2020

The Comparison of Two Diabetes Self-Management Education Programs in the Reduction of Patient A1C Levels

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THE COMPARISON OF TWO DIABETES SELF-MANAGEMENT EDUCATION PROGRAMS IN THE REDUCTION OF PATIENT A1C LEVELS

by

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A DISSERTATION

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

BIRMINGHAM, ALABAMA

2020

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HEALTHCARE LEADERSHIP

ABSTRACT

This dissertation was a quasi-experimental research study exploring the effectiveness of two educational teaching methods with patients with diabetes. One teaching method utilized an education framework called the Conversation Map™ tools, a group-based, highly interactive learning experience using colorful visual tools, activity cards and sharing of real-life experiences. The other method was a traditional, lecture-style class taught by a health educator using overhead slides and handouts.

Secondary data from a regional health system in the Western U.S. was used to test the hypothesis that participants in the Conversation Map™ classes would report a larger drop in A1c levels compared to participants in the lecture-style classes. Ten participant characteristics were used in the analysis. Group dynamics served as the theoretical framework for the hypothesis developed in this study.

Findings indicated that both the Conversation Map™ group and lecture-style group were able to reduce their A1c levels significantly, when measured before and after participation in the education programs. The Conversation Map™ group performed better, achieving the American Diabetes Association accepted goal for most non-pregnant adults of < 7.0, although the difference in change between the two groups was not statistically significant. When controlling for age, pre-intervention A1c score and number of days post-intervention A1c was measured, the Conversation Map™ method was more effective at reducing patient A1c levels than lecture-style teaching, a statistically significant result.

Findings from this study will inform policymakers, managers and health education program creators that group-based, interactive diabetes self-management education programs such as the Conversation Map™ tools may be an effective model for the reduction of patient A1c levels.

Keywords: diabetes self-management education, Conversation Map, HbA1c, group dynamics, population health, DSME

DEDICATION

For my father, Dr. Richard E. Sharpless.

Thank you for everything.

ACKNOWLEDGEMENTS

I am genuinely grateful to my committee chair, Dr. Nancy Borkowski, for her patience, perseverance, focus and guidance throughout the dissertation process. I am also indebted to Dr. Jeff Szychowski who provided indispensable navigation through my innumerable, sometimes unnecessary, statistical explorations. Thank you to Dr. Larry Hearld and Dr. Stephen J. O'Connor for your valuable feedback and advice, which challenged me to think differently and produce better work.

I would also like to recognize Leandra Celaya. I could not imagine a more delightful and committed individual to guide, entertain, and occasionally regulate my fellow classmates and me during our journey. Thank you to Dr. S. Robert Hernandez and the rest of the UAB faculty for your leadership and support.

Additionally, I would like to give a shout out to my two compatriots in this journey, Dr. Lucas Higman and Mark Lombardi. It wouldn't have been the same without you.

Finally, to my partner Bethany. You inspire me every day to bring my best work and best self to solve the challenges before me. Thank you for your loving support as we completed this journey.

TABLE OF CONTENTS

LIST OF TABLES AND FIGURES

Table *Page*

LIST OF ABBREVIATIONS

A1c	Hemoglobin A1c or HbA1c
ACA	Patient Protection and Affordable Care Act of 2010
ARRA	American Recovery and Reinvestment Act of 2009
BMI	Body mass index
CM	Conversation Map® tools
CMS	Centers for Medicare & Medicaid Services
DMP	Diabetes Management Program
DSME	Diabetes self-management education
GDP	Gross domestic product
HITECH	Health Information Technology for Economic and Clinical Health Act
IDEA	Interactive Dialogue to Educate and Activate study
IT	Information technology
PBPH	Practice-based population health
PHM	Population health management
VIF	Variance inflation factor

CHAPTER 1: INTRODUCTION

Population Health

Population health is defined as "the health outcomes of a group of individuals, including the distribution of such outcomes within the group" (D. Kindig & Stoddart, 2003; D. A. Kindig, 2007). In the field of population health, health outcomes are influenced by a number of medical and non-medical determinants of health, including social, economic, environmental, genetic and individual behavior (healthypeople.gov, 2020; D. Kindig & Stoddart, 2003). The interrelationship of these determinants, including policies and interventions that affect each, collectively influence individual and population health (healthypeople.gov, 2020; D. Kindig & Stoddart, 2003).

The Affordable Care Act (ACA) of 2010 addressed these determinants through a series of policy and funding mechanisms in an effort to give more Americans greater access to healthcare, prevention and wellness services that improve overall health outcomes, lower costs and increase quality of life (Alper, 2014; Chait & Glied, 2018; Felt-Lisk & Higgins, 2011; The Henry J. Kaiser Family Foundation, 2013). Modern day population health management (PHM) was born out of certain provisions of ACA that placed new emphases on wellness and prevention as key strategies for containing medical costs and improving the health of Americans (Alper, 2014; Chait & Glied, 2018). PHM programs target a defined population of individuals using a variety of interventions—individual, organizational and community-based—across the continuum of care to address the range of health risk factors that exist within that population, from healthy individuals to those living with chronic disease (Alper, 2014; Felt-Lisk & Higgins, 2011). These interventions encourage participants to make wiser health choices in their daily lives that positively impact health status. The goal of PHM is to improve health outcomes, lower costs and increase quality of life (Felt-Lisk & Higgins, 2011) while also addressing determinants of poor health.

Individual Behavior — a Key Determinant of Population Health

Although individuals cannot control a number of the determinants of their health, including physical, social and economic environments, as well as genetic predispositions (Goetzel et al., 2012; US Department of Health and Human Services, 2010; World Health Organization, 2020), most have some level of control over personal behavior. As a key determinant of population health, individual behavior can be influenced by a number of interventions that improve individual health and health status (Glasgow, La Chance, et al., 1997; K. R. Lorig et al., 1999a; Peyrot, 1999). When individuals improve their health status, there is a greater potential to achieve measurable improvements in the health of a defined population (Arah, 2009; D. A. Kindig, 2007). It is therefore crucial that an effective population health strategy focus on individual behavior change (Kaiser Family Foundation, 2013; Rowe, 2017).

Effective PHM intervention programs that target individual behavior are usually modeled after successful health promotion, health education and disease management programs (Fries, Fries, Parcell, & Harrington, 1992; Fries, Harrington, Edwards, Kent, & Richardson, 1994; K. Lorig, Kraines, Brown Jr, & Richardson, 1985) which may use various theoretical individual behavior change frameworks (A. Bandura, 1977; Prochaska

& Velicer, 1997; Rosenstock, 1974). These programs help participants develop the knowledge and skills to prevent the onset or manage the presence of chronic disease (K. R. Lorig et al., 1999a). By preventing or properly managing chronic conditions, individuals improve their health outcomes while concurrently influencing the outcomes of the population for which they are a member. The goal of improved population health cannot be achieved without successful behavioral change interventions at the individual level.

Chronic Disease Impact

The proliferation of PHM programs post-ACA in 2010 was a direct result of the Act's new policies and funding in response to the unsustainable growth of healthcare spending and dramatic rise in the incidence of chronic disease over the prior two decades, which continues to this day. The United States spends more on healthcare than any other nation in the world. In 2018, healthcare spending in the U.S. reached $3.6 trillion, or $11,172 per person (Centers for Medicare and Medicaid Services, 2020). Healthcare expenditures account for a considerable 17.7 percent of the U.S. GDP (Centers for Medicare and Medicaid Services, 2020).

There are numerous drivers of increased healthcare costs in the U.S., including advances in medical technology, increased life expectancy, pharmaceutical availability, coverage expansion and chronic disease—the largest driver (Aspen Health Strategy Group, 2019). The sizable increase in incidence of Americans with one or more chronic conditions has contributed significantly to the rising costs of healthcare over the past two decades (Agency for Healthcare Research and Quality, 2015; Dieleman et al., 2017; Partnership to Fight Chronic Disease, 2020). In 2014, 60% of the U.S. population had at least one chronic condition and 42% had more than one chronic condition (Buttorff, Ruder, & Bauman, 2017), accounting for 86% (Aspen Health Strategy Group, 2019) of the nation's $3.3 trillion annual healthcare expenditures (CDC, 2019). Chronic disease, including conditions such as heart disease, diabetes, asthma, arthritis and depression, are the leading causes of death, disability, and rising healthcare costs in the U.S. and account for almost 9 out of every 10 deaths (Partnership to Fight Chronic Disease, 2020). In the U.S. alone, 1,100,000 lives could be saved annually through better prevention and treatment of chronic disease (Partnership to Fight Chronic Disease, 2020).

Diabetes Impact

Diabetes mellitus, commonly referred to as diabetes, is a group of metabolic disorders characterized by elevated blood glucose concentration over a prolonged period (Ogurtsova et al., 2017). Diabetes ranks as one of the leading causes of death in the U.S. and is a primary driver of the country's $3.3 trillion in annual healthcare costs (CDC, 2019). In 2012, almost 30 million Americans, or 9.3% of the population, had diabetes, including 8.1 million undiagnosed cases, with 1.5 million new diagnoses every year (Chamberlain et al., 2017). Globally, it is one of the world's most common chronic diseases, with a rapidly increasing prevalence of type 2 diabetes, which constitutes 85% to 95% of all diabetes cases in developed nations (Matthew Reaney, Eichorst, & Gorman, 2012; Reaney, Eichorst, & Gorman, 2012; Whiting, Guariguata, Weil, & Shaw, 2011).

