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OUTCOMES OF PREDIABETES AND DIABETES EDUCATION PROGRAMS TAILORED FOR VULNERABLE POPUATIONS

by

Diana Al Sayed Hassan

A dissertation submitted to the Graduate College
in partial fulfillment of the requirements
for the degree of Doctor of Philosophy
Interdisciplinary Health Sciences
Western Michigan University
December 2015

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OUTCOMES OF PREDIABETES AND DIABETES EDUCATION PROGRAMS TAILORED FOR VULNERABLE POPUATIONS

Diana Al Sayed Hassan, Ph.D.

Western Michigan University, 2015

Diabetes is a debilitating disease and if not managed properly it can lead to multiple complications and even premature death. Diabetes continues to disproportionately affect vulnerable populations. The purpose of this three-paper method dissertation was to examine the implementation of a prediabetes and diabetes programs in a community setting to serve vulnerable populations in addition to understanding future diabetes-related educational needs.

The first paper is an evaluation of a shortened five-week diabetes prevention program for older adults with prediabetes or at a high risk for developing type 2 diabetes mellitus (T2DM). Chang in nutrition knowledge, eating and physical activity behaviors, and weight were the main outcomes of this study. Participants lost a statistically significant amount of weight over the course of six-months and increased their nutrition knowledge significantly. Participants also reported a statistically significant increase in the amount of vegetables intake in addition to their amount of daily vigorous physical activity.

The second paper examined changes in knowledge, weight, and A1c as the main outcomes of a shortened diabetes-self management education (DSME) program called IDEAS. IDEAS was a one-time, four-hour program delivered at a patient-center medical

home that served primarily low-income individuals. There was a statistically significant increase in participants' knowledge on T2DM. Clinical outcomes included weight and A1c. Participants' weight loss was not statistically significant; however it was clinically relevant. The main outcome of the study was the statistically significant improvement of participants' A1c levels.

The third paper, examined referral rates to an American Diabetes Association accredited DSME program and hours of attendance this program for patients newly diagnosed with T2DM that attended the same clinic mentioned in paper II. The study found that referral rates to DSME programs were low. In fact, only a little over half of the newly diagnosed patients received a formal referral. Furthermore, almost half of those referred did not attend a DSME program. A main outcome of the study is that patients who attended the one-hour assessment at a DSME program and patients who almost completed the DSME program (8 or more hours) had a statically significant similar improvement in their A1c levels.

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Dedicated to my precious children: Jana, Isam, and Zaid. I love you to the moon and back.

ACKNOWLEDGEMENTS

I would like to express my deepest gratitude to my advisor Dr. Amy Curtis for her continuous mentoring, guidance, and patience. My research would not have been possible without her help and the help of my committee members; Dr. Jean Kerver and Dr. Eric Vangsnes who have supported my research and provided me with continuous encouragement and guidance.

I would like to thank my coworkers at Michigan State University Extension and all my friends for supporting my research and studies.

I would also like to thank Allen Foundation, Blue Cross Blue Shield Foundation of Michigan, Michigan Department of Health and Human Services for funding my research. I would like to thank Van Buren County administration, Western Michigan University School of Medicine, for their collaboration and support. Most importantly I would like to thank all of the participants who agreed to be a part of my research.

I want to thank the most important people in my life whom without their unconditional love and support, I would have not made it this far: My amazing mom, my loving dad who sadly is not with us any more, my brother, my precious children, and my in-laws. Last but not least, I want to thank my loving and supportive husband who stood by my side every step of the way.

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CHAPTER I

INTRODUCTION

Over the past 20 years there has been a dramatic increase in the prevalence of diabetes. In fact, diabetes rates have almost doubled from 5.5% in the late 80s and early 90s to a rate of 9.3% in 2012 (Selvinn et al., 2014, & CDC, 2014) . Diabetes Mellitus is a group of ADA, chronic metabolic conditions characterized by elevated blood glucose levels due to the body's inability to produce sufficient insulin, resistance to insulin action, or both (Deshpande, Harris-Hayes, Schootman, 2008). Only five percent of individuals with diabetes have type 1 diabetes, which is an autoimmune disease, while type 2 diabetes mellitus (T2DM) accounts for the rest. This dissertation is about the prevention and self-management of T2DM.

Before an individual develops T2DM, the individual may be diagnosed with prediabetes; an intermediate condition that exists when a person's blood glucose level is higher than normal but not high enough to be diagnosed with T2DM (American Diabetes Association, 2013) and similar to diabetes, rates of prediabetes diagnosis have been increasing. There are three diagnostic tests
used in prediabetes and T2DM diagnosis. These test are fasting plasma glucose (FPG), glycosylated hemoglobin (A1c) and the two-hour oral glucose tolerance test (ADA, 2015). The most common test used for non-pregnant adults is the A1c test. A1c is a blood test that provides information about a person's average levels of blood glucose over the past three

months (National Institute of Diabetes and Digestive and Kidney Diseases, 2015). The criteria of diagnosing prediabetes is an A1c level between 5.7% and 6.4% and 6.5% or over for T2DM (ADA, 2015). The ADA also recommends that individuals with diabetes maintain an A1c value below 7.0% (2015).

Prediabetes can be reversible through lifestyle changes. However, if action is not taken, 15-30% of individuals with prediabetes will develop T2DM at some point in their lives (National Diabetes Prevention Program, 2013). T2DM is a debilitating disease that can affect quality of life of the individual affected if not managed properly (Franks, 2012). Complications from diabetes include retinopathy, nephropathy, neuropathy, cardiovascular issues, (Colwell, 1998; Forth & Jude, 2011; Deshpande, Harris-Hayes, Schootman, 2008) and even premature death (Franks et al., 2012).

Because of these serious complications, it is best to prevent (or last least delay the onset of) diabetes. There are known risk factors for T2DM some of which are unmodifiable; such as genetic predisposition, age, and being of certain race or ethnicity such as African American, Hispanic, or Native American (Haffner, 1998; ADA, 2015). The remainder of risk factors, however, are modifiable lifestyle-related factors that include physical activity level and weight (Lindstrom & Tuomilehto, 2003). Obesity has been found to be a major risk factor in the development of prediabetes (Khaodhiar, Cummings, & Apovian, 2009) and T2DM in both women and men (Colditz et al., 1995 & Chan et al., 1994). As rates of obesity have been on the rise, subsequently an increase in prediabetes and T2DM rates have been reported (Khaodhiar, Cummings, & Apovian, 2009). Obesity has been directly linked to insulin resistance. Therefore, weight loss achieved by an individual with prediabetes or T2DM will improve their insulin sensitivity

(Schencket al., 2009 & Mason et al., 2011), which in turn can lead to an improved metabolism of glucose that can lead to a reduction in A1c levels (Saudek and Brick, 2009). Although the association between physical activity (when examined independently) and T2DM incidence remains unclear (Yates et al., 2007), physical activity when paired with weight loss has been shown to prevent T2DM in individuals with prediabetes and prevent T2DM-related complications in those diagnosed (Gill and Cooper, 2008).

Prevention of T2DM in older adults

It is estimated that 50% of older adults have prediabetes. In addition, obese older adults are more likely to suffer from many other complications and chronic conditions other than diabetes such as some cancers, cognitive decline, and increased admission to nursing homes if necessary preventive measures are not taken (Felix & West, 2013 & Kirkman et al., 2012, & Klein et al., 2004).

A landmark clinical study, the Diabetes Prevention Program (DPP), examined if weight loss and increased physical activity through a lifestyle intervention or treatment with metformin could prevent or delay the onset of T2DM in study participants (DPP research group, 2002). Metformin is a type of medication that helps control glucose levels and decreases the rate of conversion from prediabetes to T2DM (Lilly & Godwin,2009). The study found that individuals in the lifestyle program and in the metformin group were both successful at preventing or delaying the onset of T2DM. In fact, participants in the lifestyle group decreased their incidence of diabetes by 58% compared to 31% in the metformin treated group (DPP Research group, 2002). The study specifically found that participants who lost 5-7% of body weigh and exercised 150

minutes at a moderate level were able to prevent or delay the onset of T2DM. The study also found that adults over the age of 60 were more successful in losing weight and preventing or delaying the onset of type II diabetes compared to participants in other age groups (Dunkley et al., 2012, Ackermann, et al., 2008).

Although the DPP study demonstrated that modifying certain lifestyle habits can slow down the progression of T2DM or even prevent it, the study was very long and included intensive one-on-one coaching (DPP research group, 2002). In addition, it was estimated the cost per participant in the first year of the DPP was about $1,399 (Ali, Echouffo-Tcheugui, & Williamson, 2012). It is questionable (unclear) There have been questions on how implementing a long and expensive program can work in targeting older adults in a rural community setting. To address these isssues, a tailored program based on the core curriculum of the DPP was developed to reach disproportionately affected older adults who may not be able to attend the full year-long DPP.

Prevention of T2DM complications in low socioeconomic status (SES) populations

In addition to prediabetes, studies have shown that complications of T2DM can be prevented through diabetes self-management education (DSME) aimed at improving patients' diabetes related outcomes. The American Diabetes Association offers guidelines to DSME programs and an accreditation status (Maryniuk, Bronzini, & Lorenzi, 2004). Currently, Centers for Medicare and Medicaid will reimburse up to 10 hours of education in the first year of diagnosis of which the first hour is an assessment in addition to two hours per year each following year (Powers et al., 2015).

