end, it counts as a curl.
2-min Step Test	Stopwatch Meter stick Tape markers	1. Participant is to bring the leg up between patella (knee cap) and iliac crest (bottom of hip) as marked on the wall. 2. On the signal "go," participant will step in place, starting with the right leg and continue to step for 2 minutes. Let participant know when 1 minute has passed and when there are 30 seconds to go. 3. Do not encourage or motivate participants, simply say the time. 4. Discontinue at sign of dizziness, pain, nausea, or fatigue 5. Allow participant to take a water break if desired	Record the total number of times the RIGHT knee reaches minimum height
Chair Sit-and-Reach	Chair 18-inch ruler	Chair against the wall; crease between top of leg and buttocks inline with the edge of the seat; place meter stick on inside of stretched leg One leg bent with foot flat on floor; preferred leg extended; hinge at the hips and dive forward with hands on top of each other. Demonstrate; 2 trial tests for participant; 2 actual tests	If participant is short of reaching the toe (minus score); distance past toe (positive score). The middle of the toe at the end of the shoe is a "0." Measure to the nearest ½ inch.

FITNESS ASSESSMENT PROTOCOL & MATERIALS NEEDED

EXERCISE	EQUIPMENT	PROCEDURE	SCORING
Back-scratch	18 inch ruler	1. Ask participant which arm is more flexible. Record answer. You can allow them to "test" which side is more flexible. 2. Ask participant to place finger tips next to each other rather than overlapping 3. "Arms out in a T, breathe, then bring hands together behind back."	If participant is short of reaching hands behind head (minus score). Distance the hands overlap (positive score). Measure distance to nearest half; circle best measure (be sure to indicate + or -)
8 Foot Up and Go	Chair Stopwatch Cone 2 research assistants (one to keep time and one to spot)	1. Chair against the wall; unobstructed 2. Seated in middle of the chair, hands on thighs feel flat 3. "This is a timed test, please walk as quickly as possible, without running, around the cone and back. I'll demonstrate, then you can start when I signal go." 4. Signal "go." Start timer whether they move or not; stop exactly when back in chair.	Record the time elapsed to the nearest 1/10th. Circle best score after completing twice

Remember:

1. **The same individuals must proctor the pre- and post- functional fitness assessments.**
2. **Allow approximately 15 minutes per person.**
3. **Use the same arm for both trials when completing the 30-second arm curl and back scratch**
4. **Use the same leg for both trials when participant is completing the Sit and Reach.**

FUNCTIONAL FITNESS TESTING

First name		**Last name**	
Pre or Post		**County**	
Instructor		**Date**	
Person completing assessment			

EXERCISE	SCORING
Balance Station 1. Mountain Pose 2. Tandem Stand 3. One-Legged Stand 4. Tandem Stand w/ eyes closed 5. Tandem Stand w/ eyes closed & head turning 6. One-legged Stand w/ eyes closed	Out of 10 1. Seconds _____ 2. Seconds _____ 3. Seconds _____ 4. Seconds _____ 5. Seconds _____ 6. Seconds _____
30-second Arm Curl (L) or (R): _____	Trial 1: _____ Trial 2: _____
2 Minute Step test	Number of steps: _____ Height of each step: _____
Chair-Sit-and-Reach **Leg (L) or (R):** _____	Trial 1: +_____ _____ Trial 2: +_____ _____
Back Scratch **Top arm (L) or (R):** _____	Trial 1: +_____ _____ Trial 2: +_____ _____
8 Foot Up-and-Go	Trial 1: _____ Trial 2: _____
Notes / modifications / injuries:	

Appendix S: Email Script to Extension Agents

Email Script

Hello, my name is Kristina Jiles, a doctoral candidate in the Department of Human Nutrition, Foods, and Exercise at Virginia Tech under the advisement of Extension Specialist, Dr. Carlin Rafie. You were identified as an Extension Agent involved with the Balanced Living with Diabetes (BLD) program and Lifelong Improvements through Fitness Together (LIFT) program study this year. I am inviting you to participate in a telephone interview for a study that I am conducting on the LIFT and BLD programs.

In the telephone interview, you will be asked a series of questions about your experiences with implementing the BLD and LIFT programs. This will include the barriers and facilitators, time commitment, and costs with implementing both programs. Should you agree to participate in this interview, your total time commitment for the interview will be 45-60 minutes.

If you would like to participate in this study and if you have any questions, please email me at krist14@vt.edu to confirm your interest to participate and for further information about this project.