Despite the increased prevalence of health promotion and diabetes education programs over the past two decades, 33% to 49% of patients still do not meet targets for glycemic control (Armstrong, 2017). The estimated economic burden associated with elevated A1c levels in 2012 was greater than $322 billion, 48% higher than 2007 (Dall et al., 2014).

Diabetes Self-Management Education

To address the economic burden of diabetes, healthcare professionals with specific expertise in chronic conditions recognize the positive outcomes and behavior changes associated with diabetes self-management education (DSME) (Funnell et al., 2008; Reaney et al., 2012). DSME is a method of learning through which individuals with diabetes obtain the proficiencies and comprehension necessary for personal behavior modification and efficacious management of the disease (Sperl-Hillen et al., 2011). Patient self-management and education are vital to the proper management of diabetes, along with appropriate clinical care (Reaney et al., 2013). The importance of DSME in the reduction of health risks and improvement of health status is considerable, driving international organizations including the American Diabetes Association, American Association of Diabetes Educators, the International Diabetes Federation and the National Institute for Health and Clinical Excellence in the United Kingdom to develop standards for structured self-management education (Funnell et al., 2008; International Diabetes Federation, 2019; National Institute for Clinical Excellence Great Britain, 2003; Reaney et al., 2012). These standards are rooted in the same theoretical underpinnings of evidence-based workplace health promotion programs of the past 30 years, informing the content and delivery of DSME which is associated with improved overall health status and management of the disease (Elasy, Ellis, Brown, & Pichert, 2001; Glasgow, Hampson, Strycker, & Ruggiero, 1997). With respect to diabetes self-management and glycemic control, there is considerable data that demonstrates participation in DSME results in statistically significant decreases in participant A1c levels (Chrvala, Sherr, & Lipman, 2016).

However, there is still considerable debate over which modalities of education are most effective at producing measurable reductions in A1c levels and improved clinical outcomes among diabetes patients (Fernandes et al., 2010). Many diabetes education interventions lack clear evidence of theory-based design in the areas of behavioral, psychosocial or educational theory (Cooper, Booth, Fear, & Gill, 2001; Loveman et al., 2003; Reaney et al., 2012). A comprehensive review of diabetes educational interventions revealed considerable heterogeneity in teaching methods and content of education, and although teaching methods that go beyond lecture-style have shown more effective outcomes than traditional teaching methods, it remains unclear what teaching modality is most effective for a given population (Elasy et al., 2001). As such, it is important to explore new methods of teaching, such as group education, to understand their effects on outcomes compared with traditional lecture-style methods.

Group Dynamics and Individual Behavior Change

Group dynamics are “the influential actions, processes, and changes that occur within a group” (Forsyth, 2018; Forsyth & McGovern, 1983). Kurt Lewin was the first researcher to study group dynamics and how a group can influence the behavior of its individual members (Burnes, 2004, 2020). Lewin defined a group as not the similarity or dissimilarity of its individual members, but the interdependence of fate of those members (Burnes, 2004, 2020; Lewin, 1939). Lewin was interested in understanding how certain forces caused groups to behave, and how these forces could be modified to achieve more desirable behavior (Burnes, 2020; Kippenberger, 1998). His research revealed that for change to be effective, all members of the group had to be involved equally and openly, a construct to approaching change called democratic participation (Burnes, 2004, 2020). This democratic decision making process enabled a “freezing” effect once group change had taken place (Burnes, 2020; Kippenberger, 1998). Lewin believed that a successful change had three components: unfreezing the current level, moving to a new level, and freezing group life at the new level (Burnes, 2020; Lewin, 1947). By identifying and reducing forces that influence negative behavior, facilitating change of behavior, and strengthening the forces at the post-change level, groups could achieve sustained behavior change (Burnes, 2020) or permanency of change (Lewin, 1947). In one Lewin experiment, a group who made a decision to have its members change their behavior was two to 10 times more effective at producing actual change than a lecture soliciting the same change (Cartwright, 1951; Lewin, 1951b). Lewin’s seminal research is the basis for group influence on individual behavior change (Burnes, 2004).

Lewin’s findings have been validated in subsequent research, confirming that individuals are more committed to change if they participate in group decision making about the change, rather than if the change is imposed (Burnes, 2004; Holt, Armenakis, Feild, & Harris, 2016). In one study by the Research Center for Group Dynamics, the researchers endeavored to compare the impact of a training workshop on trainees who came as individuals versus those who came with teams. Six months after the workshop, the members who had participated in the workshop as part of a team strongly outperformed those who were trained as individuals (Cartwright, 1951). Further research has indicated that the use of group dynamics principles of goal-setting and cohesion can increase physical activity in a variety of populations (Harden, 2012), and that group-based physical activity programs are more effective than individual programs (Burke, Carron, Eys, Ntoumanis, & Estabrooks, 2006; Harden, 2012). More recently, the increasing prevalence of chronic diseases, such as diabetes and heart disease, has resulted in a health promotion education model using small groups to deliver behavior change interventions that improve self-management of chronic disease (Borek & Abraham, 2018; K. R. Lorig, Mazonson, & Holman, 1993; K. R. Lorig et al., 2001; K. R. Lorig et al., 1999b). Group programs in diabetes education and obesity management have proven more effective than individually-delivered programs (Paul-Ebhohimhen & Avenell, 2009; Renjilian et al., 2001; Rickheim, Weaver, Flader, & Kendall, 2002; Trento et al., 2010).

Research on group health education approaches to chronic disease self-management, in particular DSME, has demonstrated better outcomes when compared with education in an individual setting (Paul-Ebhohimhen & Avenell, 2009; Rickheim et al., 2002; Sarkadi & Rosenqvist, 2004; Steinsbekk, Rygg, Lisulo, Rise, & Fretheim, 2012). Because individual behavior is a key determinant of population health, and effective population health strategy should focus on individual behavior change, it is important to understand group dynamics' impact on population health through its influence of individual behavior change.

Research Question

As such, the purpose of this study is to explore the effectiveness of two educational teaching methods with patients with diabetes. This study will examine the following research question:

Do individuals participating in a group-based interactive diabetes education program report lower A1c levels than individuals participating in a traditional lecture-style diabetes education class?

Hypothesis

Individuals participating in a group-based interactive diabetes management educational program will report lower A1c levels as compared to individuals participating in a traditional lecture-style classroom diabetes education program.

Conclusion

The goal of PHM is to improve the health outcomes of a group of individuals by addressing the upstream determinants of poor health. Considering diabetes is the most prevalent chronic disease driving precipitous increases in U.S. healthcare costs, it is imperative to understand what types of DSME programs can improve patient outcomes. Group dynamics offers a theoretical approach that can improve the impact of diabetes self-management programs through its influence on individual change. The diabetes CM program's design and delivery encompass key elements of group dynamics that positively impact individual behavior change versus education programs delivered to the individual. Accordingly, the group-based diabetes CM program should be more effective at reducing patient A1c levels than traditional lecture-style classroom teaching.

CHAPTER 2: LITERATURE REVIEW

Background

The United States spends more on healthcare than any other nation in the world. In 2013, healthcare spending in the U.S. reached $2.9 trillion, or $9,255 per person (Centers for Medicare and Medicaid Services, 2015). Although growth in healthcare spending has slowed from the double-digit annual increases common in the first decade of this century, healthcare expenditures still account for a considerable 17.4 percent of the U.S. GDP. In comparison, in 1992 the U.S. spent $3,286 per capita on healthcare (OECD, 2014). Healthcare spending has almost tripled in under 25 years. The Centers for Medicare and Medicaid Services (CMS) projects that health spending will continue to grow at an average rate of 5.8 percent per year and will account for 19.6 percent of the GDP by 2024 (Centers for Medicare and Medicaid Services, 2015). The U.S. spends significantly more on healthcare as a share of GDP than any other developed nation in the world (OECD, 2014). The continued growth of healthcare costs in the U.S. is unsustainable. Without action to contain costs, the burden of these increases will continue to put significant, and eventually, crippling financial pressure on government, employers and individual purchasers of healthcare services.

There are numerous drivers of increased healthcare costs in the U.S., including advances in medical technology, increased life expectancy, pharmaceutical availability, coverage expansion and chronic disease. The largest driver of healthcare costs in the U.S. is chronic disease. The sizable increase in incidence of Americans with one or more chronic conditions has contributed significantly to the rising costs of healthcare over the past two decades. In 2013, 46% (144 million) of the U.S. population had at least one or more chronic conditions, accounting for 84% of all national healthcare expenditures (Moses et al., 2013). Chronic disease, including conditions such as heart disease, diabetes, asthma, arthritis and depression, are the leading causes of death, disability, and rising healthcare costs in the U.S. and account for almost 9 out of every 10 deaths (Partnership to Fight Chronic Disease, 2015). Even more concerning is that chronic illness among those younger than age 65 now accounts for 67% of health care spending (Moses et al., 2013). The growth of obesity, particularly among the young, has contributed to the quadrupling of childhood chronic disease diagnoses since 1960 (Partnership to Fight Chronic Disease, 2015). The annual growth rate of five of the top 10 highest spending chronic conditions from 2000 to 2010 was 4.2 percent for heart conditions, 5.3 percent for cancer, 8.4 percent for diabetes, 3.9 percent for hypertension and 14.4 percent for hyperlipidemia (Moses et al., 2013). By 2030, an estimated 171 million Americans will have at least one chronic condition (Partnership to Fight Chronic Disease, 2015). Americans are getting sicker, and there is no end in sight to this alarming trend.