Multiple studies have found that retention rates in ADA-DSME ranged between 20% and 50% (Sarkisian et al., 2003, & Klein et al., 2013, & Norris et al., 2002)

specifically among low SES individuals, the underinsured, or Medicaid recipients who are most at risk for diabetes complications (Harris, 1999). Additionally, many of these DSME programs do not particularly cater to this population that is more likely to be transient, have less health knowledge and is likely to have barriers to attendance. There is a lack of studies examining if this high-risk population is getting DSME and if outcomes are similar to results under study conditions.

Diabetes is a burden on public health. Not only does it have a toll on individuals affected by it and their families, but it's also a costly epidemic. The ADA estimated that in 2012, the total cost of diagnosed diabetes was $245 billion, including $176 billion in direct medical costs and $69 billion in reduced productivity (ADA, 2013). One of the culprits of prediabetes and diabetes is the fact that symptoms are delayed and many may have the disease and not know it. It is estimated that nine out of 10 people with prediabetes do not know they have it (CDC, 2015) allowing it to progress to diabetes unchecked. Additionally, almost 28% of those with T2DM are undiagnosed (CDC, 2015). Hence, community educational programs that focus on prevention and self-management are crucial not only in combatting the increasing numbers of diabetes and its complications, but also to reach those vulnerable high-risk individuals who are disproportionately affected by it.

Research questions

To determine if prediabetes and diabetes programming can be offered to vulnerable populations and to understand future educational needs, I examined the following in a three-paper dissertation format:

1) Changes in diabetes knowledge and weight after participation in a shortened

prediabetes program targeting older adults (Paper 1, Chapter 2)

2) Changes in diabetes knowledge and glucose (A1c) for those with diabetes after participation in a shortened diabetes education program among a family practice clinic serving primarily low income patients (Paper 2, Chapter 3)

3) Referrals and hours of attendance at an ADA-accredited diabetes programs for persons with newly diagnosed diabetes that attended the same clinic as above (Paper 3, Chapter 4).

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CHAPTER II

OUTCOMES OF A SHORTENED DIABETES PREVENTION PILOT PROGRAM OFFERED TO OLDER ADULTS IN SOUTHWEST MICHIGAN

According to the Centers for Disease Control and Prevention (CDC), during the past 20 years there has been a dramatic increase in obesity rates in the United States (Ogden, Carroll, Kit, & Flegal,K., 2012). There has also been a simultaneous increase in diabetes rates, which is currently affecting more than 8.3% of the US adult population, with the highest prevalence among those aged 65 years or older (National Diabetes Fact Sheet, 2011). According to the CDC, the prevalence of type 2 diabetes mellitus (T2DM) among this age group is approximately 26.9%, which is equivalent to 10.9 million Americans (2011). It is estimated that the rate of diabetes will increase 64% between 2010 and 2025 (Rowley & Bezold, 2011). Obesity and lack of physical activity are major contributors to these alarming rates, which in turn can lead to an increase in body fat, which has been linked to diabetes (Dunkley et al., 2012).

Diabetes is a complex disease with multiple factors affecting its development and thus health programming has been aimed at both the pre-disease (prediabetes) and disease states (diabetes). Before an individual develops diabetes, the individual may be diagnosed with prediabetes; a condition that exists when a person's blood glucose level is higher than normal but not high enough to be diagnosed with T2DM (American Diabetes Association, 2013). Individuals with prediabetes are more susceptible to developing type

II diabetes over time if action to lose weight is not taken (ADA, 2013). As with diabetes and obesity, older adults have the highest prevalence of prediabetes (Chi, J., Lee, Y., & Wu, S., 2011). It is estimated that 50% of older adults have prediabetes and it is predicted that 15-30% of individuals with prediabetes will develop T2DM (National Diabetes Prevention Program, 2013). Older adults who are obese are likely to suffer of many other complications and chronic conditions other than diabetes such as some cancers, cognitive decline, and increased admission to nursing home if necessary preventive measures are not taken (Felix & West, 2013 & Kirkman et al., 2012, & Klein et al., 2004).

Despite the increased risk of diabetes and its complications, new health promotion and prevention programs catering to the older adults are developed less often and offered less frequently than in younger age groups (Flack et al., 2010) and the focus of prevention programs is usually geared towards the youth and younger adults (Felix & West, 2013). However, results from the National Diabetes Prevention Program (NDPP) indicate that adults over the age of 60 were more successful in losing weight and preventing or delaying the onset of T2DM compared to participants in other age groups DPP research group, 2002. Across all age groups, the NDPP study found that the incidence of diabetes dropped by 58% in those with prediabetes who achieved a 5-7% weight loss and increased their physical activity time to 150 minutes per week (Dunkley et al., 2012). Numerous similar interventions have been developed to prevent diabetes; however, most of these intensive interventions are long and expensive, and retention is a challenge (Curtis, Edson, & Sierra-Johnson, 2009). Additionally, the delivery cost of the NDPP was estimated to be $1,399 per person in the first year due to the resources offered participants, ranging from meal replacements to gym memberships (Ali, Echouffo-

Tcheugui, & Williamson, 2012). Smaller scale community-based interventions may be able to reach many individuals and can be personalized to support participants in their lifestyle-changing process that targets weight loss at a much lower cost (Curtis, Edson, & Sierra-Johnson, 2009). Although the NDPP was a successful program, it was not being implemented or available in the local community, perhaps due to these logistical issues mentioned above. That, in addition to the lack of prevention programs available to older adults who are at a higher risk for developing type 2 diabetes, motivated us to implement and evaluate a shorter diabetes prevention program developed by the Michigan Department of Community Health (MDCH).

In this study, we evaluated an intervention that utilized the MDCH five-week program, called the Michigan Diabetes Prevention Program (MDPP), that was modeled on the National Diabetes Prevention study. The program aimed at measuring knowledge and behavior change. Research questions were: Do older adults participating in the MDPP:

1. Lose weight;
2. Change their eating and physical activity behaviors; and
3. Gain knowledge related to nutrition. To our knowledge, this study is the first evaluation of this program implemented among older adults in a community setting.

Method

Participants

This pilot intervention aimed at evaluating an existing program in a community setting and utilized a nonrandomized one-group design with pre and post measures. The program was implemented at various sites in multiple communities in southwest

Michigan including six community centers, three senior apartments, two faith-based sites, and one worksite. The Human Subject Institutional Review Board at Western Michigan University approved this study. Informed consent was obtained from all participants in the program at the time of enrollment. The main goal of the MDPP is for participants to lose an average of 1-2 pounds a week to prevent or delay the onset of type II diabetes through adopting healthful nutrition practices and increasing their physical activity levels (Dunkley et al., 2012). In this study, 87 participants initially started the program. Exclusion criteria from this study, but not from the program, included participants who had existing type II diabetes (n=17) or had no diabetes risk factors and were younger than 45 (n=13). The remaining 57 participants were at risk for developing type II diabetes according to the ADA diabetes risk survey (included in index). Participants were screened at the beginning of the program using the American Diabetes Association (ADA) risk test, which is a pencil and paper test. This test is usually used for educational purposes in community settings. However, this test is not used to clinically diagnose prediabetes or diabetes (ADA, 2013). The risk test includes the questions regarding the major risk factors for diabetes: Genetic predisposition, age, sex, being overweight or obese, high blood pressure, not being physically active, or a prior diagnosis of gestational diabetes. The ADA (2014) recommends anyone over the age of 40 to take the risk test. Participants who missed two or more session were excluded from the study (n=4). Leaving us with 53 participants included in the study.

Program

The intervention included five weekly one-hour sessions with a sixth follow-up session at six months post completion of the program. Program sessions included

information on diabetes and the importance of preventing and delaying its onset, nutrition education focusing on reducing fat, physical activity, goal setting, and modifying personal environment to support behavior change. The intervention focused on assisting participants to set realistic goals towards healthy lifestyle changes through nutrition and physical activity education. The purpose of six-month follow-up session was to offer support to participants to maintain changes.

Two professional educators from Michigan State University Extension, trained in the MDPP curriculum by MDCH, delivered the program in assistance with a nurse and a clinical student who collected weight at baseline, and at the end of the five-week program. In addition, nutrition knowledge and behavior measures were also collected at the first and last session of the MDPP. Senior leaders from the community assisted in the recruitment process and assisted with the logistics of the program.

Measures

Demographic information including gender, age, education, income, race, and place of residence, in addition to height (measured in inches), were collected at the beginning of the program. The primary outcome of this study was weight loss, which was measured at baseline, after the five-week intervention, and at the six-month follow-up session. Weight was measured in pounds using HealthOMeter 349KLX digital medical scale. Secondary outcomes of the study included assessments of nutrition knowledge, eating and physical activity habits. Nutrition knowledge was assessed by utilizing the *Nutrition Knowledge Questionnaire.* This questionnaire was developed by Hawkes and Nowak (1998) and was shown to be a reliable and valid measure for cardiac patients (Hawkes & Nowak, 1998). The survey focuses on low-fat diet as an approach to weight

loss. According to Bradley et al. (2009), low-fat diets prevent type II diabetes in those at risk as opposed to low-carbohydrate diets that can be reciprocally higher in fat, which can hinder weight loss. Individuals who are at a high risk for developing type II diabetes are encouraged to follow a low-fat diet; a recommendation that is in line with the NDPP recommendations and the MDPP curriculum content (NDPP Training Curriculum, 2014; MDPP curriculum, 2010). The survey consists of 10 multiple-choice questions revolving around three main areas: fat content, cholesterol content, and fiber content in relation to weight loss. Nutrition knowledge was calculated by the sum of scores for the 10 questions; a score of 0 was entered for the incorrect answer and for answering "not sure". A score of 1 was entered for a correct answer. The maximum possible amount of points was 38.