Thank you,

Kristina Jiles

Appendix T: Extension Agent Verbal Consent

RESEARCH SUBJECT VERBAL CONSENT FORM

Title: The implementation of a retention plan in a VCE community-based diabetes lifestyle management program (BLD) using the RE-AIM Framework: A retrospective mixed methods study

Protocol No.: **IRB 18-1130**

Sponsor: N/A

Investigator: Carlin Rafie
321 Wallace Hall
295 West Campus Drive
Blacksburg, VA 24061-0430
USA

Daytime Phone Number: 540-231-3163

You are being invited to take part in a research study. A person who takes part in a research study is called a research subject, or research participant.

What should I know about this research?

- Someone will explain this research to you.
- This form sums up that explanation.
- Taking part in this research is voluntary. Whether you take part is up to you.
- You can choose not to take part. There will be no penalty or loss of benefits to which you are otherwise entitled.
- You can agree to take part and later change your mind. There will be no penalty or loss of benefits to which you are otherwise entitled.
- If you don't understand, ask questions.
- Ask all the questions you want before you decide.

Why is this research being done?

The purpose of this study is to evaluate implementation of integrating the Lifelong Improvements though Fitness Together (LIFT) Program with Balanced Living with Diabetes (BLD) Program among Family and Consumer Science (FCS) Extension Agents. The interview will include discussion of FCS Extension Agents' barriers and facilitators with implementation of LIFT and BLD programs. How long will I be in this research?

We expect that your taking part in this interview will last 15-20 minutes.

What happens to me if I agree to take part in this research?

You are invited to participate in this study. You are eligible to participate because you have been identified as an FCS Extension Agent that was involved with the BLD and LIFT Program study conducted in Feb-May 2019. The following information is provided to help you make an

informed decision whether or not to participate. If you have any questions, please do not hesitate to ask.

What are my responsibilities if I take part in this research?

You will be asked questions about your experiences with implementing the BLD and LIFT programs. This will include the barriers and facilitators, time commitment, and costs with implementing both programs. Should you agree to participate, you will be asked to participate in a 15-20-minute audio-recorded interview.

Could being in this research hurt me?

There are no more than minimal risks to participation. Semi-structured will be limited to the 15-20-minute timeframe so that they are not burdensome to you.

Will it cost me money to take part in this research?

There will be no compensation for your participation in this telephone interview.

Will being in this research benefit me?

Information from this study will allow researchers to understand your experiences with conducting the BLD program with the integration of the LIFT program. This will allow for a sense of clarity of the implementation process from your perspectives for future implementation of the LIFT program with the BLD program. No promise or guarantee of these benefits has been made to encourage you to participate.

What other choices do I have besides taking part in this research?

Your alternative is to not take part in the research.

What happens to the information collected for this research?

Study results will be used for Kristina Jiles' dissertation project and may be published in educational journals or presented at educational meetings. However, we will keep your name and other identifying information confidential. We protect your information from disclosure to others to the extent required by law.

Who can answer my questions about this research?

If you have questions, concerns, or complaints, or think this research has hurt you or made you sick, talk to the research team at the phone number listed above on the first page.

This research is being overseen by an Institutional Review Board ("IRB"). An IRB is a group of people who perform independent review of research studies. You may talk to them at (800) 562-4789, help@wirb.com if:

- You have questions, concerns, or complaints that are not being answered by the research team.
- You are not getting answers from the research team.
- You cannot reach the research team.
- You want to talk to someone else about the research.
- You have questions about your rights as a research subject.

What if I am injured because of taking part in this research?

N/A

Can I be removed from this research without my approval?

N/A

What happens if I agree to be in this research, but I change my mind later?

It is important for you to know that you are free to withdraw from this study at any time without penalty. You are free not to answer any questions that you choose or respond to what is being asked of you without penalty.

Will I be paid for taking part in this research?

There will be no compensation for your participation in this telephone interview.

Statement of Consent:

Do you understand the information that I have gone over? Do you have any questions?

Do you agree to participate in this study?

☐ Yes

☐ No

_____ Date_____
Print subject name

_____ Date_____
Co-investigator signature

Appendix U: Semi-structured Interviews

Interview with Extension Agents

IMPLEMENTATION

INNER CONTEXT

1. Describe the location(s) in which the BLD program implemented.
    a. Was this location appropriate for conducting the BLD program?
        i. How did it help the program?
        ii. How did it hinder the program?
2. Describe how the location(s) in which the LIFT program was implemented.
    a. Was this location appropriate for conducting the LIFT program?
        i. How did it help the program?
        ii. How did it hinder the program?

FIDELITY

1. What changes, if any, were made to the BLD program?
    a. Why did you make those modifications?
    b. How did you make those modifications?
2. Describe how the LIFT program was implemented.
3. What changes, if any, were made to the LIFT program?
    a. Why did you make those modifications?
    b. How did you make those modifications?