The unsustainable growth of healthcare spending and dramatic rise in the incidence of chronic disease, in addition to other factors such as lack of access, increasing disparities in care, waste and inefficiencies in service delivery, and excessive administrative costs prompted the U.S. government to begin a dramatic period of healthcare reform starting in 2009 with the HITECH Act, part of the American Recovery and Reinvestment Act of 2009 (ARRA). HITECH authorized up to $19 billion in infrastructure technology (IT) investment to improve the nation’s healthcare system by encouraging and subsidizing providers to implement health IT solutions that improve efficiency, reduce administrative costs, enable sharing of information and improve quality of care (T. Park & Basch, 2009). ARRA was followed closely by The Patient Protection and Affordable Care Act of 2010 (ACA), which would fundamentally transform the healthcare system as we know it through expanding access to care, the individual mandate, Medicaid expansion, premium equality, health insurance exchanges, cost containment, quality improvement, and a national focus on wellness and prevention (The Henry J. Kaiser Family Foundation, 2013). This policy focus on health promotion and prevention gave birth to modern-day population health management.

Population Health

The definition of population health has varied greatly over the past two decades likely due to the changing circumstances it has served. As a concept, the term itself is broad. “Population health,” in the most simplistic sense, could easily be interpreted as “the health of a population.” Early definitions, years before HITECH and ACA, attempted to provide clarity in the definition of the term “population health.”

In 1999, Dunn and Hayes offered a definition based on the Canadian Federal Advisory Committee on Population Health, writing “population health refers to the health of a population as measured by health status indicators and as influenced by social, economic and physical environments, personal health practices, individual capacity and coping skills, human biology, early childhood development, and health services. As an approach, population health focuses on interrelated conditions and factors that influence the health of populations over the life course, identifies systematic variations in their patterns of occurrence, and applies the resulting knowledge to develop and implement policies and actions to improve the health and wellbeing of those populations (Dunn &

Hayes, 1999)." This was an extremely broad definition essentially positing that every factor that affects health over an individual's life must be tracked and analyzed to determine what policies and interventions can be put in place to improve the health of the individual, thereby improving the health of the overall group.

In 2003, Kindig and Stoddart reigned in the breadth and simplified the definition offered by Dunn and Hayes, defining population health as "the health outcomes of a group of individuals, including the distribution of such outcomes within the group" (D. Kindig & Stoddart, 2003). It was their belief that health outcomes (as dependent variables) must be both defined and measurable, and focusing on health outcomes enabled researchers to identify the impact of the multiple determinants of health (independent variables) and their interactions on various outcomes (D. Kindig & Stoddart, 2003). Kindig and Stoddart do not offer specifics on what would be considered a health outcome, but extrapolating from ideas referenced and expressed earlier in their article, it appears they are referring to outcome measures derived from various health status indicators referenced by Dunn and Hayes' definition of population health. In modern day parlance, these would be indicators such as weight, HbA1c (A1c) levels, stress, life expectancy and tobacco use, to name a few. In terms of the multiple determinants of health outcomes, the authors provided several examples in their article, including medical care, public health interventions, aspects of the social environment (e.g. income, education), physical environment, genetics, and individual behavior. They stress that population health research should be primarily concerned with the interactions between multiple determinants, not necessarily how they act independently (D. Kindig & Stoddart, 2003). Their methodology also allowed for the analysis of the distribution of health across subpopulations. In their definition, populations could take on any form such as countries, employer groups, ethnic groups or prisoners (D. Kindig & Stoddart, 2003). Kindig and Stoddart also deliberately used the term “health outcomes” rather than the more narrow term “health status”, introducing the idea of a multi-year longitudinal approach to health outcomes measurement rather than focusing on a moment in time (D. Kindig & Stoddart, 2003).

As HITECH and ACA took shape in 2009 and 2010, and with ACA specifically calling for a national quality strategy built around population health (The Henry J. Kaiser Family Foundation, 2013), healthcare industry experts, associations and vendors began conceptualizing population health models and definitions to meet the challenges of healthcare reform. In particular, the goals of triple-aim became the cornerstone of population health strategy. Kindig and Stoddart’s (2003) definition also proved to be consistent with evolving ideas on what population health would look like in the U.S. healthcare system after reform. In particular, the ideas of longitudinal measurement of health outcomes resulting from various determinants of health would be a focus of healthcare organizations’ new models for population health. In 2010, Dr. Richard Hodach further refined the foundational definition of population health to address “not only longitudinal care across the continuum of care, but also personal health behavior that may contribute to or prevent healing or disease” (Institute for Health Technology Transformation, 2012). Although individual behavior had previously been identified as a key determinant of health, it now became a primary focus of population health strategy. New strategies would center on effective interventions to moderate the impact of all determinants of health, but particularly focus on personal health behaviors and lifestyle choices.

In 2011, Felt-Lisk and Higgins defined the concept of population health as "programs targeted to a defined population that use a variety of individual, organizational, and societal interventions to improve health outcomes (Felt-Lisk & Higgins, 2011)." Their model centered around stratifying a population from low-risk, healthy individuals to high risk individuals with one or more chronic conditions, and implementing interventions designed to maintain and improve health across the continuum of care (Felt-Lisk & Higgins, 2011). This model further refined the Hodach definition focusing on the individual behavior and lifestyle choices impacting health outcomes and aligned it with the burgeoning health promotion, prevention, wellness and disease management industries prevalent among early adopters of worksite health improvement programs.

Although population health is concerned with the health outcomes of a specified group (population cohort) over time, and the interactions of the multiple determinants of health on those outcomes, achieving positive results at the population cohort level requires success at the individual level in substantial numbers. The more each individual in a defined population cohort can improve his or her individual health status indicators and maintain those improvements over time, the more the population cohort learns about what interventions work. These learnings can then be applied to further develop, refine and tailor interventions that help even more individuals improve their health status indicators and maintain improvements over time. The long-term result is improved health outcomes at the population level. This approach is person-centered population health.

Health Risk Reduction

One approach for person-centered population health is health risk reduction at the individual level, utilizing a variety of strategies to promote behavior change in patients with, or at high risk for, chronic disease. Seven of the 10 most deadly diseases are associated with patient behavior (Keller & White, 1997). Often called health promotion, these programs center on promoting health through behavior change, preventing disease and proper self-management of existing disease through modifiable health risk reduction. By focusing on prevention and chronic condition management, health promotion programs can improve a patient's health status, improve quality of care and reduce costs, the key components of triple-aim. Modifiable health risk reduction is therefore a key component of population health strategy.

Research has shown a strong association between modifiable health risks and increased healthcare expenditures. In a widely cited study published in 1998, researchers concluded that seven of the top ten modifiable health risk behaviors were associated with significantly higher medical expenditures (Goetzel et al., 1998). The analysis used data from six large employers representing 46,026 employees who were tracked for three years after they completed a health risk assessment (Goetzel et al., 1998). The risk categories with significantly higher expenditures were depression (70% higher), high stress (46%), high blood glucose (35%), extremely high or low body weight (21%), former and current tobacco users (20%/14%), high blood pressure (12%) and sedentary lifestyle (10%) (Goetzel et al., 1998).

A follow-up study was conducted in 2012 by some of the same researchers utilizing the same assessment tool and a similar worksite population mix to determine if the same risk factors contributed to significantly increased healthcare expenditures. The study was meaningful, particularly with the recent passing of ACA and the shift in lifestyle behaviors that had taken place over the previous 17 years. The results were astoundingly similar. Examining the same top ten modifiable health risk factors that were linked to more than one-fifth of employer/employee healthcare spending, the researchers found that 22.4 percent of the healthcare dollars spent annually by the seven employers and their 92,486 employees were attributed to the ten risk factors studied (Goetzel et al., 2012). The 1998 study identified 24.9 percent (Goetzel et al., 1998). In the 2012 study, the same seven health risks – depression, high stress, high blood glucose, extremely high or low body weight, tobacco use, high blood pressure and sedentary lifestyle were all statistically significant positive predictors of future healthcare costs (Goetzel et al., 2012).

Because modifiable health risks such as obesity, high blood pressure and diabetes complications have been associated with increased healthcare costs for more than 20 years, forward-thinking organizations with a vested financial interest, such as large self-funded employers, have invested in the potential to reduce healthcare costs and improve employee health status by implementing evidence-based health promotion programs, also known as health education programs – and for those with existing chronic conditions, self-management programs. Between 1998 and 2015, hundreds of studies (NCBI, 2014) have been conducted to assess the effectiveness of workplace health promotion programs in the reduction of modifiable health risks and medical claims. The Centers for Disease Control and Prevention's Community Guide Task Force conducted a systematic review of worksite health promotion programs and concluded that properly designed, multicomponent programs exert a positive influence on health behaviors, biometric measures and financial outcomes to employers (Anderson et al., 2009; Goetzel et al., 2012).

