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# Diabetes Management for Low-Income Patients: Within-Case Analyses in Primary Care

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Running Head: POVERTY AND DIABETES MANAGEMENT

Diabetes Management for Low-Income Patients:  
Within-Case Analyses in Primary Care

by

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DISSERTATION

Submitted in partial fulfillment of the requirements for the degree of  
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at Antioch University New England, 2018

Keene, New Hampshire



Department of Clinical Psychology

**DISSERTATION COMMITTEE PAGE**

The undersigned have examined the dissertation entitled:

**DIABETES MANAGEMENT FOR LOW-INCOME PATIENTS:  
WITHIN-CASE ANALYSES IN PRIMARY CARE**

presented on October 30, 2018

by

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Dedication

This work is dedicated to my beloved son Donovan who was born in the middle of the grueling process that is a dissertation, and who waited for me with patient smiles to finally be done.

It is further dedicated to all those who suffer from co-occurring mental and physical illness. May you find strong health and resilience and live a long and joyful life.

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### Abstract

The study evaluated the effectiveness of a diabetes management program in a co-located mental health and primary care setting in Nashua, New Hampshire. The patient-participants were primarily underserved, low-income, working-class or homeless patients from the surrounding region. A few participants were also older adults. Examination of the literature highlighted the growing diabetes epidemic at local, state, and national levels. A review of past clinical trials of diabetes programs indicated further investigation into diabetes self-management education programs that integrate medical and behavioral health components under the biopsychosocial model. Thus, for the present study, the Stanford Diabetes Self-Management Program (SDSMP; Lorig, Ritter, Villa, & Armas, 2009), was utilized as the cornerstone for building a comprehensive program for the population of the treatment site. SDSMP is a semi-scripted six-week peer-led psychoeducation course designed to enhance self-efficacy in the self-management of diabetes. The course meets the *American Association of Diabetes Education Standards* and teaches skills and knowledge around proper diet, exercise, lifestyle, and treatment adherence. Archived quantitative data from participant medical records ( $N = 12$ ) were analyzed at the individual case level to verify whether the program was effective at increasing use of self-care practices and management of symptoms in individual diabetes patients. In addition, qualitative analysis of participant follow-up interviews ( $n = 4$ ) depicted how and why individual changes may have occurred within each case. Some of these themes included Positive Changes, Social Influences, and Workshop Feedback. Quantitative results found that depression and anxiety scores decreased modestly for the group as a whole to a similar degree as shown by previous studies (Lorig et al., 2009, 2016). One patient's depression score showed a clinically significant decrease. The group achieved similar results in their diabetes knowledge and adherence to diet

and physical activity recommendations compared to regional norms for the SDSMP (New England Quality Innovation Network–Quality Improvement Organizations, 2016). Two patients also improved medically in their BMI and HbA1c% scores after attending the program. These results implied that the SDSMP may be an appropriate fit for the site’s population.

*Keywords:* diabetes, primary care, behavioral health, biopsychosocial, self-efficacy, poverty

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and Ohio Link ETD Center, <https://etd.ohiolink.edu/edt>.

### Diabetes Management for Low-Income Patients: Within-Case Analyses in Primary Care

The purpose of the study was an evaluation of a diabetes self-management program administered at a Federally-Qualified Health Center (FQHC) called Harbor Care Health and Wellness Center, a division of Harbor Homes Incorporated that offers primary care and mental health services to primarily underserved low-income and homeless Americans in Nashua, New Hampshire. The program was implemented as a population health project guided by a Global Partnership for Education (GPE) to increase integration of behavioral health treatments into primary care services, using a population-based approach. An evaluation was conducted after the program was completed, based on archived medical and psychological assessment data collected from the site for quality improvement purposes.

The quality improvement project was guided by the model of Population-Based Participatory Research (PBPR), where patient feedback, outcome assessment, and population-specific data informed evidence-based treatment to tailor the program to the site's local context (Fauth & Tremblay, 2011). The program evaluation study utilized a within-case analysis to determine whether the program was effective at improving diabetes management at the individual patient level. That is, the study assessed whether individual patients showed progress on assessment measures across time and at post-program interviews.

A participant follow-up interview assessed a patient's perspective on the program and helped demonstrate whether it was an appropriate fit for each patient. Eliciting patient feedback may also inform future diabetes programs at Harbor Care Health and Wellness Center by highlighting which aspects of the program were deemed beneficial by particular patients, and, if any specific healthcare needs remained to be addressed in each individual patient's care.

Together, the three data sets (medical, psychological, patient interviews) in the within-case



analyses demonstrated whether the SDSMP was an appropriate program for diabetes patients at Harbor Care Health and Wellness Center and for the Nashua, New Hampshire region.

### **Diabetes Management Goals at Harbor Care Health and Wellness Center**

Five interrelated goals were identified for the diabetes program requested by Harbor Care Health and Wellness Center to:

1. Administer an effective behavioral health program for diabetes patients;
2. Improve coordination of care delivery between medical health and behavioral health providers through collaboration and consultation about diabetes patients;
3. Initiate a longer-term behavioral health program for complex diabetes patients with comorbid mental health issues;
4. Pilot a model of integrated healthcare delivery for patients with chronic diseases at the site; and
5. Evaluate the effectiveness of the diabetes management program using medical, psychological, and behavioral outcomes measures.

### **Statement of the Problem**

The following section provides an examination of the diabetes healthcare literature. The epidemiology, etiology, symptomology, and individual risk factors inherent to diabetes are reviewed. Various conceptual models of chronic disease are examined to increase understanding of the role of individual behavior in the etiology and treatment of diabetes. Integrated care models are elaborated to further conceptualize the use of behavioral health programs within a biopsychosocial treatment plan of diabetes patients. Self-efficacy theory, a major component of diabetes self-management education is also elaborated, and an explanation of the Stanford Diabetes Self-Management Program (SDSMP), the primary program of study, is also provided.

The section concludes with an explanation around the significance of the study to clinical psychology, integrated primary care, an explanation of the current research gaps, the study's research questions, and definitions of relevant terms.

### **Epidemiology**

*Diabetes mellitus* is a growing healthcare epidemic at the national level. In a recent study, the Center for Disease Control and Prevention (2014) estimated that 29.1 million individuals or 9.3% of the population was likely to have diabetes in the United States. Their estimate includes the 21 million patients who were already diagnosed, and an additional 8.1 million (27.8% of diabetes patients) were suspected to have diabetes but were not yet diagnosed within that time frame. Furthermore, aggregated data of patient blood sugar levels gathered between 2009-2012 suggested that an additional 68 million Americans or 37% of the adult population (age 20+) may have the condition of prediabetes, and researchers recognized diabetes as the seventh leading cause of death in the United States (CDCP, 2014). Based on estimates in 2000, Boyle et al. (2001) predicted that diabetes diagnoses would increase from 11 million to 29 million (165%) by the year 2050. As indicated by the above CDCP statistics, these predictions were surpassed in 2014, which means our diabetes epidemic may be growing much faster than previously thought.

The diabetes epidemic is of similar proportion in New Hampshire. In the Granite State, 7.1% reported themselves as having diabetes; however, one third or more persons with the illness may remain undiagnosed (Health and Human Services, Division of Public Health Services [NHDPHS], 2010). The primary risk factors for developing diabetes include older age, inactivity, and obesity. The Centers for Disease Control and Prevention (2016) defines obesity using the Body Mass Index (BMI), which is an individual's weight (kg) divided by the square of their height ( $m^2$ ). A BMI greater than 30.0 determines that one's body mass lies in the obese range.

The proportion of adults in New Hampshire who are obese increased from 50.1% in 1999 to 62.8% in 2009 (NHDPHS, 2010).

Obesity is further complicated by having a sedentary lifestyle, and the percentage of New Hampshire residents who reported having little to no physical activity was 21.2% during 2009 (NHDPHS, 2010). The New Hampshire State Health Improvement Plan also stated that improved prevention and treatment of diabetes is one of their top healthcare goals for 2013-2020 (Division of Public Health and Community Services, City of Nashua, New Hampshire, 2014). As a result, the effective care and treatment of diabetes have become a top priority for various healthcare clinics in the state, including Harbor Care Health and Wellness Center Inc. in Nashua, New Hampshire, the site of interest in this study.

### **Etiology and Symptomology**

In the following section, the etiology and symptomology of the various types of diabetes are reviewed. The various diagnostic criteria are also discussed, as well as the additional medical health risks associated with having diabetes.

**Types of diabetes.** The term “diabetes” includes multiple disease types that share common symptom patterns. According to the American Diabetes Association’s (ADA) *Standards of Care Manual* (2016), there are two main types of diabetes. *Type 1 diabetes mellitus* (T1D), also known as “insulin-dependent diabetes,” is an autoimmune disorder characterized by deficiency of insulin production due to destruction of beta cells within the pancreas. The exact cause of T1D is unclear, but multiple environmental and genetic factors are attributed (ADA, 2016). *Type 2 diabetes mellitus* (T2D), also known as “non-insulin dependent,” is a metabolic disorder characterized by progressive loss of insulin secretion due to increased insulin resistance in tissue cells (ADA, 2016). T2D is, by far, the most common type of diabetes and is thought to

result primarily from poor diet, lack of exercise, and obesity (CDCP, 2011). Other types of diabetes exist that are rare or were not present within the population being treated at the site such as gestational diabetes, which sometimes afflicts women in the later stages of pregnancy (CDCP, 2011).

**Symptoms and diagnosis.** According to the American Diabetes Association (2016), common symptoms of diabetes include high blood sugar, increased hunger or thirst, frequent urination, unexplained weight loss or gain, fatigue, blurry vision, and sores that do not heal. Due to the commonality of symptoms between Type 1 and Type 2 (T2D) diabetes, it is often difficult for a medical provider to differentiate between the two illnesses when forming a diagnosis. Also, T2D, when left untreated, has been shown to progress into Type 1 or “insulin dependent diabetes” (ADA, 2016). Common diagnostic tests for diabetes include fasting plasma glucose (FPG) and/or 2-hour plasma glucose (2-hPG) measurements where blood glucose levels are measured after a period of fasting or two hours after a dosage of glucose is administered. A score of less than 7 on the FPG or less than 11.1 on the 2-hPG are considered positive and two positive tests of any type are required for a diagnosis of diabetes (ADA, 2016).

**Hemoglobin A1c percentage.** The hemoglobin A1c percentage test (HbA1c%) is another blood test measuring average patient blood glucose levels that occurred over the previous three months. Hemoglobin A1c% is considered the gold standard diagnostic tool for diabetes, and two consecutive measurements of 6.5% or higher constitute a diagnosis of Type 2 diabetes (ADA, 2016). The clinical treatment target is  $> 6.5\%$ , which suggests that medical and behavioral intervention should continue until the patient’s HbA1c% decreases below 6.5% (ADA, 2016).

**Prediabetes.** Prediabetes is defined as a medical condition in which patient blood glucose or HbA1c% levels are higher than normal “but not high enough to be classified as diabetes” (CDCP, 2014, p. 1). The HbA1c% and blood glucose also have specific measurement ranges for classification of prediabetes (HbA1c%: 5.7–6.4%; and blood glucose: 39–47 mmol/mol; ADA, 2016). It is important to note that prediabetes is a classification rather than a diagnosis of a disease, and it is considered an additional risk factor for contracting diabetes and cardiovascular disease when one is classified as being “prediabetic” (ADA, 2016). Since pancreatic production of insulin has not been permanently damaged with prediabetes, there may be some potential for reversing the condition. Through proper diet and lifestyle adjustments, blood glucose levels can be brought back into the optimal range, thus reducing the risk of developing diabetes (Gray, 2015).

**Additional health risks.** Patients diagnosed with diabetes may also be at increased risk for developing a myriad of other adverse health conditions. For example, heart disease and stroke deaths occur 2 to 4 times more often in diabetes patients. In 2004, 68% and 16% of diabetic patient deaths in the United States were related to heart disease and stroke respectively (CDCP, 2011). In New Hampshire, approximately 16% of adult diabetes patients reported having cardiovascular disease and 63.3% reported having high cholesterol (NHDPHS, 2010), which increases their risk of having a heart attack or stroke. Diabetes is also the primary cause of kidney failure and lower limb amputation with 44% and 60% of these afflictions having occurred with patients respectively (CDCP, 2014). It is also the leading cause of eye problems with 4.2 million people or 28.5% of diabetes patients who reported having retinopathy that may result in vision loss (CDCP, 2014). There are numerous other health risks and vulnerabilities associated with having diabetes, which further demonstrates a necessity for managing this chronic illness.

### **Individual Risk Factors**

In the following section, the various individual risk factors associated with the development of diabetes are reviewed. Obesity, homelessness, patient age, family and community factors, and patient race and ethnicity account for some of the individual risk differences in developing diabetes, as well as disease prognosis and treatment outcome.

**Obesity.** There are multiple factors that place an individual at greater risk for developing diabetes. One of the biggest factors is excess bodyweight. Patient body mass index (BMI) is a measurement taken routinely at diabetes check-ups and other medical appointments. BMI is a ratio of weight (kg) over height (m)squared ( $\text{kg}/\text{m}^2$ ). A BMI of 18.5 to 24.9 is considered healthy range; 25 to 29.9 is considered overweight range; and 30 or higher is considered obese range. In a randomized national phone survey of 195,005 individuals, BMI was a strong predictor for also having diabetes. Compared to individuals with a normal bodyweight, those surveyed with a high body mass index ( $\text{BMI} > 40$ ) had an increased odds ratio of 7.37 for also being diagnosed with diabetes (Mokdad et al., 2003). Due to increased risk for developing diabetes in overweight individuals, screening of HbA1c% is recommended for all patients with BMI greater than 25  $\text{kg}/\text{m}^2$  (ADA, 2016).

While high BMI is the most commonly used indicator for being overweight, other measurements can make a more clinically precise calculation. Obesity is medically defined as a “state of increased adipose tissue of sufficient magnitude to produce adverse health consequences.” Therefore, obesity can be more precisely determined by calculating body fat percentage (Gómez-Ambrosi et al., 2011, p. 1439). In a cross-sectional study of 4,828 individuals of various body masses, Gómez-Ambrosi et al. found body fat percentage to be the strongest predictor for developing T2D and prediabetes. This was a particularly important

discovery as patients with waist circumference measurements lying within the normal range and who generally did not appear obese were discovered to have a higher percentage of distributed body fat, which significantly increased their risk for diabetes (Gómez-Ambrosi et al., 2011). Body fat percentage is less routinely measured in clinical practice, and therefore, such data are typically less available.

In New Hampshire, individuals with BMI > 25 were found to have a prediabetes prevalence rate of 8.8%, while in those with BMI < 25, the prevalence dropped to 3.0% (NHDPHS, 2016). In Hillsborough County where Harbor Care Health and Wellness Center is located, 62.2% of diabetes patients reported being obese (NHDPHS, 2010). As reported above, the higher the BMI of the individual and the higher the BF% they possess, the greater the likelihood that patient may develop diabetes. Therefore, there is little surprise that the prevalence of diabetes and obesity within the patient population of Harbor Care Health and Wellness Center were both found to be high.

**Homelessness.** Another risk factor for development of diabetes is homelessness. Colloquially, our conception of homelessness is highly specific, and the term “homeless” is traditionally used to refer to an individual living on an urban street. At Harbor Care Health and Wellness Center, homelessness is defined more broadly on a spectrum and may reflect varying degrees of housing instability, or rather, any individual with some sort of unstable living situation. Their operational definition of homelessness includes individuals who are staying in a shelter, living in transitional housing units, “doubling-up” (e.g., two families living in a single-family dwelling etc.), camping in the forest, as well as individuals who make their home on the street (Harbor Care Health and Wellness Center, 2016).

Homeless individuals may be at greater risk of becoming ill. A representative sample of 966 homeless individuals taken from a nationwide study called the *2003 Healthcare for the Homeless User Survey* highlights the poor health outcomes and higher incidence rates of chronic disease within this vulnerable population. In the sample, 73% of respondents reported at least one unmet healthcare need, including an inability to obtain the following: necessary medical care or surgery (32%), adequate prescription medications (36%), suitable mental health care (21%), eyeglasses (41%), and appropriate dental care (41%; Baggett, O'Connell, Singer, & Rigotti, 2010). Forty-six percent of these individuals reported having two or more comorbid chronic illnesses including diabetes, hypertension, cardiovascular disease, and/or chronic pain and disabilities (Baggett et al., 2010).

Employment may also not protect the homeless from disease. For instance, homeless individuals in a study who had held employment over the previous year were more likely to be uninsured and carry unmet healthcare needs than their unemployed and homeless counterparts (Baggett et al., 2010). The researchers of the study faulted the lack of employer-provided health insurance and the possibility that homeless workers may prioritize not missing a day of work to maintain their income level over seeking out affordable healthcare services as one potential cause. This difficult choice between going to work versus seeking attending healthcare appointments also suggests that an additional risk factor may be present for working-class families and individuals who are struggling at the poverty line and cannot afford health insurance when compared to unemployed or zero-income adults receiving Medicaid, the governmental assistance. If full-time or part-time employment does not provide feasible healthcare options, the working-class will remain underserved and, therefore, less likely to receive adequate treatment. Clearly, the poverty of low-income and homeless families may present an additional risk toward



development of chronic illnesses like diabetes.

Severe homelessness may also have an adverse impact on diabetes patient outcomes. A cross-sectional study at homeless service agencies in San Francisco revealed that 26% of those surveyed ( $N = 319$ ) reported complications arising from diabetes (Hahn, Kushel, Bangsberg, Riley, & Moss, 2006). This may be because the homeless may be subject to additional barriers, including food scarcity, difficulties following a schedule, and lack of access to medical supplies, which prevent them from adequately managing their diabetes. In a survey of 50 homeless individuals in Toronto, Ontario, Canada, 64% of respondents reported that suitable dietary options were unavailable at local shelters, while 18% reported having difficulties taking medication at regular intervals and in acquiring basic self-care equipment like insulin (Hwang & Bugeja, 2000). Hwang and Bugeja reported that 75% of homeless participants overall reported experiencing similar difficulties in managing their diabetes and that 50% exhibited poorly controlled blood sugar when tested by doctors.

**Age.** Age is another factor that increases risk for diabetes. The prevalence of prediabetes in New Hampshire was found to be higher among the elderly. In fact, the risk of contracting diabetes progresses as individuals age, increasing from 2.3% among persons 18–34 years old; 5.6% who are 35–44 years old; 6.2% among those 45–54 years old; 9.0% among individuals 55–64 years old; and 12.2% among the elderly from the age 65 years and older (NHDPHS, 2016). Interestingly, when age and BMI are adjusted for, the remaining variability of diabetes risk is accounted for by the increasing bodyfat percentage normally associated with aging, which again implicates BF% as a prominent risk factor (Gómez-Ambrosi et al., 2011).

**Lifestyle factors.** Various lifestyle factors are implicated in the development and course of diabetes. In 2009, a study from the *Archives of Internal Medicine* demonstrated that never

smoking, maintaining a healthy weight, exercising regularly, and following a healthy diet could reduce the risk of developing diabetes, cancer, and cardiovascular disease by as much as 80%. (Division of Public Health and Community Services, City of Nashua, New Hampshire, 2014). Individuals with lower health literacy or lack of specific knowledge around making proper choices in diet, lifestyle, and use of self-care practices are also at greater risk of developing diabetes and are likely to achieve poorer outcomes in diabetes treatment (Kim & Lee, 2016).

**Family and community factors.** Greater involvement of family members in the patient's care and well-being may contribute to better disease outcomes (Rosland, 2009). In a systematic review of the literature, Ross, Mirowsky, and Goldstein (1990) examined the impact of the family system on individual health, revealing that factors, such as being married, female spousal employment, and the family's socioeconomic status (SES) helped prevent the onset of T2D and other chronic diseases. Married partners in the study were shown to eat healthier, smoke less tobacco, and drink less alcohol—all of which helped prevent development of diabetes and other chronic diseases (Ross et al., 1990). Social support for the patient in the form of verbal persuasion by peers and community groups and the vicarious experience of witnessing others with T2D succeed through self-management of their illness were also shown to increase patient adherence to treatment protocols and improved self-efficacy (Allen, 2004). The powerful protection and harm reduction offered by social support from families and community are clearly an important element of diabetes management.

**Race and ethnicity.** The risk for developing diabetes may also be more significant for people of color. A national survey of adults between 2007-2009 indicated that 8.4% of Asian-Americans, 11.8% of Hispanics, and 12.6% of non-Hispanic Blacks were diagnosed with diabetes compared to 7.1% of the non-Hispanic White population (CDCP, 2016). Within the

Hispanic population, 7.6% of Cubans and Central and South Americans, 13.3% of Mexican Americans, and 13.8% of Puerto Ricans were found to be afflicted. Significant variation in normal blood sugar levels of different ethnic and racial groups further complicates diagnosis (ADA, 2016). Membership in one of these populations is significantly associated with increased risk and more robust research is needed around efficacy of diabetes treatment in racially and ethnically diverse populations (Norris, Engelgau, & Narayan, 2001).

Certain Latino populations have some of the highest rates of obesity in all age, racial, and ethnic groups. For instance, seven out of 10 Latino/a adults in California were classified as overweight or obese, and 37% of Latinos nationwide versus 34% for African Americans, and 23% of Caucasian Americans (Woodward-Lopez & Flores, 2006). Thus, Latino individuals may be at greater risk for developing diabetes sometime in their lifetime.

Researchers also advocate for development of more robust literature around diabetes management in culturally diverse settings (Norris et al., 2001). Trials for diverse populations containing subgroup analyses based on age, ethnicity, and baseline glycemic control, as well as the use of standardized behavior techniques for treatment may help determine greater specificity for population-based treatments (Pillay et al., 2015). Another study of a site-specific diabetes self-management program for 256 Mexicans and Mexican-Americans living on the Texas border showed positive results in managing HbA1c% and fasting blood glucose levels, and increasing patient use of diabetes self-care practices; however, feasibility of the program was deemed to be low due to the paucity of bilingual healthcare providers in the U.S. (Brown, Garcia, Kouzekanani, & Hanis, 2002). In another meta-analysis, Kim and Lee (2016) found addressing cultural beliefs and language gaps critical for the effective treatment of diabetes.

### **Psychosocial Components of Diabetes**

There are multiple psychosocial considerations to be made when developing diabetes management programs. First, are the behavioral components described as risk factors in the previous section that lead to development of diabetes and determine the progression of the illness. These include the patient's lifestyle, dietary, and exercise behaviors, whether they remain homeless, and whether they adhere to treatment as described later in this section. There are the social components attributed to the level of patient family and community support. Finally, there are the psychological components of the patient's mental health status. Diabetes patients are more susceptible to various mental illnesses such as depression, and patients with certain psychiatric illnesses are more vulnerable for development of the disease. Invariably, these psychosocial components have a strong effect on the development and progression of the illness.

#### **Depression**

Individuals diagnosed with diabetes are shown to be at higher risk for developing symptoms of depression and/or major depressive disorder (MDD). In a meta-analysis comparing individuals with normal glucose levels, prevalence of depression was moderately increased in patients with prediabetes (random effect odds ratio (OR) 1.11, 95 % confidence interval (CI) 1.03–1.19) and undiagnosed diabetes mellitus patients (OR 1.27, 95 % CI 1.02–1.59), and markedly increased in previously diagnosed diabetes mellitus patients (OR 1.80, 95 % CI 1.40–2.31; Chen et al., 2016).

Evidence suggests that receiving the diagnosis of diabetes has adverse psychological consequences for the patients. A systematic review of prevalence studies in patients with impaired glucose metabolism compared those who were previously diagnosed with those who were not yet diagnosed and found significantly greater prevalence of depressive symptoms in

patients who already knew they were sick (Nouwen et al., 2011). This may suggest that receiving a diagnosis of diabetes from their doctor may have a depressing effect upon the patients. In addition, De Groot, Anderson, Freedland, Clouse, and Lustman (2001) demonstrate that the burden of treatment adherence and the drastic lifestyle modifications necessary for managing diabetes have a detrimental effect on emotional well-being. Clearly, the psychological adjustment that goes along with managing diabetes is enough to warrant psychological treatment as part of diabetes management.

Depressive disorders were highly prevalent in the population of interest in this study. The most recent data from the Division of Public Health and Community Services, City of Nashua, New Hampshire (2014) indicated that 5% of city residents currently suffer from a depressive disorder while 18% have been told by a physician they had a depressive disorder at some point in their lifetime. This compares to 7% of the New Hampshire population currently suffering from a depressive disorder with 17% being told by a physician they had a depressive disorder at some point in their lifetime. The clinical population of Harbor Care Health and Wellness Center may be more acutely depressed. A recent Harbor Care Health and Wellness Center Uniform Data Systems Report (2016) indicated that 1,017 of their 2,194 total patients received a diagnosis of a depressive disorder at some point during their treatment there, which is 43% of the total patients. While it is unclear from the report how many patients currently suffered from a depressive disorder at the time of the study, the report indicates that depression was a salient problem for the target population.

### **Other Mental Health Disorders**

Patients with other mental health disorders are more likely to be diagnosed with diabetes. A study of 345 psychiatric hospital patients revealed a diabetes prevalence of 9.9% for those

diagnosed with bipolar disorder compared to only 3.4% for the rest of the population (Cassidy, Ahearn, & Carroll, 1999). An investigation of 95 patients diagnosed with schizophrenia at an inpatient facility in Italy revealed an overall diabetes prevalence of 15.8% (Mukherjee, Decina, Bocola, Saraceni, & Scapicchio, 1996). Increased tendency toward weight gain is often associated as a side effect of many antipsychotic medications posing an additional risk factor for diabetes in psychiatric patients (ADA, 2004). Last, a combined meta-analysis of 4076 adults demonstrated that 14% of diabetes patients met criteria for generalized anxiety disorder (APA, 2013), 27% with an anxiety disorder not otherwise specified (APA, 2013), and 40% with elevated levels of anxiety symptoms (Grigsby, Anderson, Freedland, Clouse, & Lustman, 2002). Anxiety may also be a risk factor associated with developing diabetes. A population-based study of 37,291 people revealed that higher endorsement of anxiety symptoms at baseline measurement had an increased risk of T2D at 10-year follow-up (Engum, 2007).

Anxiety disorders are also prevalent in the population of interest in this study. The most recent data from the City of Nashua Division of Public Health and Community Services (2010) indicated that 15% of city residents currently suffered from an anxiety disorder compared to 13% in the state of New Hampshire. Again, the clinical population of Harbor Care Health and Wellness Center may be more acute. A recent Harbor Care Health and Wellness Center Uniform Data Systems Report (2016) indicates that 663 of their 2,194 total patients received a diagnosis of an anxiety disorder at some point during their treatment there, which is 30% of the total patients. While it is unclear from the report how many patients suffered from an anxiety disorder at the time of the study, the report indicates that anxiety was a salient problem for the target population.

### **Treatment Adherence**

Another behavioral component of diabetes management is treatment adherence. Treatment adherence is generally defined as “the extent to which a person’s behavior in taking medication, following a diet, and/or executing lifestyle changes, corresponds with agreed recommendations from a healthcare provider” (García-Pérez, Álvarez, Dilla, Gil-Guillén, & Orozco-Beltrán, 2013, p. 175). In a study of 600 T2D patients, 16.6% of the patients adhered to their prescribed medication, 23.3% followed dietary recommendations, and 31.7% followed their recommended exercise regimen (Sharma, Kalra, Dhasmana, & Basera, 2014). In New Hampshire, 12% of diabetic patients reported not attending routine diabetes check-ups with their provider in 2009 (NHDPHS, 2010). The American Diabetes Association (2016) also recommends patients attend routine diabetes check-ups at a frequency of every three months to ensure that all diabetes symptoms and associated health factors can be attended to.

Comorbid depression may also worsen treatment adherence in diabetes patients. Gonzalez et al. (2008) conducted a meta-analysis of 47 independent samples showing that depression was significantly associated with nonadherence to the diabetes treatment regimen ( $z = 9.97, p = 0.0001$ ). Poor treatment adherence associated with depression is also shown to dramatically increase healthcare costs (Katon et al., 2009). The lower adherence rates of depressed diabetes patients are yet another reason to address diabetes management on psychosocial and behavioral levels, which is addressed by the current study.

### **Conceptualizing Diabetes Management**

Due to the various psychosocial and behavioral components, diabetes is notoriously difficult to manage in traditional healthcare settings. This may be due to a lack of conceptual framework for myriad interactions between biological, psychological, social, and behavioral

health components under an entirely biomedical model of disease. A more comprehensive model addressing the multiple domains of a diabetes patient may be warranted. The traditional biomedical paradigm of Western medicine is evaluated here, and a biopsychosocial model utilizing knowledge from the field of psychoneuroimmunology (PNI) is explored. The biopsychosocial model is one of the underlying models used to conceptualize diabetes and guide selection of an appropriate program model for diabetes care at the site.

### **Biomedical Model**

As demonstrated by the increasing diabetes epidemic described previously, the larger medical and healthcare systems in the United States have yet to succeed in addressing the growing prevalence of diabetes. This may be attributable to the basic philosophical assumptions of the Western biomedical paradigm where disease is conceptualized entirely in terms of “somatic parameters” and “psychosocial issues” tend to be disregarded as unscientific or lying outside the realm of medical doctors (Engel, 1977, p. 129). The assumption leads to an overemphasis on biological processes and chemical mechanisms, a bias toward more drastic surgical and pharmaceutical treatments, and a failure to address crucial psychosocial factors that contributed to pathogenesis in the first place (Suls, Luger, & Martin, 2010).

In terms of diabetes management, the multiple psychological, social, cultural, and behavioral components and risk factors discussed previously are left out of the conceptualization and treatment of the illness. Per Engel (1977), Western medicine may be perpetuating a dichotomy between mind and body where diseases like diabetes are treated solely in the biochemical and neurophysiological realm of physicians, while “diseases of living” (p. 129), such as existential anxiety and adjustment disorders, are left to non-medical professionals like therapists and are addressed separately from medical explanations. The biomedical model



circumvents the plausibility of a mind-body connection, where depressive symptoms and chronic illnesses appear to have a bidirectional relationship, and where diseases, such as diabetes with strong behavioral health components and high comorbidity with mental illnesses like depression, necessitate strong psychosocial intervention.

### **Biopsychosocial Model**

Comorbid diabetes and psychological depression can be better conceptualized using the biopsychosocial model (Engel, 1977). The biopsychosocial model of medicine is a conceptualization of the patient's condition on multiple domains or system levels (Engel, 1980). Utilizing systems theory, Engel (1980) envisioned nature as a hierarchically-arranged continuum with more complex superordinate systems levels comprised of the smaller units. He illustrated this continuum as the *Hierarchy of Systems* (see Engel, 1980). At the center of the figure lies a *Person* or the individual organism and all his or her thoughts, feelings, and behaviors. Below the Person level, the *organismic hierarchy* unfolds, which illustrates how the organism's body breaks down anatomically into smaller and smaller units (i.e., nervous systems, organ systems, tissues, cells, molecules, etc.). Above the Person level flows the *social hierarchy*, which illustrates how organisms are arranged within larger and larger social systems (i.e., a couple, family, community, culture, etc.). Each systems level is distinctive and contains its own unique set of characteristics; but at the same time, it is a component piece contributing to a larger whole. In his seminal work, Engel (1980) demonstrated how the biopsychosocial model was used to conceptualize a non-compliant cardiac patient, describing how the patient's condition unfolded through the interaction of multiple systems from the social and organismic hierarchies.

Engel's (1977) biopsychosocial model contributed to the evolution of medicine in multiple ways. First, the biopsychosocial model helped synthesize the mind-body dualism and

reductionist approach adopted by Western medicine (Engel, 1977). Illnesses would no longer be reduced to disparate systems and relegated to distinct specialists in separate domains of medicine. The patient can be treated as a whole person where biological and psychosocial treatments are brought together in the same medical setting and utilized synergistically to formulate a single treatment plan (Blount, 1998). A biopsychosocial conceptualization of an illness is also important for conceptualizing treatment of chronic illnesses containing biological, psychological, and social components, like in diabetes, where the patient's lifestyle factors must be addressed, such as improving their diet and physical activity (Suls et al., 2010). Finally, the patient's subjective emotional experience is also accounted for by the model (Borrell-Carrió, Suchman, & Epstein, 2004). For example, in the case of Engel's (1980) non-compliance cardiac patient, the man was reportedly in denial about his second impending heart attack for several hours until his supervisor referred him to the E.R. Had a psychosocial intervention been offered to the patient after his first heart attack months earlier, the patient might have been more likely to report to the E.R. on his own recognizance and thus avoided the cumulative tissue damage imposed on his heart because he had procrastinated. Honoring the subjective experience of the patient also means employment of the humanistic principle of *patient-centered care*, where the doctor employs warm and positive regard to comfort the patient and builds trust, which may lead to better patient compliance with the treatment plan (Blount, 1998; Borrell-Carrió et al., 2004).

The biopsychosocial model is an ideal model for diabetes management. First, there are the numerous self-care practices that must be carried out by the patient to control their symptoms, including: (a) medication compliance, (b) attendance of routine check-ups, (c) proper diet, (d) moderate physical activity, (e) quitting smoking, (f) checking eyes and feet etc. (ADA, 2016). In addition, a biopsychosocial model of treatment can be utilized by a single integrated

treatment team with doctors, nurses, psychologists, and health educators collaborating to create a comprehensive diabetes program for the patient (cf. Lorig et al., 2016).

Multiple studies demonstrate integrated care models as more efficacious in the treatment of diabetes than primary care alone (cf. Steinsbekk, Rygg, Lisulo, Rise, & Fretheim, 2012; Tsai, Morton, Mangione, & Keeler, 2005). This will be discussed further in the next section. Engel's biopsychosocial model (1977) was an attempt to broaden physician perspectives (Borrell-Carrió et al., 2004). By integrating healthcare teams and treatments, providers from different medical paradigms can "blur the edges" (Blount, 2002, p. 6) and develop a comprehensive and individualized treatment program for addressing the full spectrum of biological, psychological, and social components of diabetes patients (Suls et al., 2010).

### **Psychoneuroimmunology**

Another important field that may help explain the high comorbidity between diabetes and depression is psychoneuroimmunology. Psychoneuroimmunology (PNI) is the study of how "psychological states and traits (mind) are associated with immunity (body) and the biological (body) and behavioral (mind) pathways for such relations" (Blount, 2002, p. 3). In some respects, psychoneuroimmunology (PNI) can be viewed as a scientifically validated explanation of the "mind-body connection" that is purported to exist in many historical literatures. As a field, PNI has broadened our understanding of how inflammatory responses initiated by various life stressors can aggravate medical illnesses (Coe, 2010). For instance, stress and depression are shown to increase proinflammatory cytokine release, which leads to chronic inflammation, obesity, and the increased likelihood of developing T2D (Jaremka, Lindgren, & Kiecolt-Glaser, 2013). People who are overweight also tend to be more depressed as excess adipose tissue is implicated in the creation of a cytokine-induced state that is implicated in creating depressive

symptoms (Coe, 2010). In other studies, certain neuroendocrine changes associated with hyperglycemia and hyperinsulinemia promoted the development of depression symptoms through reduction in neurotropic functions that promote concentration and alertness (Behera, Mohapatra, Priyadarsini, & Panda, 2014; Golden, 2007). Thus, the physiological sequelae of having excess blood sugar in diabetes promotes the mental state of depression on a biochemical level, which reflects Engel's (1977) biopsychosocial model.

The multiple pathways by which diabetes and depression are associated may also aggravate each other through a bidirectional relationship (Behera et al., 2014; Pan et al., 2010). The cytokine-induced condition present in overweight patients was found to contain features consistent to those in patients with certain psychological disorders like depression (Coe, 2010). Thus, a physiological condition can contribute to development of psychopathology, and a psychosocial condition (e.g., depression) can contribute to development of a physiological medical condition. Stress and depression are natural sequelae to various chronic illnesses and vice versa (Coe, 2010); therefore, patients who experience significant stress in their lives are at greater risk of developing a multitude of chronic illnesses, including diabetes (Jaremka, et al., 2013). The damaging physiological correlates of stress and depression warrant further examination of how psychosocial factors contribute to the development of chronic illness as well as treatment of comorbid T2D and MDD.

The bidirectional relationship is shown to be present in multiple studies. For example, a ten-year follow-up study between 1996-2006, Pan et al. (2010) surveyed 65,381 women between the ages of 50–75 and found individuals with depressed mood and those taking antidepressants to have a 17% and 25% greater chance of developing T2D, respectively, when compared to

non-depressed individuals. Those who were diagnosed first with T2D also had a 29% greater chance of developing depression compared to non-T2D individuals. Depressed people may also exhibit symptoms, such as irregular appetite, physical inactivity, and self-isolation. Proper diet, moderate exercise, and attendance to medical appointments are necessary for diabetes management and, therefore, depressed diabetes patients may be less effective at managing their diabetes (Kim & Lee, 2016).