A behavioral measures survey was utilized to assess eating and physical activity habits and data were collected at baseline and after the five-week intervention. The survey, which accompanied the MDPP curriculum, consists of eight questions that measure the frequency of eating fruits, vegetables, and whole grains and engaging in moderate and vigorous physical activity. For fruit and vegetable intake, participants were asked how often they eat these foods per week with choices ranging from 0 to 6-7 times per week. For whole grain intake, participants were given five choices ranging from 0 to 4 or greater times per week. For physical activity, participants were given four choices ranging from 0 to 5-7 times per week. Moderate physical activity was defined as engaging in brisk walking, recreational swimming, bicycling, weight lifting, scrubbing floors, or washing windows for at least thirty minutes per occasion. Vigorous physical activity was defined as engaging in jogging or running, swimming laps, bicycling,

moving or pushing furniture, or circuit training for twenty minutes per occasion. The validity and reliability of the behavior measure survey, designed specifically for the MDPP curriculum, have not been verified in previous studies.

Analysis

Measures of central tendency (e.g., means, standard deviations (SD), medians) were used for descriptive analyses. A paired t-test was used to determine difference in nutrition knowledge between baseline and at the end of the five-week program. Wilcoxon signed-rank tests were used to determine the differences between behavior measures, which included ordinal items, pre and post the program. One way repeated measures ANOVA was used to determine differences in weight pre and post the program, and at the six-month follow-up session. Post hoc testing using the Greenhouse-Geisser correction was used to compare weight loss over time. An alpha level of .05 was used to determine statistical significance. IBM SPSS statistics version 19 (Armonk, NY: IBM Corp.) was used for analysis.

Results

Baseline population characteristics of the 53 participants who completed the MDPP intervention are presented in Table 1. The majority of participants were female (79.2%), white (86.4%), and had an average age of 65 (SD=14.08). At baseline, 46.9% of participants reported a diagnosis of prediabetes, 62.5% had hypertension, 6.3% had angina, 6.3% has had a stroke, and 3.1% had experienced a heart attack.

Table 2-1

Demographic Characteristics and Weight of the MDPP Participants (N=53)

Demographic characteristics	% (n) or mean ±SD
Age (yr)	64.6±14.0
Weight (lb)	194.6±51.7
Race (%non-Hispanic White)	86.4% (38)
Female	79.2% (42)
Prediabetes	46.9 (15)
Under a physician's care (For other conditions such as hypertension, stroke, heart attack, angina)	13.3 (25)

Analysis of data revealed that participants lost a statistically significant amount of weight from a mean of 194.8 lb. to 191.9 lb. (SD=4.28, $p<0.05$) within the five-week program and dropped to a mean of 181.1 lb at the six-month follow-up session (SD=10.6, $p=0.019$) for a mean weight loss of 13.7 lb. Mauchly's test indicated that the assumption of sphericity had been violated, $X^2(2)=15.6$, $p<.05$, therefore degrees of freedom were corrected using Greenhouse-Geisser estimates of sphericity ($\varepsilon= 0.58$). The results show a statistically significant weight loss over the course of 6 months (F (1.2, 15.04)= 6.2, $p=0.02$). These results suggest that weight loss at the six-month follow-up was statistically significant when compared to participants' weight at baseline.

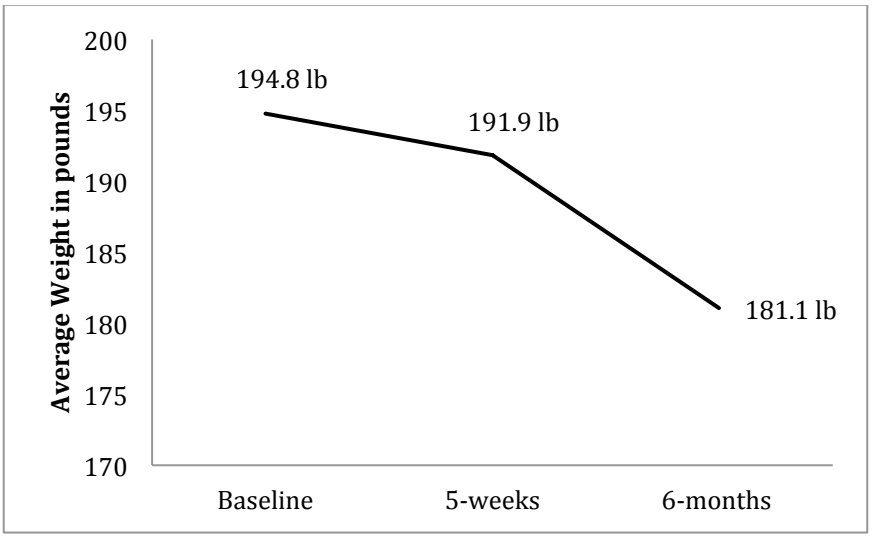

Figure 2-1 *Average weight loss over the period of 6 months*

Participants lost a statistically significant amount of weight from a mean of 194.8 lb. to 191.9 lb. (SD=4.28, $p<0.05$) within the five-week program. The results show a statistically significant weight loss over the course of 6 months (F (1.2, 15.04)= 6.2, p=0.02) when compared to baseline weight. In regards to the behavioral measures, participants showed a statistically significant increase in the reported amount of vegetable intake (Z=2.36, p=0.018) and in the amount of vigorous physical activity participants engaged in daily (Z= 2.23, p=0.026). However, no statistical significance was found for fruit and whole grains intake or for moderate physical activity. There was a statistically significant increase in the nutrition knowledge score (table 2) from a mean of 17.0 to 20.4 points (p=0.031), specifically in the subcategories fat content in foods (p=0.013) and what foods to eat less of to promote weight loss (p=0.03).

Table 2-2

Analysis of Nutrition Knowledge Before and After the Program (N=27)

Categories	Maximum possible score	Pre test (SD)	Post test	P value*
Cholesterol content	11	5.22 (3.2)	5.26 (2.7)	.959
Fat content	11	2.74 (2.3)	3.93 (2.5)	.013
Fiber content	6	3.32 (3.3)	4.08 (1.1)	.089
Food label	1	.56 (0.5)	.68 (0.4)	.185
Weight loss	9	4.44 (1.9)	5.64 (2.2)	.030
Overall assessment of knowledge	38	15.68 (8.6)	18.81 (7.4)	.030

SD Standard Deviation

**P* value by participants' t test for paired samples

Discussion

In summary in this pilot intervention of 53 individuals, the main finding is that participants lost an average of three pounds over the course of five-weeks and continued to lose an average of 11 pounds in the six months following the intervention. The average total weight loss of approximately 14 pounds equates to seven percent of total body weight, which compares favorably with national recommendations of losing five to seven percent of body weight to prevent or delay the onset of diabetes. A statistically significant increase in reported vegetable consumption in addition to an increase in reported vigorous physical activity were found in the behavioral measures survey. These behavioral changes may indicate that participants are engaging in healthy lifestyle changes that led to weight loss. Overall, participants' nutrition knowledge increased as well. However, participants' scores did not improve in the subsections of cholesterol, fiber content, and understanding the food label.

There are multiple similar interventions that focused on weight loss as a primary measure to prevent type 2 diabetes in which participants lost weight. The results of our study are comparable to these similar small-scale community interventions that reported weight loss rates anywhere between 2.5-10 lbs (Seidel et al., 2008, & Ockene et al., 2012). Our study also utilized senior leaders from the senior sites, where the program was implemented, to help with recruitment, remind participants to attend, and offer additional support to participants, which we believe led to the majority of participants completing and graduating the program at a rate of 90%, which is comparable to other similar community interventions such as the 12-week intervention conducted by Seidel et al., that had a retention rate of 88%. In another 3 month intervention of three months conducted by Mau (2010) the retention rate was also 88%. The retention rates of these shorter interventions are similar to the 24-week NDPP intervention retention rate of 93%. The NDPP incentivized participants with various resources such as meal replacements and gym memberships and was delivered in a one-to-one setting. These incentives are not feasible for future participants in most community programs. A systematic review and meta-analysis of multiple lifestyle interventions modeled on the NDPP revealed that attrition rates were not related to the length or number of sessions offered. Instead, attrition rates were related to participants' perceived risk for developing diabetes (Ali et al.,2012) If this is true, diabetes prevention programs should focus on communicating participants' future risks for developing type 2 diabetes and motivating them to change and improve their lifestyles.