BARRIERS AND FACILITATORS

Thinking about the BLD + LIFT:

1. What are your thoughts on implementing both the BLD and LIFT programs collectively?
    a. What barriers or challenges, if any, did you face implementing the LIFT program with the BLD program?
2. What barriers or challenges, if any, did you face distributing the retention materials and delivering the LIFT program?
    a. How did you use the retention materials with the LIFT program?
        i. Did you follow the retention plan accordingly when distributing retention materials to participants? (yes/no)
    b. What modifications, if any, were made to the retention plan?
        i. Why did you make those modifications?
    c. How were the retention materials distributed to participants? (Email, mail, verbal-telephone, text messages with attachments)

        i. Why did you choose to distribute the retention materials in this format?
        ii. Did all the participants receive the retention materials? (yes/no)
    d. Did you think it was redundant to use the retention materials with the LIFT program? (yes/no)

Now thinking about the BLD alone:

3. What are your thoughts on implementing the BLD without LIFT?
4. What barriers or challenges, if any, did you face implementing the BLD with distributing the retention materials?
    a. How did you use the retention materials without the LIFT program?
        i. Did you follow the retention plan accordingly when distributing retention materials to participants? (yes/no)
    b. What modifications, if any, were made to the retention plan?
        i. Why did you make those modifications?
    c. How were the retention materials distributed to participants? (Email, mail, verbal-telephone, text messages with attachments)
        i. Why did you choose to distribute the retention materials in this format?
        ii. Did all the participants receive the retention materials? (yes/no)
5. Did cost impact implementation of the BLD and BLD + LIFT program?

<u>TIME</u>

1. On average, how long (in hours) did it take to prepare for the BLD sessions each week?
    a. Did you receive/have any assistance with preparation?
    b. Did you have to work after hours or on the weekends?
2. On average, how long (in hours) did it take to prepare for LIFT sessions twice a week?
    a. Did you receive/have any assistance with preparation?
    b. Did you have to work after hours or on the weekends?
3. The BLD sessions are generally $2^{1/2}$ hours. On average, how long were each of the BLD sessions?
4. The LIFT sessions are generally 1 hour twice a week. On average, how long were each of the LIFT sessions?

<u>ACCEPTABILITY</u>

1. In the future, will you continue implementing the LIFT program with the BLD program?

SYSTEMS LEVEL MAINTENANCE

1. What impact do you think the LIFT program had on participants coming to the reunion session? On lifestyle changes made by the participants?
2. Do you have any recommendations for how it might easier to implement the LIFT program with BLD program?
3. What are your plans for the BLD program in the future?
    a. Do you plan to implement the LIFT program with the BLD program?

Quantitative Supplementary Documents

1. Chi-Square Tests

*Returned * BLD only OR BLD and LIFT identifier Crosstabulation*

			BLD only OR BLD and LIFT identifier		
			BLD Only	BLD AND LIFT	Total
Returned	no	Count	6	2	8
		Expected Count	3.7	4.3	8.0
	yes	Count	10	17	27
		Expected Count	12.3	14.7	27.0
Total		Count	16	19	35
		Expected Count	16.0	19.0	35.0

Chi-Square Tests

	Value	df	Asymptotic Significance (2-sided)	Exact Sig. (2-sided)	Exact Sig. (1-sided)
Pearson Chi-Square	3.584[a]	1	.058		
Continuity Correction[b]	2.217	1	.136		
Likelihood Ratio	3.671	1	.055		
Fisher's Exact Test				.105	.068
Linear-by-Linear Association	3.482	1	.062		
N of Valid Cases	35				

a. 2 cells (50.0%) have expected count less than 5. The minimum expected count is 3.66.

b. Computed only for a 2x2 table

2. Independent Samples T-Tests

A1c

Group Statistics of change in A1c in standard BLD and BLD with LIFT programs

	BLD only OR BLD and LIFT identifier	N	Mean	Std. Deviation	Std. Error Mean
A1c	BLD Only	13	.6385	1.44080	.39961
	BLD AND LIFT	19	.2421	.63928	.14666

Independent Samples Test of change in A1c in standard BLD and BLD with LIFT programs

		Levene's Test for Equality of Variances		t-test for Equality of Means						
									95% Confidence Interval of the Difference	
		F	Sig.	t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	Lower	Upper
A1c	Equal variances assumed	6.019	.020	1.062	30	.297	.39636	.37329	-.36600	1.15872
	Equal variances not assumed			.931	15.266	.366	.39636	.42567	-.50956	1.30227

Physical Activity (Godin Leisure Time Exercise Questionnaire)

Group Statistics of change in total weekly leisure activity in standard BLD and BLD with LIFT programs