### **Healthcare Delivery Models**

Understanding context and the broader systems of healthcare delivery is important for the development of a diabetes management program and evaluating its effectiveness in treating patients at the site. First, the limitations of the biomedical orientation of traditional primary care models are reviewed to illustrate the importance of integrated behavioral health for the treatment of diabetes. Integrated primary care and collaborative care models, which influence the diabetes management program at the site of study, are also explored to demonstrate the effectiveness of behavioral health integration in chronic disease management. Finally, the Stanford Diabetes Self-Management Program (SDSMP), the primary program used at Harbor Care Health and Wellness Center, is also elaborated.

### **Traditional Primary Care**

The review of research illustrating the growing diabetes epidemic in the previous section is evidence that our traditional healthcare systems are failing to prevent and treat diabetes in this country. Employment of integrated care models discussed in the ensuing section is shown to be more successful for treating diabetes and is fast becoming the gold standard of diabetes management (cf. Steinsbeek et al., 2012; Tsai et al., 2005). In addition, traditional primary care models that conceptualize and treat within the biomedical paradigm appear inadequate for the

treatment of depressed diabetes patients. Long-term treatment outcomes are shown to be worse when treating patients with comorbid depression and diabetes with primary medical care alone. A qualitative study of 19 healthcare professionals revealed conceptual barriers to the recognition and treatment of depression in patients with chronic illnesses on the part of providers (Coventry et al., 2011). Coventry et al. stated that normalizing depression as a normal reaction to chronic illness fails to recognize mental illness as a distinctive condition from diabetes and leads to poor long-term outcomes by leaving it untreated. The failure of primary care in distinguishing depression may result from the lack of recognition of psychosocial factors inherent to the etiology of both depression and diabetes (Engel, 1977; Suls et al., 2010). This further demonstrates the need for a behavioral health component in the formulation and treatment of diabetes that is provided by integrated care teams under the biopsychosocial model of medicine (Engel, 1977).

### **Collaborative Care Model**

The need for increased behavioral health integration into the biopsychosocial treatment of diabetes or comorbid diabetes and depression led to the adoption of more collaborative models of healthcare delivery. Formerly known as the chronic care model, the collaborative care model is a conceptual framework that integrates the knowledge from multiple disciplines to effectively treat chronic illnesses (Cretin, Shortell, & Keeler, 2004). This model increases patient-provider interaction by fostering collaboration between the various specialized providers and empowering patients with knowledge and self-management education around their disease. Patient progress in diabetes care is often monitored with a registry and progressive outreach by a care manager, who attempts to increase patient utilization of services and adherence to treatment (Robinson & Reiter, 2007). The collaborative care model is a realization of the biopsychosocial model in

healthcare organizations as medical health and behavioral health components of illnesses can be addressed simultaneously (Blount, 1998).

Collaborative care models that utilize behavioral health are an evidence-based practice. In a meta-analysis of 40 randomized control trials using collaborative care to treat depression in primary care settings, moderate effect sizes were shown for the treatment of depression as well as increasing mental and physical quality of life and social role function (*Cohen's d values*, 0.20–0.33; Woltmann et al., 2012). Another meta-analysis of 31 RCTs of CCM used to treat diabetes found beneficial results for various clinical outcomes and other processes of care, including depression, quality of life measures, and HbA1c% levels (Tsai et al., 2005). Similarly, other studies showed that collaborative care models utilizing a behavioral health component were effective in the treatment of comorbid diabetes and depression (cf. Huang, Wei, Wu, Chen, & Guo, 2013). In a meta-analysis of 9 randomized control trials with 2,238 participants, Huang et al. demonstrated that primary care teams who utilize behavioral health interventions can significantly improve important behaviors in depressed diabetes patients, such as increased adherence to antidepressant medication and oral hypoglycemic agents.

### **Population-Based Approach**

Integrated primary care and collaborative care teams may be tasked to address the problems of a specific patient population like in the present study. Any given population may be comprised of varying cultural identities, demographics, and will present with unique mental and behavioral health needs. When designing and preparing a diabetes program, a population-based approach may be indicated. When utilizing a population-based approach for program design, the care team must “assess the health needs of a specific population; implement and evaluate interventions outcomes to improve the health of that population; and provide care for individual

patients in the context of the culture, health status, and health needs of the populations of which that patient is a member” (Halpern & Boulter, 2000, p. 1). A recent joint task force of the American Diabetes Association (ADA) and the European Association for the Study of Diabetes advocated that clinics should adhere to a population-based approach in their treatment of diabetes (Inzucchi et al., 2012). Therefore, it is important to consider the local treatment context, including the specific risk factors, and individual healthcare needs of the regional and site-specific patient population as thoroughly as possible when designing and evaluating a diabetes program.

**Nashua, New Hampshire healthcare demographics.** In the City of Nashua, New Hampshire where Harbor Care Health and Wellness Center is located, 10% of adults were found to have diabetes, which is slightly higher than the national average of 9.3% (Division of Public Health and Community Services, City of Nashua, New Hampshire, 2014). On the other hand, in Hillsborough County, the more affluent surrounding county in which Nashua is located, 8.1% of adults had diabetes, which is a rate slightly lower than the national average of 9.3% (NHDPHS, 2010). Furthermore, according to the U.S. Census 2010, the City of Nashua has a population of 86,494 and diabetes was the seventh leading cause of death (2% of deaths; Division of Public Health and Community Services, City of Nashua, New Hampshire, 2014). Lack of coordinated care for specific Nashua populations is thought to be a barrier for effective local treatment. The Greater Nashua Community Health Assessment (2014) cites lack of care coordination and integration of behavioral health as obstacles to effective health care delivery in the city. This may indicate warrant further integration of behavioral health services into local clinics.

**Harbor Care Health and Wellness Center patient demographics.** At Harbor Care Health and Wellness Center in Nashua, New Hampshire, the site of this study, the most recent



uniform data system report (2016) indicated that 2,194 patients received healthcare services at Harbor Care Health and Wellness Center in 2015. Of these patients, 1,946 identified as being White (88.6%) and 236 identified as Hispanic/Latino (10.7%). Other racial and ethnic populations were present but minimal. In addition, 50% of Harbor Care Health and Wellness Center patients reported residing in the City of Nashua; 79.7% reported having income at or below the poverty level ( $\leq$  \$11,880 for one-person household); 40.9% reported receiving Medicaid; and 19.4% received Medicare. Almost 77% of Harbor Care Health and Wellness Center patients reported some degree of homelessness. A population-based approach at the site of study might address the multiple socioeconomic characteristics of the population.

During 2015, 116 patients (5.3%) received primary care at the site who were diagnosed with diabetes, a ratio that is disproportionately lower than the diabetes prevalence rate (10%) in the city of Nashua, which may indicate several complicating factors (e.g., under-diagnosis of diabetes in the population, low treatment compliance of diabetes patients etc.). However, people with private health insurance also may have been receiving services at another clinic, such as Dartmouth-Hitchcock, Nashua Primary Care, or the myriad of local private practices comprised of general practitioners. Additional information shows that 766 patients at Harbor Care Health and Wellness Center were diagnosed as overweight and 107 patients were diagnosed as clinically obese. Two-hundred and forty-one (241) patients were diagnosed with some form of substance abuse disorder, and 409 patients or 19% of the clinical population reported using tobacco. Six hundred sixty-three patients (663) met criteria for an anxiety disorder and 1,017 met criteria for major depressive disorder or another mood disorder. These prevalence rates for anxiety and depression (30% and 46% respectively) are much higher than the general population and indicate

an unmet mental health need. A population-based approach at the research site may help address the multiple comorbidities of this population that relate to or are exacerbated by diabetes.

### **Diabetes Self-Management Education**

One highly effective psychoeducational program designed specifically to treat diabetes in primary care settings is diabetes self-management education (DSME). Due to the multiple psychosocial and behavioral factors needing to be addressed in diabetes care, DSME programs aim to increase at-home patient use of self-care practices to help them moderate and cope with their own symptoms. DSME is often run as a program or series of classes, and program components can include building requisite patient knowledge about healthy diet, lifestyle, importance of medication and treatment adherence, as well as developing patient decision-making and problem-solving skills (Pillay et al., 2015). Many of the DSME programs also seek to enhance patients' quality of self-efficacy, and one of the successful and empirically-supported programs is the Stanford Diabetes Self-Management Program.

#### **Self-efficacy**

One of the primary functions of DSME is the enhancement of patient self-efficacy. Self-efficacy is defined as a patient's level of confidence or perception of their ability to perform a certain behavior and their perception that behavior will produce a desired goal (Bandura, 2006). Bandura (2006) postulates that the more confident a patient feels about performing a specific task, the more likely they are to repeat that behavior; and the more they repeat that behavior, the more likely they are to achieve the desired goal. In this section, self-efficacy is shown to be derived from social learning theory. It is also consistent with the behaviorist theory of operant conditioning, which provides one of the mechanisms by which diabetes self-care is

taught using DSME and leads to increased use of self-care practices that help manage diabetes symptoms.

**Social learning and DSME.** The theory of self-efficacy originates in Alfred Bandura's (1977) *social learning theory*. Bandura observed that thinking and behavior are learned psychosocially by observing, interpreting, and mimicking behaviors modeled by others. By witnessing others succeed or fail at specific tasks, people's behavioral responses are conditioned and reinforced vicariously. In DSME, social learning is thought to occur through interaction between participants and between participants and instructors. Skills are taught and/or modeled by instructors and participants report back about completion of weekly goals, share success stories, and offer tips and/or problem-solve with each other about changing their self-care routines. Observing and learning through others is one of the cornerstones of DSME (Pillay et al., 2015).

**Operant conditioning.** Social learning in DSME is also consistent with B.F. Skinner's theory of *operant conditioning* where patient behaviors are reinforced by rewards in their environment (Bandura, 2006). For example, social praise by classmates and instructors for completion of weekly goals or positive results reported by the doctor on a patient's latest HbA1c% measurement may influence the into patient repeating those behaviors that led to change through positive reinforcement. Social learning theory is consistent with the biopsychosocial model as it explains how certain patient behaviors are acquired or reinforced by social interaction. Therefore, it can be said that DSME helps treat diabetes behaviorally on a social level through operant conditioning, making it part of a suitable biopsychosocial diabetes program.

**Self-care practices.** Patients must build self-efficacy over several self-care practices to effectively manage their diabetes. Self-efficacy is not a global trait or character quality, but rather the patient's perception about their ability to conduct a specific behavior within a specific context (Strecher, DeVellis, Becker, & Rosenstock, 1986). In diabetes self-management, this entails following recommended dietary guidelines, exercise regimens that match their ability level, and adhering to medical treatments, such as taking their prescribed medications and attending routine follow-up appointments to effectively monitor and manage their illness. Their self-efficacy levels can also vary in magnitude between specific tasks within the same self-care practice domain, such as participating in aerobic exercises of various difficulty levels (Bandura, 2006). For example, a patient may have high self-efficacy in walking as an aerobic exercise, but not in jogging. Simultaneously, Strecher et al. showed how patient self-efficacy in a specific domain like aerobic exercise can increase incrementally. By gradually increasing the amount and intensity of walking, a patient may increase their self-efficacy for other aerobic exercises, thus making a more difficult task like jogging seem possible and attainable.

**Evidence-based practice.** Increasing patient self-efficacy with DSME is significantly associated with beneficial behavior changes in diabetes patients (Strecher et al., 1986). In a study of cardiac patients, increased self-efficacy was associated with greater frequency and intensity within a home exercise program (Ewart, Taylor, Reese, & DeBusk, 1983). A meta-analysis of 72 studies by Norris et al. (2001) also demonstrated DSME effective for increasing knowledge, frequency, and accuracy of self-monitoring blood glucose, improving dietary habits, and increasing glycemic control at a six-month follow-up. In a study of walking groups for chronic obstructive pulmonary disease patients, patients assigned to groups where walking time gradually increased showed greater increases of perceived self-efficacy (Kaplan et al., 1984).

These results may demonstrate that successful accomplishment of one's goals increases perceived self-efficacy, and furthermore, that learning how to set goals as a skill on one's own may also improve task performance during their own self-care routines. Overall, strong evidence indicates that increasing self-efficacy in self-care practices through DSME is an effective program for improving outcomes for diabetes patients.

### **Stanford Diabetes Self-Management Program.**

The Stanford Diabetes Self-Management Program (SDSMP) is an evidence-based diabetes self-management education program. It consists of a six-week program offered two and a half hours weekly by two peer leaders to groups of 7–17 people. The program follows a structured, semi-scripted format and meets the American Association of Diabetes Education Standards (Lorig et al., 2009). The program was also designed to help fulfill research gaps in evidence-based diabetes management, including the lack of standardized curricula, training procedures, and fidelity standards that would make diabetes programs uniform and testable (Lorig, Ritter, et al., 2016).

The SDSMP is an evidence-based treatment of diabetes. In a nationwide study of the SDSMP, Lorig et al. (2016) showed improvement in six of seven health indicators and in seven of seven health-maintenance behaviors at a six-month follow-up for 884 participants in a heterogeneous sample. The SDSMP may also be a culturally-sensitive treatment for Latino/a and Mexican American diabetes patients due to the program being originally developed in Spanish and having been demonstrated to be effective for improving patient HbA1c% levels, symptom distress, hypo- and hyperglycemia, and self-efficacy in those populations (Lorig, Ritter, Villa, & Piette, 2008). For a list of available studies on the SDSMP, see Table 1. Specific components of the SDSMP are elaborated in the methodology section.

The SDSMP has yet to be evaluated for its effectiveness of treatment with patients in unstable living situations. Hulton, Strang, Brooks, and Hostetter (2015) conducted a pilot study of a similar program called the Stanford Chronic Disease Self-Management Program for patients who were considered homeless in the traditional sense of living in a shelter or on the street. The pilot program's format followed the same six-week, two-and-a-half-hour weekly class schedule as the SDSMP and involved developing participant self-management skills for various chronic diseases. Hulton et al. combined the program with intensive case management (e.g., recruitment, transportation, referral to medical and psychiatric services, etc.) suitable for treating homeless individuals with chronic illnesses. The program produced positive results in participant self-reported health, symptom distress, self-efficacy, exercise behaviors, and communication skills; however, the study only had a small sample size ( $N = 9$ ). During the present study, I was unable to locate previous studies regarding the SDSMPs effectiveness of treatment for patients in unstable living situations, such as those receiving Section 8 Housing Assistance, "doubling up" the occupancy of their unit, or those who were homeless in the traditional sense of living in a shelter or on the street. Such studies may be deemed important areas for future research because having unstable housing could invariably affect the ability of a diabetes patient to store and prepare healthy food, including fresh fruits and vegetables.

### **Significance of Study**

The study intended to further inform practitioners regarding treatment of diabetes patients who were low-income, working-class, or who were homeless or have unstable living situations in the Nashua, New Hampshire region. As described earlier in this section, an unstable living situation brings additional risk factors for developing diabetes and barriers for treatment. As the researcher in this study, I was unable to locate previous studies regarding the SDSMP's

effectiveness of treatment for diabetes patients with these socio-demographics. One pilot study of a similar self-management program for patients with chronic diseases in general only assessed outcomes for homeless patients at pretest and at a six-week posttest follow-up for a small sample of six participants (Hulton et al., 2015). Adopting diabetes programs to the language, literacy, and cultural beliefs and values of a population is also critical (Kim & Lee, 2016). I intended to increase evidentiary support for the SDSMP as a treatment for diabetes patients who were low-income, working-class, homeless, or living in unstable housing.

Norris et al. (2001) identified notable gaps in the diabetes self-management literature. This included inadequate descriptions of the target population and interventions used, in addition to an emphasis on knowledge acquisition and blood glucose levels as outcomes measures at the exclusion of other more immediate variables, such as increased quality of life, self-efficacy, and problem-solving skills. Prochaska (2005) stated that illnesses requiring treatment under an integrated model must agree on uniform methods for how to adequately identify and represent the variables of study, including descriptions of the intervention and the local context of the population itself. The present study observed correlations between the SDSMP and more immediate outcomes, such as changes in self-efficacy and self-reported depression and anxiety, alongside increased participant knowledge and changes in their diabetes biomarkers, like HbA1c% levels.

Population and program-component descriptions along with their rationale were also tracked and elaborated in as much detail as possible to inform readers about the local context of the population. Follow-up interviews of participants surveyed patient perspectives to help determine how appropriate the program was for the local population attending primary care at Harbor Care Health and Wellness Center as in a population-based approach. As the researcher, I

intended my study would provide valuable feedback to guide future programs at the site and might be significant for the City of Nashua and local clinics interested in improving coordinated care for diabetes patients (Greater Nashua Community Health Assessment, 2014).

The study attempted to contribute to the literature by conducting Population-Based Participatory Research (PBPR; Fauth & Tremblay, 2011). The Institute of Medicine (2006) cited large discrepancies between evidence-based practice models and their quality of implementation in specific settings as shortcoming in contemporary healthcare delivery nationally. For example, Bauer (2000) reviewed a sample of 41 studies providing treatment adherence data and discovered that only 27% of cross-sectional and pre-post studies achieved adequate treatment adherence compared to 67% of controlled studies. Interestingly, only six of 13 studies (46%) that reported outcomes data along with treatment adherence found improved outcomes to be associated with greater rates of adherence. This seeming paradox led the Institute of Medicine to call for healthcare that is both scientifically-informed, as well as *patient-centered*, meaning that care is respectful and responsive to individual patient preferences, needs, and values (i.e., local context).

Strict adherence to evidence-based practice protocol may not be appropriate for every site, which further indicates the need for PBPR. As Prochaska (2005) stressed, overreliance on clinical efficacy trials may be one of the primary barriers to their dissemination. Randomized control trials are notoriously expensive and logistically difficult for many small sites to undertake. Prochaska's recommendation was to move towards research that is practice-centered and population-specific so that real-world heterogeneous populations can be addressed. The present study sought to follow these philosophies by evaluating a program that began with an



evidence-based treatment (SDSMP), and continued to evaluate and modify that program as a quality improvement project that addressed the needs of a particular population more effectively.

The purpose of the study was an evaluation of a diabetes management program in a primary care setting treating primarily working-class and homeless people in the medium-sized city of Nashua, New Hampshire. The primary component that was evaluated was the Stanford Diabetes Self-Management Program (SDSMP); however, several participants requested creation of an ongoing diabetes support group, which met for several months and complemented the SDSMP. First, the evaluative study helped determine whether the SDSMP was an effective short-term treatment for depression and anxiety. Second, the evaluation helped determine whether the SDSMP was effective at increasing patient self-efficacy around their diabetes care. Third, the study evaluated potential patient increases in diabetes knowledge, use of self-care practices, diabetes coping skills, healthy lifestyle behaviors (i.e., a diabetes-appropriate diet and sufficient physical activity), and whether these increases were sustained by participants one year later. Last, the evaluation examined whether these behavior and knowledge increases may have contributed to improvements in patient medical outcomes, including hemoglobin A1c percentage (HbA1c%) and body mass index (BMI) measurements at routine medical follow-up visits for patients at the site.

### **Research Questions**

To evaluate the effectiveness of the program at the primary care site, the present study utilized the following research questions. The questions were formulated in consideration of the program model, theoretical conceptualization of diabetes, and the dependent variables of self-reported depression and anxiety symptoms, attendance of routine medical appointments, and important patient biomarkers related to diabetes management (i.e., HbA1c% and BMI):

- How effective was the SDSMP program at increasing patient-reported self-efficacy in diabetes management?
- How effective was the SDSMP program in reducing depression and anxiety symptoms between pretest and posttest self-report measures?
- How effective was the SDSMP program, at increasing basic patient knowledge of diabetes, as determined through pretest and posttest measures?
- How effective was the SDSMP program at increasing patient-reported use of self-care practices?
- How effective was the SDSMP program at improving patient attendance of routine diabetes follow-up appointments?
- How effective was the SDSMP program at improving patient biomarkers related to diabetes management, including HbA1c% and BMI at routine follow-up exams?
- What aspects of the SDSMP program were most effective?
- What aspects of the SDSMP program should be modified or added?
- What behavior changes and medical and psychological outcomes were sustained or achieved by participants at the 11-month follow-up interview?

### **Conclusion**

This section overviewed the purpose of the study, which was to determine the effectiveness of a diabetes program for underserved, low-income, working-class, and homeless Americans at a primary care clinic in the city of Nashua, New Hampshire. The epidemiology, etiology, symptomology, and individual risk factors of diabetes were reviewed. Various conceptual models of chronic disease were also examined to understand how individual behavior affects diabetes. Diabetes was conceptualized, using the biopsychosocial model, which

highlighted the importance of behavioral health interventions in treating patients under the integrated care model. Diabetes self-management education, which utilizes self-efficacy theory, was also elaborated, and the primary program of the evaluation study, the Stanford Diabetes Self-Management Program (SDSMP), was also described. The section concluded with an explanation about the significance of the study to psychological practice, integrated primary care, an explanation of the current research gaps in diabetes healthcare, and the study's research questions.

### **Definition of Terms**

**Hemoglobin A1c Percentage (HbA1c%) test:** As the gold standard diagnostic tool for diabetes, the HbA1c% is a medical laboratory test indicating the patient's average blood sugar levels over the prior 3-month period (ADA, 2016). Two consecutive HbA1c% results of greater than 6.5% (48 mmol/mol) are indicated for a diagnosis of Type 2 diabetes.

**Biopsychosocial model:** An integrated framework for conceptualizing illness on biological, psychological, and sociological levels (Engel, 1977).

**Body mass index (BMI):** as a routine measure at diabetes check-ups and other medical appointments, BMI is a ratio of weight (kg) over height (m)squared ( $\text{kg}/\text{m}^2$ ) that signifies whether a patient has a healthy bodyweight. A BMI of 18.5 to 24.9 is considered healthy range; 25 to 29.9 is considered overweight range; and 30 or higher is considered obese range.

**Diabetes:** Although most patients in the study had Type 2 diabetes, the term is used in this study to refer more broadly to any patient who has any type of diabetes (e.g., T2D, T1D, prediabetes, etc.) unless otherwise specified.

**Prediabetes:** A condition in which individuals have blood glucose or HbA1c% levels higher than normal “but not high enough to be classified as having diabetes” (CDCP, 2014, p. 1).

**Collaborative Care Model:** A conceptual framework integrating the knowledge from multiple disciplines to effectively care for chronic illnesses (Cretin et al., 2004).

**Integrated care:** A healthcare delivery model combining medical and behavioral health interventions to address an illness on multiple levels as conceptualized by the biopsychosocial model (Blount, 1998).

**Diabetes self-management education (DSME):** A variety of program formats and methods used to increase self-efficacy in diabetes patients around managing their own symptoms by building requisite knowledge, diet, lifestyle, and medical treatment adherence, as well as increasing decision-making and problem-solving skills (Pillay et al., 2015).

**Obesity:** A state of increased adipose tissue often measured by body mass index (BMI) or a body fat percentage (BF%) that is of sufficient magnitude to produce adverse health consequences (Gómez-Ambrosi et al., 2011).

**Psychoneuroimmunology:** The study of how psychological states and behaviors influence the etiology of diseases processes in the body, particularly through immunological pathways (Blount, 2002).

**Self-efficacy:** Based on Bandura’s social learning theory, self-efficacy can be defined as an individual’s level of confidence or perception of his or her ability to perform a certain behavior and the belief that behavior will produce a desired goal (Bandura, 2006).

**Social learning theory:** A theory from Alfred Bandura that thinking and behavior are learned psychosocially by observing, interpreting, and mimicking behavior modeled by others (Bandura, 1977).

Stanford Diabetes Self-Management Program (SDSMP): A specific DSME program developed by Stanford University and the primary program in the present evaluation.

Treatment adherence: The extent to which a patient's behavior conforms with the recommendations of their health care provider in terms of taking medication, following a diet, and/or executing certain lifestyle changes (García-Pérez et al., 2013).

Population-based approach: A methodological approach where the health needs of a population are assessed and programs are continually adapted to fit their local context of the population; the evaluators of a program attempt to account for the needs of the specific culture, socioeconomic status, and health issues of the population for which their patients are a member (Halpern & Boulter, 2000).

### **Methodology**

This study was an evaluation of a quality improvement project conducted under a GPE grant for helping underserved diabetes patients in the Nashua, New Hampshire area. The goal of the study was to determine how effective the program was at improving the mental and physical health of the patients and to inform future diabetes programs at Harbor Care Health and Wellness Center in Nashua, New Hampshire. This section discusses the program evaluation design, participants, recruitment process, program description, data collection procedures, and data analyses used in the study are discussed along with the limitations inherent to the design and within the study itself.

### **Practice-Based Participatory Research (PBPR)**

A framework of Practice-Based Participatory Research (PBPR; Fauth & Tremblay, 2011) guided the development and quality improvement aspects of the diabetes program at Harbor Care Health and Wellness Center. The goal of PBPR is to enhance the adoption of evidence-based

treatment models into the local context of clinical settings. As such, practitioners of PBPR attempt to select, modify, implement, and evaluate research-supported treatments, and in consideration of the available resources of the site, tailor them to the specific needs and values of their site's population. The practitioners then attempt quality improvement endeavors by utilizing clinical observation and patient feedback gained during an evaluation phase to modify and improve their program. The methods and goals of PBPR are aligned with the 2005 American Psychology Association Task Force definition of evidence-based practice in psychology, which is "the integration of the best available research with clinical expertise in the context of patient characteristics, culture, and preferences" (Anderson, 2006, p. 273).

PBPR utilizes a population-based approach where the specific health needs of a site's population are assessed and the program chosen then continually adapted to suit the local treatment context and the site's population (Fauth & Tremblay, 2011; Halpern & Boulter, 2000). Different clinical sites serve different populations and a given population may be comprised of any number of individuals from various socioeconomic, educational, or rural/urban backgrounds; therefore, any given site will have a local context unique unto itself. In addition, a given population will have different epidemiological data concerning the medical and mental illnesses prevalent for patients in that region (See Epidemiology section in this paper for epidemiological data concerning the population at Harbor Care Health and Wellness Center, the site of the present evaluation study). In this way, PBPR is consistent with a post-positivist research philosophy. Various data sets are sought that demonstrate the effectiveness of a program and its adaptability to the complexity of illnesses and myriad patient identities of the population (Mertens, 2010). Treatment responsiveness for individual participants will vary due to personal risk factors and identities (see Individual Risk Factors section in this paper). Results are

interpreted in a PBPR framework to inform the program leaders on how they can improve or modify the program, which is consistent with the principles set forth by the American Psychological Association Task Force on evidence-based practice in psychology (Anderson, 2006).

**Phases of PBPR.** PBPR includes four developmental phases: (a) Planning, (b) Pilot, (c) Discovery, and (d) Quality Improvement (Fauth & Tremblay, 2011). During the Planning phase, the program for Harbor Care Health and Wellness Center, Nashua, NH, was conceptualized from available research literature on the evidence-based treatment of diabetes. The site requested that the recipients of the GPE grant help improve integrated care for diabetes patients at the site. The Stanford Diabetes Self-Management Program (SDSMP) was selected as the primary treatment for patients, and the program leaders attended a four-day training to become certified program leader/facilitators. In addition, as in the collaborative care model (Cretin et al., 2004), the program leaders served as interim “care managers” by recruiting participants, monitoring changes in their health data, booking follow-up appointments, and making reminder phone calls each week about the meeting. The program leaders also managed the patient registry, selected the psychological outcomes measures, and initiated the recruitment process.

During the Pilot phase, the SDSMP was administered to the participants and pretest and posttest measures were employed. After completing the program, patients were contacted and reminded to attend their routine diabetes check-ups, and these results were inputted into the electronic medical record by medical staff as per usual routine at the site. During the Discovery phase, all archived self-report data from the pretests and posttests were compiled in the patient registry. Previous medical data and data from the routine follow-up diabetes appointments were gathered from the electronic medical record or requested from outside clinics of patients who do

not attend primary care at Harbor Care Health and Wellness Center. All outside patient primary care data were compiled and tracked in the patient registry. In addition, an 11-month follow-up interview was conducted to survey participant perspectives on what aspects of the program were most helpful, what results they were able to maintain, and how the program could be changed or modified for the future. Information from the follow-up interview supplemented the medical and psychological outcomes data to help demonstrate how and why they benefited from the program, what changes they maintained, and what they would like from a program in the future.

**Within-case analysis.** The SDSMP was evaluated using within-case analyses for each patient. Results of these analyses helped demonstrate whether the program was effective on a case-by-case basis for each patient. A within-case analysis is consistent with the post-positivist research paradigm as it considers whether the treatment was beneficial for individual patient outcomes (Mertens, 2010). It is also consistent with the role of care manager under the collaborative care model (Robinson & Reiter, 2007). Individual monitoring of diabetes symptom progress is one of the primary tasks of a care manager that has been shown to improve patient outcomes (Tsai et al., 2005; Woltmann et al., 2012)

Within-case analyses were comprised of both the medical and psychological outcomes and the follow-up interviews for each patient. Use of multiple data sets can help strengthen the validity of any conclusions drawn in the study (Mertens, 2010). Initial baseline measurements of the psychological outcomes variables were established at the pre-program phase. Another measurement of these variables was made post-program, and additional measurements were made during the 11-month follow-up interview to help determine whether the effects on variables were sustained approximately one year later. Patient medical data comprised of diabetes-related lab test results (e.g., HbA1c% etc.) that were retrieved when available within the



time period leading up to the 11-month follow-up interview for all participants. Similar lab results were gathered from medical visits that occurred up to six months prior to the SDSMP, as available, to help establish individual baseline scores for diabetes medical symptoms. All data in the study were archived in the individual patient electronic medical records.

**Rationale.** A within-case analysis is of interest to psychology as it helps demonstrate whether the program improved psychological outcomes on an individual basis (i.e., depression, anxiety, and self-efficacy) and whether these outcomes were sustainable over time (approximately one year later). The same outcomes may be of interest to the behavioral health integration literature, as any improvements in any diabetes-related medical biomarkers (i.e., HbA1c% and BMI.) may help illustrate whether the program was an effective behavioral health program for diabetes patients. While the psychological outcomes of the study consisted of self-report data from patients, the medical data constituted objective observable data derived from patient lab results, which might contribute to the validity of any observable benefits resulting from the SDSMP (Mertens, 2010).

Results of the within-cased analysis might be of interest to stakeholders at Harbor Care Health and Wellness Center, as the study helped to evaluate whether the program was beneficial for their diabetes patients. Under a population-based approach, it is noted that individual identities and healthcare needs can vary widely (Halpern & Boulter, 2000). Therefore, it is important to consider whether the program was both efficient and effective, what needs remained to be addressed in the treatment of diabetes for each participating patient, and what changes could be made to the program to render it more effective for the patients of Harbor Care Health and Wellness Center. As patients might respond to a program differently, all patients might benefit from having their progress continually assessed by a Case Manager to ensure their

depression levels remain low and that their blood sugar levels are in the optimal range for the duration of their care at a primary care clinic. In this respect, the within-case analysis models a type of patient monitoring that could be employed at the site in the future.

### **Participants**

As stipulated by Stanford University, potential participants in the program included individuals diagnosed with any type of diabetes, prediabetes, those considered at-risk of developing diabetes (e.g., obese persons), and caregivers and family members of diabetes patients. The sample for the present study was derived from the 116 diabetes patients actively seeking treatment at Harbor Care Health and Wellness Center, who then self-referred or were referred directly by their various health providers. As Harbor Care Health and Wellness Center is a federally qualified health center and is located in a region recognized by the Health Resources and Services Administration (HRSA) of the U.S. Department of Health and Human Services as a medically-underserved area, all the participants in the study were either low-income, unemployed, elderly and retired, or disabled. Ultimately, 10 participants ( $N = 12$ ) completed the SDSMP. Gender was evenly split with six men and six women. Ages ranged from 39–80 years, a wide age range that included one young adult between age 35–45, three between age 45–55, four between age 55–65, and three who were age 65 or older. Three participants were subsisting on Social Security Disability due to suffering work-related injuries or a mental illness; four were underemployed due to having similar health problems; one was fully unemployed due to the sudden onset of Type 1 diabetes; and the three participants above age 65 were retired. Only one participant considered himself employed full-time. A majority of 6 participants were receiving some sort of housing assistance, such as Section 8. Five participants owned their own home or lived in a home owned by their family, and one participant was renting a shared apartment. None

of the participants were currently homeless in the traditional sense, but those receiving housing assistance could be considered as having an unstable living situation. Comorbidities included nine participants with high blood pressure, nine with a mood or anxiety disorder, seven with high cholesterol, five with arthritis, four with other unspecified chronic health conditions, three with heart disease, three with chronic pain, one with asthma, and one with kidney disease. Participants were of European American descent with one African American.

### **Measures**

Multiple self-report questionnaires were utilized as psychological outcomes measures to track patient self-efficacy, diabetes knowledge, and psychological symptom reduction (i.e., depression and anxiety) at pre-and post-program and again at the 11-month follow-up interview. The measures were chosen to help demonstrate whether the program had any significant benefit on psychological symptoms, diabetes knowledge, and patient self-efficacy around use of diabetes coping skills and following recommended dietary changes and physical activity levels, and whether those benefits were maintained approximately one year later. The study also utilized patient medical data retrieved from routine diabetes check-ups to see if the program helped improve diabetes symptoms over a one-year period.

**Demographics questionnaire.** A standard Patient Information Sheet stipulated by the SDSMP was administered. Patient name, contact information, age, gender, race/ethnicity, type of insurance coverage, primary care provider information, type of diabetes diagnosis, date of diagnosis, number of foot exams in the last year, whether patients smoke tobacco, and a checklist for a multitude of other health conditions were requested (i.e., high blood pressure; high cholesterol; chronic pain; depression or anxiety; arthritis; Multiple Sclerosis; osteoporosis; stroke; cancer or cancer survivor; and heart, lung, kidney, or eye disease). Other information

collected included: (a) education level, (b) previous diabetes education, (c) participant referral source, and (d) English use as primary language at home and/or other languages spoken at home.

**Patient Health Questionnaire-9 (PHQ-9).** To assess participant depression, the PHQ-9 was used (Kroenke, Spitzer, & Williams, 2001). The Patient Health Questionnaire-9 (PHQ-9) is a self-report screening tool based on DSM-IV-TR criteria (American Psychiatric Association, 2000) and is designed to assist with screening and preliminary detection of depression experiences in primary care settings (Kroenke & Spitzer, 2002). The questionnaire consists of nine items on a four-point Likert scale that screens for depressive symptoms as well as gauges severity of symptom level over the prior two-week period. Symptoms screened for include depressed mood, anhedonia, poor concentration, change of appetite and weight, and suicidal ideation. One example of the questions asked includes: “Over the last two weeks, how often have you been bothered by any of the following problems: little interest or pleasure in doing things; feeling down, depressed, or hopeless; and feeling tired or having little energy.”

The scale ranges from “0” (*not at all*) to “3” (*nearly every day*). Total scores reflect depression severity at concise cut-off points with 5, 10, 15, and 20+ points suggesting mild, moderate, moderately severe, and severe depression, respectively (Kroenke & Spitzer, 2002). When five or more items are checked at a level of “2” (*more than half the days*) or greater, and at least one of those items is depressed mood (item #2) and/or anhedonia (item #1), this suggests a positive screen for major depressive disorder (APA, 2000; Kroenke, & Spitzer, 2002). When only two, three, or four items are checked at a level of “2” (*more than half the days*) or greater, and at least one of those items is depressed mood or anhedonia, this suggests a positive screen for another depressive disorder, such as Unspecified Depressive Disorder (APA, 2000).

Following a positive screen in either case, the provider should then proceed with a clinical intake

to rule out depression caused by substance use, medication, or another medical condition, and to note the specific depression diagnosis (Kroenke & Spitzer, 2002).

The PHQ-9 is frequently used for screening of depressive disorders in integrated primary care clinics and is a well-validated measure of patient depression. Kroenke et al. (2001) administered the PHQ-9 to more than 6,000 patients spread across 15 different medical settings including eight in primary care and seven in obstetrics-gynecology. The internal consistency reliability (Cronbach's alpha) was found to be  $\alpha = 0.89$  and  $\alpha = 0.86$  in those settings respectively. Test-retest reliability was assessed first by having the patient complete the questionnaire in the clinic, followed by re-administration by a second clinician via telephone interview 48 hours later. Correlation between the scores was  $r = 0.84$ , with nearly identical mean scores between the two samples (5.08 vs. 5.03). As an outcomes measure, a change of 5 or greater on the depression score is clinically significant (Kroenke et al., 2001; McMillan, Gilbody, & Richards, 2010). See Appendix B for the PHQ-9.