There were several limitations to our study that are common in small community interventions, including utilizing a small convenience sample without a comparison

group. Another limitation was using weight and the paper diabetes risk test to identify high-risk participants. This was done due to the lack of access to the recommended clinical screening measures (e.g., two hour oral glucose test or the fasting plasma glucose test). This may have caused us to miss additional at risk participants who may have benefitted from the intervention. Also, participants had to fill out multiple forms at the beginning and end of the program including the diabetes risk test, the nutrition knowledge survey, and the behavioral measure survey that may have burdened participants and led to a low response rate in the nutrition knowledge survey. A challenge we faced was finding a validated and reliable tool to measure nutrition knowledge that aligned with the content of our program. The nutrition knowledge survey was among very few other surveys found in the literature that was a validated and reliable tool. However, multiple terminologies in the survey needed to be explained and clarified to participants, including certain types of foods commonly used in Australia, but not in the United States.

Strengths of the study include that it was a community-based intervention with local input. The more communities are invested in planning health interventions, the longer and more sustainable the results of these interventions due to the continuous support offered to participants (Shediac-Rizkallah & Bone, 1998). There were also unintended positive impacts on the seniors participating in the program and those who helped lead and facilitate it. Seniors appeared engaged, socially stimulated and most importantly awareness was raised in the community about diabetes prevention. To our knowledge, this study is the only pilot of the MDPP that demonstrates the feasibility of implementing a five-week lifestyle intervention among older adults modeled on the

NDPP with biometric measures conducted in a real-life setting as opposed to a clinical site.

Conclusion

The results of our study produced a modest, but statistically significant amount of weight loss in addition to significant nutrition knowledge gain and behavior change related to eating more vegetables and engaging in vigorous physical activity. It is important to note that participants lost an average of 0.6 pounds a week in the first five weeks of the program and continued to lose weight at the same rate during the six months follow-up. This slow, but steady weight loss rate is what is recommended for long term weight loss maintenance (Stevens et al., 2006). These results indicate that implementing a shorter version of the NDPP is feasible and may deliver comparable results if weight loss that occurred during the intervention continues during the follow up period making shorter interventions a suitable option for individuals unable to commit or attend longer programs. It is important to note that this program was created before the CDC's national efforts to standardize diabetes prevention education.

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CHAPTER III

OUTCOMES OF A DIABETES SELF-MANAGEMENT EDUCATION PROGRAM OFFERED TO VULNERABLE POPULATIONS AT A PATIENT-CENTERED MEDICAL HOME

Diabetes, a public health concern, has been on the rise. According to the CDC, approximately 9.3% of the American population was diagnosed with type 2 diabetes (T2DM) in 2012, (2014). Diabetes is a progressive disease and if it is not managed adequately, it can lead to numerous complications including retinopathy, nephropathy, neuropathy, and cardiovascular issues. (Colwell, 1998; Forth & Jude, 2011; Deshpande, Harris-Hayes, Schootman, 2008).

Growing evidence supports the importance of self-management, through diet and physical activity, to prevent diabetes-related complications in individuals with diabetes in addition to proper medical treatment (Brown, Garcia, Kouzekanani, & Hanis, 2002; Philis-Tsimikas & Walker, 2001; Diabetes Prevention Program Research Group, 2002). Furthermore, studies show that individuals who receive diabetes self-management education (DSME) have improved diabetes health outcomes (Warsi et al., 2004). Nevertheless, access to DSME is an issue among certain vulnerable populations who often need it the most, such as individuals with low socioeconomic status (SES) (Chin et al, 2001) and individuals with a low literacy level (Kemper et al. 2005). In addition to the greater incidence of diabetes, individuals of lower SES continue to suffer from more

severe complications and morbidity due to diabetes compared to those of higher SES status (Bihan et al., 2005; Grintsova, Maier, & Mielck, 2014; Chin et al, 2001). These individuals who are also disproportionately affected by the disease and its complications do not always receive quality diabetes education or adequate amounts of DSME hours (Shaw, Killeen, Sullivan, Bowman, 2011).

Even though DSME programs have been shown to be an effective tool in helping individuals manage their diabetes (Norris et al., 2002, & Norris, Engelgaw, & Narayan, 2001), attendance and retention rates in these programs continue to be a major challenge (Adams et al., 2013). In 2010, only 57.4% of adults diagnosed with diabetes ever attended a diabetes self-management program (CDC, 2014). Studies have also shown that attrition rates in DSME programs ranged between 20% and as high as 50% (Sarkisian et al., 2003, & Klein et al., 2013, & Norris et al., 2002). Studies with a longer follow-up period had even higher attrition rates; as high as 79% in one study (Siminerio, 2005). Although all the factors that impact the retention rate have not been determined (Gucciardi et al., 2007), a few surveys have shed light on these factors. A survey conducted in Maine, surveyed health care providers on their perceptions regarding barriers DSME participants faced (DSME Barrier Study, 2006). Another survey conducted in Maryland surveyed individuals diagnosed with diabetes on the barriers they face regarding attending DSME programs (Maryland's DSME survey results, 2012). Both surveys found that program length and transportation are major barriers that prevent T2DM patients' from attending DSME programs.

In addition to the previously mentioned barriers, DSME has been viewed as an alternative to a physician's clinical care creating a disconnect between physicians and

patients (Fisher et. al, 2007). Whereas, both types of education, clinical and self-management, are two complimentary steps in ensuring a successful long-term management of the patient's diabetes (Bodenheimer et al., 2002). Thus, an important supporting component of patient's diabetes self-management is the physicians' involvement in helping patients set diabetes-related goals (Lafata et al., 2012). A meta-analysis by Loverman suggests that interventions delivered by a team of multi-professional educators provides the best health outcomes for patients (2008). However, physicians in primary care practices seldom have the time to coach patients and support them through their behavior modification process (Whitlock, Orleans, Pender, & Allan, 2002).

To serve a vulnerable population in a small community in southwest Michigan, we implemented and evaluated a program; Project IDEAS: Initiative for Diabetes Education and Support to determine if having a DSME program delivered by a multidisciplinary team at a patient centered medical home (PCMH) is more accessible from a time, educational level, and literacy level perspective. Project IDEAS is not intended to replace ADA-DSME programs but to complement and fulfill the needs of patients who may not have an easy access to a DSME due to different reasons.

Methods

This is a non-randomized one-group design with pre and post measures for diabetes knowledge that aimed at evaluating the effectiveness of a DSME program delivered to T2DM patients of a patient-centered medical home (PCMH). The PCMH primarily serves low-income individuals. HSIRB approval for the study was obtained from Western Michigan University and the PCMH.

Family Medicine patients diagnosed with T2DM who exhibited poor diabetes management and were at a high risk for diabetes complications were identified and recruited by their physicians during regular check ups or clinic visits. There were nine programs offered from 2011 through 2013. Participants signed a consent form at the beginning of the program. Patients who agreed to take the class were contacted days before the program to remind them to attend. A total of 35 participants attended the program. Exclusion criteria for this analysis included no diabetes diagnosis (n=1), individuals with type 1 diabetes (n=1), repeat participant (n=1) leaving us with a sample of 32.

Program

The IDEAS program consisted mainly of a 4-hour long session, was offered quarterly, and was held at the PCMH. The session was developed based on the American Diabetes Association (ADA) standards and was built around a short cartoon video provided by the ADA called Link for Life (Link for Life, ADA, n.a.). The session consisted of 4 main topics: the basics of diabetes, complications of diabetes, nutrition & physical activity for diabetes, and medications. The program was delivered by a collaborative team of health care providers that consisted of a Family Medicine physician, a health educator, and a pharmacist. Medical charts of patients were accessed and patients were given their glycosylated hemoglobin (A1c), blood pressure, cholesterol, and triglyceride lab values in addition to a list of their current medications to increase their awareness of their current health status. This allowed participants to interact with their health care team and engage in discussions regarding their lab values, health

conditions including diabetes, and medications. Additional low literacy diabetes education materials were obtained from Learning About Diabetes, Inc.

During the first year of the program, Patient support activities such as support groups were also offered to IDEAS participants on a monthly basis. These support groups were lead by two peer health community workers who had extensive experience with diabetes.

Measures

Demographic characteristics including age (years), gender, race/ethnicity, income, and education level were collected at the beginning of the program in addition to self-reported lifestyle behaviors, and self-management practices related to diabetes. A binary question measuring patient's confidence of setting goals was included (CHECK)

A knowledge questionnaire of 10 multiple-choice questions; each question contained 4 answers, related to the 4 content areas of the program was administered pre and post the session. For each question answered correctly, the participant received 1 point with a maximum possible score of 10. Change in knowledge, a short-term outcome, was calculated as the post test score minus the pre test score. Anthropometric measures including weight (in kilograms), height (in meters), and Hgbg (%). Body Mass Index (BMI) was calculated by dividing body weight (in kilograms) by the square of height (in meters). Anthropometric measures were collected at baseline pre and post program by accessing participants' medical records.

Analysis

Measures of central tendency (e.g., means, standard deviations (SD), medians) were used for descriptive analyses. A paired t-test was used to determine difference in diabetes knowledge between baseline and at the end of the 4-hour program and was also

used to determine change in weight and HbA1c at baseline and 3 months-12 months post program.

Spearman's rho correlation coefficient was calculated to determine the correlation between ordinal measures. An alpha level of .05 was used to determine statistical significance. IBM SPSS statistics version 19 (Armonk, NY: IBM Corp.) was used for analysis. All t-test statistics were 2-tailed.