	BLD only OR BLD and LIFT identifier	N	Mean	Std. Deviation	Std. Error Mean
Total weekly leisure activity	BLD Only	7	-5.4286	20.76742	7.84935
	BLD AND LIFT	12	-4.8333	28.82181	8.32014

Independent Samples Test of change in total weekly leisure activity in standard BLD and BLD with LIFT programs

		Levene's Test for Equality of Variances		t-test for Equality of Means						
									95% Confidence Interval of the Difference	
		F	Sig.	t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	Lower	Upper
Total weekly leisure activity	Equal variances assumed	.822	.377	-.048	17	.963	-.59524	12.49040	-26.94767	25.75719
	Equal variances not assumed			-.052	16.024	.959	-.59524	11.43840	-24.84066	23.65019

Functional Fitness Tests

Group Statistics of change in functional fitness in standard BLD and BLD with LIFT programs

	BLD only OR BLD and LIFT identifier	N	Mean	Std. Deviation	Std. Error Mean
Number of balance exercises completed, out of 6 stations	BLD Only	10	.2000	.42164	.13333
	BLD AND LIFT	12	.1667	.83485	.24100
Max Number of Arm Curls in 30 seconds	BLD Only	10	1.8000	1.87380	.59255
	BLD AND LIFT	12	-2.1667	5.16691	1.49156
Number of steps: 2-minute Step Test	BLD Only	7	-14.5714	22.82438	8.62681
	BLD AND LIFT	10	13.5000	27.64959	8.74357
Max Distance of Lower Leg Flex (in inches)	BLD Only	9	1.5556	2.46785	.82262
	BLD AND LIFT	12	2.7500	4.75538	1.37276
Max Distance of Upper Arm Flex (in inches)	BLD Only	9	4.7222	5.83690	1.94563
	BLD AND LIFT	11	.6364	6.10774	1.84155
Time completion of 8 ft up and go (in seconds)	BLD Only	9	1.3333	3.86685	1.28895
	BLD AND LIFT	11	1.1273	2.90830	.87688

Independent Samples Test of change in functional fitness in standard BLD and BLD with LIFT programs

		Levene's Test for Equality of Variances		t-test for Equality of Means						
									95% Confidence Interval of the Difference	
		F	Sig.	t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	Lower	Upper
Number of balance exercises completed, out of 6 stations	Equal variances assumed	1.819	.193	.114	20	.910	.03333	.29145	-.57463	.64129
	Equal variances not assumed			.121	16.837	.905	.03333	.27542	-.54819	.61486
Max Number of Arm Curls in 30 seconds	Equal variances assumed	1.547	.228	2.297	20	.033	3.96667	1.72673	.36476	7.56857
	Equal variances not assumed			2.472	14.310	.027	3.96667	1.60495	.53139	7.40195
Number of steps: 2-minute Step Test	Equal variances assumed	.317	.582	-2.205	15	.043	-28.07143	12.72813	-55.20080	-.94205
	Equal variances not assumed			-2.285	14.475	.038	-28.07143	12.28299	-54.33491	-1.80795
Max Distance of Lower Leg Flex (in inches)	Equal variances assumed	2.819	.110	-.685	19	.502	-1.19444	1.74479	-4.84634	2.45745
	Equal variances not assumed			-.746	17.258	.465	-1.19444	1.60036	-4.56707	2.17818
Max Distance of Upper Arm Flex (in inches)	Equal variances assumed	.104	.750	1.518	18	.146	4.08586	2.69180	-1.56941	9.74113
	Equal variances not assumed			1.525	17.511	.145	4.08586	2.67896	-1.55371	9.72542

Time completion of 8 ft up and go (in seconds)	Equal variances assumed	.284	.601	.136	18	.893	.20606	1.51388	-2.97448	3.38660
	Equal variances not assumed			.132	14.614	.897	.20606	1.55895	-3.12441	3.53653

Physical Activity (BLD Questionnaire)

Group Statistics of change in health behavior in standard BLD and BLD with LIFT programs

	BLD only OR BLD and LIFT identifier	N	Mean	Std. Deviation	Std. Error Mean
In the past 3 months, how many days a week did you usually track how much you walked or exercised?	BLD Only	14	.7143	2.12779	.56867
	BLD AND LIFT	10	1.2000	2.82056	.89194
In the past 3 months, how many days a week did you usually walk or exercise?	BLD Only	15	.6667	3.30944	.85449
	BLD AND LIFT	14	.4286	2.06488	.55186

Independent Samples Test of change in health behavior in standard BLD and BLD with LIFT programs