**Generalized Anxiety Disorder-7 (GAD-7).** To assess participant anxiety, the GAD-7 scale was used (Spitzer, Kroenke, Williams, & Löwe, 2006). The GAD-7 is a self-report instrument used to screen for symptoms of generalized anxiety and their severity level. Items reflect DSM-IV-TR symptom criteria for Generalized Anxiety Disorder (APA, 2000) and include questions about feeling anxious, difficulty controlling worry, restlessness, irritability, and trouble relaxing. Symptoms are endorsed and then rated for severity on a four-point Likert scale ranging from "0" (*not at all*) to "3" (*nearly every day*). Total scores for the scale range from 0–21 and higher scores indicate higher levels of anxiety. One example of items includes: "Over the last two weeks, how often have you been bothered by any of the following problems: feeling

nervous, anxious, or on edge; not being able to stop or control worrying; and worrying too much about different things.”

Spitzer et al. (2006) validated the GAD-7 using a sample of 2,739 patients in primary care clinics spread across 12 states. Internal consistency reliability was strong with (Cronbach's alpha)  $\alpha = 0.83$ . Convergent validity of the GAD-7 was also good with strong correlations between the GAD-7 and the Beck Anxiety Inventory ( $r = 0.72$ ) and the anxiety subscale of the Symptom Checklist-90 ( $r = 0.74$ ). The GAD-7 also has clear diagnostic criterion validity at a cut-off point of 10, as 89% of patients previously diagnosed with Generalized Anxiety Disorder (GAD) had GAD-7 scores of 10 or greater, whereas 82% of patients without the disorder had scores of less than 10. See Appendix B for the GAD-7.

**Patient Activation Survey.** Administration of the Patient Activation Survey is stipulated by Stanford University and the New England Quality Innovation Network, the regional directing agency overseeing training and administration of the SDSMP in the New England area. The measure was administered to participants as a pretest and posttest measurement of their diabetes knowledge, self-efficacy, and compliance with various diabetes self-care practices (coping skills, dietary suggestions, and recommended physical activity level). The 14-item self-report questionnaire is divided into three categories of questions: *Knowledge* (four items), *Coping* (five items), and *Behavior* (five items). Results for the Knowledge items are based on the participants' correct responses to multiple choice questions about basic diabetes-related knowledge, such as “Carbohydrates (starches and sweets) break down inside your body into what?” and “How does exercise affect blood sugar?” Knowing the correct information about physiology and the impact of individual behaviors on physical health may help increase patient self-efficacy around making diet, exercise, and lifestyle choices, which are some of the self-care practice domains for

managing diabetes. Gaining self-efficacy in all relevant domains of a complex task is requisite to achieving self-efficacy in that larger task like diabetes self-management (Bandura, 2006).

Responses to Coping questions are also graded on a five-point Likert scale and are designed to assess the participant's perceived level of self-efficacy around carrying out additional coping skills related to emotional regulation and communication with their diabetes medical providers. Per Bandura (2006), self-efficacy is not a global trait but a differentiated set of self-beliefs linked to a distinct realm of functioning. Therefore, self-efficacy measures are not one-size-fits-all and must be developed specifically for measuring patient self-efficacy in diabetes self-management behaviors, as relevant to the present study. Questions must be task-specific and reflect the respondents' perception of their ability to persevere and complete a specific action (Bandura, 2006). Coping items are phrased in terms of "I can \_\_\_\_\_," which asks patients to assess their self-perceived ability level, as opposed to items phrased as "I will \_\_\_\_\_," which merely reflects an intention (Bandura, 2006). Examples of Coping items that reflect Bandura's criteria include "Do you feel you can make a plan with goals that will help control your diabetes?" and "Do you feel you can ask your doctor questions about your diabetes?" Patients are asked to respond on a five-point Likert scale ranging from "*Yes I can*," to "*No I can't*." A positive response for statistical purposes is considered to be "*Yes I can*" or "*Maybe I can*" however, higher-numbered responses may indicate more successful adoption of that coping skill (New England Quality Innovation Network–Quality Improvement Organizations, 2016).

Patient responses to Behavior items are rated on an eight-point frequency response scale indicating patient adherence to healthy behaviors recommended for diabetes patients. The purpose of the scale was to measure whether the program led to change in frequency of participant-reported adherence to healthy behaviors suggested during the course. Such behaviors

include: (a) following a diet high in fruits and vegetables, (b) maintaining a moderate physical activity level of 30 minutes/day on three or more days per week, (c) checking the condition of one's feet daily, (d) monitoring one's blood sugar daily, and (e) taking medication as prescribed by one's doctor. For example, question number 10 asks "In the past week, how many days did you eat five or more servings of fruits or vegetables?" The participant must select a response from "0" to "7" indicating the number of days over the previous week they accomplished this task.

The Patient Activation Survey has several properties defining how it should be used for research and clinical purposes. While multiple diabetes coping skills and behaviors are being assessed for self-efficacy or adherence, only a single question is included for each item, and responses on the measure are to be analyzed as a proportion (Yes/No; Personal Communication S. H. Ho, Ph.D. Director of Analysis, Qualidigm. March 15, 2018). Each coping skill or behavior being assessed has a clinical target score and a level of self-efficacy or adherence that is optimal for the patient to reach that will better control their diabetes. For example, on the Behavior scale, if the patient responds they eat five servings of fresh fruits and vegetables at the level of three days/week or higher, this constitutes a positive response that the patient has met the clinical target for their dietary behavior. On the Knowledge scale, a positive response occurs when the participant selects the correct answers to multiple choice questions about diabetes. Positive responses on Coping are considered to be at a level of "most of the time" or higher and healthy "yes" responses on Behavior are considered to be at the level of three days/week or higher; however, higher-numbered responses may indicate more successful adoption of that self-care practice (New England Quality Innovation Network–Quality Improvement Organizations, 2016).



As researcher in this study, I was unable to locate empirical support within the available literature on the Patient Activation Survey validating specific clinical targets.

The Everybody with Diabetes Counts Project continually tracks regional population data from the Patient Activation Survey. As of October 31, 2016, the project aggregated data from a total of 994 participants in the New England states (i.e., New Hampshire, Massachusetts, Maine, Vermont, Connecticut, and Rhode Island). The sample included a diverse make-up of White (75.5%), Black (9.7%), Other (7.4%), and Unknown (7.4%). Biological sex was mostly female (72.5%) and male (27.5%). The population was mostly geriatric in age range with groups under age 64 (23.6%), age 65–74 (46.9%), age 75–84 (24.0%), and above age 85 (5.5%); however, breakdown of Patient Activation Survey results across race, gender, and age is not available.

Two additional measures, the Alcohol Use Disorders Identification Test (AUDIT) and the Primary Care Posttraumatic Stress Disorder Screen (PC-PTSD) were administered as part of the routine screening procedures used for patients during treatment at Harbor Care Health and Wellness Center; however, these two measures are not used for evaluation purposes. The two measures are administered periodically and to all new patients upon first entering medical or mental health services at Harbor Care Health and Wellness Center to screen for potential depression, anxiety, and alcohol use disorders. Positive screens on any measure constitute a referral for a mental health assessment.

**Alcohol Use Disorders Identification Test (AUDIT).** The AUDIT is designed to screen for hazardous alcohol consumption by patients in primary care settings (Saunders, Aasland, Babor, De la Fuente, & Grant, 1993). The AUDIT was developed by the World Health Organization (WHO), which orchestrated a large-scale collaboration between primary health care facilities in Australia, Bulgaria, Kenya, Mexico, Norway, and the United States (Allen,

Litten, Fertig, & Babor, 1997). It consists of a 10-item questionnaire on a 5-point Likert scale scored from 0 to 4, giving a maximum possible score of 40 on the test. Questions screen various domains of alcohol consumption, drinking behavior, and alcohol-related problems that may indicate a potential alcohol use disorder in the responder. Some examples of items include: “How often do you have one drink containing alcohol?” “How often during the last year have you found that you were not able to stop drinking once you had started?” and “Have you or someone else been injured as a result of your drinking?”

Saunders et al. (1993) administered an original 150-item questionnaire to an ethnically diverse sample of 1,888 individuals from six different countries, including Australia, Bulgaria, Kenya, Mexico, Norway, and the USA. Participants were inventoried about their quantity of alcohol consumption and were qualified as “non-drinkers” (alcohol abstainers who consume less than 3 drinks per year), “normal drinkers” (who consume four or more drinks per year, but do not exhibit a sufficient number of problematic behaviors to be diagnosed with alcohol use disorder and were not diagnosed in the past), and “problem drinkers” (patients have been recently diagnosed with alcohol use disorder and were either receiving or seeking treatment for alcohol use disorder at the time of the study). Questions to which two percent or less of problem drinkers answered in the affirmative, and those with item-to-total Cronbach’s alpha of less than 0.70, were eliminated. On the resulting 10-item measure, 92% of problem drinkers scored an 8 or more, and 94% of those with non-hazardous consumption scored less than 8 (Saunders et al., 1993). The AUDIT is the fourth most empirically-supported screening tool for alcohol use disorders (Allen et al., 1997). Its brevity, ease of administration, lack of copyright fee, and the diverse population on which it was normed make it a highly versatile assessment tool (Allen et al., 1997). See Appendix B for the AUDIT.

**Primary Care Posttraumatic Stress Disorder Screen (PC-PTSD).** The PC-PTSD is a four-item questionnaire used to screen for presence of Posttraumatic Stress Disorder (PTSD) (APA, 2013) in busy primary care settings. The four questions screen for the four main symptom clusters of PTSD: (a) re-experiencing, (b) numbing, (c) avoidance, and (d) hyperarousal (Cameron & Gusman, 2003). For example, one item asks, “In your life, have you ever had any experience that was so frightening, horrible, or upsetting that, in the past month, you were constantly on guard, watchful, or easily startled.” All items are endorsed with either a “yes” or “no” response indicating symptom presence/absence. Cameron and Gusman administered the measure along with the Clinician Administered Scale for PTSD (CAPS), a well-validated PTSD diagnostic tool, to 188 Veterans Affairs primary care patients ( $N = 124$  females). The sample had a PTSD prevalence rate based on the CAPS of 24.5%. A cut-off score of 3 was determined for a positive screen with a sensitivity rate of 0.78, a specificity rate of 0.87, a positive predictive value of 0.65, and a negative predictive value of 0.92. See Appendix B for the PC-PTSD.

**Medical data.** Archived medical data were gathered for all SDSMP participants. Pre-program records from up to six months prior to the SDSMP (as available) were used as a baseline measure. Post-program data from follow-up appointments occurring up to 11 months after the SDSMP (as available) were used to assess any changes that may have coincided with the program. Data collected included lab results for patient hemoglobin HbA1c percentage (HbA1c%) and body mass index (BMI). These measures are taken at routine medical check-ups for most patients with diabetes and represent important medical biomarkers for the progression of the disease. According to recent American Diabetes Standards of Care (ADA, 2016), two consecutive measurements of HbA1c% above 6.5% constitutes a diagnosis of diabetes. A measurement of 6.5% is the clinical treat to target where further intervention is warranted until

the patient's HbA1c% is under this percentage. For BMI ( $\text{kg}/\text{m}^2$ ), measurements of 18.5 to 24.9 is considered healthy range; 25 to 29.9 is considered overweight range; and 30 or higher is considered obese range. Additional weight loss interventions are warranted for a patient with a BMI greater than  $25 \text{ kg}/\text{m}^2$ .

**Participant interviews.** A participant interview was conducted as an 11-month follow-up study of the participants' perspective on the program. The interview was conducted by a third-party, the current SDSMP leader at Harbor Care Health and Wellness Center who was also a doctoral student attending a one-year practicum at the site. The three main goals of the interview were to: (a) Assess the effects of the program after approximately one year and whether and to what degree the behavior changes were sustained, (b) Elicit feedback from the patients about what they liked and did not like about the program, and (c) Elicit feedback about the preferred format for future diabetes programs at Harbor Care Health and Wellness Center. See Appendix C for the interview questions.

### **Procedures**

The full SDSMP was administered twice by the program leaders during a six-month period. A recruitment phase occurred over a two-month period leading up to the first meeting of the first administration and followed a three-step recruitment process. First, flyers were posted around the clinic describing the SDSMP and instructing interested parties to contact the program leaders through a phone number or email address. Second, doctors, nurse, and psychiatric medication managers of Harbor Care Health and Wellness Center were asked to refer any patients with diabetes, prediabetes, or patients at risk of developing diabetes they believed might benefit from and be able to attend the six-week program. Providers either flagged these potential participants on the electronic medical record, or they directly booked these patients with a

half-hour appointment to meet with the program leaders and discuss the SDSMP. Patients flagged on the electronic medical record were contacted by program leaders and offered a similar half-hour appointment. The third step of recruitment occurred during the half-hour appointment where the SDSMP was explained, patient questions were answered, and all paperwork was completed if the patient chose to sign-up. If a patient seemed hesitant, some brief motivational interviewing was offered to assess their readiness and encourage them to sign up if appropriate.

**First SDSMP.** As the SDSMP is designed for groups of 7–17 participants, the leaders wanted to ensure enough patients were recruited to keep the group full even if some eventually dropped out. Before the first administration, 32 clinic patients were contacted about the group. Two of these patients had reached out to the leaders themselves after seeing the flyer. Five of these patients were booked directly with the half-hour appointment during a routine primary care or medication management appointment. One referral occurred by “warm hand-off” where the patient was recruited directly during a routine primary care appointment. The remaining 24 patients were flagged on the electronic medical record for the program leaders, and multiple attempts were made to contact them by telephone. Eleven of those calls resulted in a live phone conversation, while the other 11 patients did not return voicemail messages or their phone number was found to be disconnected. Only two of the patients spoken with directly declined interest in the SDSMP. The other nine patients agreed to attend the half-hour appointment with the program leaders.

Between patients booked by providers and those contacted in some form by the program leaders, 17 patients total signed up for a half-hour appointment to meet and discuss the SDSMP; however, three of these patients either canceled or no-showed for that appointment. Two of the no-show appointments had been booked by the patient’s primary care providers; thus, the

patients had never spoken directly with the program leaders. Only one patient booked by a program leader no-showed for her appointment. Contact with a program leader seemed to increase likelihood the patient would attend the half-hour appointment. A total of 14 patients attended the half-hour appointment, and all completed their paperwork and officially signed up for the program. Attendance of the half-hour appointment seemed to suggest a high degree of commitment to attending the course. Three additional patients who were my regular therapy clients completed paperwork during routine therapy appointments, making a total of 17 participants who had officially signed up.

**Program attendance and treatment fidelity.** Program attendance for the 17 participants who had signed up varied. Two days before the first program meeting, all participants were given a reminder phone call. At that point, three patients dropped out due to scheduling conflicts with work or family care and two patients no-showed for the first program meeting for unspecified reasons. This brought the sample down to 12 participants who would actively attend program meetings. Three of these attending participants had previously stated they would be unable to attend the first meeting and started receiving treatment during the second meeting. Stanford University stipulates successful completion of the program is contingent on attendance of four-out-of-six weekly program meetings. Two of the 10 participants who started the program attended an insufficient number of meetings, bringing the total down to ten participants ( $N = 10$ ) who successfully completed the first program; however, only two of the ten remaining participants attended all six weekly program meetings. The other eight attended four or five meetings, the minimum number of weekly meeting attendances stipulated by Stanford for a successful completion of the program. Not one of the participants who were my therapy patients successfully completed the program.

**Second SDSMP.** A second SDSMP was administered two months later. A similar recruitment process was initiated. A total of nine new referrals were made over the electronic medical record and attempts were made to contact them. Five of these phone calls resulted in successful booking of the half-hour appointment with the program leaders. Only one patient declined the appointment and three were unable to be contacted. While two patients no-showed due to illness, three patients attended the appointment, completed paperwork, and signed up for the program. Two patients who had previously completed the program signed up to take it again, and three patients who had filled out paperwork during the first round but had not attended reaffirmed their intentions to attend. This brought the total to eight patients who had signed up for the second SDSMP. Two of the participants no-showed for the first class, and two more participants attended an insufficient number of sessions, making a total of three participants who completed the second SDSMP; however, one of these participants was a patient repeating the program a second time. The combined sample size between the first and second rounds was  $N = 12$  with one additional patient completing the SDSMP twice.

**Participant interview.** An 11-month participant follow-up interview was used to assess patient perspectives about the program. A third-party interviewer reached out to the previous participants of the SDSMP over the telephone and invited them to attend a voluntary interview to offer feedback about their experiences in the program. Participants were given the option to complete the interview in-person at Harbor Care Health and Wellness Center or over the phone if attendance in person was not feasible. During that same phone call, participants were informed about the purpose of the interview which was to evaluate the effectiveness of the SDSMP as part of my dissertation study for my doctoral degree in clinical psychology and to acquire feedback for Harbor Care Health and Wellness Center about how to improve future diabetes programs.

The interview process was also explained: The interviewer would ask a series of questions about their experience in the diabetes program, how things were going with their self-care routines, and what they would like to get out of the program in the future. Participants were informed that their participation was voluntary and any data acquired from the interview would be kept confidential and securely stored in accordance with HIPAA regulations. If the participant agreed to attend, the interviewer offered to set up a meeting time that was convenient for the patient, such as the same date of their next therapy or medical appointment.

Upon meeting for the interview, appropriate informed consent was acquired (see next section). Once again, the patient completed a PHQ-9, GAD-7, and Patient Activation Survey to assess their current levels of depression, anxiety, and self-efficacy. This follow-up data informed whether any beneficial psychological outcomes were sustained approximately one year after the SDSMP. The interviewer proceeded by asking a series of open-ended questions designed for the study (see Appendix C) with minimal prompting. All responses were recorded with an electronic audio recorder, which was delivered to me for transcription. Audio files were deleted at the completion of the dissertation process.

**Moderating positive response bias.** In order to decrease potential positive bias in the participants, the interview was conducted by the new diabetes program coordinator who was a doctoral student doing clinical practicum at the site and was also my classmate. A third-party interviewer was used to decrease positive bias in the participants so that they might feel less of a need to “please” me as their program leader if I were conducting the interview myself. The new diabetes program coordinator had no prior acquaintance with any of the program participants; therefore, the participants may have been less likely to answer with a positive bias about their



experience of the program. The new program coordinator was not expected to hold any bias about the treatment outcome in this study.

**Benefits to participants and Harbor Care Health and Wellness Center.** Having the interview conducted by the new coordinator might have offered some modest benefits to Harbor Care Health and Wellness Center. First, it was used as an opportunity for the new coordinator to reengage the participants in the latest installment of the Harbor Care Health and Wellness Center diabetes management program. Second, any feedback gained by the new coordinator conducting the interviews herself might have offered helpful guidance for the new diabetes program. Eliciting patient feedback was consistent with the role of care manager per the collaborative care model. Under the collaborative care model, the role of the care manager is to check-in with patients regularly to ensure their needs are being met by their healthcare team (Robinson & Reiter, 2007).

Participants in the study represented a vulnerable population and might have felt obliged to attend the interview; therefore, the interview needed to offer some value to the participants in return. Many of the interview questions presented an opportunity for participants to reflect upon their current health behaviors and self-assess if they may still need further assistance. For instance, one series of questions asked the participants: “How did your life change after the workshop?” and “How well have you been able to maintain those changes?” By answering these questions, the participant simultaneously reflected on their own progress in maintaining diabetes self-care routines and whether they required further intervention to help improve their self-care behaviors.

**Participant anonymity and confidentiality.** As I was the primary researcher in this study and also one of the program leaders for the SDSMP, the identities of the study’s

participants were known to me. Thus, I needed to acquire informed consent for the program and the evaluation study. During the initial half-hour recruitment appointment for the SDSMP, all participants were advised of the nature, format, and goals of the program and the evaluation study both verbally and in writing. Participants completed all the necessary sign-up paperwork: a patient information sheet requesting demographic information and a signed release of information and consent for treatment form (see Appendix A). All participants consented to partake in both the program and the study, and they signed all the necessary releases of information and consent for treatment forms. The consent form was regarded as HIPAA compliant by Harbor Care Health and Wellness Center administrators and was routinely used at the site (See Appendix A).

Participants were also assured during the half-hour interview that their healthcare data would be kept confidential, stored securely in compliance with HIPAA, and their names and other identifying information would not be included in any report, presentation, nor future publication of the study. For the purposes of data gathering, all patient names were converted to a number and letter (Patient 1AB, 2A, 3A, . . . 1B and 2B) indicating whether they attended the first SDSMP (A), second SDSMP (B), or both (AB). The gender of the participant is given (m = male; f = female) as well as the approximate age range (35= 35 years old). For example, Patient 1AB-m-54 indicates “patient 1 who attended both the first and second SDSMP is male and 54 years old.” All other identifying information were removed before data sets were removed from the site. An additional consent form required by Stanford University and the Everybody with Diabetes Counts project was signed by the patient at this point, granting separate permission for release of medical data to the SDSMP for their own research purposes.

At the beginning of the 11-month follow-up interviews, participants were requested to provide additional consent that any information gained during the interview could be used in the study. An additional release form (see Appendix D) was signed acknowledging consent for this as well as granting permission to audio-record the interview. The interview purposes and procedures were explained again during the consent process, and participants were reminded that participation was voluntary and that they were free to decline participation at any time without penalty nor exclusion from services at Harbor Care Health and Wellness Center. Participants were advised the same confidentiality and secure storage procedures would apply for their healthcare data just as it did during the SDSMP. The audio-recorded interviews were transcribed onto a password-protected word document and the audio files were deleted at the conclusion of the dissertation defense. See Appendix D for Informed Consent to Interview and Answer Questionnaires.

### **The Stanford Diabetes Self-Management Program**

The Stanford Diabetes Self-Management Program (SDSMP) is a psychoeducational and behavioral change program for increasing a patient's knowledge and abilities around self-manage their illness and was shown to improve patient health outcomes. The program consists of a six-week series of classes (two and a half hours one day per week) by two trained program leader/facilitators to groups of 7–17 participants. The program leaders are encouraged to forgo disclosure of their titles as healthcare providers in the context of leading the program and to approach the program as a “peer” of other diabetes patients by discussing their personal life experiences with diabetes. The structured, semi-scripted format of the program meets the American Association of Diabetes Education Standards for patient diabetes education (Lorig, et

al., 2009). The two program leaders attended a four-day training where veteran leaders modeled the entire course, and they became certified “peer-leaders.”

The program curriculum (see Lorig et al., 2009) is designed to improve diabetes self-management skills and patient symptom outcomes by increasing participant knowledge about diabetes-related symptoms and physiology, and the use of self-care practices, such as lifestyle modification (e.g., following a diabetes-specific diet low in carbohydrates, maintaining moderate physical activity level of 30 minutes, three times/week or more); self-monitoring of diabetes symptoms (e.g., checking blood sugar measurements daily, routine foot self-exams); coping strategies (e.g., emotional awareness, stress management, use of relaxation techniques, effective communication with family about the illness); and treatment adherence (e.g., taking medications like Metformin as prescribed by one’s provider, attending regular routine diabetes check-ups, and communicating efficiently with doctors). These self-care practices are shown to help to stabilize symptoms and help to manage the illness more effectively (Lorig et al., 2009).

Each of the six weekly meetings covers various modules describing these self-care practices in detail. For example, the module entitled “Healthy Eating” discusses the importance of monitoring carbohydrate intake to help the patient balance their blood sugars. Participants also learn how to plan a diabetes-appropriate meal during a group exercise and are encouraged to adopt a diet high in low starch fruits and vegetables and whole grains, while moderating high starch vegetables and complex carbohydrates, such as bread, pasta, cereals, and potatoes.

Each weekly SDSMP meeting employs participatory exercises designed to increase group interaction and social learning of various coping strategies. For example, the module on Dealing with Difficult Emotions begins with a group brainstorming exercise where participants are tasked to brainstorm answers to a specific question: “What are symptoms of depression?” Participants

follow up with another brainstorm about potential strategies to deal with depression that is supplemented with additional suggestions by the SDSMP leaders. Each weekly meeting also begins with individuals reporting back about their weekly Action Plan. The Action Plan is a set of specific goals and criteria set by participants at the end of the meeting that they would like to achieve over the coming week. For example, a participant may elect to go jogging for 30 minutes, 3 times/week, on Monday, Wednesday, and Friday. The participant then states their confidence level for completing the plan on a scale from “1” (very low confidence) to “10” (extremely confident). If their confidence level is below seven, the group problem-solves together on how to modify the plan so the participant will be more likely to succeed. The following meeting begins with the report back on the patient’s success with their elected goals, and other participants offer feedback with praise given for full or partial completion of the goals, and problem-solving or moral support offered for those who wish to improve for next time. Social learning of the various coping strategies and problem-solving skills occurs during these group feedback exchanges, and along with self-care practices discussed above, these are some of the critical mechanisms of change in effective diabetes self-management education (DSME; Pillay et al., 2015).

### **Research Hypotheses**

The following hypothesizes were made regarding the previously-stated research questions:

1. The SDSMP will result in a decrease in individual patient depression and anxiety between pretest and posttest scores on PHQ-9 and GAD-7 questionnaires. These results will be maintained at the 11-month follow-up.

2. The SDSMP will result in an increase in individual patient self-efficacy, self-care practices, and diabetes knowledge scores on the Patient Activation Survey between pretest and posttest questionnaires. These results will be maintained at the 11-month follow-up.
3. The SDSMP will result in an improvement in important diabetes medical biomarkers at follow-up visits for each patient over a six-month period, including HbA1c%, blood pressure, LDL, cholesterol, and bodyweight measurements.
4. The SDSMP will result in an increase in each patient's attendance of routine follow-up appointments over an 11-month period.

### **Quantitative Data Analyses**

Data came from three sources for each of the within-case analyses: psychological outcomes, medical data, and the 11-month follow-up interview. Psychological outcomes measures and patient medical data consisting of diabetes medical biomarkers (e.g., HbA1c%, etc.) came from archived data in patient electronic medical records, which were compiled into the patient registry for the study. Due to the small sample size ( $N = 12$ ), psychological assessment outcomes of pretest, posttest, and at 11-month follow-up, and use of medical data from routine diabetes medical appointments six months prior to and up to one year following the program were analyzed on a case-by-case basis. The following sections describe how each set of data was compiled and analyzed using the within-case design.

**Psychological assessment outcomes.** Each individual participant's set of psychological assessment data was calculated as scores. Charts and graphs tracking pre, post, and 11-month follow-up scores on the PHQ-9, GAD-7, and Patient Activation Survey visually demonstrated whether scores changed over time for patient-reported depression, anxiety, diabetes knowledge,

diabetes coping skills, and health behaviors. In addition, scores from the Patient Activation Survey were compared to the mean scores of aggregated regional data sets of the Everybody with Diabetes Counts project (New England Quality Innovation Network, 2016). This comparison helped demonstrate how participant self-efficacy for individual patients from Harbor Care Health and Wellness Center compared to regional norms post-program.

**Patient medical data.** Data from past routine medical visits up to six months prior to the SDSMP (as available) were used to establish a baseline and compared to data from routine follow-up appointments up to 11 months after the SDSMP (as available) to see if any changes occurred for patients. The data consisted of lab results for diabetes-related medical biomarkers, including HbA1c% levels and body mass index (BMI). Data were inserted into charts and graphs to track measurement changes over time within each case. Visual comparative analyses between the two combined data sets—the psychological outcomes assessments and medical biomarkers—helped demonstrate indicate patients’ psychological and medical status across time from pre-program to follow-up. Attendance to medical appointments after the program were also reported.

### **Qualitative Analysis of Interviews**

Transcripts from the participant follow-up interviews were analyzed using basic thematic analyses (Braun & Clarke, 2006). First, each transcript was perused to identify broader topic areas or over-arching themes, helping create domains of information that were informed by the research literature. Second, transcripts were assessed for the core ideas of individual participants, which fell under these broader domains. Third, the core ideas were cross-analyzed between participants and arranged under interrelated categories if any such relationships existed. Results from the thematic analyses were reported as a narrative within each case, detailing from each

patient's perspective how they believe they benefited from the program, what changes they maintained and what they wanted from a program in the future. In combination with participant self-reported psychological assessments and the more objective diabetes-related medical biomarkers, a depiction of each patient's ideographic perspectives of their experiences of the diabetes management program began to emerge. Although the sample size was small ( $n = 4$ ), cross-case analysis of data categories also suggested a group experience of the program and of the program leaders themselves. The emerging patient perspectives of the program constituted the third data point that helped enrich conclusions about how and why outcomes might have occurred in each case (Mertens, 2010). Both quantitative and qualitative results provided valuable feedback about evidence-based practice in diabetes management in the primary care setting of Harbor Care Health and Wellness Center (Anderson, 2006; Fauth & Tremblay, 2011).

**Moderating potential researcher bias.** Based upon empirical support of the SDSMP in the diabetes literature, I hypothesized beneficial outcomes for the program. Beyond receiving training as a program leader for the SDSMP, I had no relationship with Stanford University and his relationships with Harbor Care Health and Wellness Center and Harbor Care Health and Wellness Center' patients terminated in July 2017; therefore, I believed I held no conscious bias around whether the program was effective. The study was guided by a PBPR framework, which concerns the implementation of evidence-based practice into the local context of real-world treatment settings (Fauth & Tremblay, 2011). Failure of a program to improve patient outcomes can produce equally valuable information regarding how to implement evidence-based protocols with a target population.

To help overcome potential researcher confirmation bias, the analyses were audited by another doctoral-level student with an interest in qualitative research and behavioral health. The



auditor assisted with the thematic analysis by reviewing the various domains, core ideas, and categories I created. As I come from a cultural background, socioeconomic status, education level, and current health status that are markedly different from the participants', I could have inadvertently interpreted their responses according to my own values system and construed an entirely different meaning than the participants intended. Use of a third-party auditor can help overcome such biases by offering alternative perspectives and interpretations of the interview data (Hill, Thompson, & Williams, 1997).

Self-reflection notes helped me monitor my own pre-existing biases. Prior to data analysis, I reflected on my own value systems and preexisting schemata about what information would arise during the interview that I may assume was most relevant and what I might likely exclude. I discussed these potential biases with the auditor before the qualitative analysis and audit took place. Sharing self-reflection notes with an auditor can help reveal and overcome inherent biases. I continued my self-reflection process through the duration of the analyses, upon observing my first analysis, and upon reviewing the draft product and feedback from the auditor to attempt to moderate my biases and increase my learning.

### **Conclusion**

This section described the methodology of the program evaluation study. The philosophy of PBPR and the evaluation framework of within-case analyses were also elaborated. Program participants and measures were discussed, along with procedures for recruitment and communication with patients about release of information, informed consent, and confidentiality. The program components of the SDSMP were described, along with research hypotheses, quantitative data analyses, and qualitative data analyses with a discussion of how attempts were made to moderate potential biases towards vulnerable, underserved diabetes patients.

## Results

This chapter presents the results for the 12 patients in the study using a multiple single case design. Data on psychological outcomes measures and diabetes lab results are reported as were available, using the multiple single case format. Symptom severity levels and clinical cutoff scores are noted, as well as whether and to what extent a patient improved in each variable. Each section concludes with a case summary of notable changes for that patient. In addition, thematic analyses of follow-up interviews revealed certain themes for four patients who participated in the interview. Several themes and sub-themes emerged, and sample quotations are provided in support of the themes. Finally, in a subsequent section, remarkable themes and quotations are integrated with case summaries of interviewees. All patients were assigned a number along with a letter that signified whether they attended the First SDSMP (A), Second SDSMP (B), or both (AB). For example, Patient 2B-m-80 attended the Second SDSMP; and Patient 1AB-m-54 attended both SDSMPs. Several patients attended the monthly diabetes support group (SG) and indication of this is apparent by the additional psychological outcomes measures listed in the single case results.

The qualitative findings are presented first to provide an overview of participants' personal experiences and subjective views of the SDSMP's psychoeducation. Then this broad picture is narrowed down to the presentation of individual cases' scores on various variables measured over time

### Qualitative Findings

Four program participants attended the follow-up interview, which occurred 11 months after the program was completed: Patients 1AB, 7A, 8A, and 10A. Their interviews were transcribed from audio recordings, and the transcripts coded with identified salient themes. As

researcher, I posited that some of the themes would correspond with the workshop curriculum, (see Lorig et al., 2009) and the protocol of the Participant Interview Questions (see Appendix E). However, themes were allowed to emerge organically. I attempted to remain objective regarding theme interpretation; however, being the program leader, I could potentially have been vulnerable to a positive bias. I might have wished the participants to improve. I might have been vulnerable to interpretation bias by schematically interpreting interviewee responses within subject areas of the workshop. Or I might have missed subtle nuances or new ideas. Because of these potential biases, the themes and transcripts were audited by a third-party, another fourth-year doctoral student in my clinical psychology program. The auditor had previously received training in qualitative research methods during her doctoral training and approved my coding of themes.

Overall, there were nine themes, and seven of these contained two to three subthemes each (see Table 2). Examples of participant responses illustrating the various themes and subthemes can be found in Table 3. The frequency of responses in each category of theme or subtheme for each participant can be found in Table 4. The following section provides a narrative example of several themes and subthemes that emerged from the four participants' responses.

**Feedback on workshop structure.** One of the most common themes was Workshop Feedback, which was comprised of participant comments about the workshop's structure, content, format, or schedule, as well as their suggestions about what to include in future diabetes workshops. For example, when Patient 1AB-m-54 was asked: "How well did the schedule work for you?" he responded stating

It worked out to a point. It was a little difficult, but that's just from my standpoint. I would go probably not as long. But you're like in a two-hour class or two-and-a-half-hour class with one 20-minute break for people to walk around and loosen up—you know make a phone call or whatever, walk around, get your legs moving. Cuz (sic) I am fidgety as it is now, and I'm trying to get comfortable—and I can't.

Patient 1AB-m-54's response seemed to express his desire for a more relaxed class schedule with frequent breaks occurring that would better cater to his physical condition (e.g., neuropathic pain related to diabetes) and cognitive learning style (“I am fidgety as it is.”)

**Social Influences.** Another theme was Social Influences, which is defined as factors pertaining to individual learning in a group environment. Social Influences contained two sub-themes: *Social Support* and *Social Hindrance*. Social Support constituted various Social Influences of the group setting that assisted individual learning or the patient's diabetes self-care. Patient 7A-m-60 spoke of his experience receiving Social Support from the group:

It helped me to realize that—unique as I feel sometimes with type 1 diabetes—that I'm not alone in these feelings . . . I can ask for advice and, generally, show my feelings more than I might have if I didn't participate in the group.

Social Hindrance constituted any Social Influences of the group setting that may have hindered individual learning or the patient's diabetes self-care. Patient 10A-m-49 spoke of his experience of social hindrance in the group setting:

Individuals that didn't care about being there were there anyway . . . I would ask people to leave that don't really want to be there. They're there for whatever reason they're there but don't really care about diabetes or their health or their weight or what they put in their body . . . Because, for people who've been working for many years to keep their diabetes

in check, it's frustrating to listen to some hooper (sic) that doesn't give a—but is still sitting there.

**Positive Changes.** Another theme that emerged was Positive Changes, which refers to new self-care skills the patient learned or other benefits the patient received from the workshop. This theme contained two subthemes: *New Skills Learned* and *Benefits from Attending*. New Skills Learned referred to specific diabetes self-care skills the patient said they learned during the workshop; skills that may have been taught as part of the workshop curriculum.

Patient 10A-m-49 exemplified the New Skills Learned subtheme when he referred to a specific self-care skill that he had learned and later utilized for managing his exercise regimen: “I typically do 72–100 lengths, four to five days a week during the week days....” The specific skill the participant was referring to is called Goal Setting, which was taught in the workshop curriculum. Goal Setting is where a participant sets a specific behavioral goal that fulfills the criteria of being specific, measurable, and actionable; and the place, time, frequency, and specific days the participant carries it out, as established in the plan. The rationale is that greater specificity around goal setting enables the participant to carry out the plan and be accountable.

Benefits from Attending referred to other benefits or changes the patient maintained after attending the workshop. Patient 7A-m-60 indicated one such benefit: “I found that once you get away from the sugar, though, you don't crave it like you do when you're eating it.” Here, she was referring to an experiential change of diminished sugar cravings that resulted from reducing her sugar intake, which the workshop taught as a guideline for healthy eating. All patients with diabetes were recommended to consume reduced amounts of refined sugars and complex carbohydrates to better control their blood sugar. Patient 7A-m-60 discovered that after she adopted this recommendation her experience of cravings for the unhealthy foods diminished.