Results

Baseline characteristics are shown in table 1. The majority of participants were female (75.8%), white (63.6%), had an average age of 66 (SD=12.93), had a high school degree as their highest educational attainment (39.4%), and had a yearly income below $20,000 (48.5%). Of the participants, physical characteristics of participants include that 48.8% were obese and 36.4% were morbidly obese with a mean BMI of 38.8 kg/m^2 (SD=10.58). Baseline A1c level for participants was 7.73% (SD=2.02), a value that's above the clinical cutoff for individuals with T2DM.

Table 3-1

Demographics and Baseline Health Measures of IDEAS participants (N=32)

Demographics (N=32)	% (N) or mean ±SD
Age	56±12.93
Female	75.8% (25)
Race (%non-Hispanic White)	63.6% (21)
HbA1c (%)	7.73±2.02
BMI (kg/m^2)	
Morbidly Obese	36.4% (12)
Obese	48.5 %(16)
Overweight	9.1%(3)
Normal	6.1%(2)
Education	
High school or less	39% (13)
Some college	18% (6)
College/post-college	12% (4)
Missing	30% (10)
Income	
Less than $20,000	45.5% (15)
$20,000-$39,000	21% (7)
$40,000 or more	6% (2)
Missing	27.5% (9)

Results of the program are shown in table 3-2. Participants' diabetes knowledge related to the content of the program significantly increased from mean score of (M= 5.93) to (M=8.63), (*t,* -8.39*; p*<.001). Participants post period measurements were taken anywhere between three to 12 months for an average of 242 days (8 months). Clinical outcomes of participants included participants' weight and A1c levels. No significant change was found in patients' pre (M= 106.9) to post (M= 104.7) weight (*t*, 1.85; *p*=0.074. This change in weight, however, is clinically relevant. Analysis of data also revealed that patients' A1c levels improved significantly by -0.8% from a baseline value of 7.73% to 6.93% post program (*t,* 2.46, *p*=0.02). A spearman's rank-order correlation

was run to determine the relationship between patients abilities to set diabetes related goals and their pre and post A1c levels. We found a statistically significant negative correlation between patients' ability to set goals related to diabetes management and their pre A1c levels (r_s=-0.37, p=0.03) as well as their post levels (r_s=-0.41, p=0.02).

Table 3-2

Nutrition Knowledge and Anthropometric Values for IDEAS Participants at Baseline and Follow-up

	Baseline	Follow-up	P value*
Nutrition Knowledge	5.93	8.63	.003
Clinical Outcomes			
A1c%	7.8	6.9	.018
Weight (kg)	106.7	104.6	.067

Discussion

This study tested the feasibility and effectiveness of a 4-hour DSME program that was culturally tailored to low income and low literacy individuals with T2DM at a patient centered medical home. In this program, eventhough no statistical significance was found in weigh loss, of the 33 participants 15 were able to reduce their weight by an average of 6.9 pounds. Participants were also able to reduce their A1c to a level below the clinically significant value recommended for individuals with diabetes. According to the ADA, most individuals with T2DM should maintain an A1c level under 7% (2012).

The results of improving diabetes knowledge and lowering participants' A1c level found in our study are consistent with a few other studies. Participants in a study by Ryan et al. (2013) in which participants attended a 12-hour DSME program delivered over four

weeks with a 6-month follow-up period were able to gain knowledge in addition to significantly lowering their A1c level post the program and at the 6-month follow-up. Another study, a meta analysis, conducted by Norris et al. (2002) examined multiple DSME studies and the factors that affected the success of participants in lowering the A1c levels. The meta analysis proved the effectiveness of DSME programs in improving participants' glycemic control and it also found that educator-participant contact was the only factor that predicted effect indicating that longer interventions with more contacts may be more effective in helping participants lower their A1c. However, long interventions have lower retention rates (Adams et al., 2013) and may not be suitable for many participants who may only be able to attend a one-time program. Our results also showed that the length of the follow-up period was positively correlated to A1c levels indicating that behavior change occurs in the early stages of the program, but could change with time (Norris et al., 2002) indicating the need to offer participants follow-up or support opportunities during their behavior change process. Other studies that delivered DSME programs culturally tailored to disadvantaged populations did not find a significant reduction in A1c levels (McNeil et al., 2012; Utz et al., 2008), which could be attributed to cultural and perception differences about disease management. It is important to note that our one-time 4-hour program that was delivered in one setting, is a DSME program with the shortest time commitment compared to other DSME programs found in our literature search.

This program was delivered by a collaborative multidisciplinary team consisting of health care providers that play a major role in the patients' diabetes self-management and care plan. Having the program at the PCMH provided patients with an opportunity to

discuss their health conditions including their clinical lab values and current medications and allowed patients to set goals regarding their disease management with their health care team in a relaxed environment not constricted by time such as in a clinical or office visit. Multiple studies indicate that patients with T2DM who set goals collaboratively with their health care team, report a higher self efficacy, which has been correlated in the literature with improved clinical health outcomes, specifically a lower A1c (Lafata et al 2013, & Krichbaum, Aarestad, Buethe, 2003).

In our study, participants who had a higher self-efficacy, measured by participants' perceived ability to set diabetes-related self-management goals, consistently had a lower A1c pre and post the program. This finding is also consistent with the literature showing that individuals with a high perceived self-efficacy have better management of their diabetes. This may indicate that a vital component of DSMEs should be to focus on increasing participants' perceived self-efficacy to manage diabetes. That can be achieved through a delivery system that offers patients an opportunity to set collaborative goals with their health care provider team.

There were several limitations to our study related to recruiting participants. First, we utilized a small convenience sample without a comparison group. Implications of this limitation is that those who self-selected to be in the program could've been highly motivated to make behavioral changes. Second, the total number of patients referred to our program was not captured so we were not able to assess attendance rates. It was noticed that a more streamlined process is needed to recruit patients since there was variation in determined eligibility and recruitment among physicians. Another limitation is the wide range of the follow-up period, which ranged between three months and a year.

We had no control over that because the follow-up period for each participant was determined by their visit to the PCMH.

Conclusion

In conclusion, our program demonstrated the feasibility of implementing a short DSME program that was tailored to vulnerable populations. Participants lowered their A1c and gained knowledge in diabetes related topics indicating that a shorter program offered at the PCMH may augment patients' needs. These results indicate that DSME programs offered at the PCMH may make the program more convenient and available for participants to attend. It is well documented in the literature that certain populations are underserved due to their low SES and low literacy levels; two intertwined factors that have a complex effect on patients' access to the programs they need. Literature also shows that culturally tailored programs that accommodate these groups are beneficial in helping individuals understand the effects of their lifestyle on their diabetes clinical outcomes and in learning how to make changes.

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CHAPTER IV

DIABETES SELF-MANAGEMENT EDUCATION: REFERRAL AND ATTENDANCE AT A PATIENT-CENTERED MEDICAL HOME

Diabetes is a debilitating and progressive disease with serious, but preventable health complications (Colwell, 1998; Forth & Jude, 2011; Deshpande, Harris-Hayes, Schootman, 2008). Growing evidence supports the effectiveness of diabetes self-management education (DSME) in helping individuals with diabetes improve their health outcomes, specifically glycemic control and prevention of diabetes complications (Brown, Garcia, Kouzekanani, & Hanis, 2002; Philis-Tsimikas & Walker, 2001, & Warsi et al., 2004). Although evidence shows that DSME is an effective tool to help individuals improve their health outcomes, there remain a large number of individuals not attending DSME, whether due to barriers that limit access to DSME or lack of interest (Graziani, Rosenthal, & Diamond, 1999). Health outcomes of those with low education and/or income with diabetes remain worse than their counterparts with higher education or income (Brown et al., 2004). Understanding how frequently these individuals in regular care are receiving referrals to DSME and the number of DSME hours they are receiving is important to determine as well as the outcomes that occur when such a valuable resource is utilized.

DSME is a general term for the ongoing process of delivering diabetes-related information and knowledge that focuses on empowering individuals with diabetes to self-manage their disease. This process encompasses obtaining knowledge and setting goals in collaboration with the patient's healthcare team to improve patients' diabetes-related health outcomes and their overall quality of life (Haas et al., 2014). The American

Diabetes Association accredits DSME programs and offers guidelines to non-accredited programs (Haas et al., 2014).

Even though educational level and health literacy have not been directly linked, poor health literacy is common among individuals with low education level (Van Der Heide et. al., 2013). Individuals with low education have higher diabetes diagnosis rates (Cutler & Lleras-Muney, 2006) and experience worse diabetes complications and outcomes. Multiple studies show that this disadvantaged population benefits from DSME in achieving glycemic control; however, attrition rates remain high among this population causing them not to receive the recommended hours of DSME (Rothman et al., 2004, Shaw, Killeen, Sullivan, &Bowman, 2011). Attrition rates in various DSME programs found in literature ranged between 20% and 55.5% (Sarkisian et al., 2003, & Klein et al., 2013, Norris et al., 2002, & Ryan et al., 2013) and attrition often occurs after the initial or second session (Masuda, 2006). In fact, a CDC report mentioned that among the newly diagnosed with T2DM, only 6.8% of individuals with private insurance (Li R. et al., 2014) and only 4% of uninsured and Medicaid participants attend DSME (Shaw et al., 2011). The phenomenon of low attendance rates in these DSME programs is not fully understood. However, some studies have found that factors associated with attendance include length of DSME program, logistic barriers such as transportation (DSME Barrier Study, 2006; Maryland's DSME survey results, 2012), full-time work (Adams, 2013), intermittent insurance coverage, co-pay and deductible fees, and a curriculum that was ill-suited to the culture, language or literacy of participants (Mensah, 2006).