	Levene's Test for Equality of Variances	t-test for Equality of Means

									95% Confidence Interval of the Difference	
		F	Sig.	t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	Lower	Upper
In the past 3 months, how many days a week did you usually track how much you walked or exercised?	Equal variances assumed	1.126	.300	-.482	22	.635	-.48571	1.00824	-2.57668	1.60525
	Equal variances not assumed			-.459	15.976	.652	-.48571	1.05780	-2.72842	1.75700
In the past 3 months, how many days a week did you usually walk or exercise?	Equal variances assumed	1.061	.312	.230	27	.820	.23810	1.03332	-1.88209	2.35828
	Equal variances not assumed			.234	23.678	.817	.23810	1.01721	-1.86283	2.33902

Group Statistics of change in self-efficacy in standard BLD and BLD with LIFT programs

	BLD only OR BLD and LIFT identifier	N	Mean	Std. Deviation	Std. Error Mean
How sure are you that on most days you can walk or exercise?	BLD Only	13	.0769	.86232	.23916
	BLD AND LIFT	12	.3333	1.07309	.30977
How sure are you that on most days you can walk or exercise when you have other things to do?	BLD Only	14	.0714	.82874	.22149
	BLD AND LIFT	10	.4000	.69921	.22111
	BLD Only	13	-.1538	1.46322	.40583

How sure are you that on most days you can keep track of how much you walk or exercise?	BLD AND LIFT	11	.2727	1.10371	.33278

Independent Samples Test of change in self-efficacy in standard BLD and BLD with LIFT programs

		Levene's Test for Equality of Variances		t-test for Equality of Means						
									95% Confidence Interval of the Difference	
		F	Sig.	t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	Lower	Upper
How sure are you that on most days you can walk or exercise?	Equal variances assumed	1.401	.249	-.661	23	.515	-.25641	.38785	-1.05875	.54593
	Equal variances not assumed			-.655	21.138	.519	-.25641	.39136	-1.06996	.55713
How sure are you that on most days you can walk or exercise when you have other things to do?	Equal variances assumed	.376	.546	-1.020	22	.319	-.32857	.32227	-.99692	.33978
	Equal variances not assumed			-1.050	21.286	.306	-.32857	.31296	-.97889	.32174
How sure are you that on most days you can keep track of how much you walk or exercise?	Equal variances assumed	.431	.519	-.794	22	.436	-.42657	.53752	-1.54133	.68818
	Equal variances not assumed			-.813	21.758	.425	-.42657	.52482	-1.51569	.66254

Dietary Behaviors (BLD Questionnaire)

Group Statistics of change in health behavior in standard BLD and BLD with LIFT programs

	BLD only OR BLD and LIFT identifier	N	Mean	Std. Deviation	Std. Error Mean
In the past 3 months, how many days a week did you usually track what you ate?	BLD Only	14	.2143	3.23867	.86557
	BLD AND LIFT	12	.5000	3.08957	.89188
In the past 3 months, how many days a week did you usually eat 5 servings of fruits and vegetables?	BLD Only	15	.8000	2.24245	.57900
	BLD AND LIFT	12	.2500	2.76751	.79891
In the past 3 months, how many days a week did you usually eat 3 servings of whole grains?	BLD Only	13	1.0000	3.74166	1.03775
	BLD AND LIFT	11	.9091	3.14498	.94825
In the past 3 months, how many days a week did you usually eat 3 servings of milk or dairy or other foods high in calcium?	BLD Only	13	.4615	2.47034	.68515
	BLD AND LIFT	11	.0000	1.94936	.58775
In the past 3 months, how many days a week did you usually use the Plate Method?	BLD Only	14	.9286	2.09263	.55928
	BLD AND LIFT	10	2.4000	3.23866	1.02415

Independent Samples Test of change in health behavior in standard BLD and BLD with LIFT programs

	Levene's Test for Equality of Variances		t-test for Equality of Means						
								95% Confidence Interval of the Difference	
	F	Sig.	t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	Lower	Upper

In the past 3 months, how many days a week did you usually track what you ate?	Equal variances assumed	.140	.712	-.229	24	.821	-.28571	1.24755	-2.86052	2.28909
	Equal variances not assumed			-.230	23.694	.820	-.28571	1.24285	-2.85258	2.28115
In the past 3 months, how many days a week did you usually eat 5 servings of fruits and vegetables?	Equal variances assumed	.242	.627	.571	25	.573	.55000	.96328	-1.43390	2.53390
	Equal variances not assumed			.557	21.031	.583	.55000	.98666	-1.50168	2.60168
In the past 3 months, how many days a week did you usually eat 3 servings of whole grains?	Equal variances assumed	.040	.843	.064	22	.950	.09091	1.42695	-2.86840	3.05022
	Equal variances not assumed			.065	22.000	.949	.09091	1.40574	-2.82441	3.00623
In the past 3 months, how many days a week did you usually eat 3 servings of milk or dairy or other foods high in calcium?	Equal variances assumed	.284	.600	.501	22	.621	.46154	.92117	-1.44885	2.37192
	Equal variances not assumed			.511	21.917	.614	.46154	.90271	-1.41097	2.33405
In the past 3 months, how many days a week did you usually use the Plate Method?	Equal variances assumed	4.728	.041	-1.355	22	.189	-1.47143	1.08590	-3.72345	.78059
	Equal variances not assumed			-1.261	14.289	.228	-1.47143	1.16691	-3.96947	1.02662