**Summary of qualitative results.** The following themes were most prevalent amongst the four interviewees, and the number in parentheses indicates the total number of times the participants responded with them: Workshop Feedback (19); Health Factors: Personal Obstacles (17); Lifestyle: Self-Care (17); Social Influences: Social Support (16); Perceived Barriers (15); and Self-Efficacy: Self-Efficacy (15). Perhaps the most indicative of specific workshop factors that benefited participants was Social Influences: Social Support. All four interviewees remarked of the value of social support and collaborative learning about their diabetes that resulted from the group setting. Also, the two themes Health Factors: Personal Obstacles and Perceived Barriers appeared relevant as they represented a list of the personal obstacles and barriers that inhibited these participants from successfully managing their diabetes. Some of their reported obstacles and barriers were environmental (e.g., financial difficulties); some were internal, such as other health conditions further complicating their diabetes (e.g., heart disease). Responses under the theme Lifestyle: Self-Care included specific ways in which participants had learned to care for their diabetes, including practices and skills learned in the workshop. Several Self-Efficacy statements indicated various topics of self-perceived skills or expertise of the patients.

### **Quantitative Findings**

Patient psychological and medical health outcomes were analyzed and presented in the multiple single case design format. Both sets of outcomes were assessed visually, using tables or line graphs, as appropriate. Trends across time are reported here descriptively, noting clinical cut-off scores, severity levels, and any changes of clinical significance (e.g., change in PHQ-9 score of five points is clinically significant (Kroenke et al., 2001; McMillan et al., 2010).

Results of the pre- and post-program Patient Activation Surveys were compared with aggregated data from a large pool of participants in the New Hampshire and New England areas in 2016. This comparison helped determine whether study participants improved in their diabetes self-efficacy in relation to other diabetes patients from their geographic region.

**Program and appointment attendance.** The amount of psychological and medical outcomes data available in each of the following cases varied based on factors of attendance. In addition to the SDSMP, several participants attended a monthly diabetes support group, the 11-month follow-up interview, and one participant attended both SDSMPs. Attending the support group, 11-month follow-up interview, or a second SDSMP allowed participants to complete additional psychological outcomes measures over time. Celeration lines on the various line graphs denote the various phase changes when these treatment components were being administered in a given month (Pr = baseline or pre-program; A = First SDSMP; B = Second SDSMP; SG = Support Group; Po = post-program; and Int = 11-month follow-up interview). A key with this information is included alongside each participant's chart. Denoting phase changes allowed for visual interpretation of the effects of the particular treatment component(s) the participant attended and how attending a second SDSMP or the support group in addition may have affected each variable.

***Diabetes medical appointment attendance.*** Lab results from routine diabetes medical appointments occurring before and after the various program components are depicted on similar line graphs showing changes over time. Changes are assessed visually and compared with clinical cut-off scores, per the American Diabetes Association Standards of Care Manual (2016). Participant attendance at routine diabetes appointments occurred on different dates and at different frequencies; therefore, the case HbA1c% and BMI results are graphed to reflect the

given month in which the lab result was taken. However, several participants were receiving diabetes care at other clinics and their medical data were not available for the study. Available medical data are analyzed visually and compared to patient-reported healthy behavior changes on the Patient Activation Survey to determine whether any changes might have resulted from attending the program for each patient.

***Individual case summaries.*** A case summary follows each individual case, noting any significant changes in their psychological or diabetes medical health, respectively. Salient themes from the 11-month follow-up interview are integrated in the case summary for the four patients who participated.

***Single case results.*** The following sections elaborate psychological outcomes measures and diabetes medical outcomes (lab tests) results on a case-by-case basis, noting any relevant changes to symptom severity in relation to clinical targets and cut-off scores.

**Patient 1AB-m-54.**

***Depression.*** Patient 1AB-m-54 was a 54-year-old, Caucasian male with Type 2 diabetes. He participated in the first SDSMP and the second SDSMP. Pre-First SDSMP, his PHQ-9 depression score was 19, which indicated moderately severe depression. Pre-Second SDSMP his depression score was 21, which indicated severe depression. Post-First SDSMP his depression score was 17, which indicated moderately severe depression. Post-Second SDSMP, his depression score was 19, which indicated moderately severe depression. At the 11-month follow-up interview, the patient's depression score remained 19. Overall, Patient 1AB-m-54's depression score fluctuated between moderately severe and severe depression. Both SDSMPs did not appear to affect his depression level (See Figure 1).



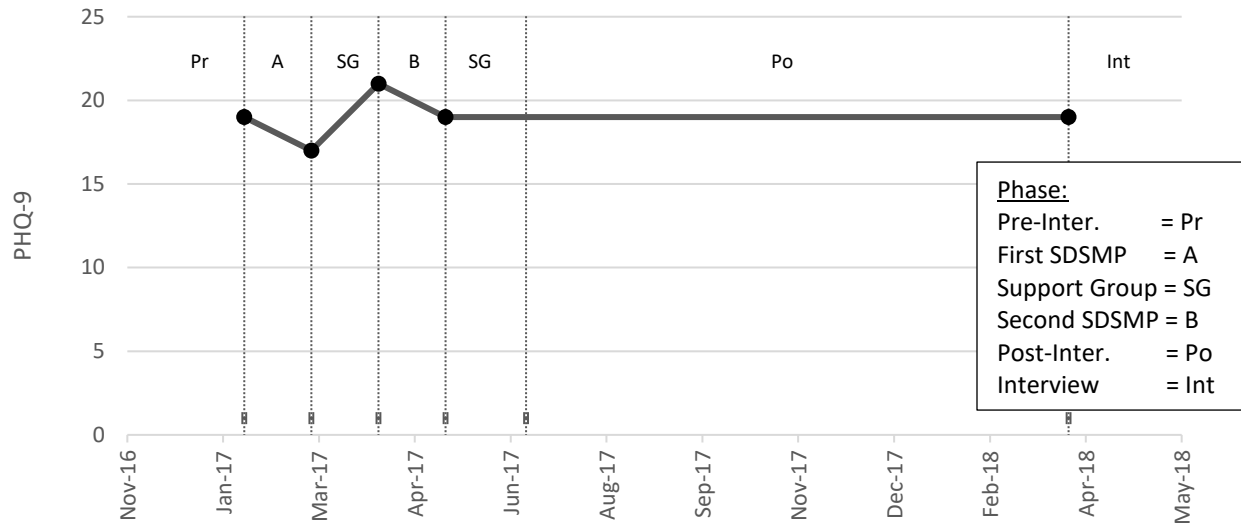


Figure 1. Changes in depression score on the PHQ-9 over time for Patient 1AB-m-54

**Anxiety.** Patient 1AB-m-54 scored a 15 on the GAD-7 at Pre-SDSMP, which indicated severe anxiety; he scored a 19 one month later at Pre-Second SDSMP, which indicated severe anxiety. He scored a 15 at Post-First SDSMP, which indicated severe anxiety; and scored an 18 at Post-Second SDSMP, which indicated severe anxiety. Near the end of the first SDSMP, he reported experiencing a significantly stressful health-related event, which may have resulted in the 4-point increase in his GAD-7 score. At the 11-month follow-up interview, the patient’s anxiety score remained 18. The patient’s anxiety remained severe throughout the study and suggested he had a severe anxiety disorder. The SDSMP did not appear to affect his anxiety (See Figure 2). Further monitoring and treatment of this patient’s anxiety were warranted based on severity level.

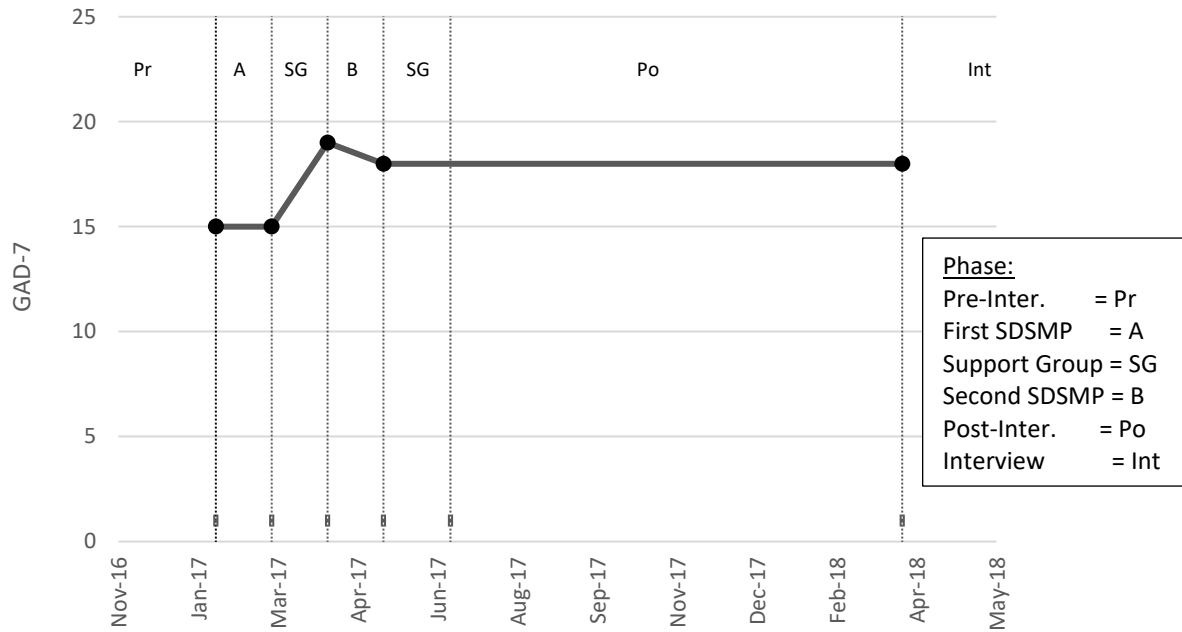


Figure 2. Changes in GAD-7 anxiety scores over time for Patient 1AB-m-54

**Self-Efficacy.** On the Pre-First SDSMP administration of the Patient Activation Survey (PAS) the patient scored 50% correct on Knowledge; 80% positive on Coping; and 40% healthy on Behaviors. On the Post-First SDSMP administration of the PAS, the patient scored 75% correct on Knowledge; 40% positive on Coping; and 40% healthy on Behaviors. After attending the first SDSMP, this patient increased on Knowledge but maintained the same score on Coping and Behaviors. On the Pre-Second SDSMP, the patient scored 50% correct on Knowledge; 60% positive on Coping; and 20% healthy on Behaviors. On the Post-Second SDSMP, the patient scored 100% correct on Knowledge; 40% positive on Coping; and 40% healthy on Behaviors. At the 11-month follow-up interview, the patient scored 50% on Knowledge; 80% positive on Coping; and 40% healthy on Behaviors. Overall, the patient’s self-efficacy appeared to fluctuate in his retention of Knowledge and he did not sustain any critical changes in his Behavior after attending the SDSMP twice as shown by the 11-month follow-up (See Figure 3: Patient

1AB-m-54 Self-Efficacy Over Time). In relation to the study group and the geographic regions, the patient's level of diabetes knowledge, diet, and physical activity levels as depicted by results on the Knowledge and Behavior scales were found lower than average; however, he scored slightly higher at the 11-month follow-up in Coping, but this was a regression to his previous level at Pre-First SDSMP (See Figures 3–7). As Figure 7 demonstrates, over time, the patient exhibited no change in Knowledge, Coping, or Behavior.

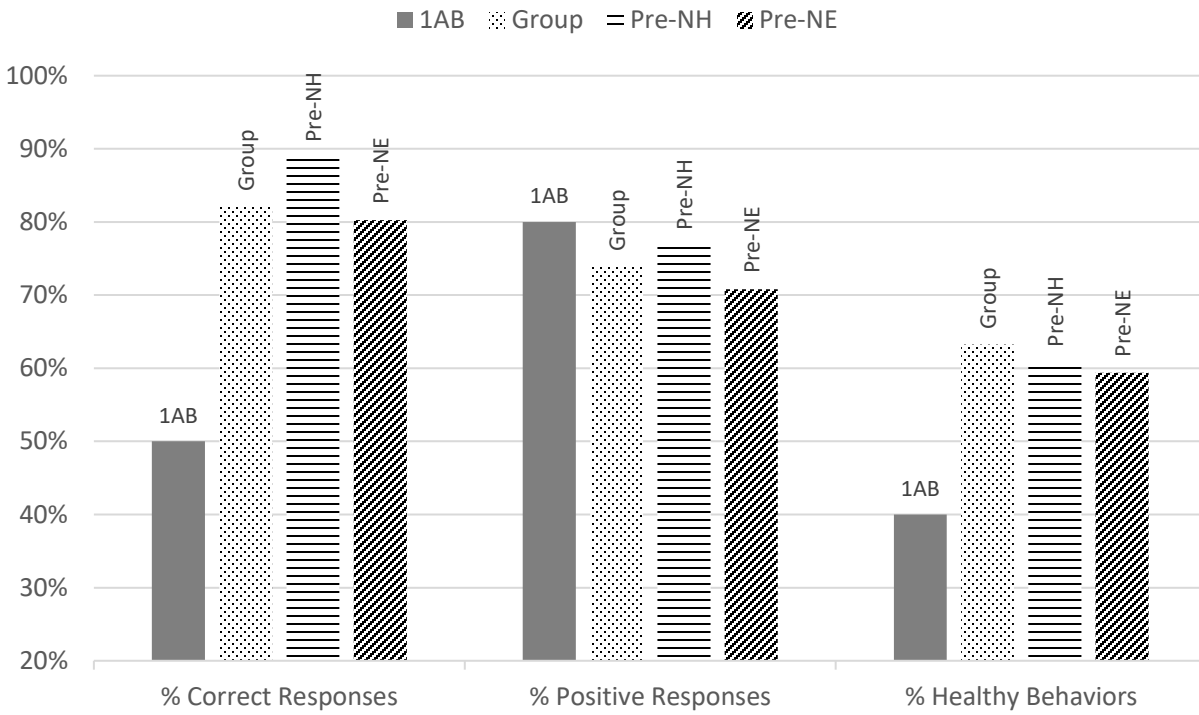


Figure 3. Pre-First SDSMP self-efficacy scores on the PAS for Patient 1AB-m-54

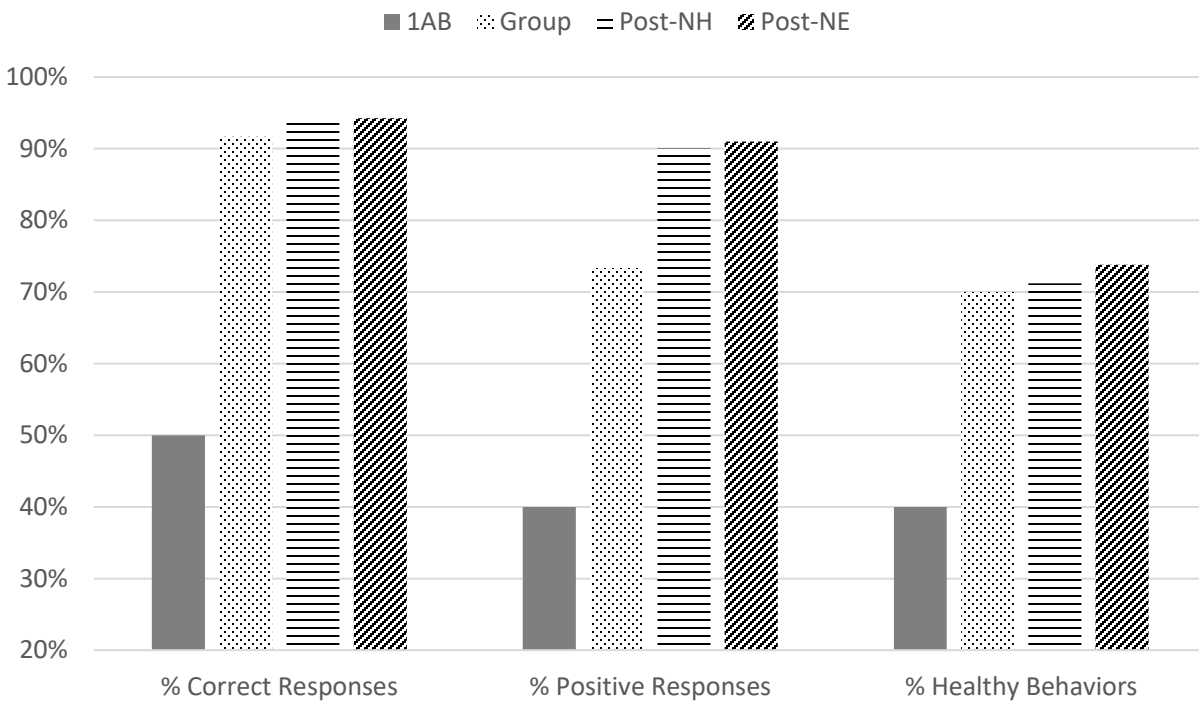


Figure 4. Post-First SDSMP self-efficacy scores on the PAS for Patient 1AB-m-54

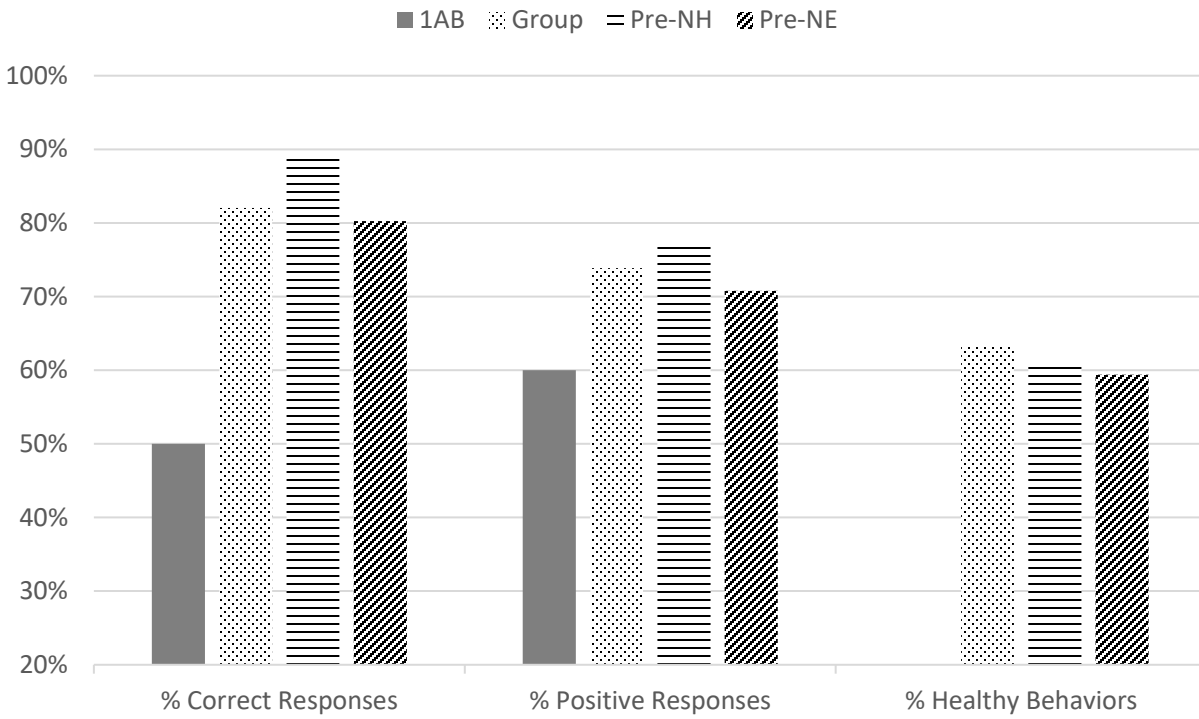


Figure 5. Pre-Second SDSMP self-efficacy scores on the PAS for Patient 1AB-m-54

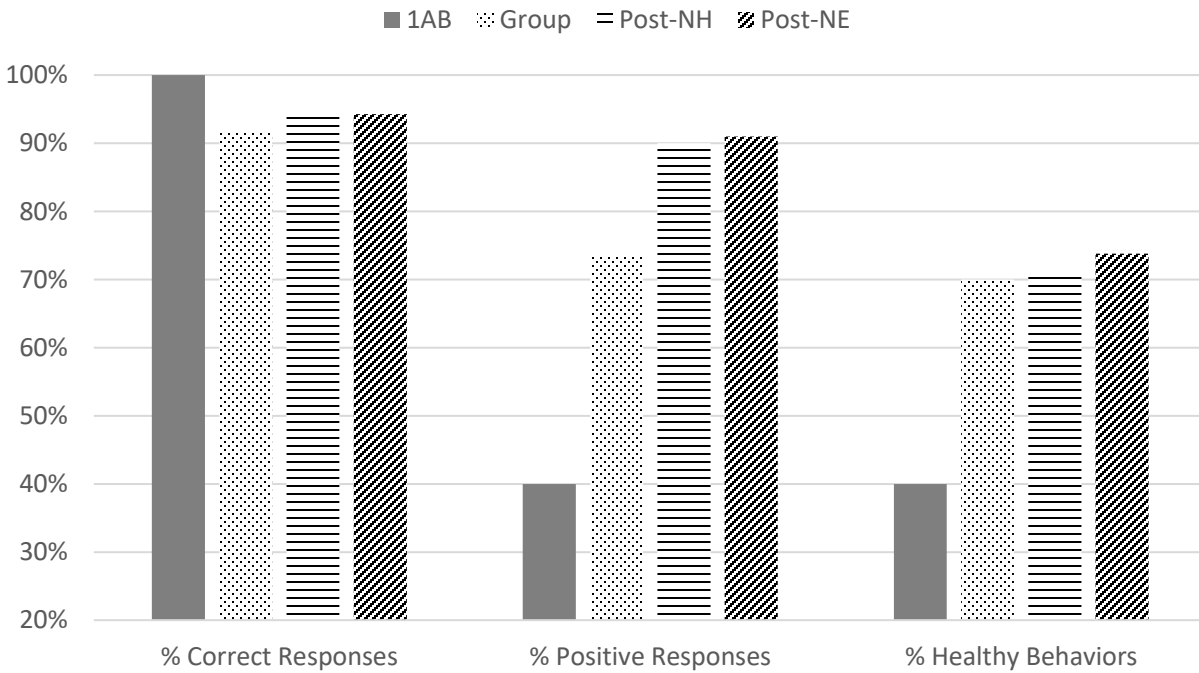


Figure 6. Post-Second SDSMP self-efficacy scores on the PAS for Patient 1AB-m-54

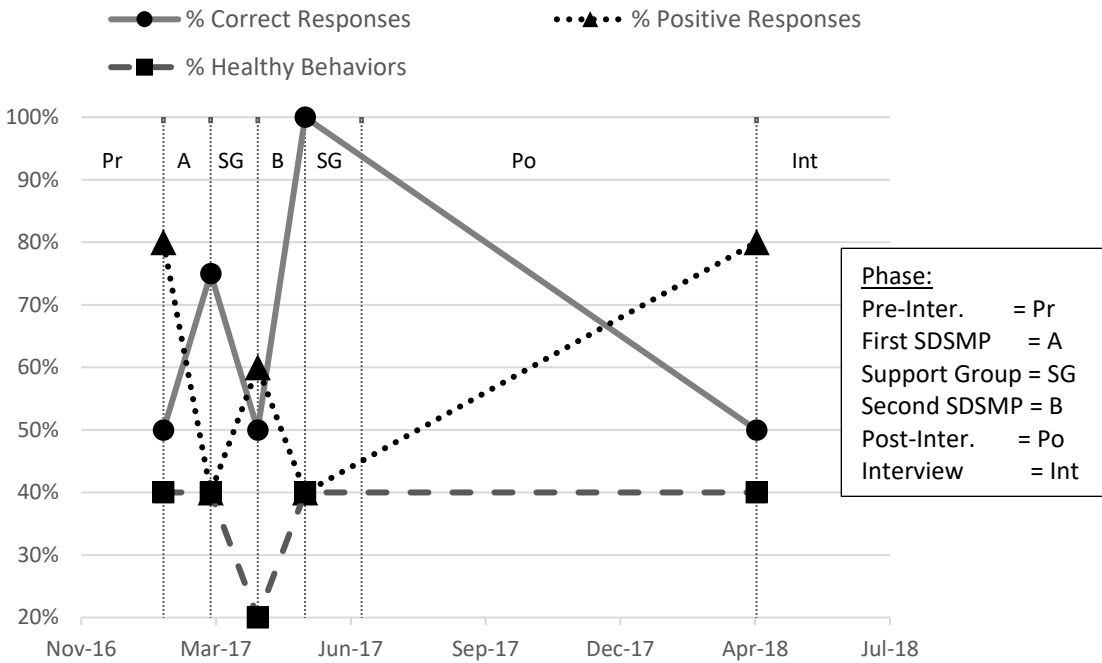


Figure 7. Changes in self-efficacy scores on the PAS over time for Patient 1AB-m-54

**HbA1c%.** As a baseline, this patient was measured with HbA1c% of 5.9% in December 2016, which was one month before the beginning of the first SDSMP. In February 2017, during Phase 1 of the first SDSMP, his HbA1c% was 6.4%; then in July 2017 it was 6.3%. After attending both the first and second SDSMP, the patient’s lifestyle may have resulted in a 0.4% increase in HbA1c%; however, the measurement was just below 6.5%, which was the clinical target indicated by the American Diabetes Association (2016). Continued monitoring was warranted to ensure his HbA1c% remains below target (See Figure 8).

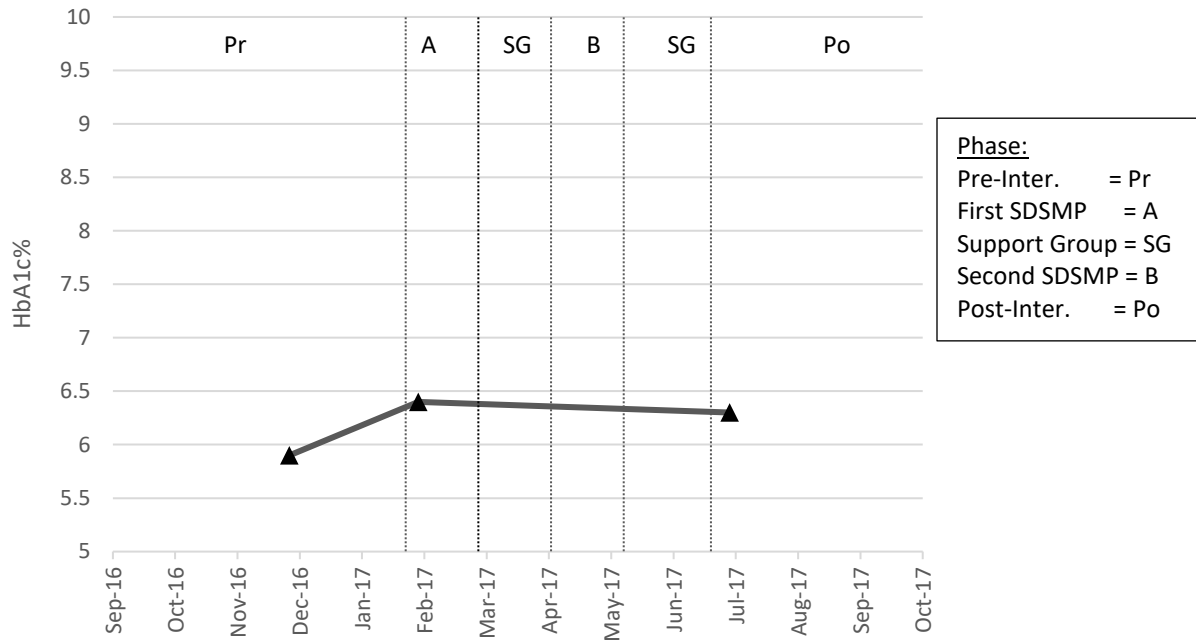


Figure 8. Changes in hemoglobin a1c percentage (HbA1c%) over time for Patient 1AB-m-54

**Body mass index.** As a baseline, this patient’s BMI ranged from 40.83 in July, 2016 to 42.47 in December, 2016. By March, 2017 after completing the first SDSMP, it had risen to 43.66 and continued to increase to 44.10 after he completed the second SDSMP in May, 2017. By November, 2017, his BMI continued to rise to 44.65. Any self-care changes implemented by this patient did not improve his BMI; if anything, the patient’s lifestyle continued to contribute to weight gain (See Figure 9: Patient 1AB-m-54 Body Mass Index Over Time). Further intervention was warranted as this patient was in the obese range.

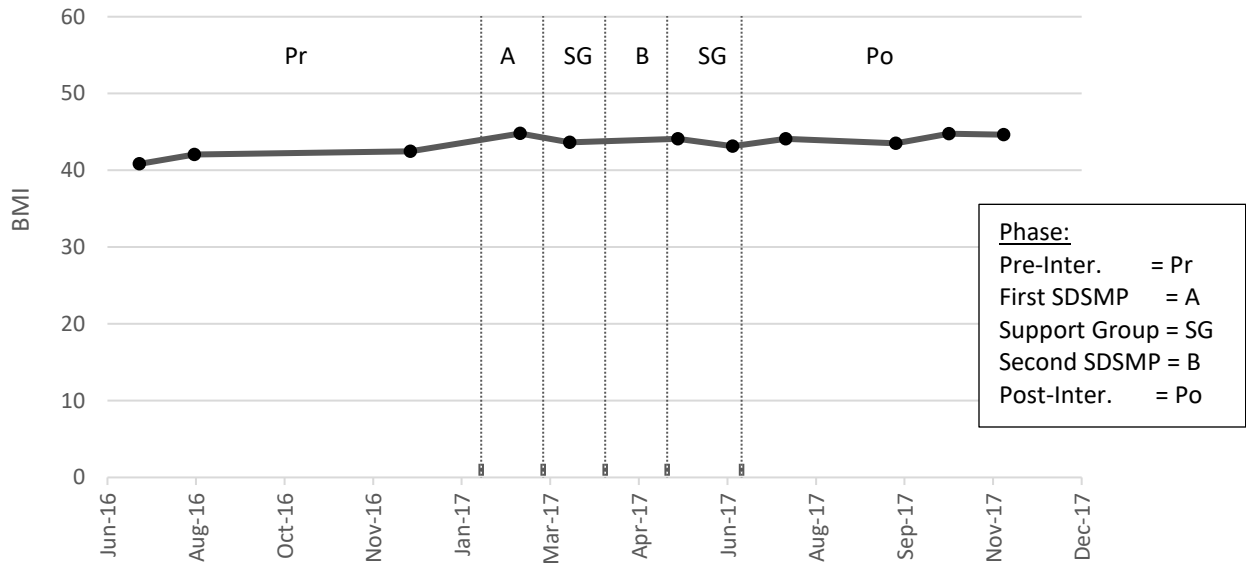


Figure 9. Changes in body mass index (kg/m<sup>2</sup>) over time for Patient 1AB-m-54

**Case Summary: Patient 1AB-m-54.** Overall, Patient 1AB-m-54 exhibited no detectable change regarding his depression or anxiety from attending the workshop, and symptoms remained severe for both variables. His level of self-efficacy appeared to fluctuate during both workshops, but any benefits were lost by the 11-month follow-up. Patient 1AB-m-54’s HbA1c% remained below clinical target level; however, he was severely obese as indicated by high BMI. During the follow-up interview, he made seven statements that fell under the theme, Workshop Feedback, eight statements about Perceived Barriers, and eight statements about his Health Factors: Unmet Health Needs. To further understand his lack of improvement, one example of his Workshop Feedback included:

I’m more of a hands-on, visual versus reading it in the book and then not understanding it. And you got a lot of people who will read books and grasp it. Me? I have to have visual things to see exactly what I’m being shown to actually understand it.

Patient 1AB-m-54 appeared to be describing his learning style as being visual and he was remarking how this need was not accommodated by the workshop. A lack of adapting to his



learning style may have been one of the reasons Patient 1AB-m-54 did not seem to have benefited from the workshop psychoeducation.

**Patient 2A-f-57.**

**Depression.** Patient 2A-f-57 was a 57-year-old Caucasian female with Type 2 diabetes. Pre-First SDSMP, her PHQ-9 depression score was 3, which indicated minimal to no depression. Post-First SDSMP her depression score was six, which indicated mild depression. Her depression score increased by three points after the SDSMP, which was, however, not clinically significant; the score rose from the minimal to the mild depression range (See Figure 10). The SDSMP coincided with a modest increase in patient depression; therefore, further monitoring was warranted because clinical judgment over whether to treat is indicated for scores in the mild range.

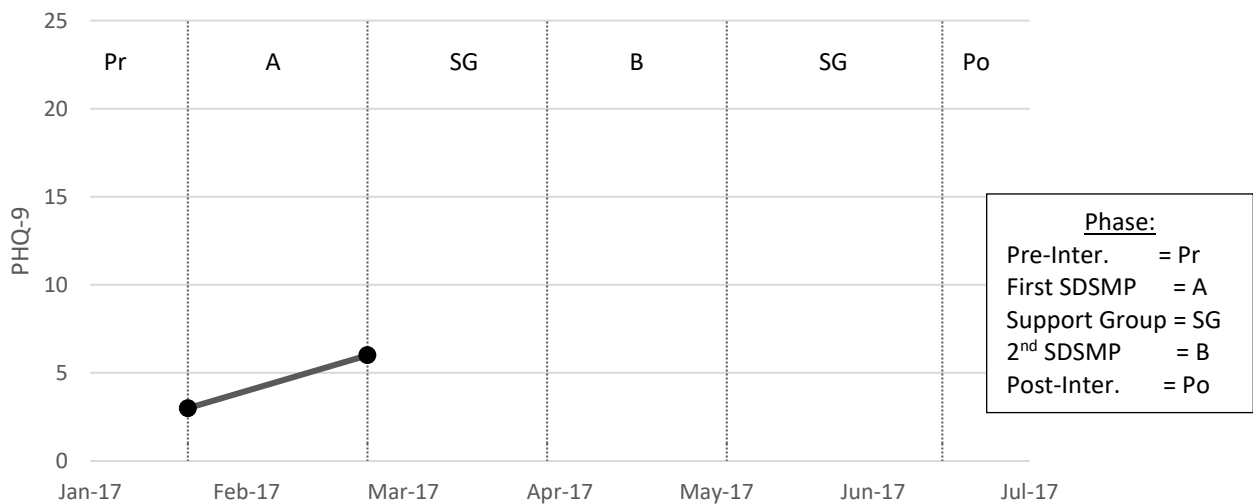


Figure 10. Changes in PHQ-9 depression scores over time for Patient 2A-f-57

**Anxiety.** Patient 2A-f-57 scored a 1 on the GAD-7 at Pre-SDSMP, which indicated minimal to no anxiety; she scored a 1 at Post-First SDSMP, which indicated minimal to no anxiety; thus, her anxiety appeared to be minimal throughout the study (See Figure 11). Further

monitoring of her anxiety scores was still warranted as patients with diabetes are at increased risk of anxiety disorders.

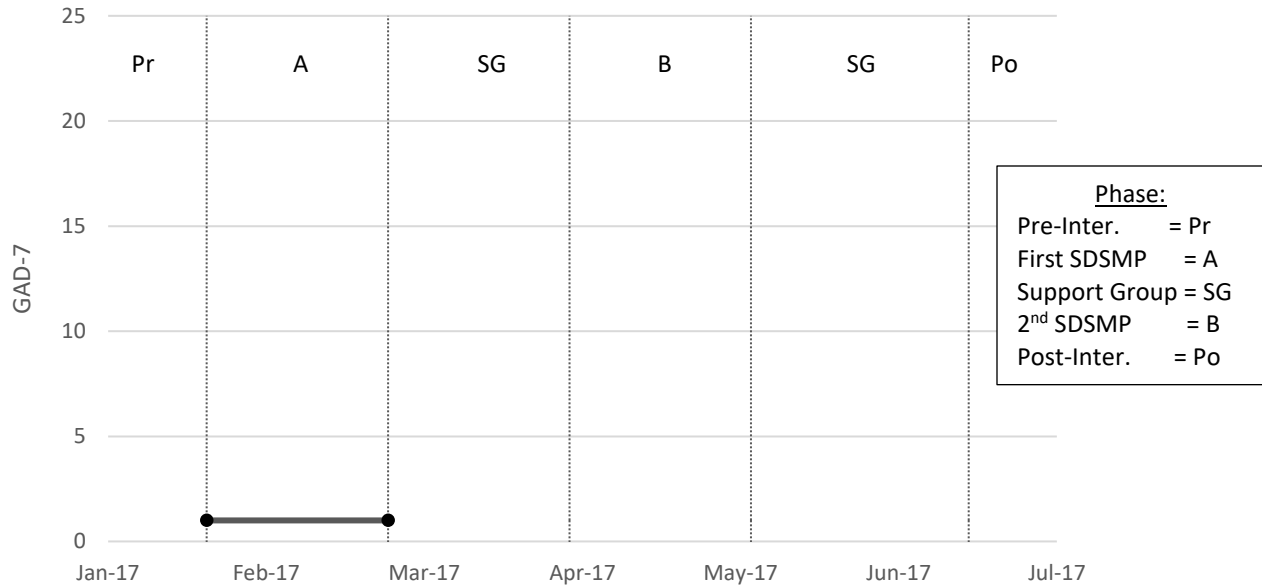


Figure 11. Changes in GAD-7 anxiety score over time for Patient 2A-f-57

**Self-Efficacy.** On the Pre-First SDSMP administration of the PAS the patient scored 100% correct on Knowledge; 80% positive on Coping; and 100% healthy on Behaviors. Post-First SDSMP, the patient scored 100% correct on Knowledge; 80% positive on Coping; and 80% healthy on Behaviors. While attending the first SDSMP, this patient remained strong in Knowledge and Coping but decreased slightly in Behaviors, remaining above the group average, regional norms, and clinical targets in all three domains (See Figures 12–13).