The Foundations of Self-Management Education

The 2000s saw a rapid growth in workplace health promotion programs (also known as worksite wellness, health improvement, chronic disease prevention and employee health and productivity programs), as the wellness industry gained credibility, more programs were implemented and more research conducted. By 2010, the public sector had made wellness a tenant of ACA, both section 4303 of ACA and section 2705 of the Public Health Service Act of 1944, which was amended by ACA, contained provisions that incentivized employers to implement comprehensive workplace health promotion programs (Baicker, Cutler, & Song, 2010; Goetzel et al., 2012). The motivation behind these provisions was rooted in the premise that modifiable health risks are associated with increased health care costs, poorer health outcomes, poorer employee health status, and lower productivity — three of the four key components of triple-aim.

In 2005, a meta-evaluation of worksite health promotion economic return studies evaluating 56 peer review journal articles, which qualified through rigorous selection criteria, representing 483,232 employees at multiple organizations with an average study duration of 3.66 years, showed strong evidence for reductions in sick leave, health plan costs and workers' compensation and disability costs of more than 25% (Larry S. Chapman, 2005). This meta-evaluation was followed up in 2012, with the addition of 10 new studies, and the results were consistent with the 2005 study (Larry S Chapman, 2012).

Over the past 30 years, the number of organizations offering their employee populations workplace health promotion programs has increased dramatically, with nearly 90% of all workplaces with greater than 50 employees offering some type of employee health promotion program by 2000 (Soler et al., 2010). By 2015, 30 years of research has shown that well-designed, comprehensive workplace health improvement programs can achieve long-term and lasting behavior change and risk reduction among working populations.

Modern-day self-management programs have benefitted greatly from the learnings of the 30-year-old workplace health promotion industry. Workplace health promotion programs have been in use since the 1980's, with particular growth during the 1990's as a response to the double-digit annual increases in health care costs experienced by employers. A properly designed and implemented workplace health promotion program has shown to improve overall health and reduce organizational health care costs (Fries et al., 1992; Fries et al., 1994; Goetzel & Ozminkowski, 2008; K. Lorig et al., 1985; Ozminkowski et al., 2000; Vickery, Golaszewski, Wright, & Kalmer, 1988) since the quality of health is highly influenced by lifestyle habits (Albert Bandura, 2004). Experts agree, that effective, evidence-based workplace health promotion programs provide individually-tailored risk reduction counseling, a healthy company culture, strong management support, programs grounded in behavior change theory, dedicated staff and high quality interventions, with ongoing evaluation of effectiveness (Goetzel et al., 2012).

Successful evidence-based workplace health promotion programs implemented between 1980 and 2010 informed and influenced the future development of self-management education programs as a method of achieving behavior change, improved health status and health risk reduction for both individuals and populations. One such group of programs that was born from the theoretical underpinnings of three decades of workplace health promotion programs are diabetes self-management education (DSME) programs.

Diabetes Self-Management Education

The term self-management in healthcare refers to the engagement of an individual in a health promoting activity such as healthy eating, exercise or day-to-day management of a chronic condition such as diabetes (K. R. Lorig & Holman, 2003). For most diabetics, this is a lifetime effort involving a myriad of self-management skills including problem solving, decision making, action planning and resource utilization that are influenced by an individual's self-efficacy, or the perception of his or her own ability to succeed in reaching a goal (K. R. Lorig & Holman, 2003).

DSME is the process of teaching diabetes patients the skills and knowledge needed to properly manage diabetes, and sustain those management capabilities over the long-term (Beck et al., 2018). DSME is a fundamental component of high quality diabetes care, with the goal of promoting individual self-efficacy and self-management of the disease, while improving health outcomes and quality of life (American Diabetes Association, 2018; International Diabetes Federation, 2019). Because the day-to-day management of diabetes falls primarily on the individual with the disease, diabetes education must be comprehensive and individualized to meet the needs of each person (Beck et al., 2018; Funnell, 2010; International Diabetes Federation, 2019).

Evidence-based DSME promotes the learning and skillsets needed for diabetes self-management, enabling individuals to learn behavior change techniques that lead to sustained daily activities that positively support diabetes self-care (Beck et al., 2018; Funnell et al., 2009). Ongoing self-management and behavior change are critical factors in the prevention of acute and long-term complications including improved glucose outcomes and reduced A1c levels (American Diabetes Association, 2018; Beck et al., 2018). As such, DSME is a necessary standard used by healthcare professionals to improve patient outcomes (American Diabetes Association, 2018; Funnell et al., 2009). Quality DSMEs continue to be an essential component of care for all individuals with diabetes (Beck et al., 2018).

Several national and international organizations publish guidelines for standards for diabetes self-management education, including the International Diabetes Federation, American Diabetes Association, American Association of Diabetes Educators, Centers for Disease Control and Prevention and the Academy of Nutrition and Dietetics (American Diabetes Association, 2018; Beck et al., 2018; International Diabetes Federation, 2019; Powers et al., 2016). The purpose of these guides is to describe well-designed diabetes self-management education programs and counsel educators on the provision of evidence-based education (Funnell et al., 2009). Guidance is reviewed twice per decade to account for the rapidly changing environment of diabetes care and available interventions.

The standards set forth an organization and delivery model that enables educators to deliver consistent, evidence-based care. A properly-designed structure includes an organization with: defined mission and goals, an appointed advisory group with quality oversight, properly identified target populations, a designated coordinator to oversee education, instructors trained or certified in diabetes education, a curriculum based in evidence and practice guidelines, a model to evaluate outcomes, tailored assessment and education planning with participants, personalized action plans, participant goal measurement, and organization outcomes measurement (Beck et al., 2018; Funnell et al., 2009). Programs are also rooted in theoretical approaches of behavior change (A. Bandura, 1977; International Diabetes Federation, 2019; Prochaska & Velicer, 1997; Rosenstock, 1974), as successfully implemented for decades in workplace health promotion programs.

Recent studies have shown improved clinical outcomes and quality of life, while reducing hospitalizations and healthcare costs through the use of evidence-based DSME programs (Chrvala et al., 2016; Duncan et al., 2009; Pillay, Armstrong, Butalia, Donovan, Sigal, Chordiya, et al., 2015; Pillay, Armstrong, Butalia, Donovan, Sigal, Vandermeer, et al., 2015; Strawbridge, Lloyd, Meadow, Riley, & Howell, 2017). DSME is also associated with improved knowledge and self-care behaviors, and reduced A1c levels in patients (American Diabetes Association, 2018; Chrvala et al., 2016; Hornsten, Stenlund, Lundman, & Sandstrom, 2008; Redmond et al., 2007). Participants in DSME programs are more likely to follow provider recommendations and have lower medical claim costs (Duncan et al., 2009). Although the outcomes of recent research has been promising, only 5-7% of individuals eligible for DSMEs through commercial or government health plans actually participate in the programs (Li et al., 2014; Strawbridge, Lloyd, Meadow, Riley, & Howell, 2015).

With respect to diabetes self-management and glycemic control, there is considerable data that demonstrates participation in DSME results in statistically significant decreases in participant A1c levels (Chrvala et al., 2016). A general clinically-accepted A1c goal for most non-pregnant diabetic adults is < 7% (American Diabetes Association, 2017; Chamberlain et al., 2017; Chrvala et al., 2016). Decreases in A1c levels toward this goal have been demonstrated in studies of both structured group and individual education programs which have resulted in better outcomes than regular care or other interventions (Norris, Engelgau, & Narayan, 2001; Reaney et al., 2013). One such structured group DSME program that has achieved successful clinical outcomes (Dorland & Liddy, 2014; Hung et al., 2017; Yang & Fang, 2016) is the diabetes Conversation Map program.

Diabetes Conversation Maps

The diabetes Conversation Map education program (CM), is a DSME program designed to support self-management of type-2 diabetes (Healthy Interactions Inc., 2020a; Reaney et al., 2012). CM is a patient-centered, group conversation-based program facilitated by a trained health educator (Hung et al., 2017; Reaney et al., 2012; Reaney et al., 2013). Patients learn about diabetes and disease self-management tactics by focusing on their personal interests and real-life experiences in conversation with the facilitator and other group members (Reaney et al., 2012). This learning methodology enables participants to realize greater meaning in the information they review, and apply it to every day scenarios they might encounter (Reaney et al., 2012). More than three million people (Reaney et al., 2012) have participated in a CM program in more than 100 countries (Hung et al., 2017; MacNeill, 2012), while more than 25,000 health educators have been trained in facilitating CM programs (Reaney et al., 2012).

The CM program's design was influenced by successful workplace health promotion and DSME programs of the previous decades that used behavior change and other theoretical approaches to improve participant health and clinical outcomes. The content for CM was developed through discussions with healthcare providers, focus groups and patient interviews and guided by adult learning principles to ensure participants experienced a tailored approach to their learning style (Reaney et al., 2012).