PAM (Patient Engagement)

Group Statistics of change in patient engagement in standard BLD and BLD with LIFT programs

	BLD only OR BLD and LIFT identifier	N	Mean	Std. Deviation	Std. Error Mean
PAM Score	BLD Only	16	.3688	8.42090	2.10523
	BLD AND LIFT	13	-2.7692	16.91579	4.69160
PAM Level	BLD Only	16	.0625	.77190	.19298
	BLD AND LIFT	13	-.2308	1.09193	.30285

Independent Samples Test of change in patient engagement in standard BLD and BLD with LIFT programs

		Levene's Test for Equality of Variances		t-test for Equality of Means						
									95% Confidence Interval of the Difference	
		F	Sig.	t	df	Sig. (2-tailed)	Mean Difference	Std. Error Difference	Lower	Upper
PAM Score	Equal variances assumed	2.670	.114	.651	27	.520	3.13798	4.81910	-6.75000	13.02597
	Equal variances not assumed			.610	16.775	.550	3.13798	5.14228	-7.72238	13.99835
PAM Level	Equal variances assumed	1.601	.217	.846	27	.405	.29327	.34646	-.41761	1.00414
	Equal variances not assumed			.817	20.959	.423	.29327	.35910	-.45362	1.04016

Appendix W:Qualitative Supplementary Documents

Table 1
Data extracts with codes applied

Data Extract	Coded for:
"..so if our class fell during the time that they happen to be at a doctor's appointment or be able to get taken to the eye doctor or something like that then they certainly were going to take those opportunities, because that was their only opportunity to do that…and even things not medical related like going to the grocery store."	**Group Cohesion**
"There were some of them towards the end that were just like "I don't want to come today."	
"Because you don't have people attending, so then the people who are attending, you're not getting that group cohesion because you don't really have a group."	
"So just competing health challenges that made it hard for them to continue participating."	
"So maybe they normally came on Tuesdays and the we had moved them to coming on Mondays and they were like "I don't want to be here on Mondays…I have other things that I like to do on Mondays."	
"I had a very active group (LIFT)."	
"This group bonded very well…they were supportive of each other."	
"I created the phone tree so that they could talk to each other in between LIFT and on the weekends, to either have a walking group or something, and they were very receptive."	
"I'm not sure that they had as much control over their lives to make decisions about their behavior change."	**Lack of Autonomy**
"But again, this group, a lot of them told me "I don't cook for myself"…so a lot of folks in our group were not necessarily making a lot of their own food decisions."	
"There were a few people whose schedules got changed and they definitely let me know they weren't happy	

about it…so again, I'm not sure that those participants got to make those choices as much." "They had power of attorney or something like that and they wanted their children to read over the information before they could sign."	
"But also, they struggled to do a lot of things that we were asking them to do, even if we were doing adaptations and stuff…we had people with really bad shoulders or who needed a walker to be able to stand." "LIFT itself, I mean, I tried to stick pretty close to the recommendations…again a lot of people had mobility issues…these folks, we sat down to do arm curls and that kind of stuff just because a lot people weren't real steady on their feet." "They (LIFT class) usually ran shorter because they were more like 45 minutes." "We used weights and I did have to modify some of the exercises for a client, a participant that was wheelchair bound." "The only other modification was the first week, I didn't have access to the weights, so we did the exercises without the weights." "We probably had maybe an hour and 15 minutes because we had a lot of conversation."	**Modifications and Adaptations to LIFT**
"…the biggest change was that we definitely had to shorten it right? Because the time that people go there kept being later and the time we needed to be out, because this was a common area that they used for other things, so we definitely had to abbreviate things." "We didn't spend as much time showing the food demo…we just didn't have enough time to dedicate to it." "We were doing the food demo as "here try this food" rather than, "here's how you can make it at home." "A lot of people came in late right? Generally, I think we started and tried to do it within an hour and a half."	**Modifications and Adaptations to BLD**