ADA-accredited programs typically contain one hour of assessment followed by 10 hours of education delivered either individually or in a group setting. The 10 hours

must be attained in the first year of diabetes diagnosis. Traditionally, DSME programs have been delivered in multiple short sessions progressing from one distinct topic to another (Haas et al., 2014 &), which may be contributing to the high attrition and low attendance rates.

Given that diabetes rates and its dire medical complications disproportionately affect disadvantaged populations and that DSME is a tool that could be utilized to curb these negative consequences, in this study, we examine the completion of DSME by newly diagnosed T2DM patients at a federally qualified clinic. We also examine whether the number of DSME hours predicts any change in A1c during this first year after diagnosis. Because attrition has been shown to be a problem, determining associations between hours of DSME and outcomes would be important to determining how much emphasis should be given to completion of all DSME recommended hours versus shortening programs.

Methods

This study consisted of a secondary data analysis of patient electronic medical records obtained from a federally qualified family medicine clinic, Family Medicine, and two area hospitals that provide laboratory testing and ADA-DSME courses. Exemption from HIPAA and HSIRB approval were obtained from Western Michigan University, Western Michigan University School of Medicines (WMed) and two participating hospitals where patients received their ADA-DSME hours.

A chart review was conducted and we identified 142 adult patients of a family practice clinic with a new T2DM diagnosis from January 1, 2006 through December 31, 2009. The clinic primarily serves Medicaid/Medicare-eligible, low income individuals.

Participants were excluded if they did not have at least two A1c lab results 3-12 months apart during the study period (n=37), leaving 105 participants in the final sample.

Measures

Demographic data collected included age (years), gender (male/female) and race/ethnicity (non-Hispanic white, non-Hispanic black, Hispanic, and other). Age at the time of diabetes education was extrapolated from patient date of birth and the date of the first ADA-DSME class. The age and gender variables were exported from the clinic medical records. The race/ethnicity variable was self-reported and exported from hospital medical records.

A1c values were exported from hospital medical records and measured in percentage. Baseline A1c values were defined as A1c results taken within one to three months before attending the first education session or within 30 days after attending the session. Follow-up A1c values selected were the first A1c collected 3-12 months after completing the last ADA-DSME session. To be included, the time difference between the first and second A1c value could not exceed 12 months. Because A1c values were highly skewed and to account for differential baseline A1c values, change in A1c was defined as a percent change. This was calculated by subtracting baseline A1c values from follow-up A1c values then dividing the difference by baseline A1c values and multiplying by 100. Hours of DSME were obtained (continuous variable). In addition, we categorized the hours into four groups: 1) no education - participants who did not receive any ADA-DSME, 2) assessment - participants who received one hour of ADA-DSME that is focused on assessment only, 3) partial education - participants who received 1.5-7.5 ADA-DSME hours, 4) full education - participants who received 8 or more hours of

DSME. For those participants in the partial education category, all individuals received only 1.5-4.5 hours. Due to the bimodal distribution of the data and small size of the third group (n=4), they were excluded from the final regression analysis. Referral was analyzed as a binary variable that identified individuals who were formally referred by their health care provider to an ADA-DSME program during the study period, yes or no.

Analysis

Descriptive analyses included calculations of means, standard deviations (SD), medians and percentages). Statistical comparisons of groups were conducted using Pearson Chi-Square test for categorical data and linear regression analysis to compare percent change in A1c by hours of ADA-DSME (categorical variable). The alpha level was set at five percent for statistical significance while performing two-sided hypotheses. IBM SPSS statistics version 19 (Armonk, NY: IBM Corp.) was used for analyses.

Results

Out of the final sample of 105 participants, 66% (n=69) received no diabetes education, 17% (n=18) received one hour of assessment, 4% (n=4) received partial education (excluded from the remaining analyses), and 13% (n=14) received full education, i.e at least eight hours. Demographic characteristics of our participants (n=105) are shown in Table 1. The majority of participants were female (63%), white (69.5%), had an average age of 50.5 (SD=12.8).

Table 4-1

Demographics of Participants (N=105)

Demographics of our sample	
Age	50.5 (SD=12.8)
Gender (females)	63 (60%)
Race	
White	73(69.5%)
Black	29(27.6%)
Hispanic	2(1.9%)
Referred	56(53.5%)
DSME hours	
None	69(65.7%)
Assessment	18(17.1%)
Partial	4 (3.8%)
Full	14(13.3%)

When examining referral rates for the total sample, we found that only 53.5% (n=56) were referred to ADA-DSME. Ninety percent (n=44) of those not referred (n=49) did not receive any ADA-DSME hours. Out of these 49 patients, 10.2% (n=5) received one hour of assessment despite the lack of referral; none attended any DSME beyond the one hour. Out of those referred (n=56), 55% (n=31) received at least some hours of ADA-DSME. Forty-two percent (n=13) of those who received ADA-DSME completed one hour, 7% completed 1.5-4.5 hours, and 45% completed eight or more hours with the majority of them being women (86%). This compares to 90% of the 49 unreferred that received no ADA-DSME.

Table 4-2

Referral Rates of Participants (N=105)

	Referred (n=56)	Unreferred (n=49)
Age		
Gender (female)	36(57.1%)	27(42.9%)
Race:		
White	39(52.7%)	35(47.3%)
Black	15(51.7%)	14(48.3%)
Hispanic	-	2(100%)
DSME hours		
None	25(44.6%)	44(89.8%)
Assessment	13(23.2%)	5(10.2%)
Partial	4(7.1%)	-
Full (8 or more hrs)	14(25%)	-
Baseline A1c (median)	6.8	6.6

The baseline A1c median for those who did not receive any type of diabetes education was 6.6 (SD=1.9), compared to 7.5 (SD=2.6) for participants who received one hour of DSME, 6.3 (SD=1.8) for participants who received partial DSME, and 6.6 (SD=2.4) for participants who received eight or more hours of ADA-DSME. Baseline and follow-up A1c values were non-normally distributed with skewness of 1.8 (SE=0.24), 1.8 (SE=0.24) and kurtosis of 1.5 (SE=0.34), 1.89 (SE=0.34), respectively. The median value of baseline A1c was 6.7 (n=105) with a 25^{th} percentile and 75^{th} percentile values of 6.2 and 8.3 respectively. The median value for follow-up A1c was 6.4 (n=105) with a 25^{th} percentile and 75^{th} percentile values of 6.1 and 7.6 respectively. A1c values were further explored by the number of DSME hours, which are shown in table 2.

Table 4-3

Selected Characteristics of Patients of a Family Practice based on Number of ADA-DSME Hours Received (N=105)

DSME Hours (N)	None (69)	Assessment (18)	Partial (4)	Full (14)
Baseline A1c median	6.6	7.5	6.3	6.7
Follow-up A1c median	6.6	6.4	5.4	6.2
Percent change in A1c	-0.6%	-16%	-14.3%	-11.4%
Uncontrolled baseline A1c %	25 (36%)	12 (67%)	1 (25%)	5 (36%)
Uncontrolled follow-up A1c %	27 (39%)	4 (22%)	1 (25%)	2 (14%)
Gender (females)	37(54%)	12 (67%)	2 (50%)	12(86%)
Race:				
White	49 (71%)	13 (72%)	3 (75%)	9 (64%)
Black	19 (28%)	5 (28%)	1 (25%)	4 (29%)
Hispanic	1 (1%)	0%	0%	1 (7%)

Table 4-4

Linear Regression of Association between Hours of ADA-DSME and Percent Change in A1c Values of Patients at a Family Practice

	β	Confidence Intervals		p values
		Upper bound	Lower bound	
Hours of ADA-DSME				
No Hours (reference)	Referent			
Assessment	-0.34	-24.8	-7.15	0.001
8 or more hrs of DSME	-0.22	-21.2	-1.67	0.022

Linear regression of percent change in A1c values (continuous dependent variable) and number of ADA-DSME house received (categorical independent variable), revealed that receiving one (p=0.001) or eight or more hours of ADA-DSME (p=0.022) had a significant negative relationship with the percent difference in A1c values

compared to the group who received no ADA-DSME. Also, those who had an hour of assessment (16% reduction) had a similar percent reduction in A1c to those who had partial DSME (14.3% reduction).

Discussion

This study examined ADA-DSME referrals and attendance as well as outcomes related to attendance at a federally qualified clinic among newly diagnosed T2DM patients. We found that only a little over 50% of our patients were formally referred by their healthcare provider. Referred participants were more likely to attend DSME than those who were not referred; however, almost half of those referred did not attend any DSME hours. Additionally, those who attended DSME had better outcomes than those who received no hours. However, those who had only one hour of assessment had similar results to those who received eight or more hours.

Referral to DSME

The low referral rate of only about 50% of our sample reaffirms low referral rates that other studies have identified as a barrier to enrolling in DSME (Powers et al. 2015). A study by Ruppert el al. (2010) found that only 24% of their sample was referred to a rural DSME despite their educator's effort in increasing physicians' awareness of the availability of DSME in their area. A needs assessment study conducted among eight clinics that served the uninsured and Medicaid recipients found that patients are referred to DSME with little or no referral follow-up by their physicians (Shaw et al., 2011). The ADA developed an "Algorithm of Care" that identifies four critical points at which patients with T2DM should be referred to DSME (Powers et al., 2015). Despite the fact

that the first critical point in the algorithm is “at diagnosis”, referrals of newly diagnosed patients remains low (Powers et al., 2015).