The CM program is a global intervention created by Healthy Interactions, in collaboration with the International Diabetes Federation, and sponsored by Lilly Diabetes (Healthy Interactions Inc., 2020a; Reaney et al., 2013). The design of the CM program is intended to foster an interactive small group discussion using a colorful display and activity cards and facilitated by a trained health educator (Healthy Interactions Inc., 2020a; Reaney et al., 2013). The six elements of the CM program include visual maps that are three to five feet illustrations with pictures of people in daily living scenarios, conversation questions, discussion cards, group interaction, facilitation and action planning (Fernandes et al., 2010; MacNeill, 2012). Participants relate events depicted on a map to their own daily life experiences, and facilitators promote conversation that enables discussion among the group and experiential learning (MacNeill, 2012). Healthy Interactions describes their program as:

> *"We believe in facilitated small-group, discovery learning, combined with visual learning principles. We believe these principles integrated with a stimulating Socratic approach (questions that elicit dialogue and conclusions) are a dramatically more effective technique to creating personal health engagement than traditional didactic learning."* (Healthy Interactions Inc., 2020b)

Groups meet once per week over a four week period for two-hour sessions, covering a new topic area every week using one of four CM visuals (Fernandes et al., 2010). Participants are encouraged to bring a support person to the group class, which consists of a target size of eight to 10 people (Sperl-Hillen et al., 2011).

The teaching modality described above in a CM program class is different than a traditional lecture-style classroom, where information tends to flow mostly from the teacher to a passive audience of students. CM utilizes an interactive teaching modality, with the teacher typically trained as a health educator, nurse, dietician or certified diabetes educator (Fernandes et al., 2010), who serves as a facilitator of the group discussion and interaction (Sperl-Hillen et al., 2011).

The overall goal of the group format interactive education sessions is to empower individuals with diabetes to take responsibility for managing their diabetes and quality of life with the disease, driving positive behavior change and improving clinical outcomes (Fernandes et al., 2010; Healthy Interactions Inc., 2020a; MacNeill, 2012; Merck, 2019). One primary goal is the proper management of glycemic control, which reduces the risk of complications associated with the disease (Hung et al., 2017; Reaney et al., 2013).

The CM program has shown to reduce participant A1c levels in a number of published studies (Dorland & Liddy, 2014; Hung et al., 2017; Yang & Fang, 2016). In a 2017 pre-post study on the long-term effectiveness of the CM program among type-2 diabetics, CM improved the level of diabetes literacy in the CM experimental group (n=49) versus the control group (n=46) ($P<0.01$), who received routine care and did not participate in an education program (Hung et al., 2017). This effect was maintained for an additional three months after the CM program had been completed (Hung et al., 2017). Additionally, the experimental group had a significantly larger reduction in BMI ($P<0.01$) than the control group, an effect that was also maintained for the three month post-intervention period (Hung et al., 2017).

In a 2016 meta-analysis of 22 randomized control trials of the impact of CM tools in patients (n=3,360) with type-2 diabetes, the investigators found that fasting blood glucose levels were significantly reduced in patients who participated in the CM program compared to the control group (Yang & Fang, 2016). A significant reduction in patient A1c levels was also observed, a weighted mean difference of -0.63 in A1c level ($P<0.001$) (Yang & Fang, 2016).

However, results of the impact of CM programs versus traditional diabetes care or education are mixed. In a 2013 multi-national randomized control trial of the impact of CM versus regular diabetes care on participants' diabetes knowledge using the Audit of Diabetes (ADKnowl) questionnaire, participants in both CM and regular diabetes care increased their diabetes knowledge significantly ($P<0.001$), depending on the country (Reaney et al., 2013). In Spain, the CM group performed better than regular diabetes care group ($P<0.001$). In Germany, regular care scored higher than CM ($P<0.001$) (Reaney et al., 2013). In both countries and both groups, median A1c decreased similarly (Reaney et al., 2013). These mixed results were also reported in the U.S. IDEA study, a randomized control trial comparing CM to individual education and regular care that resulted in positive short-term effects ($P<0.05$) of both CM and individual education versus regular care (Fernandes et al., 2010).

In 2016, Srulovici et al. (2015) conducted a systematic literature review of CM and health outcomes, identifying 24 studies that indicated non-significant differences between CM intervention and control groups. Most notably, conflicting results were identified in relation to the influence CM had on patient A1c (Srulovici et al., 2015). The conclusion of these conflicting results highlights the need for further study to determine the potential promise of CM reducing patient A1c levels and impacting long-term health outcomes.

Theoretical Framework — Group Dynamics

In Kurt Lewin's 1951 book *Field Theory in Social Science*, Lewin posited that non-material entities such as social fields exhibited the same behavior as physical fields, concluding that the collective properties of a dynamic whole are different than the structural properties of its subparts (Lewin, 1951a). Just as a piece of steel made up of a number of individual elements, including iron, carbon and chromium, collectively form to create a new physical product with a different purpose than its individual parts, a social field such as a group of individuals, when collectively formed for a specific purpose, will exhibit different behavior than its individual members. Groups, although not physical things, exhibit structural properties of the physical world. These properties can be observed to gather reliable data on the relation between the group and the behavior of its individual members (Lewin, 1951a).

The happenings within a social field such as a group are influenced by what Lewin called the distribution of forces throughout the field. Lewin believed that the more a group held to a social standard, the harder it would be for an individual member to stray from that standard (Lewin, 1951a). Applying this theory to DSME, and more specifically group-based CM programs, the key to individual behavior change is establishing a high group standard and raising individual members to meet that group standard. In the case of CM, a high group standard would be an education program with motivated, engaged patients willing to learn self-management skills that permanently change behavior and improve individual health and glycemic control. According to Lewin's theory, if the CM group is motivated, so will the individuals be.

Lewin discovered that it is "*usually easier to change individuals formed into a group than to change any one of them separately* (Lewin, 1951a)." This is the core premise of this study. Group-based education is more effective than individual-based education, because once a high group standard is established, it will have a stronger impact and lasting effect than individual education. Any resistance an individual may have had prior to joining a CM group will likely be eliminated once the tools and techniques of the facilitator are deployed to create a group effect. Additionally, once group values are achieved, individual members will resist changes more strongly (Lewin, 1951a).

Because a change to a higher level of group performance can be ephemeral, permanency at the higher level is a critical factor in the long-term success of the group, and therefore its individual members (Lewin, 1951a). For application to CM, achieving an ideal state of permanent behavior change is a goal of the program. Lewin's theory is applicable here. He offered the concept of three stages in the process of achieving higher level group performance: (1) unfreezing the present level, if necessary; (2) moving to the new level; and (3) freezing group life at the new level (Lewin, 1951a). For the unfreezing step, a catharsis might be necessary to remove prejudices (Lewin, 1951a). With CM, the unique program design, facilitator and group influence are keys to achieving higher level performance.

Lewin provided evidence of his theory of group decision as a change procedure in a study of housewives who had visited the maternity ward of the State Hospital of

Iowa. In his study of educating women on the importance of increased milk consumption, one cohort was given an individual lecture and the other was involved in a group discussion with a group decision. The change in milk consumption was checked at two and four week intervals after the intervention. At both intervals, the group decision was superior to individual instruction (Lewin, 1951a). This permanency of change concept was tested again with a study on the feeding of cod liver oil to babies, which showed similar results as the milk consumption study, proving again the superiority of the group decision procedure over individual education (Lewin, 1951a).

The challenge with individually-focused education efforts is that the individual's predispositions act as a force field resistant to change. On the contrary, when education successfully changes group standards, this force field will influence change in the individual members and help to stabilize individual conduct at the new group level (Lewin, 1951a). In group decision making, individual preferences tend to be disregarded so the individual can act mainly as a group member (Lewin, 1951a). Once in the group and adhering to group standards, the individual's motivations become highly influenced by the group, and a freezing effect is accomplished due to the individual's tendency to stick to his decisions as a result of his commitment to the group (Lewin, 1951a).

What conclusions can be drawn from Lewin's theory and examples? Individual behavior, attitudes, values and beliefs are grounded in the same beliefs as the group to which he belongs (Armenakis & Bedeian, 1999). A group exerts influence over its members, and accordingly are stronger mediums of change than individual efforts. Because of this, group-based DSME is more likely to achieve its goals of sustainable long-term behavior change and improved health outcomes than individually-targeted

DSME with the same objective. Accordingly, group-based CM programs should be more effective at reducing patient A1c levels than traditional, lecture-style education focused on individual students.

Lecture-Style Teaching

Traditional classroom design, with lecture-style education of individual students, has not changed since medieval times (E. L. Park & Choi, 2014). In a traditional lecture-style classroom, a teacher stands at the front of a classroom and delivers a lesson plan to students, often utilizing an analog visual communication tool that accompanies verbal instruction such as a chalk board, white board, overhead projector or a digital tool such as a PowerPoint presentation. The teacher's objective is to impart knowledge to students through information transfer, while students passively receive this information and internalize it through memorization (Michel, Cater III, & Varela, 2009). This is a primarily one-way form of education where the teacher speaks while the students listen (Van Eynde & Spencer, 1988). This method of teaching enables teachers to impart a large amount of information in a short period of time (Haidet, Morgan, O'malley, Moran, & Richards, 2004; Miner Jr, Das, & Gale, 1984).

One of the shortcomings of this teaching method is that students tend to lack attention (Dorestani, 2005) and are not as actively engaged in the materials as needed to develop a full competency of the information. Information is delivered in a formal manner, sometimes with little interaction from students.