"We did have an occasion where it did not offer the sample and that was because there was only one of us there."	
"I know with the Keysville one, we may have had to shorten it maybe about 20 to 30 minutes just because they started lunch earlier than the other program."	
"It's face to face so I handed them out."	**Retention Plan Format**
"I distributed them after that week's class so whatever week that was, on the second day of our class I'd distribute those materials for them and the we followed up at the next class."	
"I think I may have started it (the retention plan) a little bit sooner than I was supposed to. I'm not sure but they got all the retention plan."	
"…but I did not change anything on the materials themselves, no."	
"I went to the site to deliver (the retention materials)."	
"I went they way it (the retention plan) was designed to be done."	
"…I went to Charlotte County just to deliver the materials, and have a face-to-face conversation with the participants, and went over if they had any questions about what they were receiving, and just made that connection."	**Retention Plan follow-up**
"I don't know if they were read. I don't know how much they were utilized but I definitely sent them home."	
"…any retention materials outside of that (BLD), I'm not sure if they are actually reading them, because there's really no way to tell unless you pick up the phone and call them if you have their number…"	
"I think exercise was pretty low on the priority list for many of them."	**Participants' attitudes/perceptions toward LIFT**
"I feel that they participants enjoyed it."	

"The ones who were willing to go through and were very in tune with wanting to do something better stuck with it."	
"Because I was working out, I didn't hurt myself."	
"They were being provided transportation, which we know can sometimes be an issue in our community."	**Resources**
"We knew that folks were already coming there to get many of their medical services, so they had a dietitian, doctors, nurses on staff that could really identify people in the program that needed the BLD."	
"I really wish, especially for this type of senior group, that there would've been a way to bring in family members to BLD with them because I just got the impression that, like I said, so many of them weren't really making their own food choices."	
"And so, I think being able to incorporate more family support and get them on the same page would be a recommendation if you're dealing with the senior population that really is much higher need in the care that they're receiving."	
"So, I had Master Food Volunteers help me during the class (BLD) and then for some weeks, I had the dietetic interns."	
"The participants had transportation or transportation was provided to the location, which was a good part in having them be consistent."	
"I definitely would suggest that if they're doing the LIFT together with the BLD that maybe they have another either volunteer or agent to assist."	
"She (another Extension Agent) worked on the food demonstration and I worked on the presentation component."	
"Right around the beginning of LIFT schedules changed because the days that we had LIFT was not necessarily the days that all of our participants normally were at the center."	**Program Logistics**

"…it seemed like there was ongoing confusion about when they were supposed to be there when they weren't so that was a challenge."	
"Starting (LIFT) directly after BLD I think was a good cause, but it does take some planning and preparation for that extended class."	
"There were some challenges trying to get the paperwork back and the information that we needed, and the authorization of the doctor."	
"The challenge that I had with Victoria was the physician in the area right before the classes started was moving her practice, and it was hard for them (participants) to gain access to a physician to authorize them (for LIFT)."	
"I think it's a good idea (BLD + LIFT), but everyone need to know their role…I think we were having problems there.	
"I think by it being a random doing, it was kind of confusing to all of us because we didn't know the site…both of them was looking forward to it (LIFT) and we couldn't tell them anything because we didn't know."	
"Get the information in before you're ready to start and you could just go right in."	
"But I definitely would suggest that if they're doing the LIFT together with the BLD that maybe they have another either volunteer or another agent to assist."	
"So, to just prep for the class (BLD) itself I would say was maybe two hours a week and then you have to add another hour for the produce thing…I would say it's more like three hours a week."	**Time commitment**
"I mean in the beginning, it (LIFT) probably took me closer to two hours because I was getting used to it…by the end, it was more like an hour."	
"The restrictions for time travel probably, they wouldn't be as restrictive, because it took me about 45 minutes to get to that particular site, whereas if it was at a closer	

location, I might be more willing to do it (BLD + LIFT) on a long term basis.

"Yes, it was a big commitment of time but to me it was worth it."

"Because I've done it before, it would probably take me up to on the generous side an hour, just to make sure I had copies."

"Again it (LIFT) was probably about an hour with copying time and making sure I was familiar with the exercises and the process."

"I think it's really good together."

Benefit of BLD + LIFT

"I think BLD is effective in and of itself…like I said, I think LIFT can really be good for those folks who want to continue to be in a group and have something that keeps them all connected."

"So one of the early weeks of LIFT, we were talking about why exercise is important to you and his (BLD + LIFT participant) comment was that he has to stay healthy because he wants to be able to walk and go see his wife every day."

"When we got up to being able to do 12 reps and stuff, you could tell she (BLD + LIFT participant) was proud of herself …she was like oh in the beginning, I remember we did six and now I can do 12."