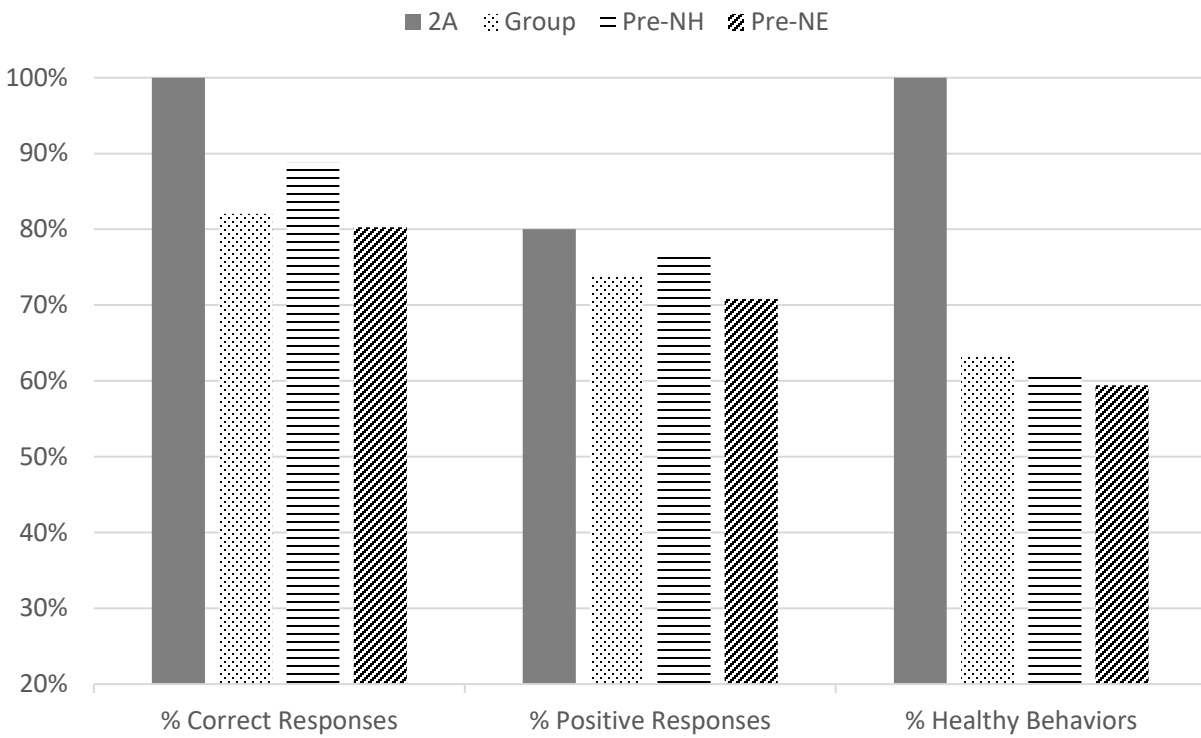


Figure 12. Pre-First SDSMP scores in self-efficacy on the PAS for Patient 2A-f-57

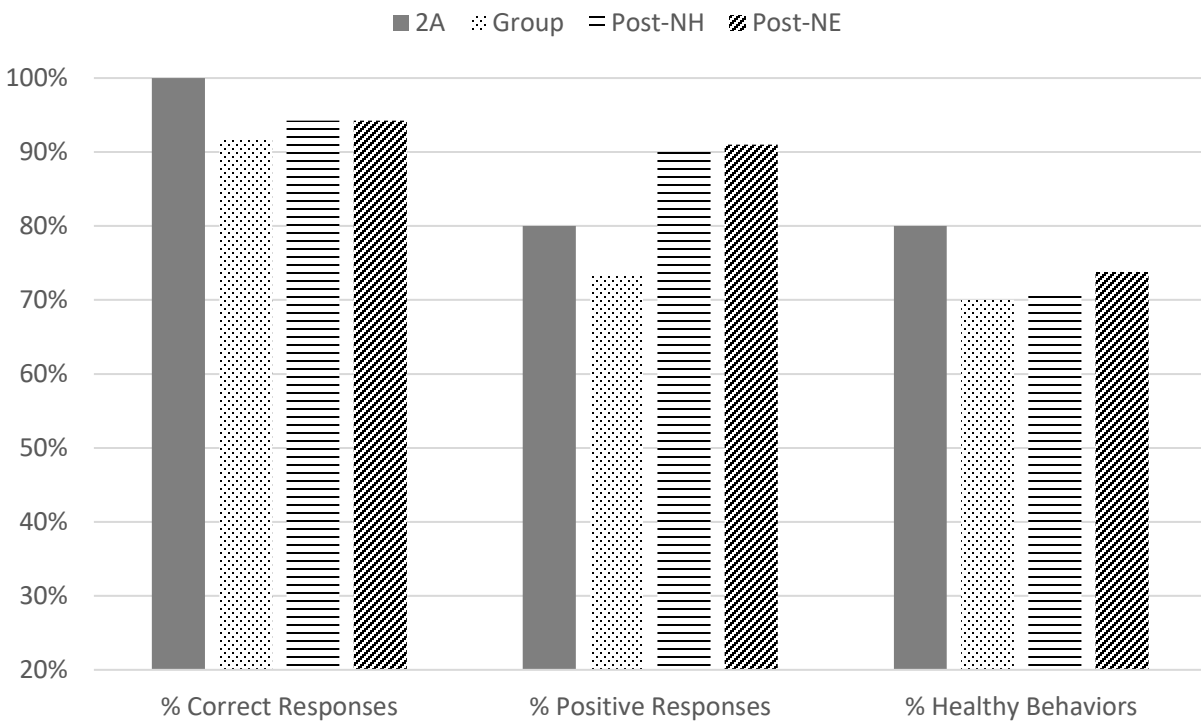


Figure 13. Post-First SDSMP scores in self-efficacy on the PAS for Patient 2A-f-57

**HbA1c%.** As a baseline, Patient 2A-f-57 was measured with HbA1c% of 9.8% in October 2016 three months before the first SDSMP and 8.9% in January 2017, which was the month when the first SDSMP began. No further measurements of the patient’s HbA1c% were available following the study. As these measures were above the clinical target, further assessment and intervention was warranted (See Figure 14).

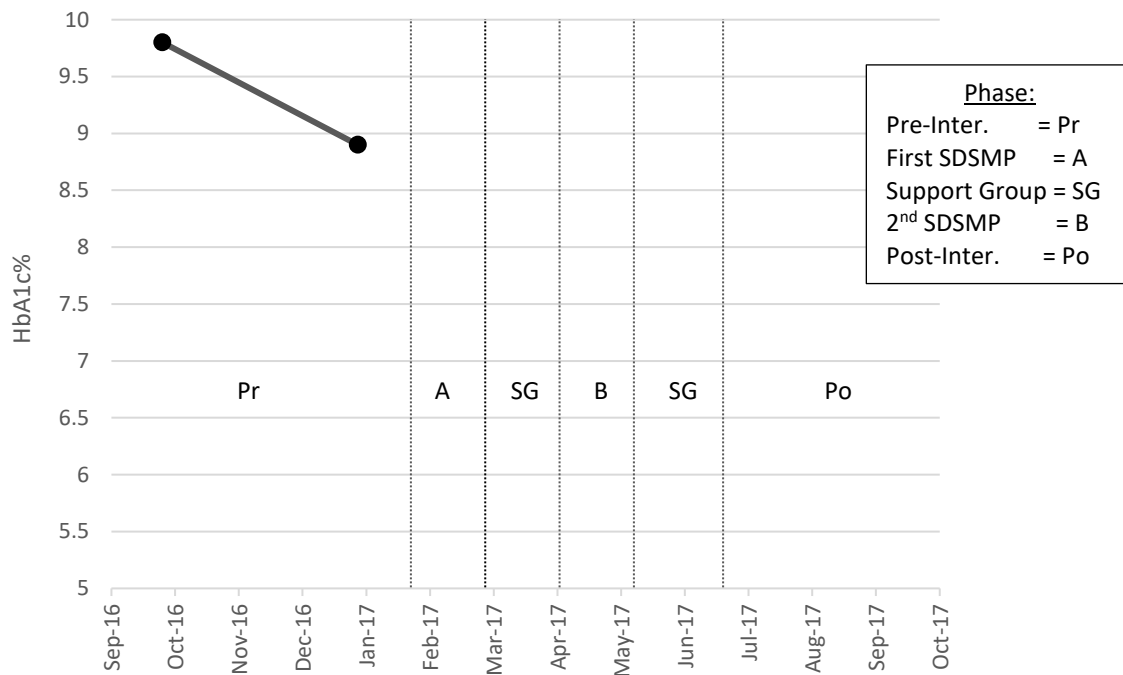


Figure 14. Changes in hemoglobin A1c Percentage (HbA1c%) over time for Patient 2A-f-57

**Body mass index.** As a baseline, this patient’s BMI ranged from 53.60 in September 2016 to 54.33 in October 2016, which was above the clinical target. Follow-up data were not available for this patient. Further assessment and intervention were warranted as this patient was in the obese range (See Figure 15).

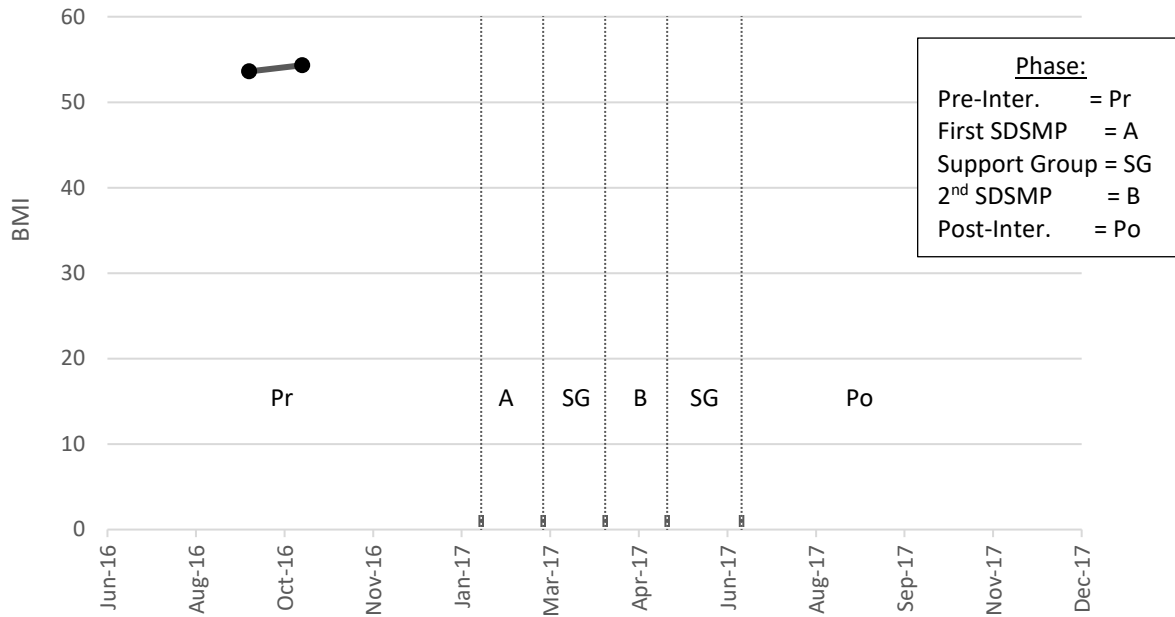


Figure 15. Changes in body mass index (kg/m<sup>2</sup>) over time for Patient 2A-f-57

**Case summary: Patient 2A-f-57.** Patient 2A-f-57’s anxiety remained negligible; however, her depression increased slightly—though not significantly—to the level of mild depression. For self-efficacy, her scores on Knowledge, Coping, and Behavior exceeded those of the group and the norms of both regions; however, Patient 2A-f-57’s HbA1c% and BMI also exceeded the clinical targets and further intervention for her diabetes was warranted.

**Patient 3A-f-67.**

**Depression.** Patient 3A-f-67 was a 67-year-old Caucasian female with Type 2 diabetes. Pre-First SDSMP, her PHQ-9 depression score was 4, which indicated minimal to no depression. Post-First SDSMP her depression score was 3, which indicated minimal to no depression. Her depression score decreased by one point after the SDSMP, which was not clinically significant, and the score was in the minimal to no depression range; thus, no further treatment was indicated (See Figure 16: Patient 3A-f-67 Depression Over Time). Further monitoring was still warranted as diabetes patients are at increased risk for developing depression.

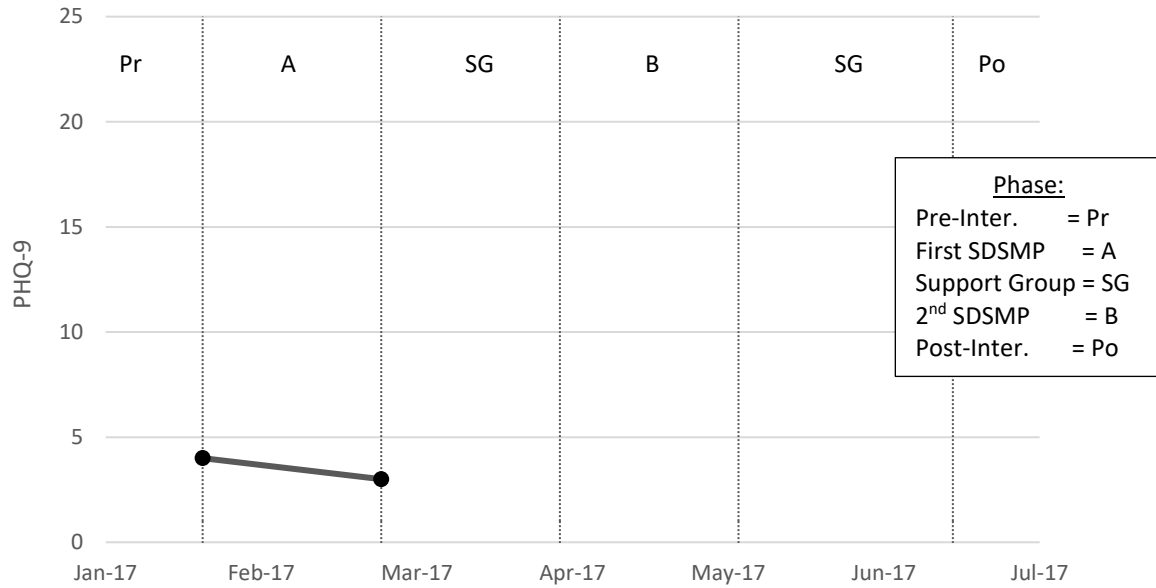


Figure 16. Changes in PHQ-9 depression score over time for Patient 3A-f-67

**Anxiety.** Patient 3A-f-67 scored a 4 on the GAD-7 at Pre-SDSMP, which indicated minimal to no anxiety; she scored a 0 at Post-First SDSMP, which indicated minimal to no anxiety. Her anxiety level decreased by four points after the first SDSMP and remained in the minimal to no anxiety range. Further monitoring of her anxiety scores was still warranted as diabetes patients are at increased risk for developing anxiety disorders (See Figure 17).

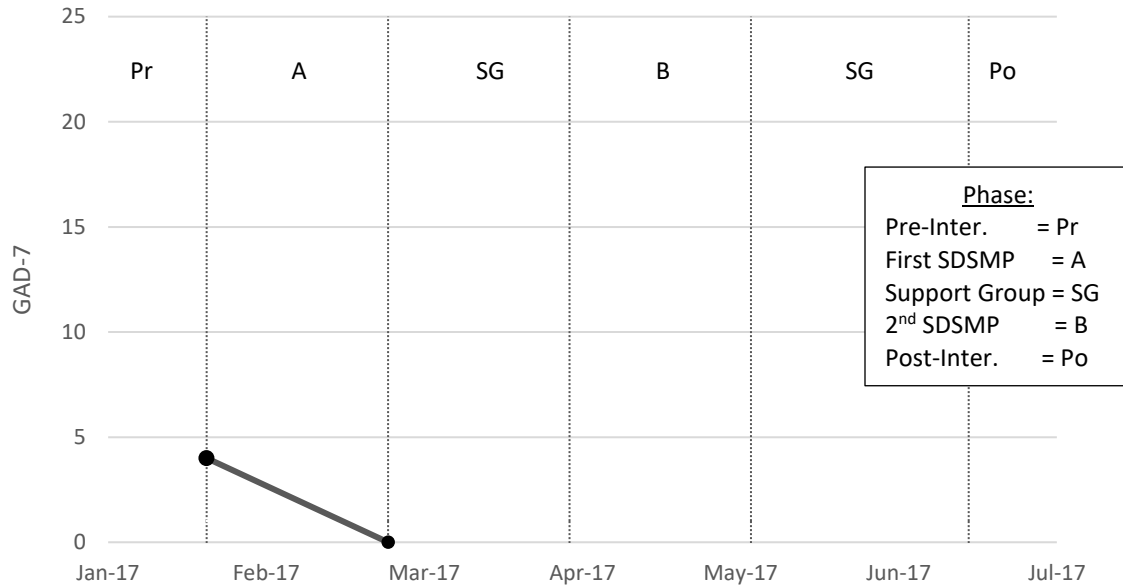


Figure 17. Changes in GAD-7 anxiety score over time for Patient 3A-f-67

**Self-Efficacy.** On the PAS at Pre-First SDSMP the patient scored 100% correct on Knowledge; 100% positive on Coping; and 60% healthy on Behaviors. On the Post-First SDSMP, the patient scored 100% correct on Knowledge; 80% positive on Coping; and 60% healthy on Behaviors. While attending the first SDSMP this patient remained strong on Knowledge and Behaviors but dropped slightly in Coping. All three scores were above clinical target in the positive direction (See Figures 18–19: Patient 3A-f-67 Self-Efficacy Pre- and Post-SDSMP).

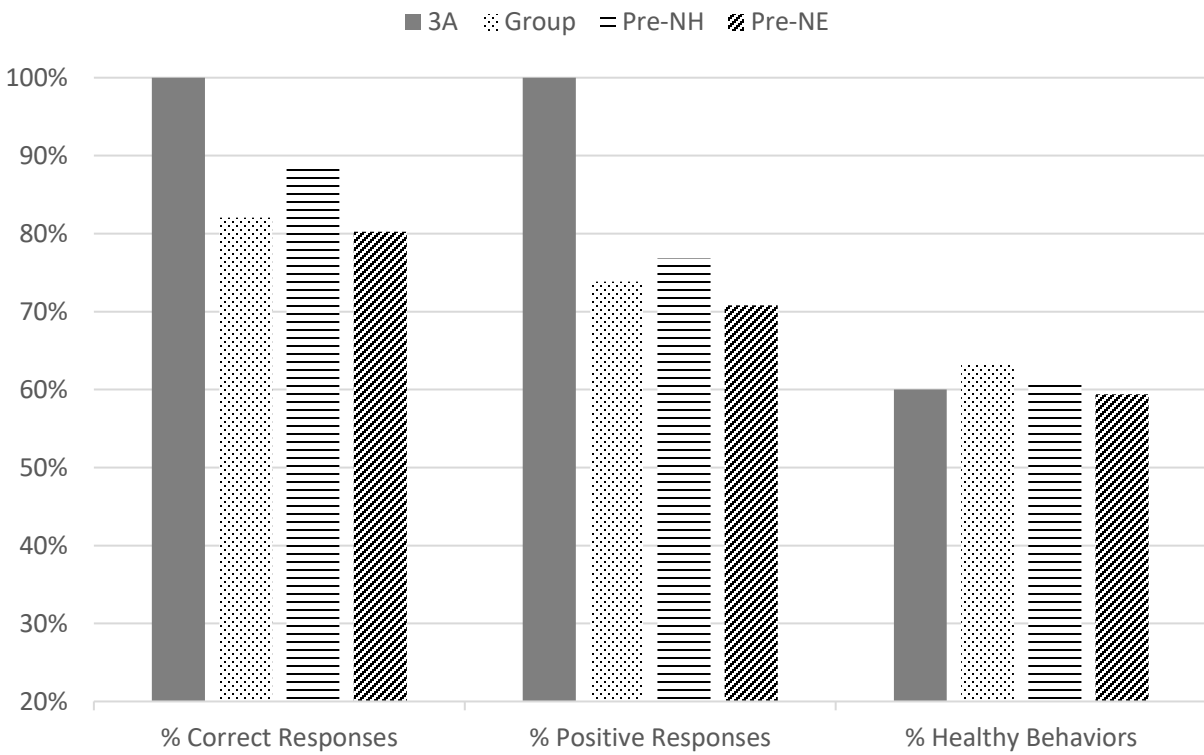


Figure 18. Pre-First SDSMP self-efficacy scores on the PAS for Patient 3A-f-67

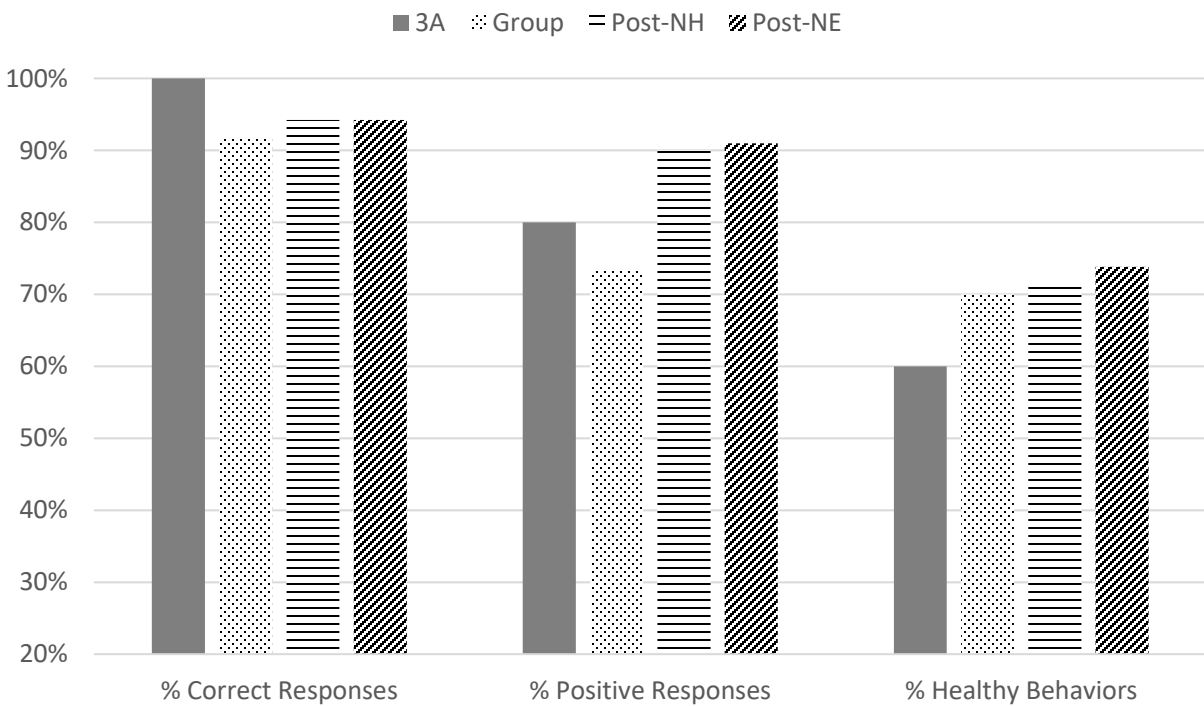


Figure 19. Post-First SDSMP self-efficacy scores on the PAS for Patient 3A-f-67



**Case summary: Patient 3A-f-67.** Patient 3A-f-67 presented with minimal to no depression and anxiety Pre-First SDSMP, and both these variables decreased slightly after she attended the program. Regarding self-efficacy, she began Pre-First SDSMP scoring higher than the group and regional norms. Post-First SDSMP, she scored in a similar range to the group and regional norms on Knowledge and Coping but lower than both on Behavior. Her Coping score rose slightly after the workshop, but her Behavior score remained the same.

**Patient 4A-f-39.**

**Depression.** Patient 4A-f-39 was a 39-year-old Caucasian female with a pre-diabetes diagnosis. Pre-First SDSMP, her PHQ-9 depression score was 19, which indicated moderately severe depression. Post-First SDSMP her depression score was 16, which indicated moderately severe depression. Her depression score decreased by three points after the SDSMP, which was not clinically significant; however, her scores were in the moderately severe range and further treatment was indicated. The program may have resulted in a modest decrease in the patient’s depression, but the decrease was not clinically significant (See Figure 20. Changes in PHQ-9 depression scores over time for Patient 4A-f-39).

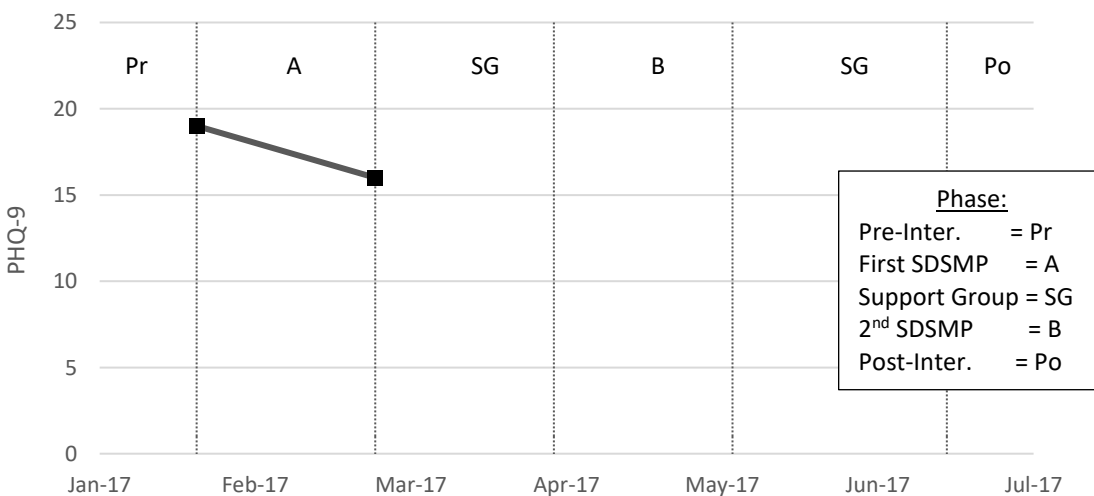


Figure 20. Changes in PHQ-9 depression scores over time for Patient 4A-f-39

**Anxiety.** Patient 4A-f-39 scored a 15 on the GAD-7 at Pre-First SDSMP, which indicated severe anxiety and presence of an anxiety disorder; she scored a 17 at Post-First SDSMP, which indicated a severe anxiety disorder. Her anxiety level increased by two points after the first SDSMP and remained in the severe range. Attendance at the SDSMP showed a modest increase in this patient’s anxiety (See Figure 23). Further monitoring and treatment of her anxiety were warranted due to severity level.

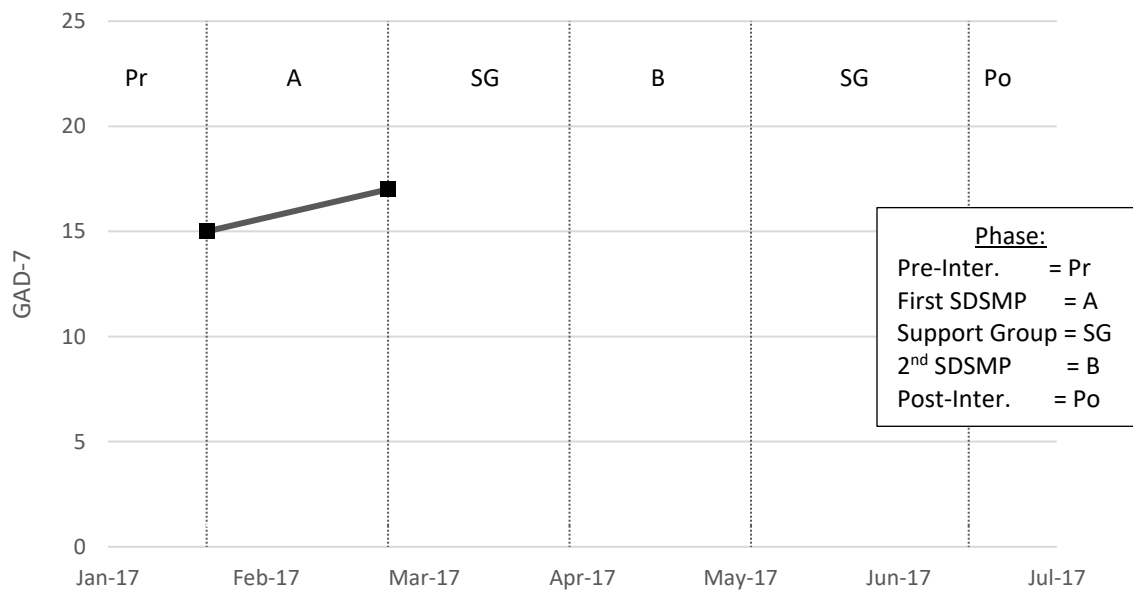


Figure 21. Changes in GAD-7 anxiety scores over time for Patient 4A-f-39

**Self-Efficacy.** On the Pre-First SDSMP administration of the PAS the patient scored 75% correct on Knowledge; 20% positive on Coping; and 25% healthy on Behaviors. On the Post-First SDSMP, the patient scored 75% correct on Knowledge; 80% positive on Coping; and 75% healthy on Behaviors. After attending the first SDSMP, this patient remained strong in Knowledge and improved in Coping and Behaviors. She finished above the group average and clinical target in Coping, but below regional norms. She also finished above group, clinical target, and regional norms in Behaviors (See Figures 24–25).

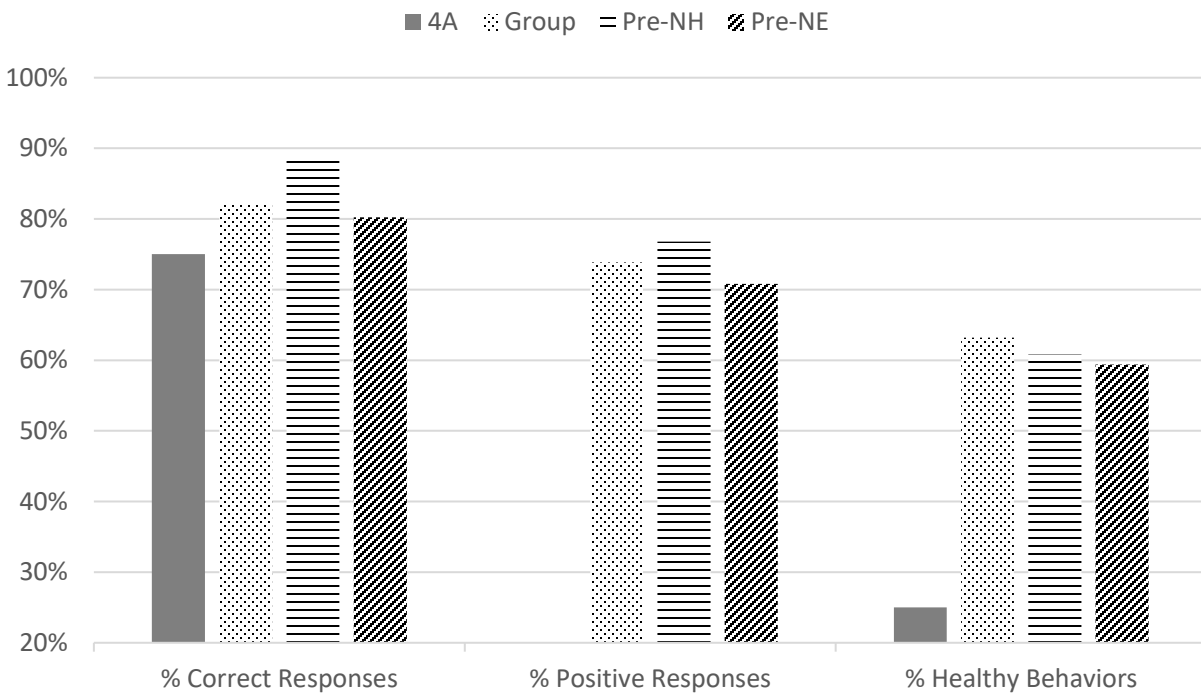


Figure 22. Pre-First SDSMP self-efficacy scores on the PAS for Patient 4A-f-39

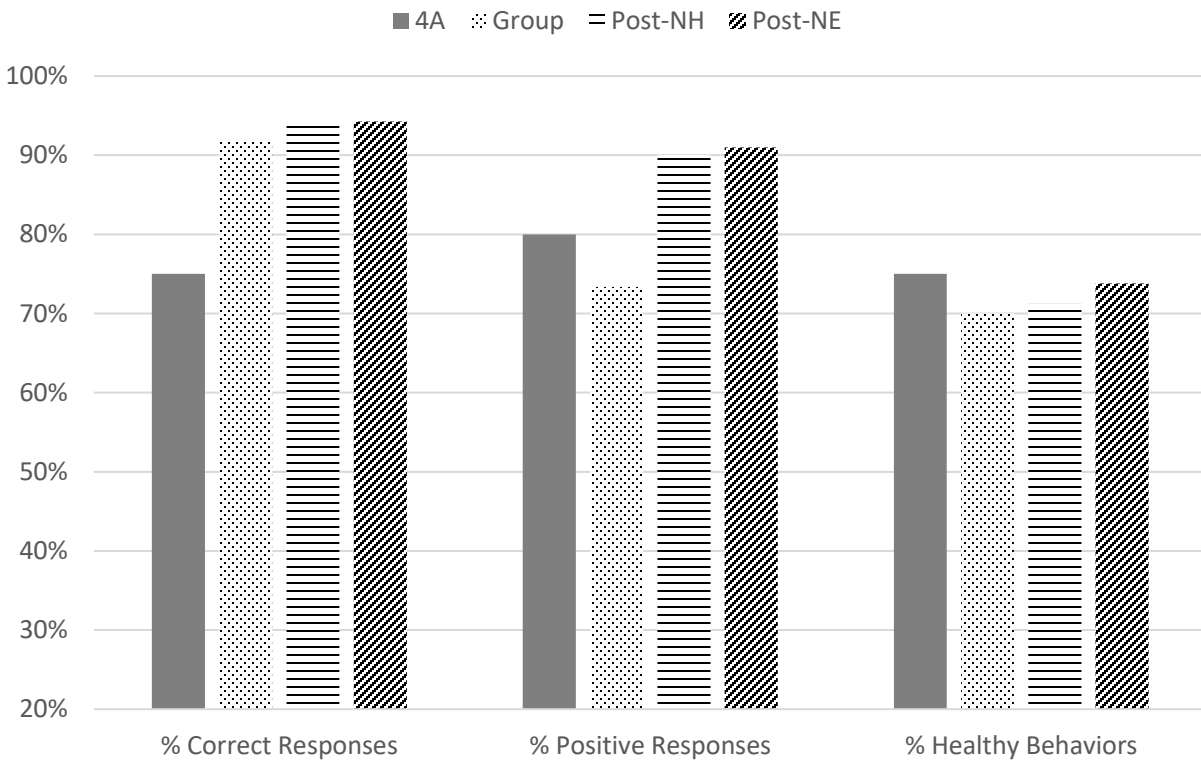


Figure 23. Post-First SDSMP self-efficacy scores on the PAS for Patient 4A-f-39

**Case summary: Patient 4A-f-39.** Patient 4A-f-39's depression and anxiety remained in the severe range and further intervention was warranted. For self-efficacy, Patient 4A-f-39 remained strong in Knowledge and improved in Coping and Behaviors. She finished above the group average and clinical target in Coping, but below regional norms. She finished above group, clinical target, and regional norms in Behaviors. Medical data were not available for this patient.