The traditional lecture-style DSME program that is part of this study followed this model, with teachers utilizing PowerPoint to didactically present information to students in each weekly class, with some limited student interaction at certain points of the lecture where individual students who were willing may have shared personal experiences with the class. Because of the limited interaction with the instructor and other students, traditional classrooms have been seen as vehicles of individual learning. Research has shown that individual learning is not as effective as group learning in the delivery of DSME and other chronic condition self-management programs (Paul-Ebhohimhen & Avenell, 2009; Renjilian et al., 2001; Rickheim et al., 2002; Sarkadi & Rosenqvist, 2004).

Purpose of Study

The purpose of this study is to evaluate the effectiveness of two teaching methods of DSME, and which method – traditional lecture-style class education or CM interactive group-based learning – had a greater influence on the reduction of participant A1c levels. Results of the proposed study will inform providers, healthcare industry managers and government agencies on effective models of intervention in the area of DSME, in addition to further contributing to the PBPH, DSME and CM literature. Understanding which types of DSME programs have a true impact on reducing patient A1c levels may help to improve overall health status for patients, reduce healthcare costs for employers and risk-bearing healthcare organizations, and improve quality of life for millions of people worldwide.

CHAPTER 3: METHODS

Overview

This study compares two DSME programs sponsored by a regional health system in the Western U.S. Both programs were offered on-site at three different provider locations on a monthly basis and were called the Diabetes Management Program (DMP) even though each location had a different program design and teaching modality. Two of the site's DSME programs utilized the CM intervention program created by Healthy Interactions Inc., a group-based, interactive and conversational health education program facilitated by a trained health educator (CM Group). The CM Group program consisted of four group education sessions over a four week period. The third site's DSME program was a traditional, lecture-style classroom program developed by health system staff and taught by a trained health educator (Lecture Group). The Lecture Group program consisted of four classroom education sessions over a four week period.

All participants in the DMP programs from January 2013 through March 2017 were assigned to either the CM Group or Lecture Group based on the teaching modality of the class they attended. Data were collected for these participants who attended at least one of the four program classes and had an A1c test within 180 days of the first class attended and an A1c test 30 to 365 days after the last class attended. The primary outcome was the reduction in participant A1c levels, and the study goal was to compare the magnitude of these changes between participants receiving the interactive/conversational style teaching modality (CM) and those receiving the classic lecture-style teaching modality.

Data & Variables

The data were derived from EMR visit records for participants in the DMP at three locations from January 2013 through March 2017. A1c records were merged with visit data to determine if pre- and post- A1c measures were available. The following parameters were required for inclusion in the data set: (a) participant attended at least one of the four DMP classes as part of the program; (b) participant had an A1c test within 180 days of the first class attended; (c) participant had an A1c test between 30 days and 365 days of the last class attended.

Variables included gender, age, insurance type, date first class attended, date last class attended, total classes attended, pre A1c measure, post A1c measure, teaching modality, location, number of days before first class A1c measured, number of days after last class A1c measured, paid or free.

Figure 1

Variables Used in the Study

Variable	**Type**	**Operational Definition**
gender	uc	The gender of the patient
age	c	The age of the patient
insurance type	uc	The type of insurance patient had (e.g. HMO, PPO)
date first class	d	Date of the first class attended
date last class	d	Date of the last class attended
classes	uc/c	Total classes attended (out of four)
pre-A1c	c	The HbA1c level of the patient before intervention
post-A1c	c	The HbA1c level of the patient after intervention
teaching modality	uc	Indicates which program patient attended: 1 = Lecture, 2 = CM
location	uc	The location patient attended the classes
days pre-A1c	c	The number of days before the first class attended the patient's A1c level was measured
days post-A1c	c	The number of days after the last class attended the patient's A1c level was measured
paid status	uc	Identifies if the patient had a co-pay for the program: 0 = not paid 1 = paid
A1c change	c	The calculated change in A1c score: (pre-A1c - post-A1c) = A1c change

Type key: c = continuous; d = date; uc = unordered categorical

Study Design

The design of this study was a quasi-experimental study design comparing the treatment group (CM Group) to the comparison group (Lecture Group) using a non-randomized pre-test/post-test study design. A significance value of $p < 0.05$ was set for the study. Stata was used as the statistical software for the analysis.

Descriptive statistics were conducted on all variables to identify missing values or outliers, calculate frequencies, and confirm coding. Summary statistics were calculated on unordered categorical variables to determine frequencies and modes, while the same statistics were calculated on each group separately to identify baseline characteristics. Summary statistics were determined on all continuous variables, then again for each group separately, to calculate the means, standard deviations, skewness and kurtosis of each variable. Medians were calculated and used when appropriate. Histograms and boxplots were constructed to check for normal distributions. Skewness and kurtosis tests were conducted to validate any skewness identified in the histogram and boxplots.

Chi-square and complementary exact tests were used for categorical variables, and results presented as the number and percentage. For continuous variables, variances were checked, then two-sample *t*-tests or Wilcoxon rank-sum tests, as appropriate, were used to compare groups. Means, standard deviations or medians (Q1-Q3) were presented for these variables. Variables with a statistically significant mean difference between the two groups were used as covariates in the regression analysis.

Paired *t*-tests or sign-rank tests, as appropriate, were used to measure the change within each group before and after the intervention. Pre- and post- means were reported.

Two-sample *t*-tests were used to test whether the mean change in the outcome from pre- to post- intervention differed between the two groups.

Sensitivity analyses were performed to confirm the same results occurred with alternate methods such as Wilcoxon rank-sum tests for medians.

Multivariable linear regression was used to test whether the mean change in A1c, adjusted for pre-test scores, differed between the two groups when controlling for demographic variables that may have hid treatment effects. The dependent variable was the change in A1c values (*A1c change*) calculated as (*pre-A1c* - *post-A1c* = *A1c change*), where a negative value for *A1c change* indicates a reduction in A1c level, representing a positive outcome for the patient. The primary independent variable was *teaching modality* (where 1 = Lecture and 2 = CM). Variables age and days post-A1c were used as covariates. Diagnostic checks for residuals were conducted.

The estimated regression model is:

$$\hat{Y} = b_0 + b_1X_1 + b_2X_2 + \cdots + b_kX_k.$$

The model expressed with variable names is:

$$A1c\ \widehat{change} = b_0 + b_1(teaching\ modality) + b_2(age) + b_3(pre\text{–}A1c) + b_3(days\ post\text{–}A1c).$$

Goal of Study

The goal of the study was to determine whether the CM Group intervention was more effective at reducing patient A1c levels than the Lecture Group intervention. In the statistical hypothesis testing framework, the null hypothesis is there is no difference in the change in patient A1c levels for individuals who participated in a group-based interactive diabetes management educational program compared to individuals who participated in a traditional classroom lecture-style diabetes education program. The alternative hypothesis is individuals who participated in a group-based interactive diabetes management educational program will report a different mean change in A1C levels as compared to individuals who participated in a traditional lecture-style classroom diabetes education program.

CHAPTER 4: RESULTS

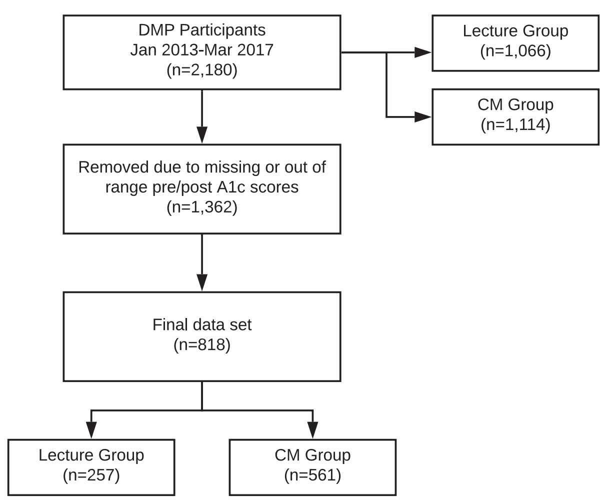
Results Overview

The purpose of this study was to explore the effectiveness of two educational teaching methods on the reduction of patient A1c levels in patients with diabetes. One teaching method utilized the CM program, an interactive, group-based teaching modality (CM Group) while the other method utilized a traditional lecture-style classroom teaching modality (Lecture Group). Both programs were considered well-designed DSME programs taught by trained health educators and sponsored by a regional health system in the U.S. West.

The initial data set received from the health system included participants in the two DMP programs at three locations for the date range January 2013 through March 2017 (n=2,180). One location utilized the lecture-style teaching modality and the other two locations CM teaching modality. Figure 2 describes the data selection process.

Figure 2

Flow Chart of Data Selection



The initial data set had a fairly even distribution of male (*n*=1,006) and female (*n*=1,174) participants. The teaching modality was also closely distributed in the initial data set between the CM Group (*n*=1,114) and Lecture Group (*n*=1,066). The initial data set of DMP participants was refined using inclusion criteria for available pre- and post-A1c test results. To be included in the final data set, a participant must have received a pre-intervention A1c test (*pre-A1c*) within 180 days of the first class attended (*days pre-A1c*) and a post-intervention A1c test (*post-A1c*) from 30 to 365 days of the last class attended (*days post-A1c*). After filtering the initial data set for these criteria and further inspection to confirm no missing values, the final data set used for the analysis included 818 participants.