"I just felt that the benefits of doing the BLD with the LIFT, my particular participants were very engaged, and I felt that it was an enhancement to it."

"They to me were stronger, so I know that they were doing their exercises, because they worked me."

"The girl in the wheelchair said she had fallen but she didn't hurt herself so I'm thinking by having more movement, being a little more flexible, that she was able to pick herself back up out of the chair."

"I think it's a good idea to put both of them together, especially working with our seniors."

"Going through the Balanced Living with Diabetes Program, is it's such a good program for communities…but with seniors, the LIFT program is also important because they need to eliminate a lot of falls and things like that to strengthen them."

Figure 1: Initial Thematic Map

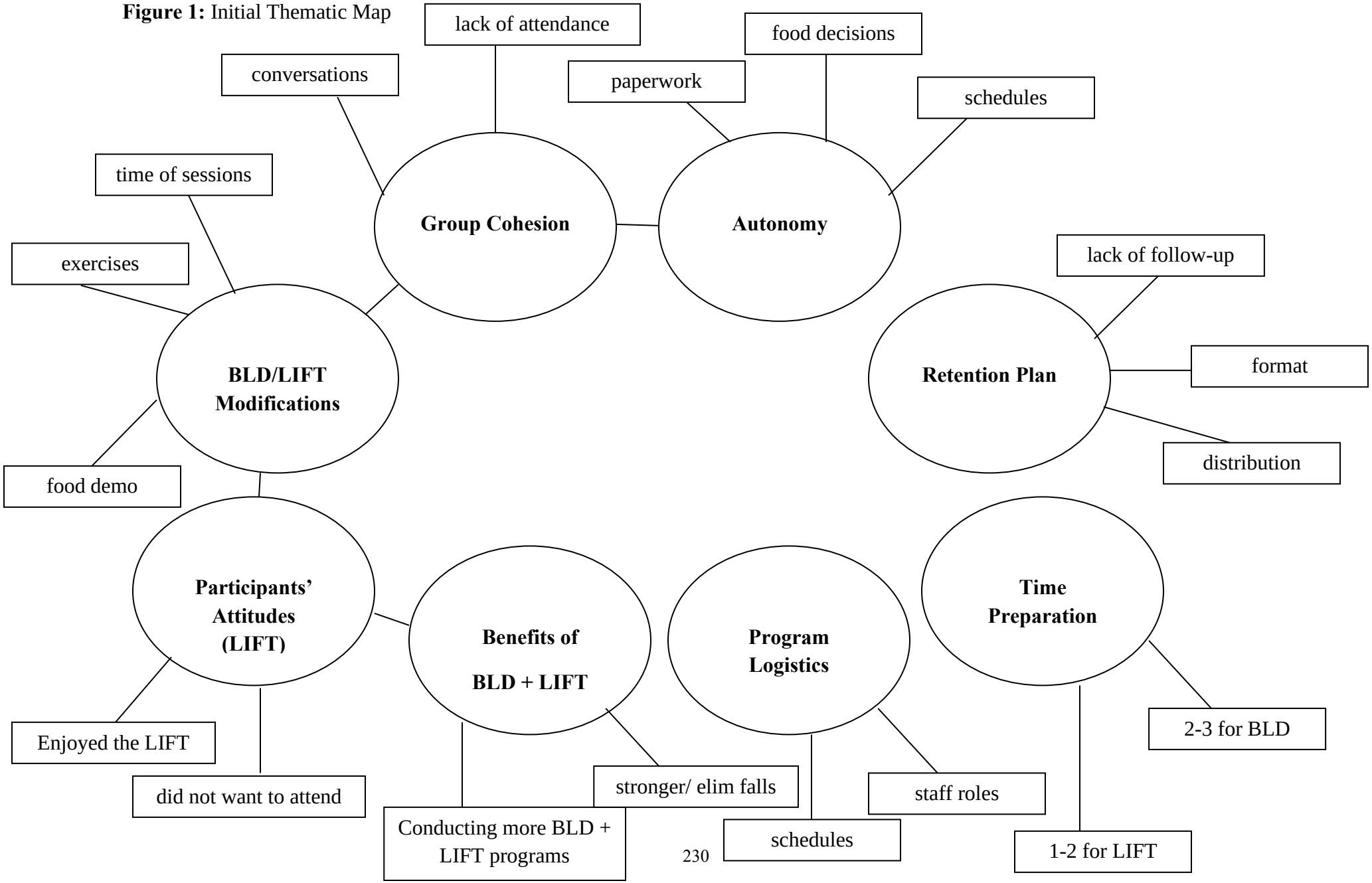


Figure 2: Final Thematic Map