Reasons behind low referrals were examined by some studies. For example, a study by Peyrot et al. (2009) found via a survey that physicians may face barriers to referrals such as not knowing and not understanding at what point to refer a patient in addition to the complicated process of referrals. Another study revealed that some physicians may not think DSME is effective or necessary for those who already have a controlled A1c value and they might only refer those at a high risk for complications (Sunaret, 2011). This may be true given the fact that the median baseline for our unreferred patients was 6.6, which from a clinical perspective is a controlled value for an individual with T2DM. Obtaining a referral to DSME is, however, perceived by patients as a motivating factor to attend DSME (Sprague et al., 1999) indicating the importance of the healthcare provider’s role in motivating their patients. Further exploration of the process of referral should be a target focus to increase participation in DSME.

Attendance and retention

When further examining referred patients by the amount of DSME hours they received, we found that approximately a quarter of them each received only one hour of assessment or eight or more hours of education and less than ten percent received partial education. These participants’ rate of attendance is similar to national data and other studies that show that only about half of people with diabetes receive any DSME (Nelson et al., 2005, and Gucciardi et al., 2007). When examining our referred participants further based on their A1c characteristics, we found that all of the four groups’ median baseline A1c were controlled (<7%) except for the group who attended the one hour assessment

that had a median baseline A1c greater than 7.0, indicating that the clinic was reaching the right target population with poorest glycemic control for that group. Additionally, the one hour assessment group had the largest reduction in A1c, which was very similar to the reduction participants in the full education group achieved, perhaps indicating that the initial contact between the patient and educator is a very critical point in the patient's process to self-management of diabetes. Of those who started DSME, our findings suggest that that those who completed one hour were more likely to be uncontrolled with a median value of 7.5% than those who completed eight or more hours of DSME who had a median A1c value of 6.7% although both groups were able to obtain a controlled A1c value by the follow-up period. Therefore, not completing the DSME program did not prohibit those who only attained the one hour of DSME from reaching a controlled A1c level.

With retention being a concerning issue for DSME programs (Sarkisian et al., 2003, & Klein et al., 2013, Norris et al., 2002, & Masuda, 2006), our findings suggest the importance of accommodating participants' circumstances by offering DSME sessions in various formats. Since ADA-accredited DSME program topics have been traditionally offered in a structured and progressive manner in multiple sessions (Tang et al., 2011), it is important to further examine the possibility of delivering DSME programs in a one-time session format. We were not able to find any studies that evaluated "formal" DSME programs delivered in one-session. However, at this same clinic, a shortened program was offered, Project IDEAS (Chapter 3 of dissertation). The four-hour long one session program was based on ADA-DSME recommendations; however the topics were shortened. The program was convenient for participants because it was delivered at their

"medical home". Many participants attended the program on the same day they had their routine medical visits with their healthcare providers. In Project IDEAS, participants A1c levels dropped from a baseline of 7.7 to a follow-up value of 6.3 (Chapter 3 of dissertation). The follow-up period A1c measurement was taken anywhere between 3 to 12 months for an average of eight months indicating a possible long-term controlled A1c. It is important to note that the population at this PCMH is a transient and low population that is in a high need for DSME. Reaching this population and focusing on program retention requires exploring other delivery methods than what traditionally has been offered.

One of the most important results of this study is that patients in the assessment group achieved over a one point reduction in A1c after the initial assessment. A national study (UK Prospective Study by King et al. 1999) found that a 1% reduction in A1c was associated with 37% decrease in risk in developing microvascular complications, 21% reduction in the risk of other diabetes-related complications and death. This may suggest that a more comprehensive and possibly shorter program should be offered as an alternative to the traditional DSME program, especially among these high risk transient populations.

My literature search did not reveal any studies that examined the outcomes of patients who initiated enrolling in DSME by attending the assessment session only. I only found studies that grouped patients into completers and non-completers of DSME. Given the finding here that those that completed one assessment hour had similar percent changes in A1c to those that completed eight plus hours, further studies are needed to determine if this finding is replicated and, if so, what explains this result.

A major limitation of this study is that we had to exclude participants who did not have a second A1c lab value, which reduced our sample size from 142 to 105 participants. These participants were most likely a transient population who either moved out of the area or changed their medical care provider; a common phenomenon among low SES populations. This issue has not allowed to us to follow these participants and examine their long-term self-management of T2DM. Also, because this was a retrospective review of patients' medical charts, we were not able to look at other factors that may have impacted their attendance such as employment and readiness to change assessments that would allow us to better understand the behaviors of our patients and the reasons of them dropping out of DSME.

Conclusion

In conclusion, we found that the rate of newly diagnosed T2DM patients referred to DSME was low despite the documented benefits of DSME. Even when referred, the majority of patients did not enroll in the ADA-DSME (despite its availability) and those who enrolled experienced high attrition rates and often prematurely dropped out of the education after the one hour assessment session. More studies need to be conducted to understand this phenomenon and whether the bimodal distribution of hours attended is similar in comparable settings (PCMH) and population. Our study results suggest the need for considering including additional educational substance in the first hour of assessment. Attendance at and attrition from ADA-DSME programs remains an important issue and understanding why the A1c results are similar among those with one versus full participation is key as new programs are developed.

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CHAPTER V

CONCLUSION

Summary

The purpose of this dissertation was to examine the feasibility of implementing prediabetes and diabetes programs in community and medical home settings to serve vulnerable and underserved populations. In addition, this work was conducted to improve knowledge regarding future educational needs for those with diabetes or at risk for diabetes. In this section of the dissertation, a summary of the findings of each study will be presented in addition to limitations, implications, and future recommendations.

In the first paper (chapter II), a shortened five-week community-based diabetes prevention program for older adults with prediabetes or at a high risk for developing type 2 diabetes mellitus (T2DM) was evaluated. Changes in nutrition knowledge, eating and physical activity behaviors, and weight were examined in this study at baseline, immediately after participation, as well as approximately six months post program. Participants lost a statistically significant amount of weight over the course of six-months and increased their nutrition knowledge significantly. Participants also reported a statistically significant increase in the amount of vegetables intake in addition to their amount of daily vigorous physical activity. However, there was no statistically significant change in participants' fruits and whole grains intake in addition to their daily moderate physical activity.

In the second paper (chapter III), changes in knowledge, weight, and A1c were examined after participation in a shortened diabetes-self management education program called IDEAS. IDEAS was a one-time, four-hour program delivered at a patient-center

medical home that served primarily low-income individuals that was based on a program developed in Georgia called Project IDEAL. There was a statistically significant increase in the program's content knowledge. Clinical outcomes included weight and A1c. Participants' weight loss was not statistically changed, but it clinically relevant that no weight increase occurred; however, A1c levels did decrease statistically and clinically after participation in the program.

In the third and final paper (chapter IV) referral rates to diabetes self-management education program (DSME) and hours of attendance at an ADA- accredited DSME program for patients with newly diagnosed T2DM was examined among patients that attended the same clinic (medical practice was same used in paper II). This record review study found that referral rates to DSME programs were low in this primarily Medicaid population. In fact, only a little over half of the newly diagnosed patients received a formal referral that was noted in the medical chart. Furthermore, almost half of those referred did not attend a DSME program. A main outcome of the study is that patients who attended the one hour assessment at a DSME program and patients who completed at least eight of the possible 10 hours of the DSME program had similar, statistically significant and clinically relevant similar improvement in their A1c levels compared to those who attended no classes.

Discussion on overall findings

As mentioned in the introduction, vulnerable populations are disproportionately affected by chronic illnesses in general. This dissertation focused mainly on two populations: older adults who are at a higher risk for developing T2DM and individuals with a low SES who are at a higher risk of developing T2DM complications. Two main

findings of this dissertation are: 1) that vulnerable populations are seldom referred to DSME and if referred, their attendance is sporadic, and 2) it is possible to tailor community- and medical home-based programs to meet the needs of vulnerable and underserved populations and still obtain positive results.

Meeting the needs of vulnerable populations through *shortened programs*

Interventions that target older adults are lacking specifically related to preventing T2DM; a condition that they are at a high risk for developing, considering U.S. national data suggesting that half of the older adults have prediabetes (CDC, 2011). It is believed that older adults are left out of such programs due to the complexity of their health status such as having one or multiple chronic conditions (Kirkman et al., 2012). In the largest diabetes prevention trial; the DPP, approximately 20% of participants were over the age of 60. Despite the lack of emphasis on this population, the study found that older adults were more successful in losing weight; an outcome desired in the prevention of T2DM (Dunkley et al., 2012, Ackermann, et al., 2008). In fact, there are other studies showing that older adults are able to maintain their weight loss (Messier et al., 2004; & Villareal et al., 2011) even longer than younger adults (LaRose et al. 2013). It is important; however, to note that translating such large studies into community settings and reaching large numbers of older adults in need can be difficult due to costs, time commitment, and other barriers older adults face such as transportation (Glasgow, Lichtenstein, & Marcus, 2003). Additionally, many older adults with delayed T2DM symptoms may appear to be in good health that have the disease and not know it due to the fast progression from prediabetes to T2DM (Kirkman et al., 2012). Therefore, reaching as many older adults in their early stages of prediabetes is crucial in preventing T2DM and its complications

through community programs that are tailored to their needs. The program evaluated in Chapter 2, demonstrated that successful weight loss can occur in five-week programs that is sustained over a 6 month follow up period.