Routine pre-analysis screening procedures of the data were used to assess normality and homogeneity of variance. Histograms and box plots generated from the data revealed positive skewness for the *pre-A1c*, *post-A1c*, *days pre-A1c* and *days post-A1c* variables. Further investigation utilizing skewness and kurtosis tests revealed significance for skewness and kurtosis on all four variables at a significance level of $p < 0.001$, indicating a statistically significant lack of normality. With such a large sample, however, the assumption of normality was less crucial in the analysis. Table 1 presents the baseline characteristics of the final data set.

Table 1

Baseline Characteristics

Characteristic	All participants n=818 n (%)	Lecture Group n=257 (31.4%) n (%)	Maps Group n=561 (68.1%) n (%)	P Value
Age, years	60.5 ±12.4	59.1 ±12.9	61.1 ±12.1	0.028
Gender				0.906
Male	389 (47.6%)	123 (47.9%)	266 (47.4%)	
Female	429 (52.4%)	134 (52.1%)	295 (52.6%)	
Paid status				0.299
Paid	170 (20.8%)	59 (23%)	111 (19.8%)	
Not Paid	648 (79.2%)	198 (77%)	450 (80.2%)	
Insurance				0.053
HMO	324 (39.6%)	99 (38.5%)	225 (40.1%)	
PPO	246 (30.1%)	80 (31.1%)	166 (29.6%)	
Medicare	97 (11.9%)	26 (10.1%)	71 (12.7%)	
Medicare HMO	85 (10.4%)	31 (12.1%)	54 (9.6%)	
Medicare Advantage	11 (1.3%)	1 (0.4%)	10 (1.8%)	
Medicaid	17 (2.1%)	11 (4.3%)	6 (1.1%)	
EPO	6 (0.7%)	2 (0.8%)	4 (0.7%)	
Cash pay	2 (0.2%)	0 (0.0%)	2 (0.4%)	
Not reported	30 (3.7%)	7 (2.7%)	23 (4.1%)	
Total classes attended	3.3±1.0	3.3±1.0	3.3±1.0	0.659
One	76 (9.3%)	26 (10.1%)	50 (8.9%)	
Two	85 (10.4%)	27 (10.5%)	58 (10.3%)	
Three	150 (18.3%)	46 (17.9%)	104 (18.5%)	
Four	507 (62.0%)	158 (61.5%)	349 (62.2%)	
Pre-A1c	8.2 ±2.0	8.2 ±2.2	8.2 ±1.9	0.928
Days pre-A1c	49.1 ±34.1	52.2 ±37.4	47.6 ±32.4	0.092

Note: mean ± SD are reported as well as n (%)

The mode for teaching modality was the CM Group, with 69% of the total participants (*n*=561) and 31% participating in the Lecture Group (*n*=257). There were slightly more female participants at 52% (*n*=429) than male participants at 48% (*n*=389). The mean age ± standard deviation was 60.5±12.4 years with a statistically significant difference at baseline identified in mean ages between the Lecture Group 59.1±12.9 and CM Group (*M*=61.1±12.1), $p < 0.05$. The mode of number of classes attended was 4 with the mean number of classes attended of 3.3 (*SD*=1.0), with 62% of participants (*n*=507) attending all 4 classes. A majority of participants (79%) did not pay for the program (*n*=648). The majority of participants were enrolled in commercial health plans, with HMO being the largest group at 39.6% (*n*=324) and PPO the second largest at 30.1% (*n*=246). There were no statistically significant differences at baseline between the CM Group and Lecture Group for variables gender, paid status, insurance type and classes attended.

Two-sample *t*-tests were performed on the continuous variables assuming equal and unequal variances based on the variance test results. *Age* showed a statistically significant difference ($p<0.05$) between baseline Lecture Group (*M*=59.1±12.9) and CM Group (*M*=61.1±12.1), $t(816)=-2.21$, $p=0.028$.

To evaluate the change within each group as a result of the educational interventions, a paired-samples *t*-test was conducted to compare same group participant *pre-A1c* scores to *post-A1c* scores (Table 2). In the Lecture Group, the mean A1c scores dropped by 1.0 point, a statistically significant difference for *pre-A1c* scores (*M*=8.2±2.2) and *post-A1c* scores (*M*=7.2±1.7), $t(256)=9.65$, $p<0.001$. In the CM Group, the mean A1c scores dropped by 1.3 points (*M*=1.3±1.8), a statistically significant difference for *pre-A1c* scores (*M*=8.2±1.9) and *post-A1c* scores (*M*=6.9±1.2), $t(560)=16.69$, $p<0.001$. Within both the Lecture Group and CM Group, A1c scores dropped significantly, $p<0.001$.

Prior to performing the two-sample *t*-tests, variances were compared for all continuous variables *age*, *pre-A1c*, *post-A1c*, *days pre-A1c*, *days post-A1c* and *number of classes attended*. The assumption of homogeneity of variance was violated for *pre-A1c*, *post-A1c* and *days post-A1c* at the $p<0.001$ significance level, and also violated for *days pre-A1c* at the $p < 0.05$ significance level.

Post-A1c (unequal) scores showed a significant difference ($p<0.05$) between baseline Lecture Group (M=7.2±1.7) and CM Group (M=6.9±1.2), $t(382)=1.97$, $p=0.0495$. There was a significant difference ($p<0.001$) in the number of *days post-A1c* (unequal) between baseline Lecture Group (M=123.8±83.4) and CM Group (M=96.8±69.6), $t(428)=4.52$, $p<0.001$.

Table 2 presents the mean changes within and between groups.

Table 2

Mean Changes Within and Between Groups

	Lecture Group (n=257)	**Maps Group (n=561)**	
	Mean	**Mean**	**P Value**
Post-A1c	7.2 ±1.7	6.9 ±1.2	0.0495
A1c change	-1.0 ±1.7	-1.3 ±1.8	0.0985
Days post-A1c	123.8 ±83.4	96.8 ±69.6	<0.001

A two-samples *t*-test with unequal variances was conducted to evaluate the change in A1c scores between the Lecture Group and CM Group before and after each intervention, using an A1c difference calculated variable (*pre-A1c* - *post-A1c* = *A1c change*). There was not a significant difference in *A1c change* between the Lecture Group (M=-1.0±1.7) and CM Group (M=-1.3±1.8), $t(512)=1.66$, $p=0.0985$. Immaterial differences were found in the results of sensitivity analyses using Wilcoxon rank-sum tests for medians.

These results suggest that although both lecture-style and CM interventions showed statistically significant effects reducing patient A1c scores, CM may not be more effective at reducing patient A1c scores than lecture-style teaching.

A multivariable linear regression was conducted to assess whether *teaching modality* as the primary independent variable significantly predicted dependent variable *A1c change* when controlling for covariates *pre-A1c*, *age* and *days post-A1c*. Routine pre-analysis screening procedures of the data were performed to identify potential missing values, errors, and to assess linearity. All observations fell within appropriate ranges, no errors were present, and the variables exhibited linearity.

A standard multiple regression on the dependent variable provided the results in Table 3, used to initially assess the relationships between the four candidate predictor variables and *A1c change*.

Table 3

Initial Linear Regression on A1c Change

Variable	***B***	***SE***	***t***	***P>|t|***	**95% CI**
(Intercept)	3.70	0.34	10.87	<0.001	[3.028, 4.362]
Conversation Map	-0.19	0.09	-2.11	0.035	[-0.366, -0.013]
Age	0.01	0.00	1.91	0.056	[0.000, 0.013]
Pre-A1c	-0.63	0.02	-30.37	<0.001	[-0.670, -0.589]
Days post-A1c	0.002	0.00	3.30	0.001	[0.001, 0.003]

Note. Results: $F(4,813) = 257.65$, $p < 0.001$, $R^2 = 0.56$, Adjusted $R^2 = 0.56$

The results of the initial linear regression model were significant, $F(4,813)=257.65$, $p<0.001$, $R^2=0.56$, indicating that approximately 56% of the variance in *A1c change* is explainable by *teaching modality*, *age*, *pre-A1c*, and *days post-A1c*. The CM category of *teaching modality* was significantly associated with *A1c change*, B=-0.19, $t(813)$=-2.11, p=0.035. This result suggests that compared to the lecture teaching modality, the CM teaching modality is associated with a 0.19 point reduction in A1c, while accounting for *pre-A1c*, *days post-A1c* and *age*. *Age* was not statistically significantly associated with *A1c change*, B=0.01, $t(813)$=1.91, p=0.056. *Pre-A1c* scores significantly predicted *A1c change*, B=-0.63, $t(813)$=-30.37, p<0.001. This indicates that on average, a one-unit increase of *Pre-A1c* level is associated with a decrease in the value of *A1c change* by 0.63 point. *Days post-A1c* significantly predicted *A1c change*, B=0.002, $t(813)$=3.30, p=0.001. This indicates that on average, a one-day increase of *days post-A1c* will increase the value of *A1c change* by 0.002 points.

CM teaching modality had a weak but statistically significant effect, β = -0.050, p<0.05. *Days post-A1c* had a weak but statistically significant effect, β = -0.079, p<0.01. *Pre-A1c* had a strong, statistically significant effect, β = -0.724, p<0.001. Overall, there is a highly significant relationship between *A1c change* and the 4 predictors. The test of linear hypothesis after estimation using the collective combination of each two variables in the model all had a statistically significant effect on the outcome variable, p<0.001.