**Patient 5A-f-57.**

**Depression.** Patient 5A-f-57 was a 57-year-old Caucasian female with Type 2 diabetes. Pre-First SDSMP, her depression score on the PHQ-9 was 11, which indicated moderate depression. Post-First SDSMP her depression score was 7, which indicated moderate depression. One month later, she attended the support group and her depression score remained 7. This patient's depression score decreased by four points after the SDSMP, which, however, was not clinically significant. Her depression severity decreased from moderate to mild range and remained mild for one additional month. The program may have resulted in a modest decrease in the patient's depression, but this change was not clinically significant (See Figure 24). Further monitoring was warranted, as well as clinical judgment about whether treatment was indicated for depression scores in the mild range.

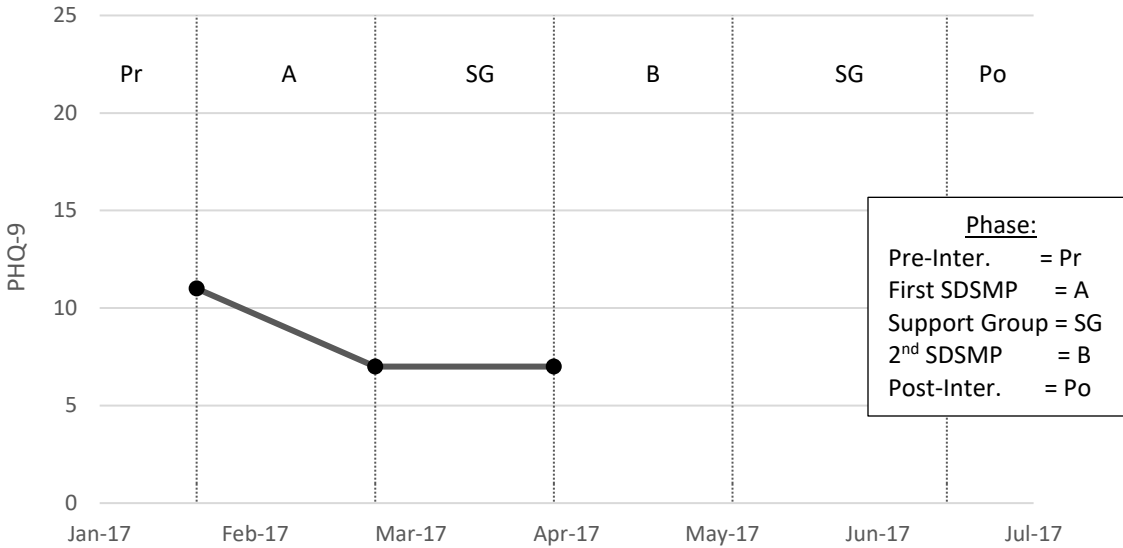


Figure 24. Changes in PHQ-9 depression scores over time for Patient 5A-f-57

**Anxiety.** Patient 5A-f-57 scored an 8 on the GAD-7 at Pre-SDSMP, which indicated mild anxiety; she scored a 1 at Post-First SDSMP, which indicated minimal to no anxiety; and she scored a 3 one month later at a meeting of the support group, which indicated minimal to no anxiety. Her anxiety level decreased by seven points after the first SDSMP and increased by two points over the next month remaining in the minimal to no anxiety range. The SDSMP may have led to a decrease in this patient’s anxiety (See Figure 25). Further monitoring of patient anxiety scores was still warranted as diabetes patients are at increased risk of developing anxiety disorders.

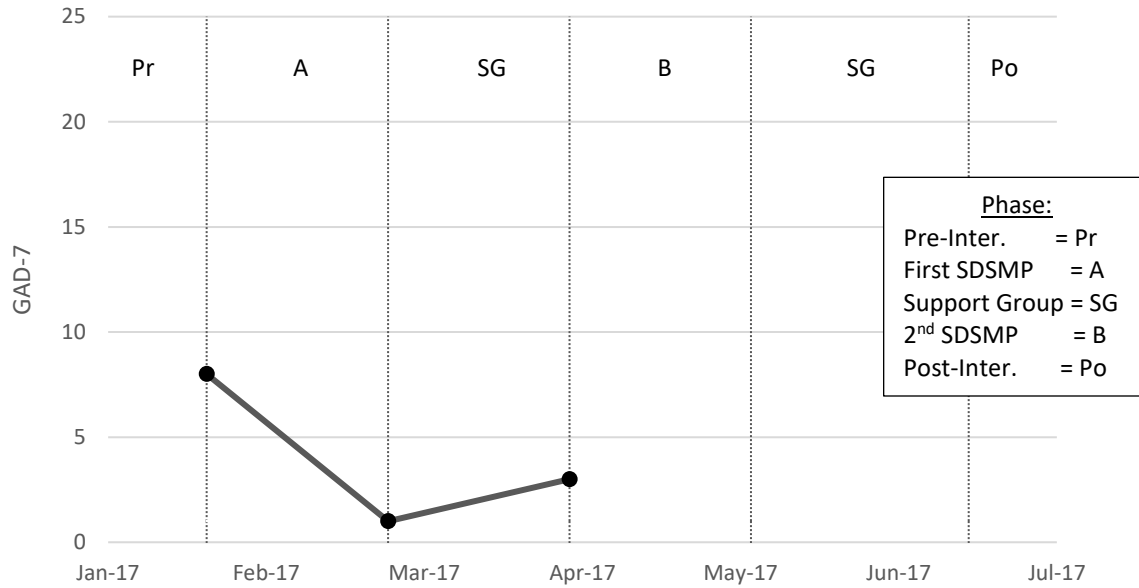


Figure 25. Changes in GAD-7 anxiety scores over time for Patient 5A-f-57

**Self-Efficacy.** On the Pre-First SDSMP administration of the PAS, this patient scored 100% correct on Knowledge; 80% positive on Coping; and 60% healthy on Behaviors. On the Post-First SDSMP, the patient scored 100% correct on Knowledge; 100% positive on Coping; and 100% healthy on Behaviors. After attending the first SDSMP this patient remained strong on Knowledge and improved in Coping and Behaviors, reaching above clinical targets, group averages, and regional norms (See Figures 26–27).

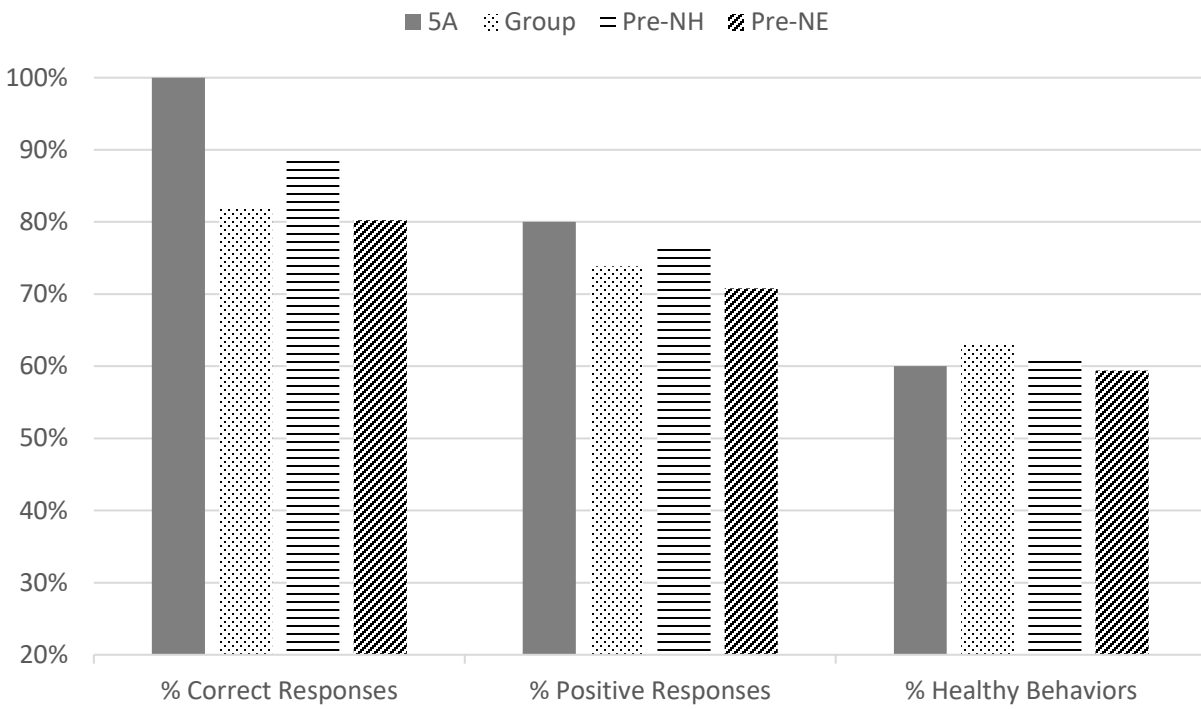


Figure 26. Pre-First SDSMP self-efficacy scores on the PAS for Patient 5A-f-57

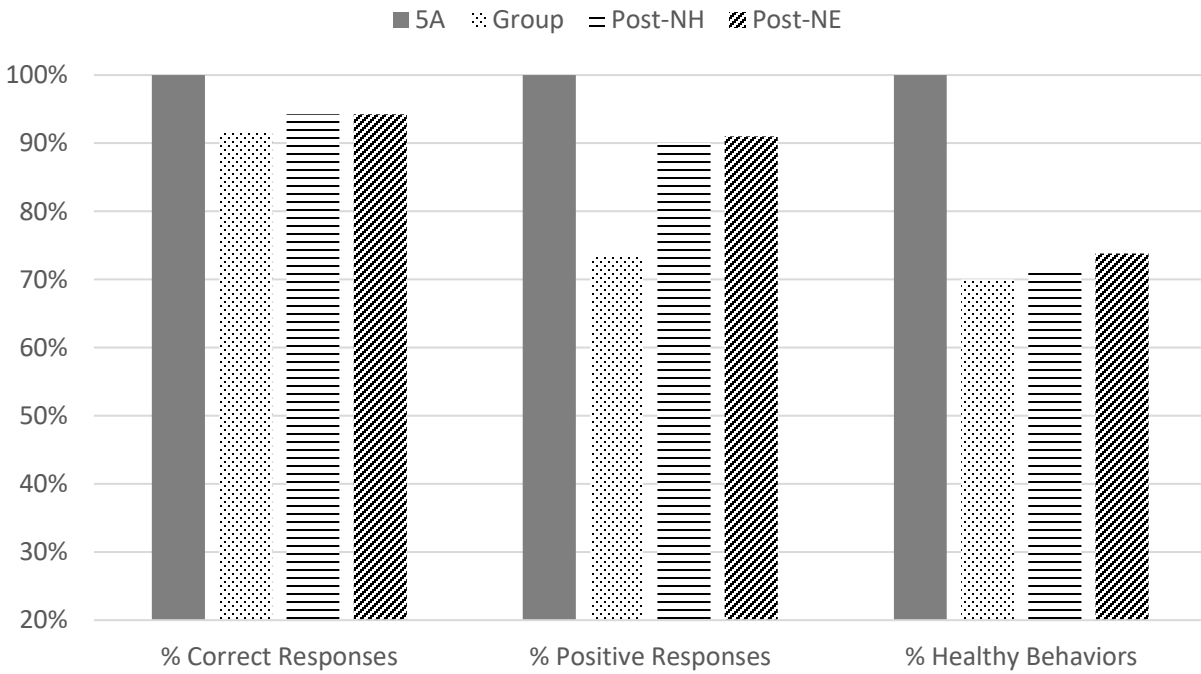


Figure 27. Post-First SDSMP self-efficacy scores on the PAS for Patient 5A-f-57

**HbA1c%.** As a baseline, this patient was measured with HbA1c% of 7.2% in October 2016, which was three months before the first SDSMP. In September 2017, the patient was measured with 6.4%, which was just under the clinical target of 6.5%. After attending the first SDSMP, this patient’s self-care behaviors may have contributed to a 0.8% reduction in HbA1c% (See Figure 28).

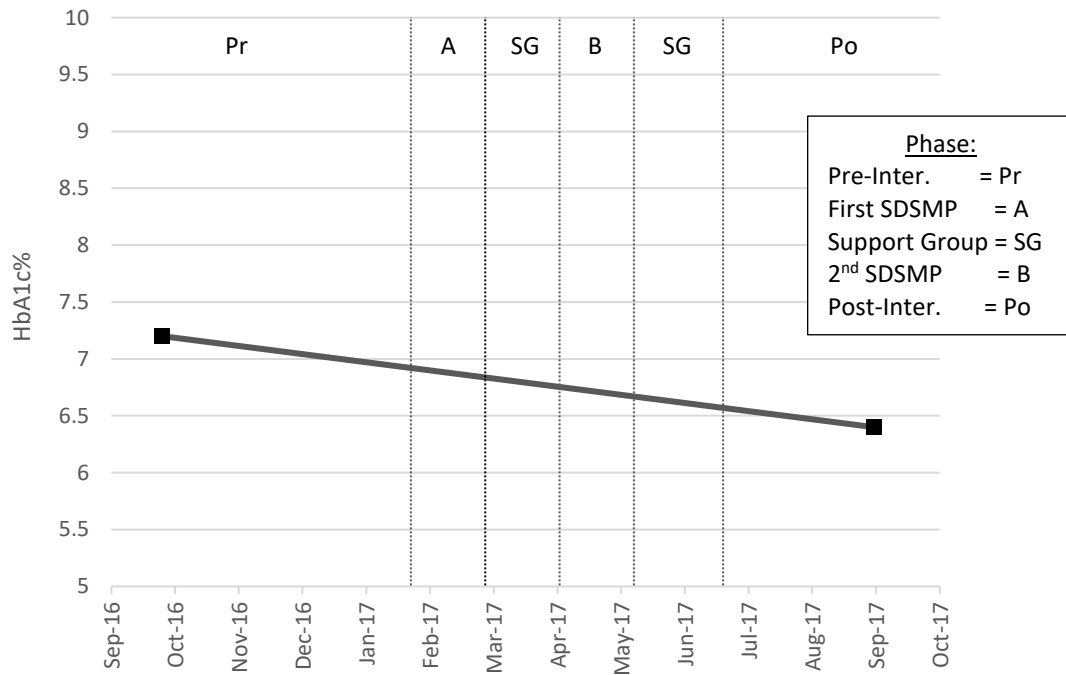


Figure 28. Changes in hemoglobin A1c Percentage (HbA1c%) over time for Patient 5A-f-57

**Body mass index.** As a baseline, this patient’s BMI ranged from 39.07 in October 2016 and 39.22 in November 2016, then decreased to 38.15 January 2017 at the beginning of the first SDSMP. By April 2017, after completing the first SDSMP, the patient’s BMI had dropped to 35.86; however, by September 2017, it had increased again to 37.84. Any benefits this patient had obtained from the program may have diminished six months later with BMI remaining slightly below baseline but still above the clinical target. Further intervention was warranted as this patient was in the obese range (See Figure 29).



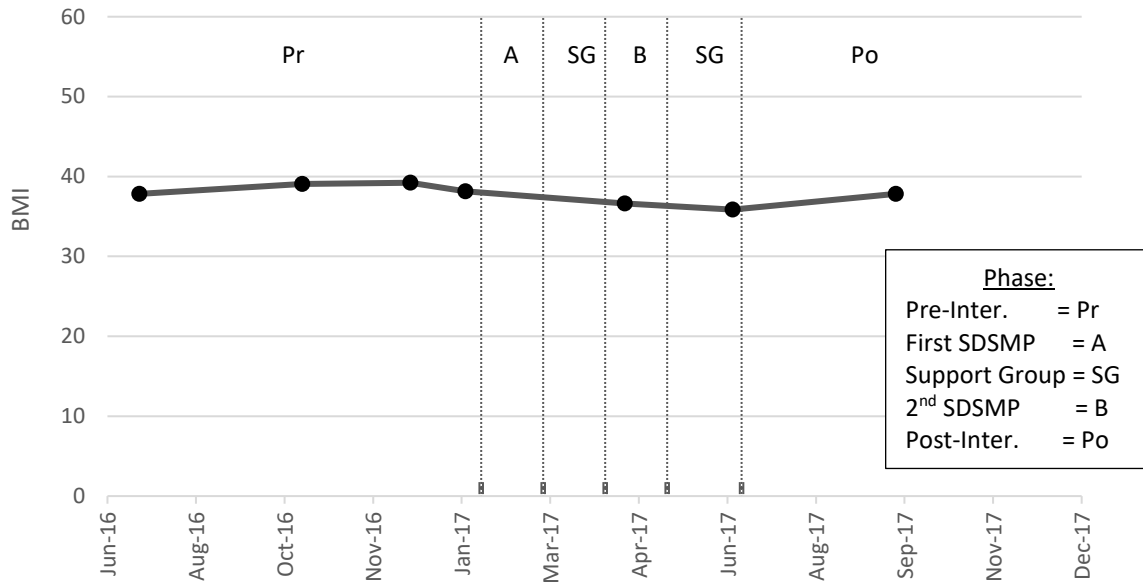


Figure 29. Changes in body mass index (kg/m<sup>2</sup>) over time for Patient 5A-f-57

**Summary: Patient 5A-f-57.** After attending the First SDSMP the patient achieved modest improvements in depression and anxiety, with depression decreasing from moderate to mild and anxiety decreasing from low to minimal or no anxiety. For self-efficacy, her diabetes Knowledge remained strong and she showed improvements in Coping and Behaviors, which indicated her self-efficacy may have increased because of the program. She exceeded the group average, regional norms, and clinical targets in all three areas. Prior to the program, her HbA1c% was above the clinical target, and several months post-program it was below target; however, the patient’s BMI fluctuated showing no change and she remained in the obese range, which suggested a further weight loss program was warranted.

**Patient 6A-m-54.**

**Depression.** Patient 6A-m-54 was a 54-year-old, African-American male with Type 2 diabetes. Pre-First SDSMP, his depression score on the PHQ-9 was 14, which indicated moderate depression. Post-First SDSMP his depression score was 13, which indicated moderate depression. His depression score decreased by one point after the SDSMP, which was not

clinically significant. While the program may have resulted in a modest decrease in the patient’s depression, the change was not clinically significant, and the patient’s depression remained moderate; therefore, further treatment was warranted (See Figure 30).

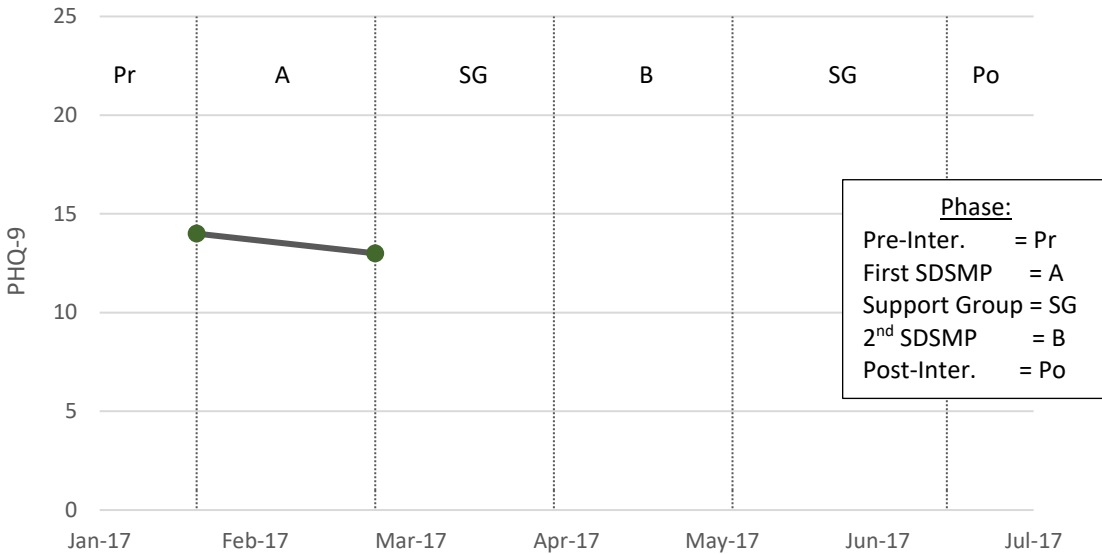


Figure 30. Changes in PHQ-9 depression scores over time for Patient 6A-m-54

**Anxiety.** Patient 6A-m-54 scored a 19 on the GAD-7 at Pre-SDSMP, which indicated severe anxiety, and he scored a 19 at Post-First SDSMP, which indicated severe anxiety. His anxiety level remained in the severe range throughout the study, and he was likely suffering from an anxiety disorder. The SDSMP appeared to result in no change in this patient’s anxiety.

Further treatment and monitoring were warranted (See Figure 31).

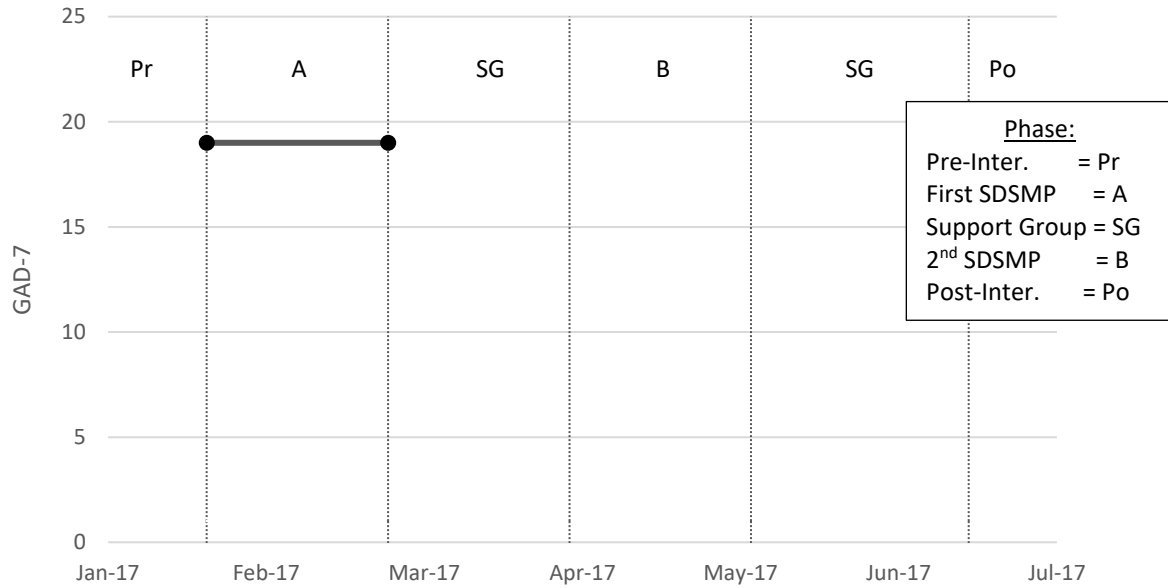


Figure 31. Changes in GAD-7 anxiety scores over time for Patient 6A-m-54

**Self-Efficacy.** On the Pre-First SDSMP administration of the PAS, the patient scored 50% correct on Knowledge; 40% positive on Coping; and 40% healthy on Behaviors. On the Post-First SDSMP, the patient scored 75% correct on Knowledge; 40% positive on Coping; and 60% healthy on Behaviors. While attending the first SDSMP this patient improved in Knowledge and Behaviors reaching above clinical targets, group averages, and regional norms. However, he remained below target on Coping (See Figures 32–33).

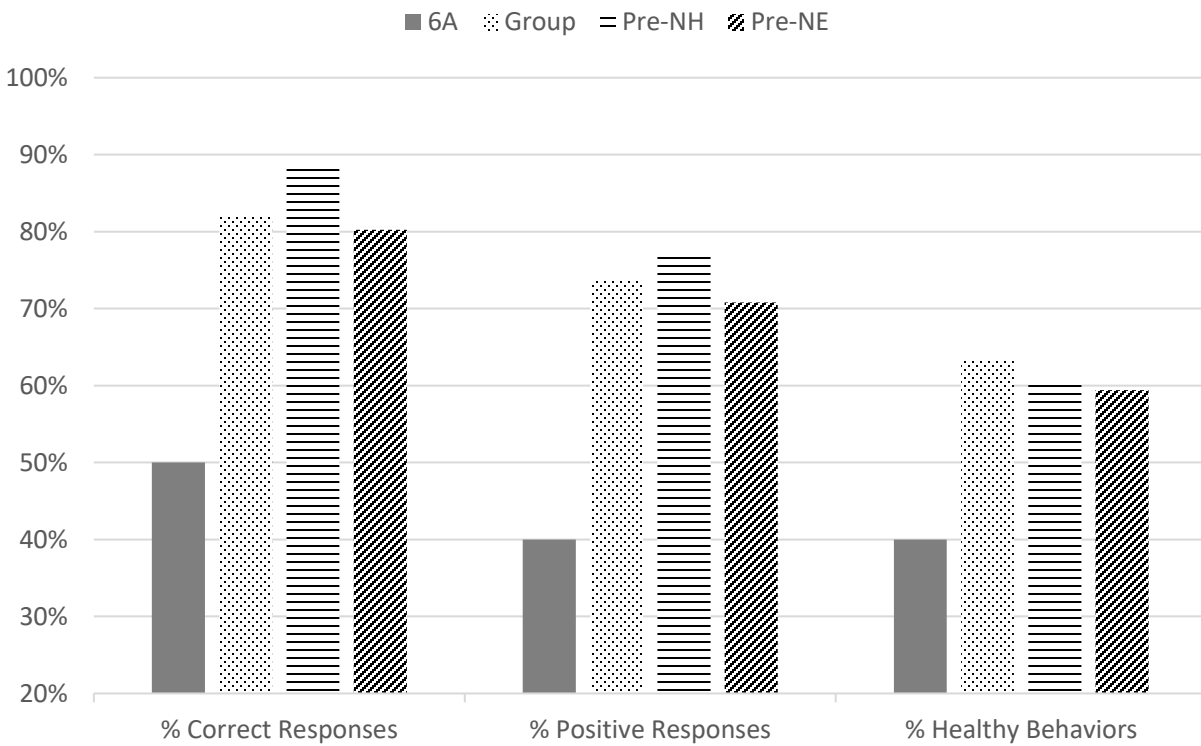


Figure 32. Pre-First SDSMP self-efficacy scores on the PAS for Patient 6A-m-54

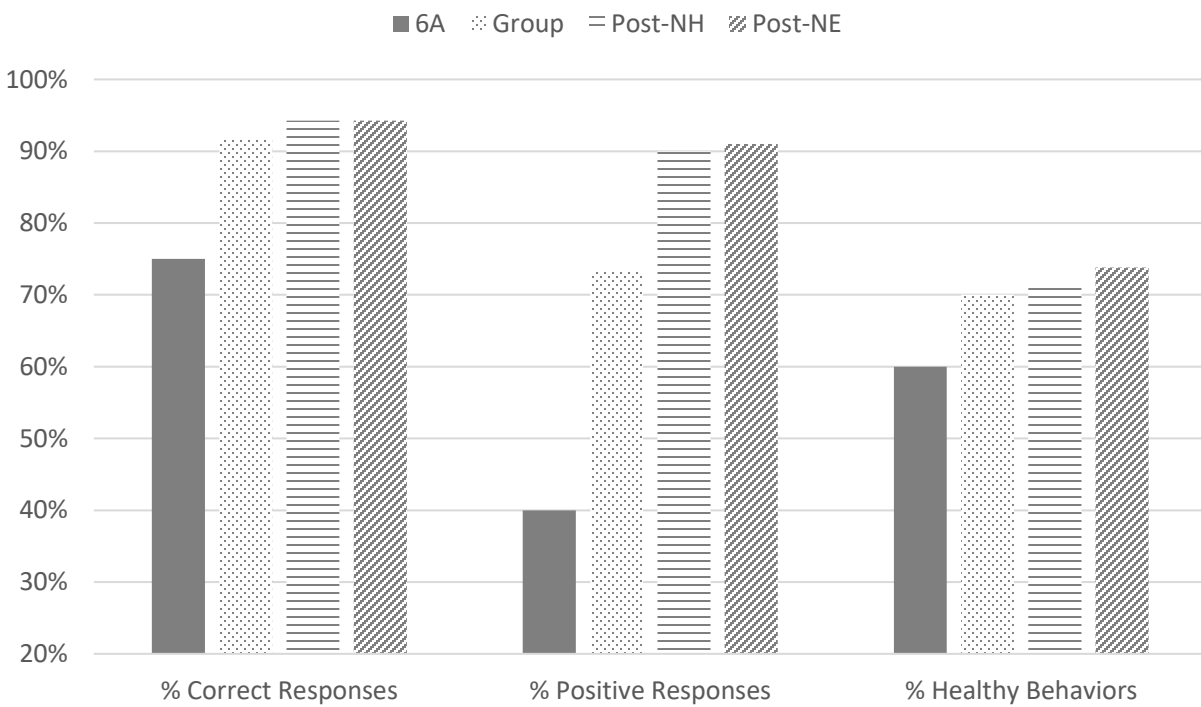


Figure 33. Post-First SDSMP self-efficacy scores on the PAS for Patient 6A-m-54

**HbA1c%.** As a baseline, this patient measured HbA1c% at 7.8% in December 2016, which was one month before the first SDSMP, and 7.0% for HbA1c% in January 2017, as the first SDSMP began. In November 2017 the patient measured 5.7% for HbA1c%, which was below the clinical target of 6.5%. After attending the first SDSMP, this patient’s self-care behaviors may have resulted in a 1.3% reduction in HbA1c% (See Figure 34).

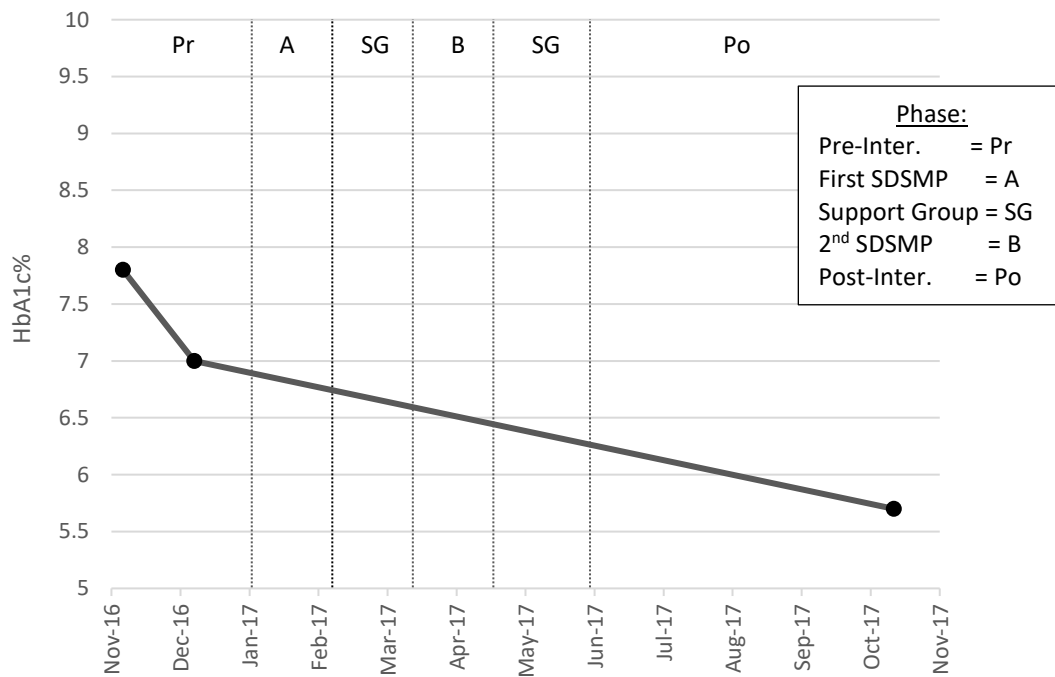


Figure 34. Changes in hemoglobin A1c percentage (HbA1c%) over time for Patient 6A-m-54

**Body mass index.** As a baseline, this patient’s BMI ranged from 43.42 in September 2016 to 42.06 in December 2016. After completing the first SDSMP, his BMI had dropped slightly to 41.92 and by October 2017 it had decreased to 40.15. This patient may have successfully adopted self-care behaviors from the program that contributed to successful decrease of body mass index; however, his BMI remained above the clinical target and further intervention was warranted as he was in the obese range (See Figure 35: Patient 6A-m-54 Body Mass Index Over Time).

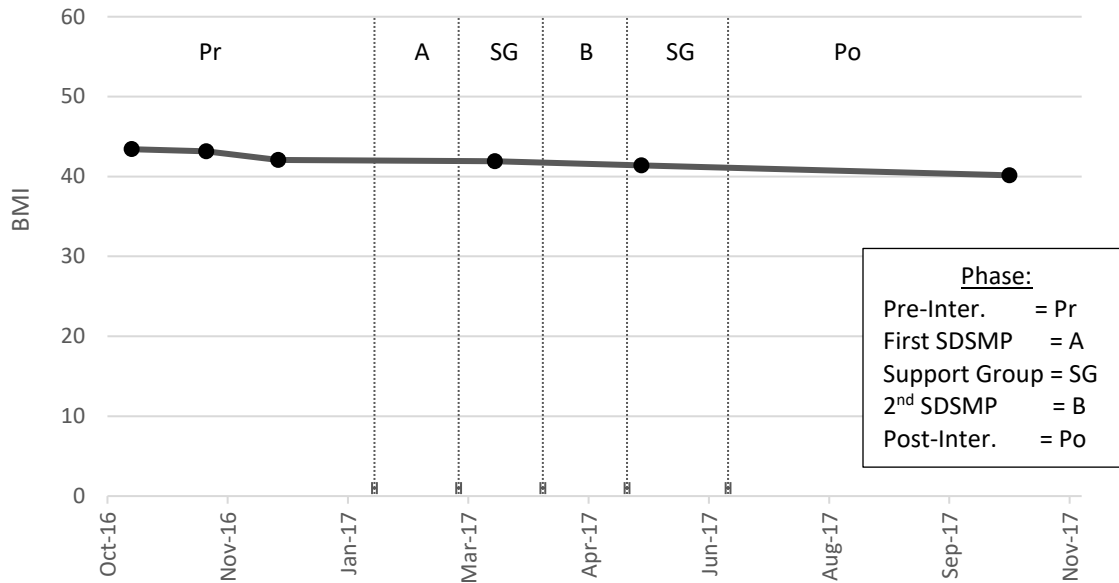


Figure 35. Changes in body mass index (BMI) over time for Patient 6A-m-54

**Case summary: Patient 6A-m-54.** At the end of the program, Patient 6A-m-54’s depression and anxiety remained in the moderate to severe range. In terms of self-efficacy, Patient 6A-m-54 patient improved on Knowledge and Behaviors reaching above clinical targets, group averages, and regional norms; however, he remained below target on Coping. Patient 6A-m-54’s BMI remained in the obese range throughout the study; however, his HbA1c% decreased from above to below the clinical target by approximately 2%, which was an improvement.

**Patient 7A-m-60.**

**Depression.** Patient 7A-m-60 was a 60-year-old Caucasian male with Type 1 diabetes. Pre-First SDSMP, his depression score on the PHQ-9 was 14, which indicated moderate depression. Post-First SDSMP his depression score remained 14. One month later, he attended the support group and his depression score was 18, which indicated moderately severe depression. During that time, he disclosed experiencing a significantly stressful health-related event. One month later, he attended another meeting of the support group and his depression

score had fallen to 13, which indicated moderate depression. This patient’s depression score did not change after the SDSMP; rather, his depression score increased by four points when he arrived at the support group, which elevated his depression from the moderate to the moderately severe range. His score then decreased five points by the next meeting of the support group, which was clinically significant. At the 11-month follow-up, he scored 24, which indicated severe depression. The SDSMP did not coincide with a decrease in the patient’s depression; however, the support group may have contributed to a clinically significant drop in the patient’s depression that was temporary because his depression increased once again before the interview. It was also posited that this patient’s polymorbid medical conditions were related to his depression. Further treatment was indicated as this patient may be severely depressed (See Figure 36).