Similar to older adults, low SES individuals have multiple barriers to attending programs such as lack of transportation, limited access to healthcare and financial recourses, and dealing with personal or family disorders related to substance abuse and mental health (Glasgow, Lichtenstein, & Marcus, 2003; Flaskerud & Winslow, 1998). Due to these barriers they may be facing on a daily basis, individuals from these populations are not expected to seek programs and interventions that focus on preventive measures and self-care, especially longer programs delivered in multiple sessions (Jacob et al., 2014). Instead, programs that target these populations should be proactive in nature (Eakin et al., 2002). To meet the needs of this population, project IDEAS was created. IDEAS is a unique program in that it targeted a vulnerable group of individuals, it was offered at a patient centered medical home (PCMH) through a collaborative effort by an interdisciplinary health care team the patient is familiar with, and was a one-time program that patients could attend on the same day as their primary health care visit at their PCMH. Participants in the program significantly improved patients' A1c levels and knowledge about diabetes. However, enrollment in the program remained a barrier despite physician's recruitment efforts.

Studies have shown that recruiting participants during their routine visit to attend diabetes education programs that are scheduled on the same day in primary care settings is a growing and effective method in reaching this population (Siminerio, Piatt, & Zgibor, 2005). Another growing approach is involving the medical team in primary care settings

in the delivery of diabetes education to assist patients with self-management and decision-making. By further examining a traditional ADA-DSME offered through two local hospitals to explore its outcomes, it was found that referral to both these programs was low. Similarly, referral to the ADA-DSME was only at about 50% of those newly diagnosed. Not only referral rates were low, but attendance and retention were low as well. A major finding in the third study is that those who attended the one hour assessment of DSME had a statistically significant reduction in their A1c levels similar to those who attended eight or more hours.

There's a plethora of high quality metanalyses (Norris et al., 2002; Deaken et al., 2005; Gary, 2003; SBU, 2009) and systematic reviews (Norris et al., 2001; Ismail, 2004) that found that DSME is effective in helping patients control their T2DM. However, when further examining the studies included in these metanalyses and systematic reviews, none of these studies evaluated clinical outcomes of a shortened single-session DSME program that targeted low-income populations.

With that being said, there a few studies that shed some light on the process of self-management among patients with diabetes most of which are qualitative studies. These studies indicate that self-management activities consist of a complex and dynamic set of stages that are deeply embedded in the individual's unique life situation, which can vary from person to person (Moser et al., 2008). A qualitative study by Price (1993) described that patients with diabetes go through multiple stages of the life-process of diabetes self-management that starts at diagnosis. Price describes that the first stage is characterized by participants' adherence to medical advice as close as possible. This

could be a plausible explanation as to why those who attended only the first hour of assessment did as well as those who attended eight or more hours of the program.

By further examining the content of the first hour of assessment to better understand what's delivered in that session, it was found that the assessment is an individualized session that addresses/measures self-evaluation through creating specific and measurable goals as participants are expected to self-manage their diabetes. Awareness of ones capabilities and appraisal of ones-self can predict health outcomes (Judge, Locke, and Durham,1997). Boehm et al. (1997) found that self- evaluation is the strongest predictor in diabetes self-management specifically related to eating behaviors. It is possible, but could not be examined in this dissertation, that project IDEAS participants and those DSME participants who only received the one hour of assessment were highly motivated with a positive self-evaluation that could've led to making dietary changes and subsequently lowering their A1c.

Implications

Although not specific to older adults, a study that utilized data from the 2005-2006 National Health and Nutrition Examination Survey found that only half of US adults with prediabetes are aware of their high risk for developing T2DM and only half made any behavioral changes with the intention to prevent the disease (Geiss et al., 2010). What's even more alarming is that the majority of them did not receive any guidance from their healthcare provider regarding modifying their behaviors to reduce their risks of T2DM (Geiss et al., 2010). While prediabetes is underdiagnosed and those diagnosed are not receiving health advice from their healthcare providers, a study shows that those with a medical trigger such as a medical diagnosis have better health outcomes

in short-term interventions specifically related to weight loss and weight loss maintenance (Gorin et al., 2004). This indicates the need to: 1) offer short-term programs for older adults who are at risk for developing T2DM yet have been shown to be successful in weight loss and maintaining weight loss, an important outcome to prevent T2DM and 2) identify more efficient methods to increase awareness of healthcare providers and patients to prediabetes and the behavioral changes required to prevent its progression through tailored community based programs.

Similar to individuals with prediabetes, individuals with T2DM report that besides logistical barriers, lack of information from their physician, and lack of referrals to DSME programs are two of the main barriers to not attending DSME (Winkley et al., 2015). Healthcare providers may be more inclined to refer those at a high risk of T2DM-related complications compared to those who have a better glycemic control (Sunaret, 2011). This indicates that communicating these findings to healthcare providers and systems is an important first step in addressing this issue.

As health disparities related to diabetes are increasing, it is important for this type of work to continue. A common recommendation for such studies (MDPP and IDEAS) would be a long-term evaluation to assess patients' outcomes; however, with older adults or low SES populations, this may not be realistic due to their transient status. Instead, the focus should be on changing systems and health care settings to increase referrals to high-quality community-based programs that focus on prevention and even offer these programs on-site while prioritizing the needs of vulnerable populations.

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APPENDIX

HUMAN SUBJECTS INSTITUTIONAL REVIEW BOARD (HSIRB) LETTERS OF APPROVAL

HSIRB APPROVAL FOR THE MICHIGAN DIABETES PREVENTION PROGRAM (CHAPTER II)

WESTERN MICHIGAN UNIVERSITY

Human Subjects Institutional Review Board

Date: January 21, 2011

To: Amy Curtis, Principal Investigator
Catherine Kothari, Student Investigator
Elyse Connors, Student Investigator
Diana Hassan, Student Investigator

From: Amy Naugle, Ph.D., Chair

Re: HSIRB Project Number: 11-01-09

This letter will serve as confirmation that your research project titled "Evaluation of the Michigan Diabetes Prevention Program (MDPP), Kalamazoo Pilot" has been **approved** under the **exempt** category of review by the Human Subjects Institutional Review Board. The conditions and duration of this approval are specified in the Policies of Western Michigan University. You may now begin to implement the research as described in the application.

Please note that you may **only** conduct this research exactly in the form it was approved. You must seek specific board approval for any changes in this project. You must also seek reapproval if the project extends beyond the termination date noted below. In addition if there are any unanticipated adverse reactions or unanticipated events associated with the conduct of this research, you should immediately suspend the project and contact the Chair of the HSIRB for consultation.

The Board wishes you success in the pursuit of your research goals.

Approval Termination: January 21, 2012

Walwood Hall, Kalamazoo, MI 49008-5456
PHONE: (269) 387-8293 FAX: (269) 387-8276

HSIRB APPROVAL FOR PROJECT IDEAS (CHAPTER III)

WESTERN MICHIGAN UNIVERSITY

Human Subjects Institutional Review Board

Date: February 16, 2012

To: Amy Curtis, Principal Investigator
Catherine Kothari, Student Investigator
Diana Hassan, Student Investigator

From: Amy Naugle, Ph.D., Chair

Re: HSIRB Project Number: 12-02-44

This letter will serve as confirmation that your research project entitled "Evaluation of Project IDEAS" has been **approved** under the **exempt** category of review by the Human Subjects Institutional Review Board. The conditions and duration of this approval are specified in the Policies of Western Michigan University. You may now begin to implement the research as described in the application.

Please note that you may **only** conduct this research exactly in the form it was approved. You must seek specific board approval for any changes in this project. You must also seek reapproval if the project extends beyond the termination date noted below. In addition if there are any unanticipated adverse reactions or unanticipated events associated with the conduct of this research, you should immediately suspend the project and contact the Chair of the HSIRB for consultation.

The Board wishes you success in the pursuit of your research goals.

Approval Termination: February 16, 2013

HSIRB APPROVAL FOR THE DIABETES EDUCATION: ACCESS AND OUTCOMES STUDY (CHAPTER IV)

WESTERN MICHIGAN UNIVERSITY

Human Subjects Institutional Review Board

Date: November 10, 2011

To: Amy Curtis, Principal Investigator
Catherine Kothari, Student Investigator
Diana Hassan, Student Investigator

From: Victoria Janson, Interim Chair

Re: HSIRB Project Number 11-11-09

This letter will serve as confirmation that your research project titled "Diabetes Education: Access & Outcomes" has been **approved** under the **exempt** category of review by the Human Subjects Institutional Review Board. The conditions and duration of this approval are specified in the Policies of Western Michigan University. You may now begin to implement the research as described in the application.

Please note that you may **only** conduct this research exactly in the form it was approved. You must seek specific board approval for any changes in this project. You must also seek reapproval if the project extends beyond the termination date noted below. In addition if there are any unanticipated adverse reactions or unanticipated events associated with the conduct of this research, you should immediately suspend the project and contact the Chair of the HSIRB for consultation.

The Board wishes you success in the pursuit of your research goals.

Approval Termination: November 10, 2012

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