Post-regression diagnostics were performed to test the assumptions of linear regression. Two-way scatterplots were generated using residuals versus *age*, *pre-A1c* and *days post-A1c*, and all variables exhibited linearity with the outcome variable, meeting the assumption of linearity. Diagnostic methods were used to test the assumption of normality, which indicated an issue with the heteroscedasticity of the residuals. The assumption of homoskedasticity was tested using a residual versus fitted plot which indicated some variation in the size of residuals. The variance for smaller fitted values was greater than for larger ones, indicating heteroskedasticity, which was confirmed using the Breusch-Pagan test, $p<0.001$.

Variance Inflation Factors (VIFs) were calculated to detect the presence of multicollinearity between predictors. All predictors in the regression model had VIFs in the range of 1.03 to 1.05 indicating no concern of multicollinearity. Potential outliers were examined using added-variable plots and all data points seemed to be in range with no outliers observed.

The violation of normality was less concerning, considering the sample size and verification of data correctness for cases with the highest leverage. These influential cases were characterized with high *pre-A1c* scores, high *days post-A1c* or both. Several transformations were attempted on the most influential variable, *pre-A1c*, but none of the transformations resulted in an improved model. Quantile regression was explored but also did not provide an improved model. No transformations were available for the dependent variable *A1c change*.

Summary

This chapter presented results from analyses supporting the primary hypothesis of this study.

H1: Individuals participating in a group-based interactive diabetes management educational program will report lower A1c levels as compared to individuals participating in a traditional lecture-style classroom diabetes education program.

Results indicated that both lecture-style and CM teaching modalities were effective at reducing patient A1c levels by 1.0 ($p<0.001$) and 1.3 ($p<0.001$) points respectively, both statistically significant reductions. Although CM did not reduce patient A1c levels more significantly than lecture-style in the between groups analysis, when controlling for *age*, *pre-A1c* and *days post-A1c*, CM was more effective at reducing patient A1c levels by 0.19 points than lecture-style teaching, a statistically significant result ($p<0.05$). After identifying violations of normality and homoskedasticity, we were unable to produce improved results to the initial regression through variable transformations or alternative tests. Results should be interpreted cautiously.

CHAPTER 5: DISCUSSION

Introduction

Since the passage of ACA in 2010, PHM has been a key priority of the government, employers, payers, providers and policy makers as an effective strategy to lower healthcare costs and improve the health outcomes of millions of Americans living with chronic disease. A key component of PHM is chronic disease management, which includes intervention programs that educate individuals on the appropriate management and care of their disease in an effort to improve individual health status and reduce unnecessary utilization of the healthcare system. DSME programs were developed to accomplish these goals, and for diabetes specifically, help patients meet targets for glycemic control to avoid complications of the disease. Studies have shown that participation in DSME programs has resulted in statistically significant decreases in participant A1c levels (Chrvala et al., 2016). This study supports this finding.

Summary of Findings

Both the CM Group and Lecture Group participants were able to reduce their A1c levels significantly, when measured before and after the DSME interventions. For the Lecture Group, A1c levels dropped 1.0, from 8.2 to 7.2 after participating in an average of 3.3 classes during a one month period. The CM Group did better, dropping A1c levels 1.3 points from 8.2 to 6.9, also averaging 3.3 classes attended over a one month period. This result exceeded the American Diabetes Association indication that a clinically-accepted goal for A1c levels for most non-pregnant adults is < 7.0 (American Diabetes Association, 2017; Chamberlain et al., 2017; Chrvala et al., 2016). When applied at scale, the implications of achieving the clinically-accepted A1c goal of <7.0 could have far-reaching effects on the improvement of health status and reduction in associated patient complications and costs of diabetes care.

The purpose of this study was to evaluate the effectiveness of a group-based interactive DSME program compared with a traditional lecture-style classroom DSME program in the reduction of patient A1c levels. The hypothesis was that individuals participating in a group-based interactive diabetes management educational program would report lower A1c levels when compared to individuals who participated in a traditional lecture-style classroom diabetes education program. The results of this study suggest that group-based education using the CM teaching modality may be more successful at reducing participant A1c levels than the lecture style program by 0.3 points. Although not statistically significant in the initial two-sample *t*-test, the regression testing found the reduction of 0.19 points to be significant ($p<0.05$).

A number of CM studies have shown to reduce patient A1c levels when compared with regular care or no intervention (Dorland & Liddy, 2014; Hung et al., 2017; Yang & Fang, 2016), however, there is little information on the comparison of CM with other teaching modalities. This study provides early insight into the performance of CM versus a lecture-style teaching modality that is likely common amongst clinics and health systems around the world.

It is interesting to note, that the initial data set received from the health system included a fairly even distribution of participants in both the CM Group and Lecture Group. However, after refinement of the data to ensure criteria for pre- and post- A1c tests that fell within the requisite time frames were met, the distribution of cases shifted to the CM Group, which represented 68% of all cases in the final data set. One possible conclusion is that the CM program was more successful at encouraging compliance with A1c testing, and therefore its participants received a post-A1c test within the defined range of the study. Local staff at the CM sites may have also influenced the testing, if they encouraged participants to receive pre- and post-A1c tests before program enrollment and after program completion in a more effective manner than at the Lecture Group location.

Also interesting in the findings was that a patient's pre-A1c level was significantly associated with their A1c change. In particular, the higher the pre-A1c score, the larger the drop in mean A1c score as a result of an intervention. This suggests that targeting patients with higher starting A1c levels might be an effective strategy for improving clinical outcomes for the highest risk patients.

Finally, the results suggested that participants who received A1c tests further out from the last class of the intervention experienced diminished effects on A1c change. For every additional day that went by after the last class attended, participant A1c scores went up a small fraction. Over time, this could mean that participant A1c scores eventually regress to the pre-intervention mean, and the reductions associated with the interventions are not maintained over the long term.

Significance of Findings

At the outset of this study, there was still considerable debate over which modalities of education were most effective at producing measurable reductions in A1c levels in diabetes patients. These findings will contribute to the literature to help policy makers, providers and healthcare executives justify investments in properly designed

DSME programs that support PHM initiatives. Furthermore, interactive group-based DSME programs may be more effective at reducing A1c levels than traditional lecture-style teaching methods. This could influence the development of future diabetes and non-diabetes chronic disease management programs, encouraging designs that promote group-based learning as a more effective modality of teaching.

Limitations

These results should be interpreted cautiously, as a number of violations of normality were identified during the statistical procedures that were not improvable through alternative tests. A handful of influential cases with high *pre-A1c* values, high number of *days post-A1c* values, or both, may have strongly influenced results. The quality of the *paid status* data was questionable, as this was not a discrete field in the EMR system but rather typed into the EMR notes field by the program coordinators. This study was also limited to three locations.

Additionally, only participants who received a pre- and post- A1c test within the defined timeframe were included in the study. Any A1c tests taken by participants at facilities outside of the health system were not recorded in the EMR, which could have limited the number of participants in the study.

Recommendations for Future Research

Areas for future research may include a control group study, expanding the sample size of participants, increasing the number of locations in the study, testing other group-based DSME programs with CM, and broadening the types of data collected to further control for factors that could influence results. Data points such as race, income, education, years with diabetes, prior DSME participation, home environment and support system could have an influence on outcomes and results. A time-series approach to A1c testing with more rigid time frames for pre- and post- intervention A1c testing, with testing at multiple intervals from 30 days to one year after the DSME program could provide interesting insight into the ability of these programs to sustain A1c change over time.

Another question for future research is whether group-based DSME programs are cost-effective when compared with traditional lecture-style teaching or other modalities of education. Does the investment associated with licensing the CM program, training a facilitator and reducing the number of class participants justify a 0.19 point A1c reduction in patient A1c levels?

Conclusion

This study provides encouraging information that shows CM might be a more effective DSME intervention than traditional lecture-style classroom programs. As policy makers and program designers consider future development and implementation of chronic disease intervention programs, not just for diabetes but for all chronic conditions, the knowledge that individuals may be more committed to change if they participate in group learning about the change will be an important consideration.

APPENDIX A: IRB APPROVAL LETTER

THE UNIVERSITY OF ALABAMA AT BIRMINGHAM
Office of the Institutional Review Board for Human Use

470 Administration Building
701 20th Street South
Birmingham, AL 35294-0104
205.934.3789 | Fax 205.934.1301 | irb@uab.edu

NHSR DETERMINATION

TO: Sharpless, Edward

FROM: University of Alabama at Birmingham Institutional Review Board
Federalwide Assurance Number FWA00005960
IORG Registration # IRB00000196 (IRB 01)
IORG Registration # IRB00000726 (IRB 02)

DATE: 19-May-2020

RE: IRB-300005284
The comparison of two diabetes self-management education programs in the reduction of patient A1c levels.

The Office of the IRB has reviewed your Application for Not Human Subjects Research Designation for the above referenced project.

The reviewer has determined this project is not subject to FDA regulations and is not Human Subjects Research. Note that any changes to the project should be resubmitted to the Office of the IRB for determination.

if you have questions or concerns, please contact the Office of the IRB at 205-934-3789.

Additional Comments:

Analysis of de-identified data

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