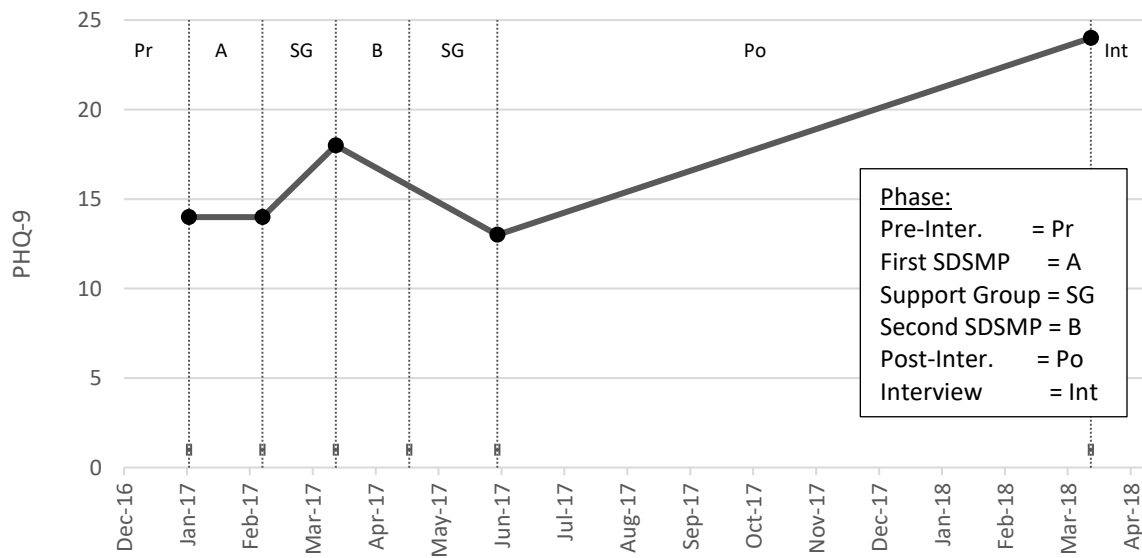


Figure 36. Changes in PHQ-9 depression scores over time for Patient 7A-m-60

**Anxiety.** Patient 7A-m-60 scored a 10 on the GAD-7 at Pre-SDSMP, which indicated moderate anxiety; he scored a 12 at Post-First SDSMP, which indicated moderate anxiety; he scored a 9 one month later at a meeting of the support group, which indicated mild anxiety; and he scored a 10 two months later at another meeting of the support group, which indicated moderate anxiety. Although the patient’s anxiety increased from mild to moderate severity during the support group, the change was only one point; thus, his anxiety remained at the low end of moderate. However, by the 11-month follow-up interview, the patient’s anxiety increased dramatically to 21 points, indicating severe anxiety. Although the program may have offered some temporary symptom relief, his anxiety was again severe at the interview (See Figure 37). Further treatment and monitoring of this patient’s anxiety scores were warranted.

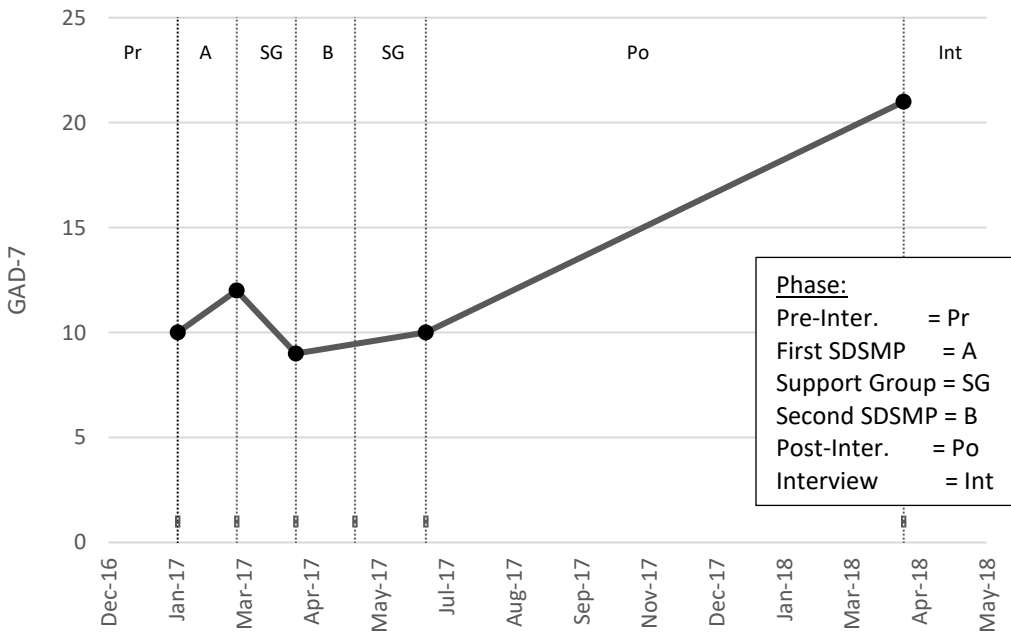


Figure 37. Changes in GAD-7 anxiety scores over time for Patient 7A-m-60

**Self-Efficacy.** On the Pre-First SDSMP administration of the PAS, the patient scored 100% correct on Knowledge; 80% positive on Coping; and 100% healthy on Behaviors.



Post-First SDSMP, the patient scored 100% correct on Knowledge; 80% positive on Coping; and 100% healthy on Behaviors. By the 11-month follow-up, he scored the same again with 100% correct on Knowledge; 80% positive on Coping; and 100% healthy on Behaviors. The patient remained above clinical target and outperformed group and regional norms in all areas except for post-program Coping, where he was below regional norms (See Figures 38–40).

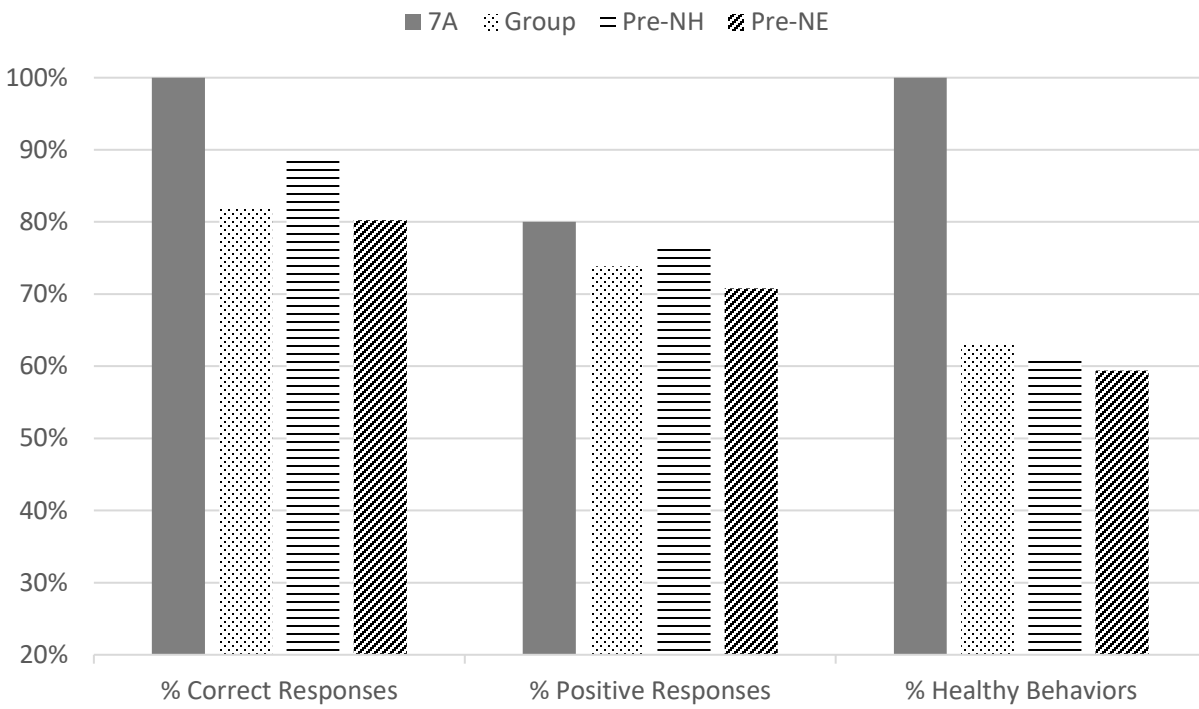


Figure 38. Pre-First SDSMP self-efficacy scores on the PAS for Patient 7A-m-60

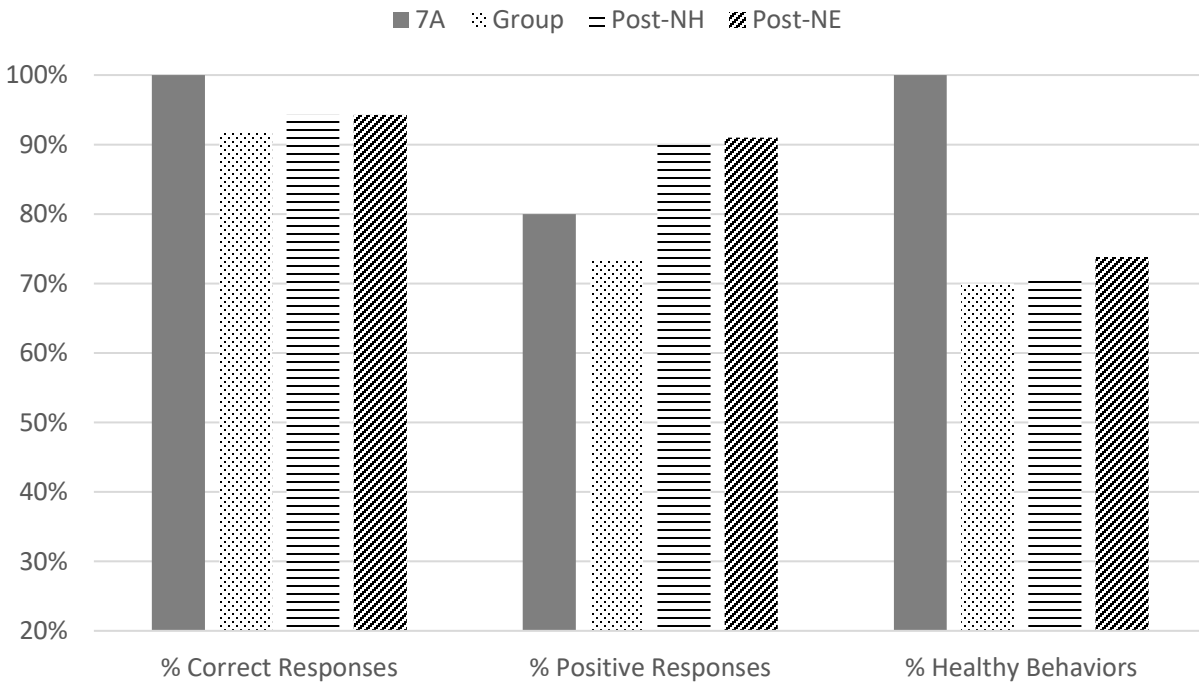


Figure 39. Post-First SDSMP self-efficacy scores on the PAS for Patient 7A-m-60

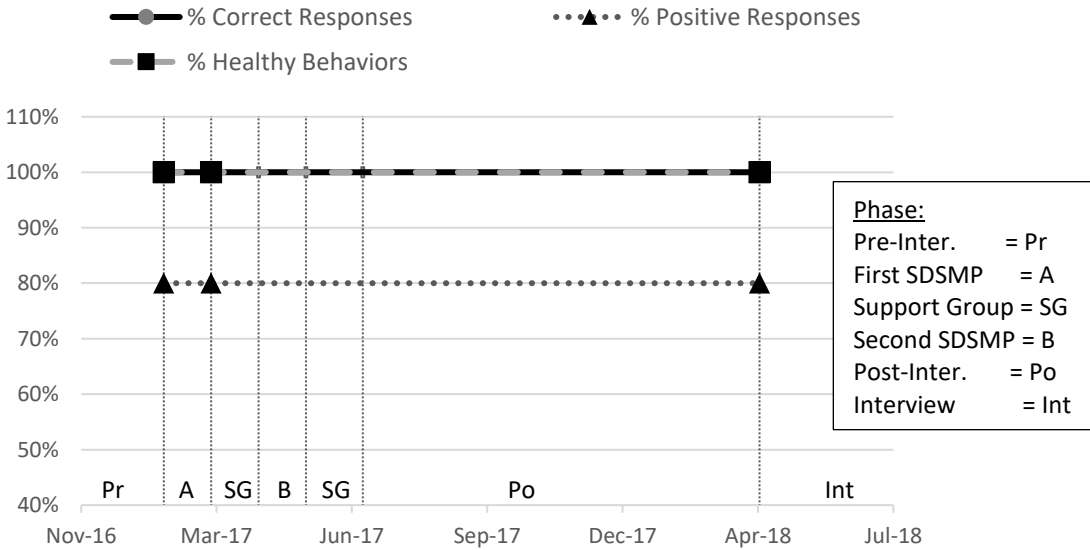


Figure 40: Changes in self-efficacy scores on the PAS over time for Patient 7A-m-60. Data points for % Correct Responses and % Healthy Behaviors are overlapping and lines are not distinguishable.

**HbA1c%.** This patient measured 6.9% for HbA1c% in April 2017, which was one month after the First SDSMP. This was above the clinical target of 6.5%; thus, further intervention was warranted. As no baseline measures were available, it cannot be determined whether the program led to a change in the patient’s behavior that may have lowered his HbA1c% (See Figure 41).

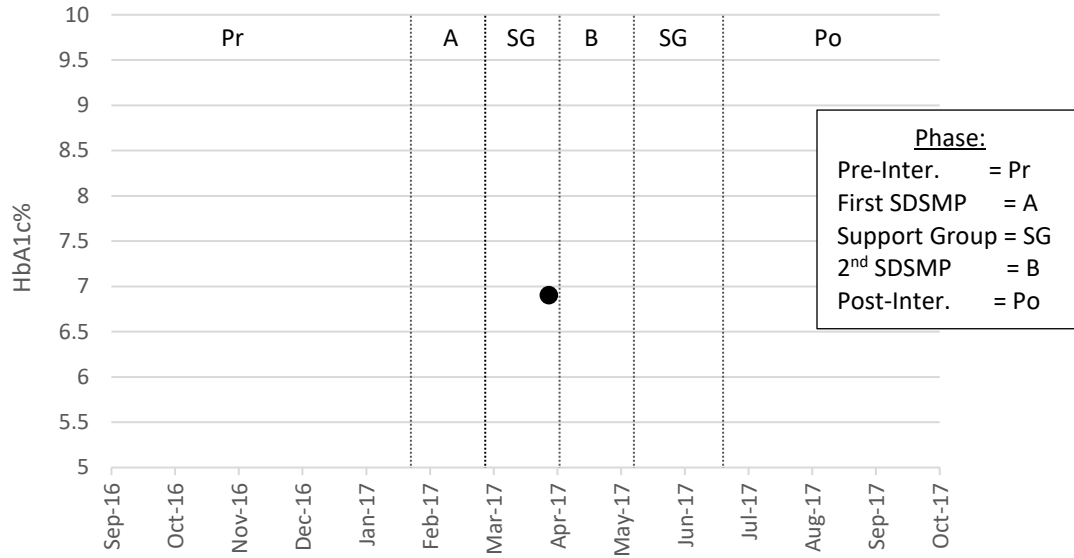


Figure 41. Changes in hemoglobin A1c percentage (HbA1c%) over time for Patient 7A-m-60

**Body mass index.** As a baseline, this patient’s BMI ranged from 30.51 in December 2016 to 31.07 in January 2017 at the start of the first SDSMP. By April 2017, and after completing the program, the patient’s BMI had increased to 32.33 and remained in that range at a six-month follow-up appointment in October 2017 at 32.19. This patient did not appear to adopt self-care behaviors sufficient to control his BMI as a result of attending the SDSMP. BMI remained above the clinical target, and further intervention was warranted as this patient measured in the obese range (See Figure 42).

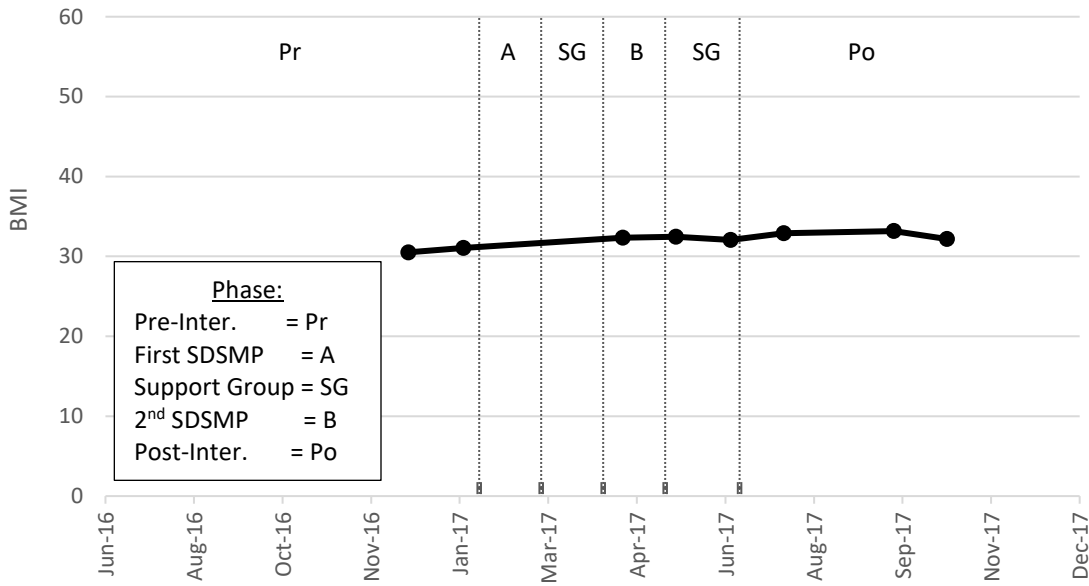


Figure 42. Changes in body mass index (BMI) over time for Patient 7A-m-60

**Case summary: Patient 7A-m-60.** Patient 7A-m-60 may have received some temporary relief from depression and anxiety while attending the program, and particularly, the support group; however, his most recent assessment indicated he was still severely anxious and depressed. For self-efficacy, the patient remained above clinical target and he outperformed the group and regional norms on all measures, except for post-program Coping, where he trailed regional norms slightly.

During the interview, this patient made 10 statements that fell under the theme Social Influences: Social Support, six statements about Self-Efficacy: Self-Efficacy, nine statements about Self-Efficacy: Motivation, and two statements about his Self-Efficacy: Learning Style. One noteworthy response about Social Influences: Social Support made by him was: “It helped me to realize that—unique as I feel sometimes with Type 1 diabetes—that I’m not alone in these feelings.” Here, the patient was referencing the emotional support he received from the group. Another notable response about Self-Efficacy: Motivation was “Change comes hard but you

have to be willing, you know? . . . Personally, I find it exciting to . . . I’ve always liked to cook and I’ve always been a good cook.” Here, the patient seemed to be indicating his passion and self-efficacy around preparing healthy meals for himself.

**Patient 8A-f-75.**

**Depression.** Patient 8A-f-75 was a 75-year-old Caucasian female with Type 2 diabetes. Pre-First SDSMP, her PHQ-9 depression score was 10, which indicated moderate depression. Post-First SDSMP her depression score was 4, which indicated moderate depression. Two months later, she attended the support group and her depression score remained 7. This patient’s depression score decreased by six points after the First SDSMP, which was clinically significant, and she dropped from having moderate to minimal or no depression. However, scores at a later time indicated that her depression increased by three points, when she attended the support group two months later, which was not clinically significant; however, the patient was in the mildly depressed range again. The SDSMP may have resulted in a clinically significant decrease in the patient’s depression (See Figure 43). Further monitoring and treatment were still warranted for a patient with diabetes and mild depression.

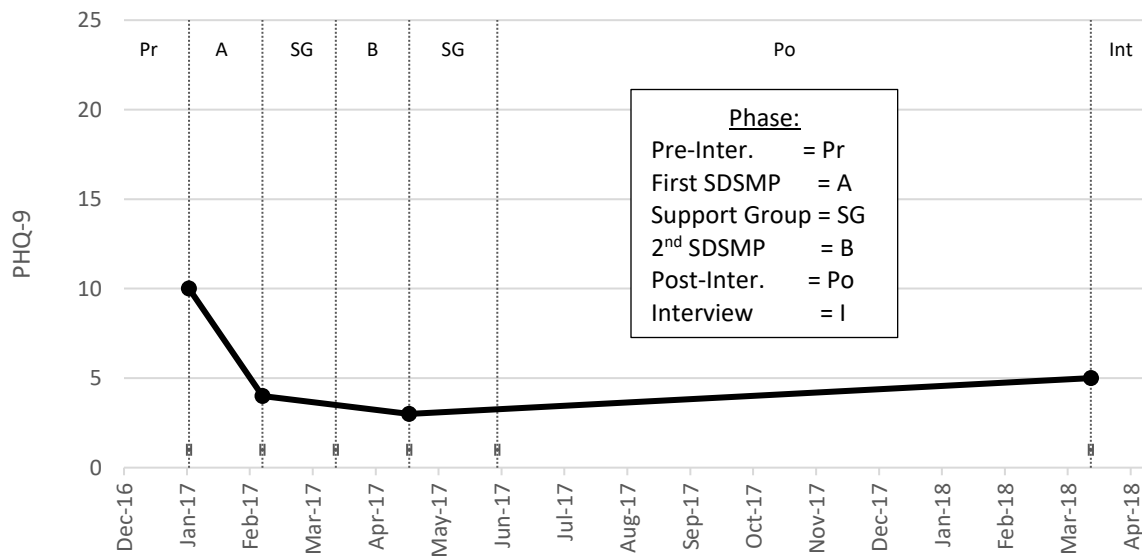


Figure 43. Changes in PHQ-9 depression scores over time for Patient 8A-f-75

**Anxiety.** Patient 8A-f-75 scored a 12 on the GAD-7 at Pre-SDSMP, which indicated moderate anxiety; she scored a 1 at Post-First SDSMP, which indicated minimal to no anxiety; and she scored a 2 one month later at a meeting of the support group, which indicated minimal to no anxiety. Her anxiety level decreased by 11 points—dropping from moderate to minimal range after the first SDSMP. She dropped by one point over the next month but remained in the minimal to no anxiety range. The SDSMP may have contributed to a decrease in this patient’s anxiety (See Figure 44). Further monitoring of her anxiety is still warranted as diabetes patients are at increased risk of developing anxiety disorders.

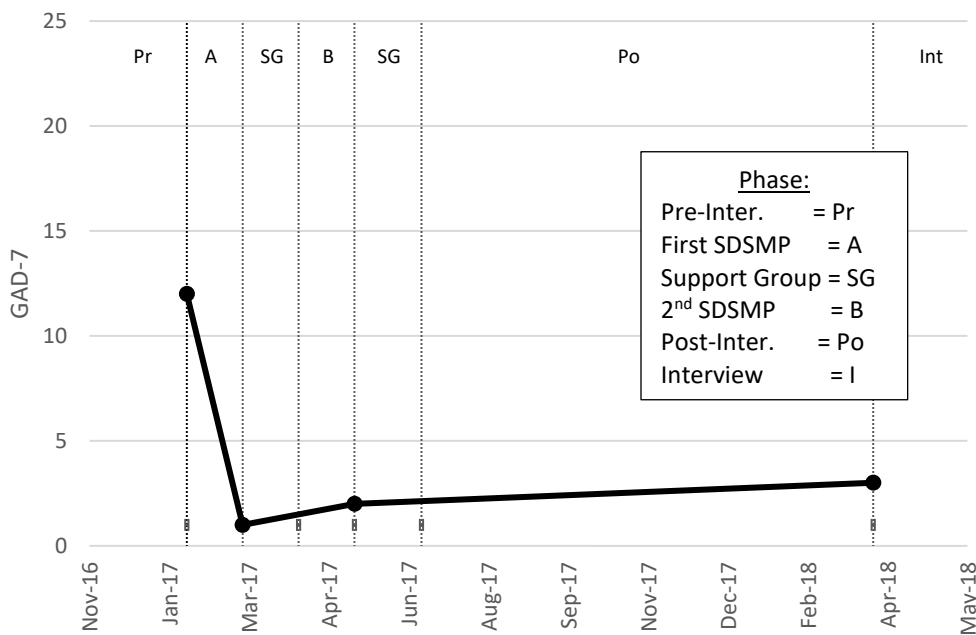


Figure 44. Changes in GAD-7 anxiety scores over time for Patient 8A-f-75

**Self-Efficacy.** On the Pre-First SDSMP administration of the PAS, the patient scored 50% correct on Knowledge; 80% positive on Coping; and 80% healthy on Behaviors. Post-First SDSMP, the patient scored 100% correct on Knowledge; 100% positive on Coping; and 80% healthy on Behaviors. At the 11-month follow-up, she scored 50% correct on Knowledge; 80%

positive on Coping; and 80% healthy on Behaviors. While attending the first SDSMP this patient improved in Knowledge and Coping and remained strong in Behaviors; however, these gains in Knowledge and Coping decreased to baseline by the 11-month follow-up. At the end of the study, her Knowledge was below clinical target, but her Coping and Behavior were above clinical target. She outperformed the group and regional norms in all areas except for Coping where she trailed the regional norms slightly (Figures 45–47).



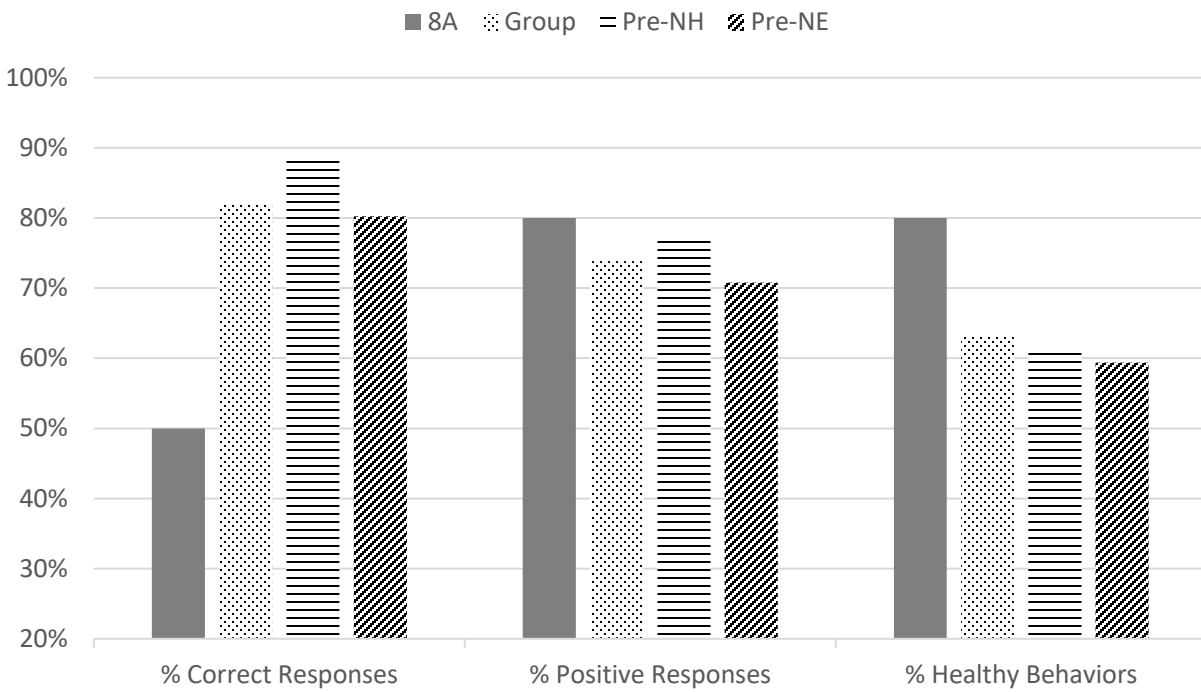


Figure 45. Pre-First SDSMP self-efficacy scores on the PAS for Patient 8A-f-75

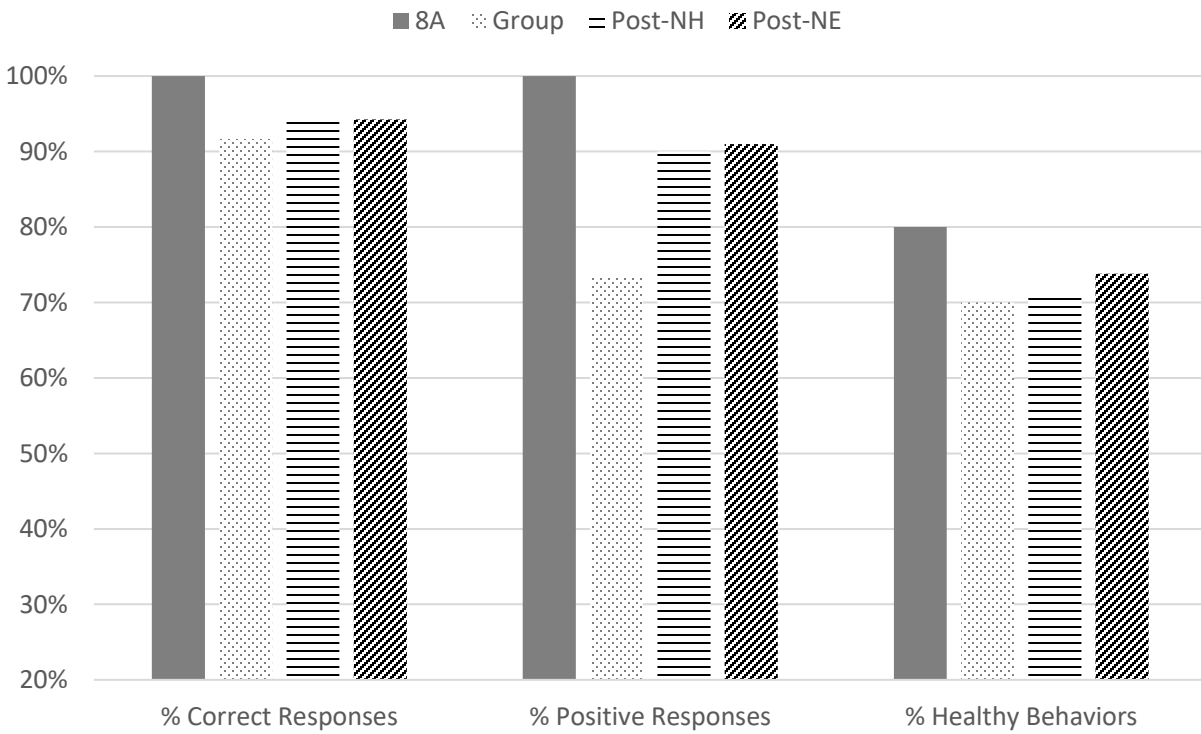


Figure 46. Post-First SDSMP self-efficacy scores on the PAS for Patient 8A-f-75

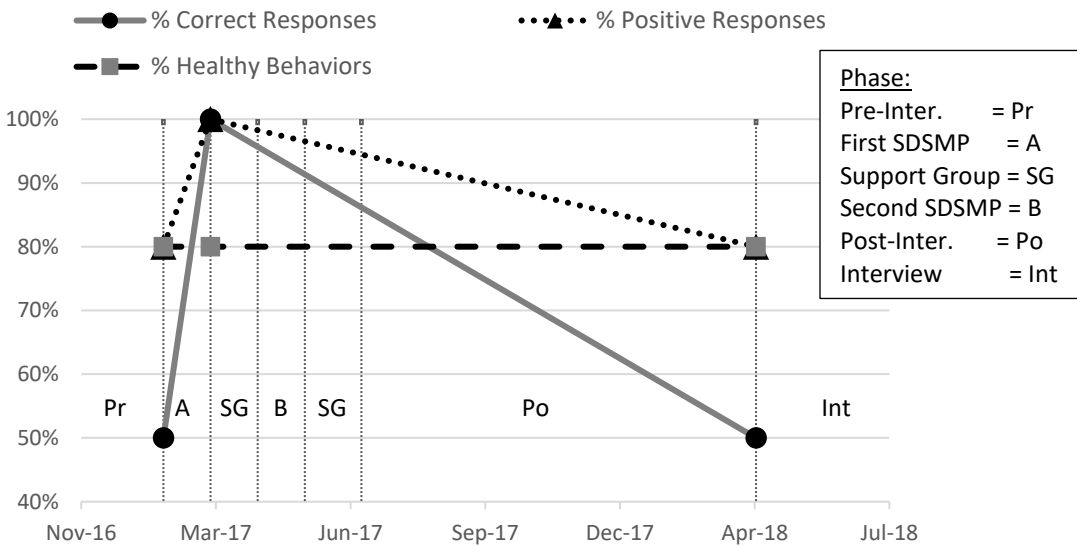


Figure 47. Changes in self-efficacy scores on the PAS over time for Patient 8A-f-75

**Case summary: Patient 8A-f-75.** Patient 8A-f-75 experienced a significant decrease in depression and anxiety after attending the first SDSMP. In terms of self-efficacy, this patient improved in Knowledge and Coping and remained strong in Behaviors; however, these gains in Knowledge and Coping dropped to baseline by the 11-month follow-up. At the end of the study, her Knowledge was below clinical target, but her Coping and Behavior were above clinical target. She outperformed the group and regional averages in all areas except for Coping where she trailed the regional norms slightly. During the interview, she responded with eight statements about her Positive Changes: New Skills Learned; five statements about Positive Changes: Benefits from Attending; three statements about Lifestyle: Diet; two statements about Lifestyle: Exercise; and six statements about Lifestyle: Self-Care. One noteworthy example of how she benefited from the program was:

What I want to eat now—I always leave something extra on the plate. I don’t need the whole thing and I’m eating fruit for a snack in the afternoon, popcorn, and I eat whole wheat bread which I didn’t eat before.

Again, she was referencing how she implemented various dietary changes into her lifestyle that were recommended by the workshop.

**Patient 9A-m-62.**

**Depression.** Patient 9A-m-62 was a 62-year-old, Caucasian, male with Type 2 diabetes. Pre-First SDSMP, his PHQ-9 depression score was 5, which indicated mild depression. Due to a significantly stressful life event, this patient did not attend the final meeting of the first SDSMP and did not respond to further outreach; therefore, his Post-First SDSMP psychological outcomes were not assessed (See Figure 48). Further monitoring was still warranted as diabetes patients are at increased risk for developing depression.

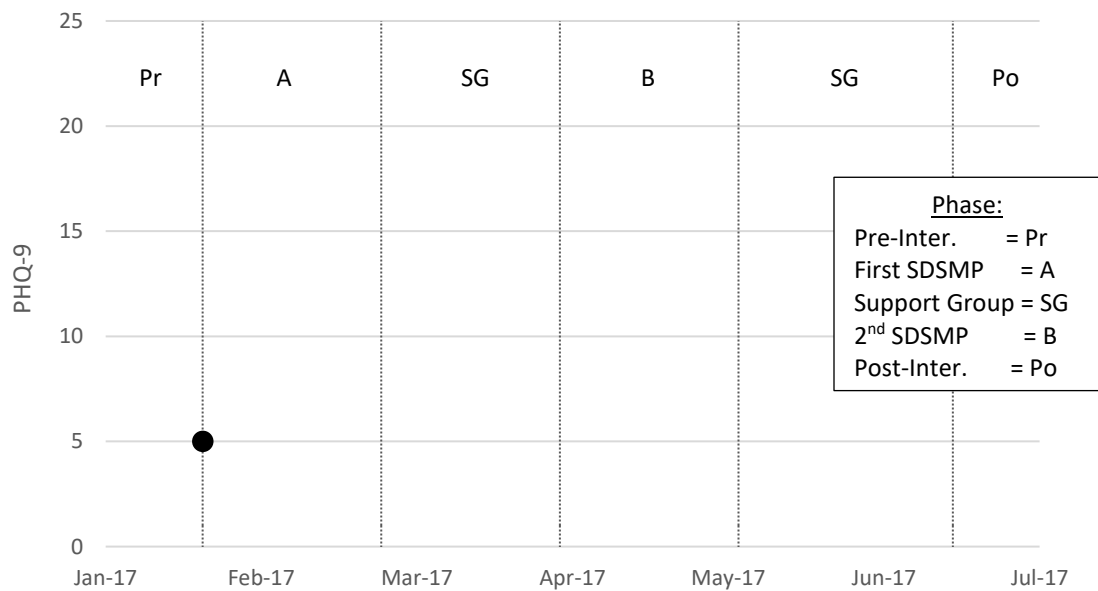


Figure 48. Changes in PHQ-9 depression scores over time for Patient 9A-m-62

**Anxiety.** Patient 9A-m-62 scored a 2 on the GAD-7 at Pre-SDSMP, which indicated moderate anxiety. Due to a significantly stressful life event, he did not attend the final meeting of the SDSMP and did not respond to outreach; therefore, his Post-First SDSMP psychological

outcomes were not assessed. Further monitoring of this patient’s anxiety levels was still warranted as diabetes patients are at increased risk for anxiety disorders (See Figure 49).

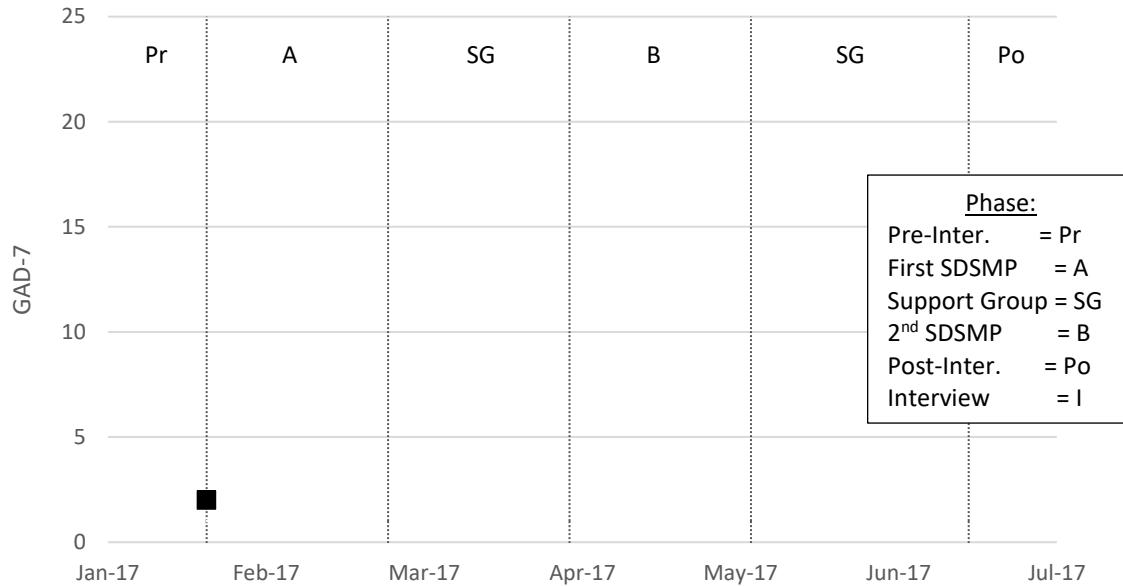


Figure 49. Changes in GAD-7 anxiety scores over time for Patient 9A-m-62

**Self-Efficacy.** On the Pre-First SDSMP administration of the PAS, the patient scored 100% correct on Knowledge; 100% positive on Coping; and 100% healthy on Behaviors, which was above clinical targets, group averages, and regional norms (See Figure 50). Due to a significantly stressful life event, this patient did not attend the final meeting of the SDSMP and did not complete the Post-First SDSMP administration of the PAS.

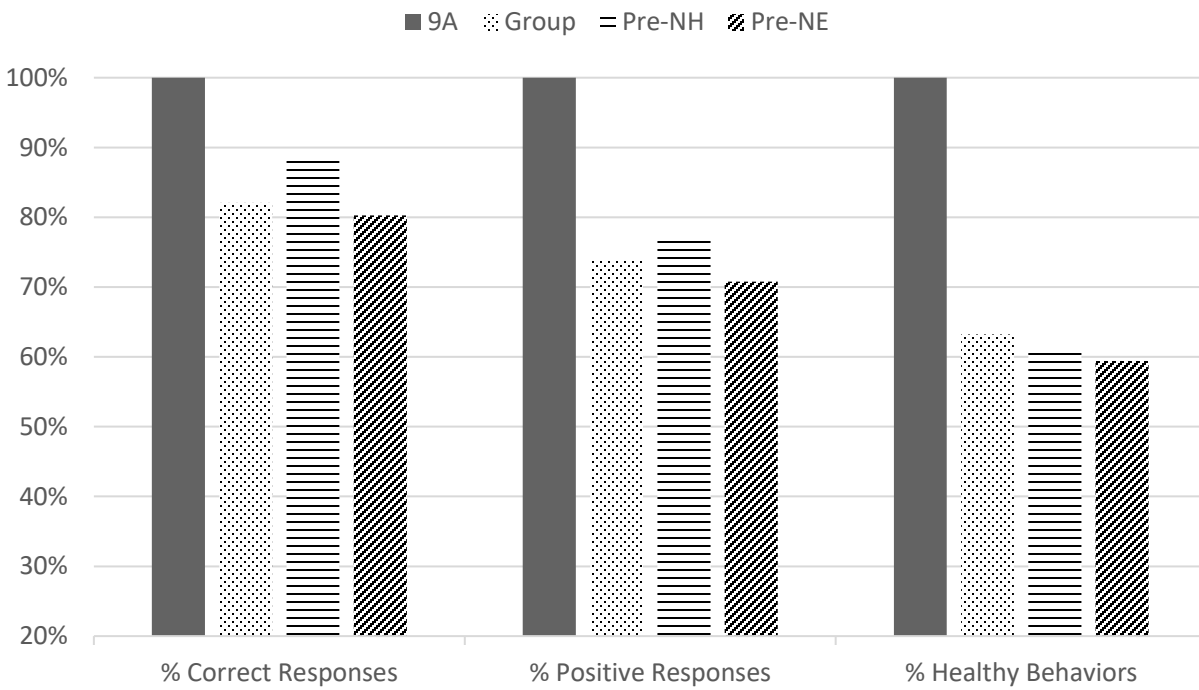


Figure 50. Pre-First SDSMP self-efficacy scores on the PAS for Patient 9A-m-62

**HbA1c%.** As a baseline, this patient was measured with HbA1c% of 8.4% in September 2016, which was four months before the First SDSMP; and 7.3% in December 2016, which was one month before the first SDSMP. In September 2017 the patient measured at 9.4%, which was still above the clinical target of 6.5%; therefore, further intervention was warranted. After attending the first SDSMP, this patient’s lifestyle may have resulted in a 2.1% increase in HbA1c% (See Figure 51).

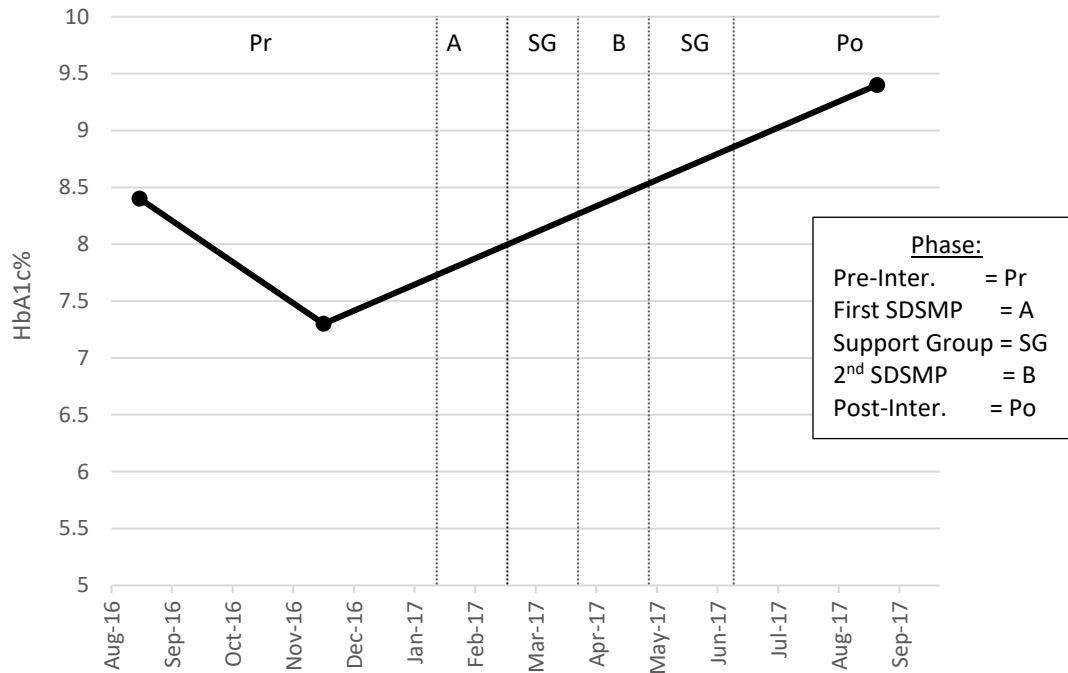


Figure 51. Changes in hemoglobin A1c percentage (HbA1c%) over time for Patient 9A-m-62

**Body mass index.** As a baseline, this patient’s BMI ranged from 33.17 in September 2016 to 33.45 in December 2016. By March 2017, after completing the first SDSMP, his BMI had dropped to 32.33, still above the clinical target; however, by the six-month follow-up in September 2017 his BMI had decreased to 30.23, which was just above the clinical target. This patient may have successfully adopted self-care behaviors from the program that contributed to a decrease of BMI; however, his BMI remained above clinical target so further intervention and monitoring were warranted (See Figure 52).

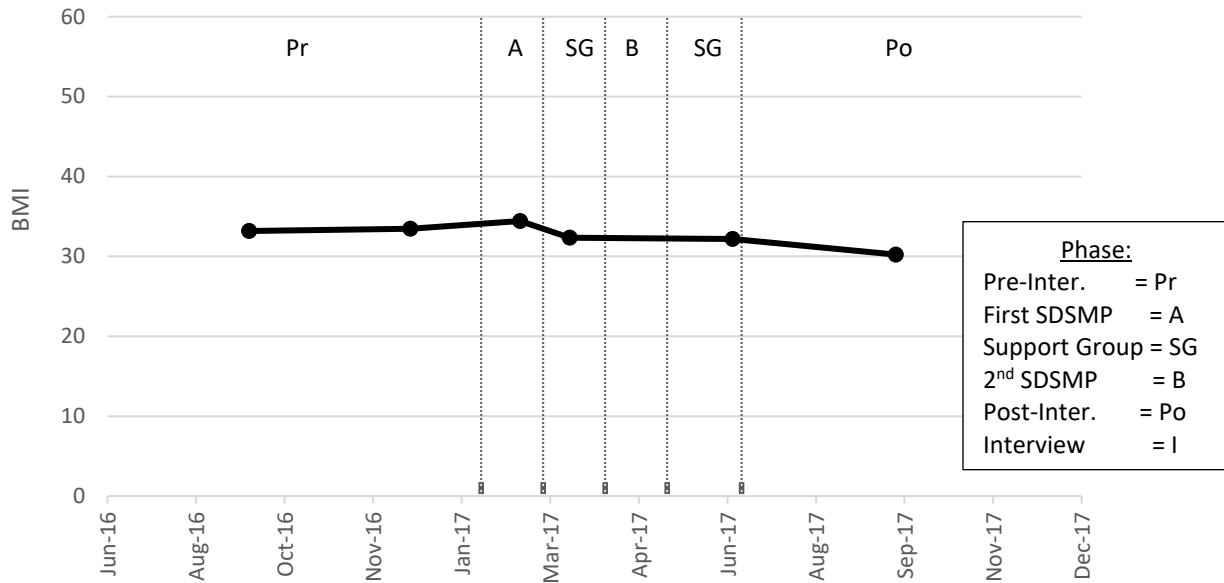


Figure 52. Changes in body mass index (kg/m<sup>2</sup>) over time for Patient 9A-m-62

**Case summary: Patient 9A-m-62.** Psychological outcomes post-program for Patient 9A-m-62 were not available; however, he may have been mildly depressed at the beginning of the program. Although he scored above the clinical target, group averages, and regional norms for all three areas for self-efficacy, his BMI remained in the obese range and his HbA1c% continued increasing and was well-above the clinical target for several months after the program. Further assessment of this patient’s depression and diabetes biomarkers was warranted.

**Patient 10A-m-49.**

**Depression.** Patient 10A-m-49 was a 49-year-old Caucasian male with Type 2 diabetes. Pre-First SDSMP, his PHQ-9 depression score was 12, which indicated moderate depression. Post-First SDSMP his depression score was 17, which indicated moderately severe depression. One month later, he attended the support group and his depression score was 13, which indicated moderately severe depression. One month later, he attended another meeting of the support group and his depression score had increased to 16, which indicated moderate depression. One month after that, he attended a third meeting of the support group and his depression score had

fallen to 11, but it increased again to 12 at the 11-month follow-up, which indicated moderate depression. This patient’s depression score appeared to fluctuate over the duration of the study, and it appeared the program had little effect on his depression (See Figure 53).

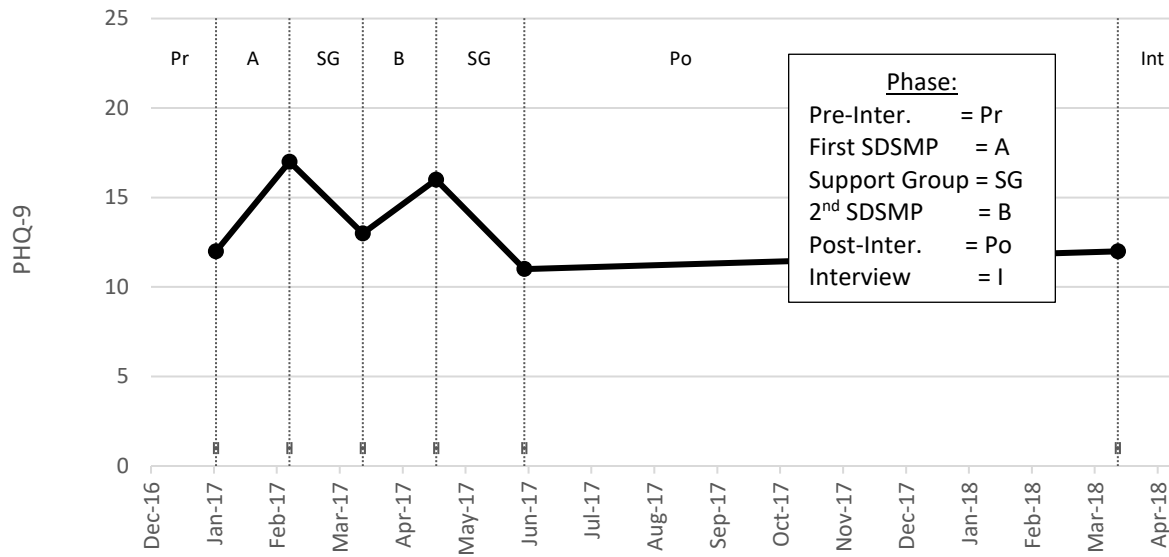


Figure 53. Changes in PHQ-9 depression scores over time for Patient 10A-m-49

**Anxiety.** Patient 10A-m-49 scored a 14 on the GAD-7 at Pre-SDSMP, which indicated moderate anxiety; he scored a 13 at Post-First SDSMP, which indicated moderate anxiety; he scored a 13 one month later at a meeting of the support group, which indicated moderate anxiety; he scored a 10 one month later at another meeting of the support group, which indicated moderate anxiety; and he scored an 8 one month later at another meeting of the support group, and it increased again to a 9 at the 11-month follow-up, which indicated mild anxiety. Over the duration of the study, his anxiety score decreased by a total of five points; a benefit which was sustained for the most part as his anxiety score increased by only one point over the next 11 months (See Figure 54). Further monitoring of patient anxiety levels is still warranted as diabetes patients are at increased risk for anxiety disorders.



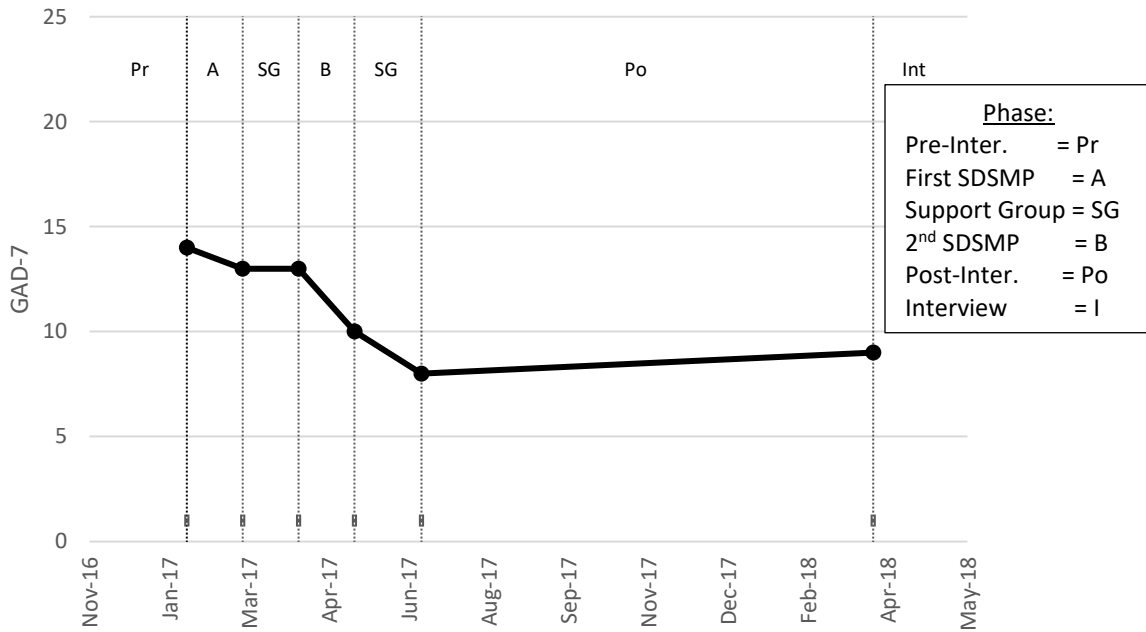


Figure 54. Changes in GAD-7 anxiety scores over time for Patient 10A-m-49

**Self-Efficacy.** On the Pre-First SDSMP administration of the PAS, the patient scored 75% correct on Knowledge; 60% positive on Coping; and 40% healthy on Behaviors. Post-First SDSMP, the patient scored 100% correct on Knowledge; 60% positive on Coping; and 60% healthy on Behaviors. At the 11-month follow-up interview, the Knowledge score decreased to 75%; Coping remained 60%; and Behavior decreased to 40%. After attending the first SDSMP and support group, this patient increased in his Knowledge, but these changes decreased to baseline by the 11-month follow-up; however, his Knowledge and Behavior were above clinical targets but below the group average and regional norms (See Figures 55–57).

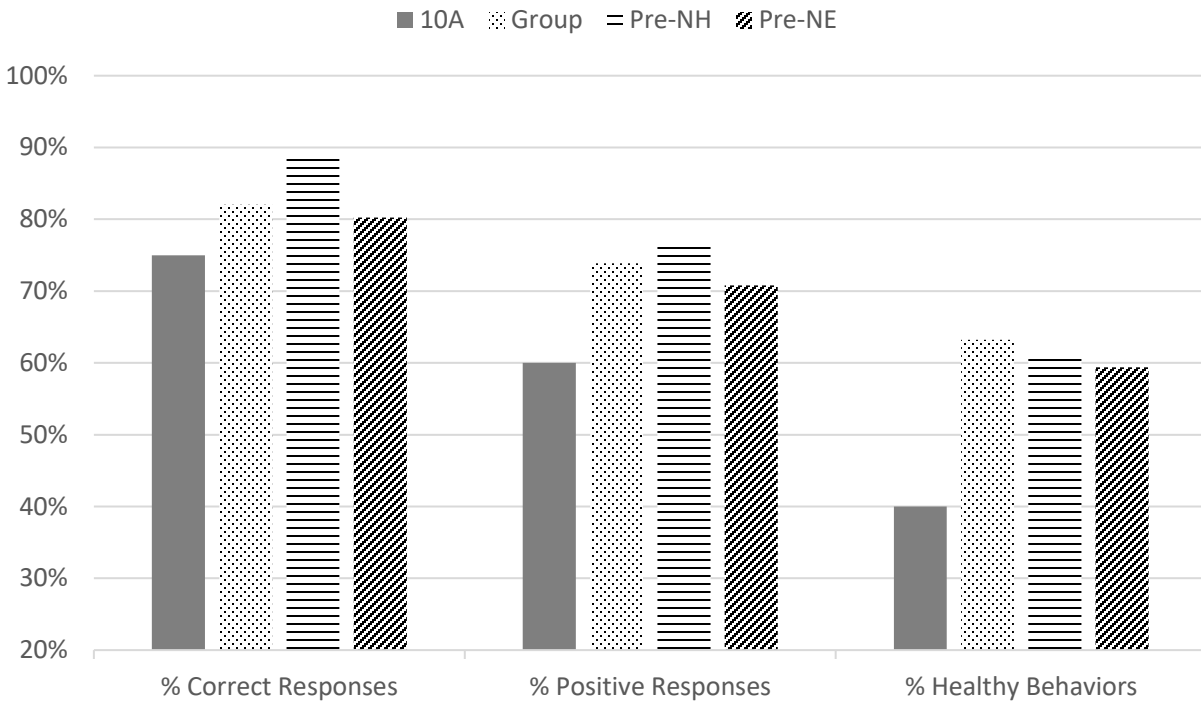


Figure 55. Pre-First SDSMP self-efficacy scores on the PAS for Patient 10A-m-49

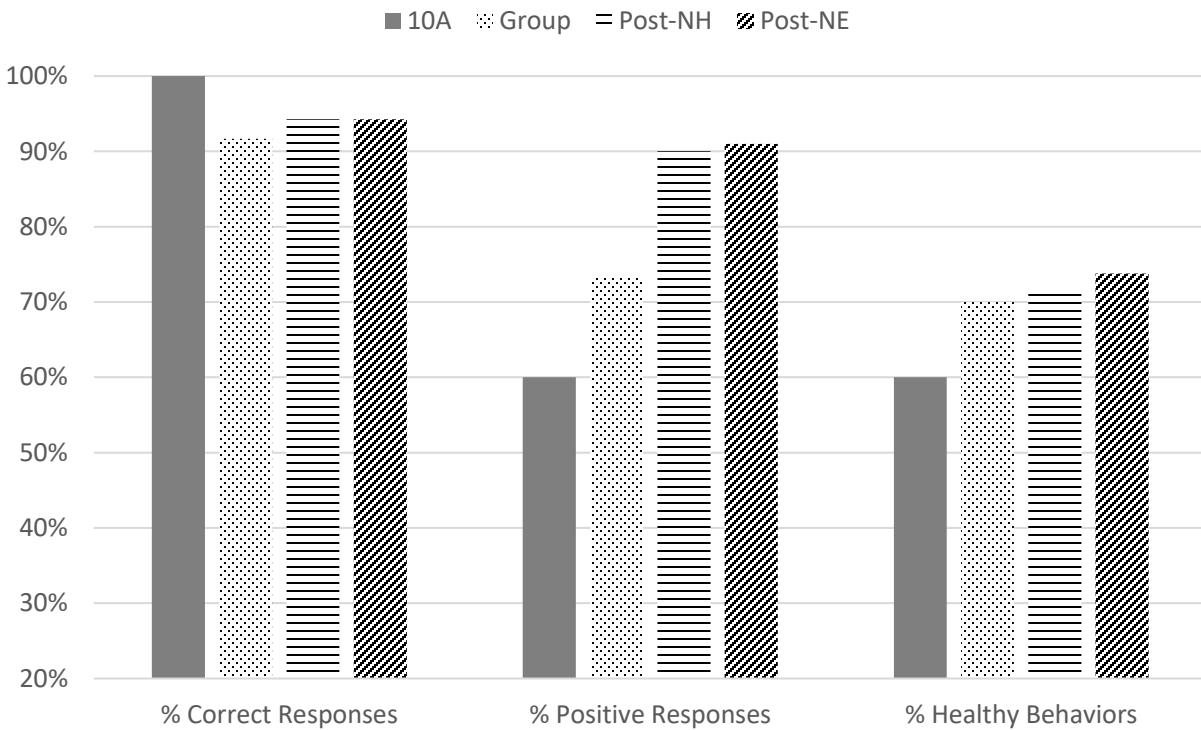


Figure 56. Post-First SDSMP self-efficacy scores on the PAS for Patient 10A-m-49

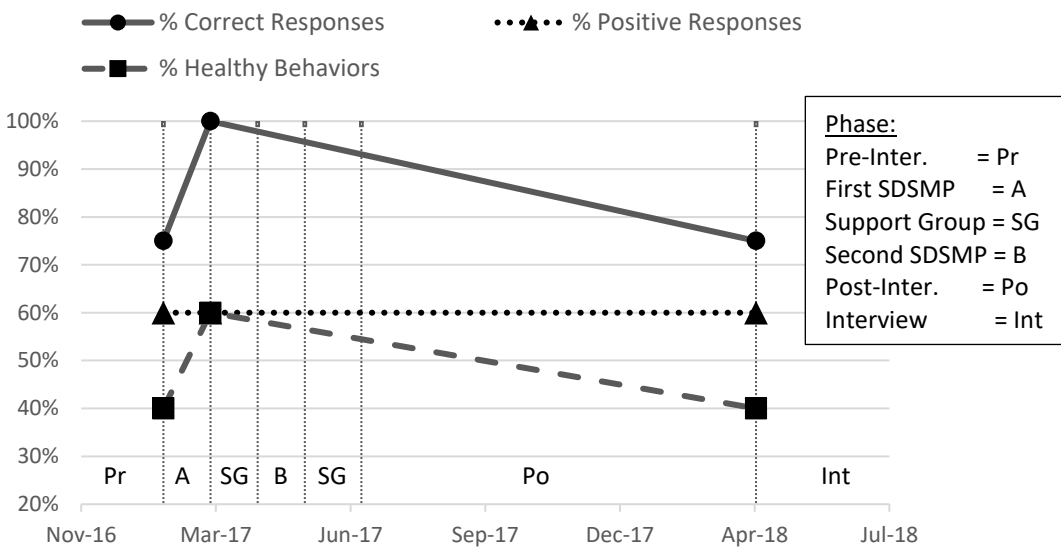


Figure 57. Changes in PAS self-efficacy scores over time for Patient 10A-m-49

**Case summary: Patient 10A-m-49.** The program appeared to help decrease the patient’s anxiety, which was a benefit sustained over time; however, it had little effect on his depression scores. In terms of self-efficacy, this patient improved in his Knowledge, but these changes decreased to his baseline by the 11-month follow-up; however, his Knowledge and Behavior were above clinical targets but below the group average and regional norms.

During the interview, the patient responded with some remarkably heartfelt Practitioner Feedback statements about Harbor Care Health and Wellness Center, certain practitioners on his care team there, and one of the program leaders. About Harbor Care Health and Wellness Center, the patient stated,

When I first got diabetes, I’d never seen a needle or syringe before, and this place was kind enough to let me come in when I was shooting five times a day—three times fast-acting, two times slow-acting insulin—and they would let me come in here and shoot it with me. No doctor’s office in the freaking country would be willing to do that and this

place has some really awesome things about it that no one else has, and that can never change.

The patient seems to be expressing his gratitude for his clinic and how they appeared to go above and beyond his expectations about healthcare service. Toward one of the practitioners at Harbor Care Health and Wellness Center, the patient stated,

What they could do is keep the good employees employed—here that’s how they helped me, such as Dr. ----, ----, and ----. Those people are—have . . . Dr. ---- saved my life. This goes back years—that’s the bottom line. I’d be dead. My blood sugar was 609. I was put in the hospital. When I first got diagnosed I couldn’t even walk. I couldn’t move. I was dead. I was in ketoacidosis. So—yeah—keep their employees that care.

The patient seemed to be expressing his gratitude toward his diabetes care provider and several administrators who work at the clinic. Toward me as one of the program leaders, the patient stated,

Samuel was a good man—easy to listen to. Sometimes there are other people that we’re doing it that were not as easy as Sam. Yeah, Sam was easy to listen to. You know pleasant. He was a people person and to have just people persons doing it is the only thing that they should always focus on because non-people people make it hard for someone to sit there.

Here, the patient was referencing an interpersonal quality that contributed to his learning and experience of the workshop. The practitioner-specific feedback he was offering seemed to reference various aspects of his experience that led to the successful outcomes he reported experiencing.

**Patient 1B-f-60.**

**Depression.** Patient 1B-f-60 was a 60-year-old, Caucasian, female with Type 2 diabetes. Pre-Second SDSM, her PHQ-9 depression score was 1, which indicated minimal to no depression. Post-Second SDSMP her depression score was 6, which indicated mild depression. During that time, the patient reported experiencing a significantly stressful life event. One month later, she attended the support group and her depression score was 0. This patient’s depression score increased by five points after the SDSMP, which was clinically significant—but this increase may have resulted from the significantly stressful life event that she had experienced. Her score had decreased by six points one month later at the support group. Overall, it was unclear how the program affected her depression due to the stressful life event (See Figure 58). Further monitoring was still warranted as diabetes patients are at increased risk for developing depression.

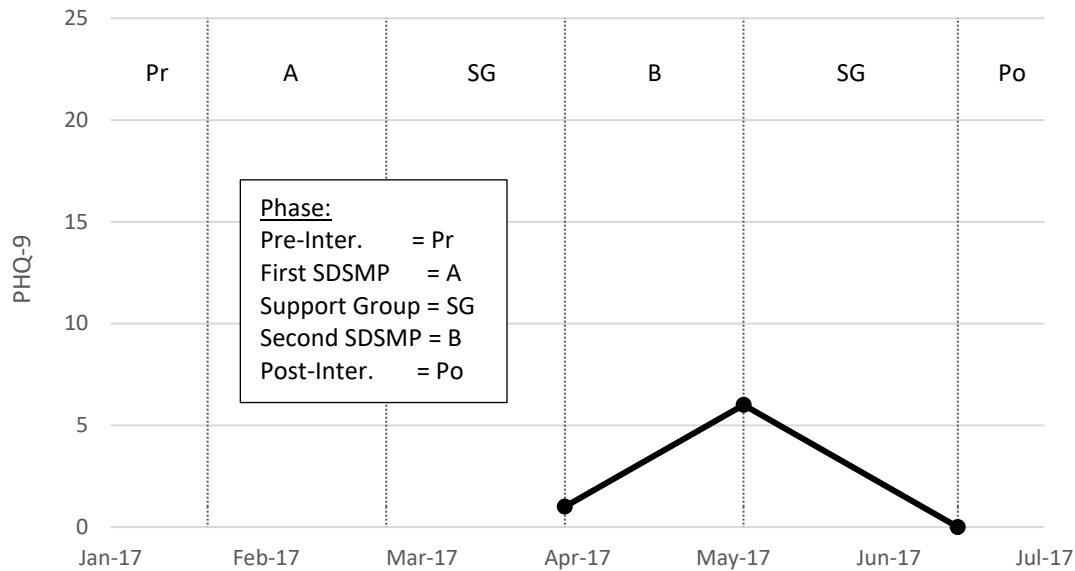


Figure 58. Changes in PHQ-9 depression scores over time for Patient 1B-f-60

**Anxiety.** Patient 1B-f-60 scored a 0 on the GAD-7 at Pre-Second SDSMP, which indicated minimal to no anxiety; she scored a 5 at Post-Second SDSMP, which indicated mild anxiety; and she scored a 0 one month later at a meeting of the support group, which indicated minimal to no anxiety. She reported a significant stressful life event near the end of the second SDSMP, which may have explained the five-point score increase elevating her depression the mild anxiety range. As her anxiety score then dropped by five points at the next meeting of the support group, it is unclear how the SDSMP affected her anxiety level (See Figure 59). Further monitoring of diabetes patient anxiety was still warranted due to their increased susceptibility to anxiety.

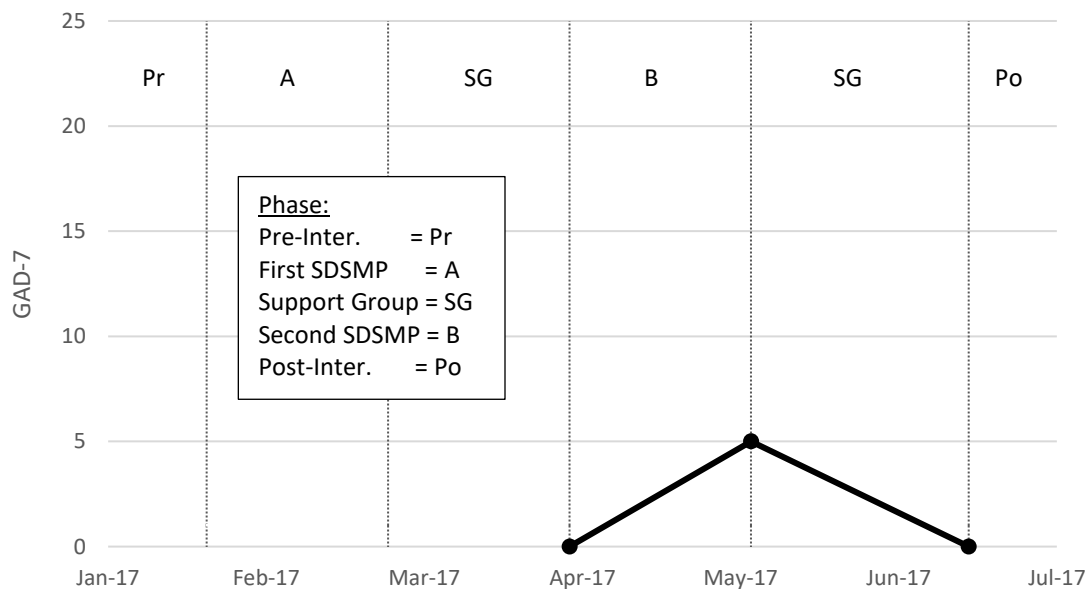


Figure 59. Changes in GAD-7 anxiety scores over time for Patient 1B-f-60

**Self-Efficacy.** On the Pre-Second SDSMP administration of the PAS, the patient scored 100% correct on Knowledge; 80% positive on Coping; and 50% healthy on Behaviors. Post-First SDSMP, the patient scored 100% correct on Knowledge; 100% positive on Coping; and 60% healthy on Behaviors. While attending the first SDSMP this patient remained strong in

Knowledge and improved in Coping and Behaviors. She outperformed the group and regional norms in Knowledge and Coping but underperformed in Behaviors; however, she was above clinical target for all three (See Figures 60–61).

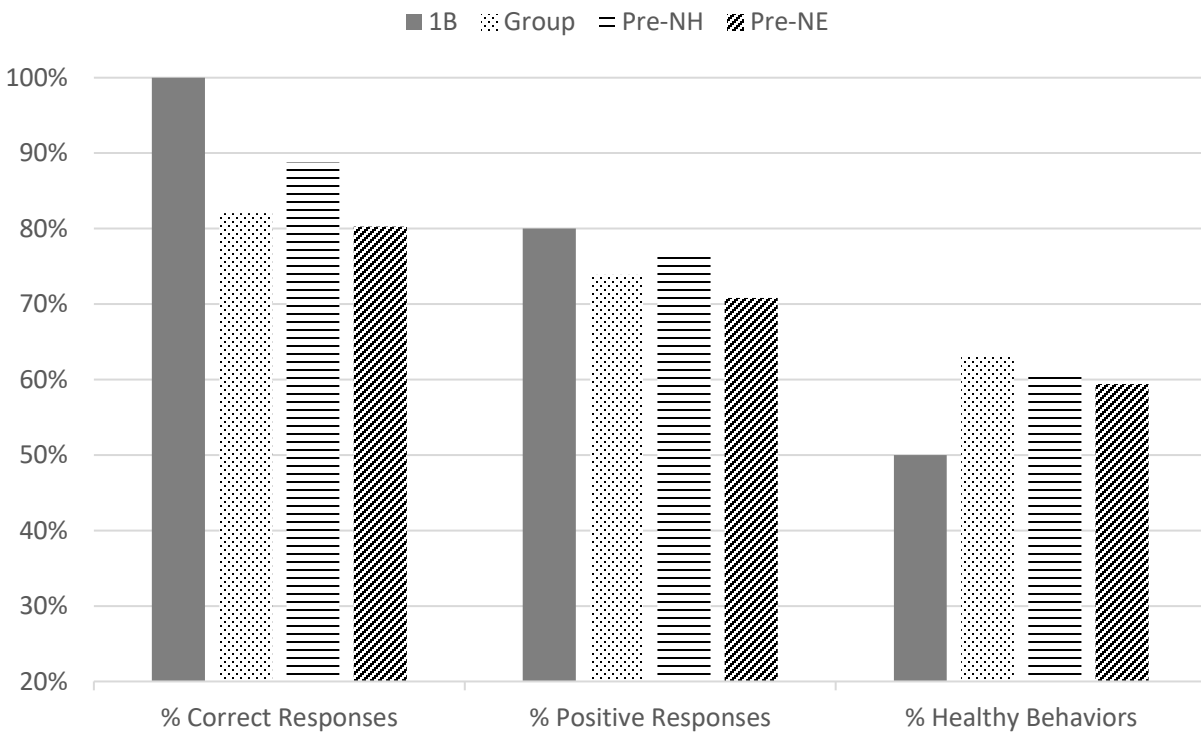


Figure 60. Pre-Second SDSMP self-efficacy scores on the PAS for Patient 1B-f-60

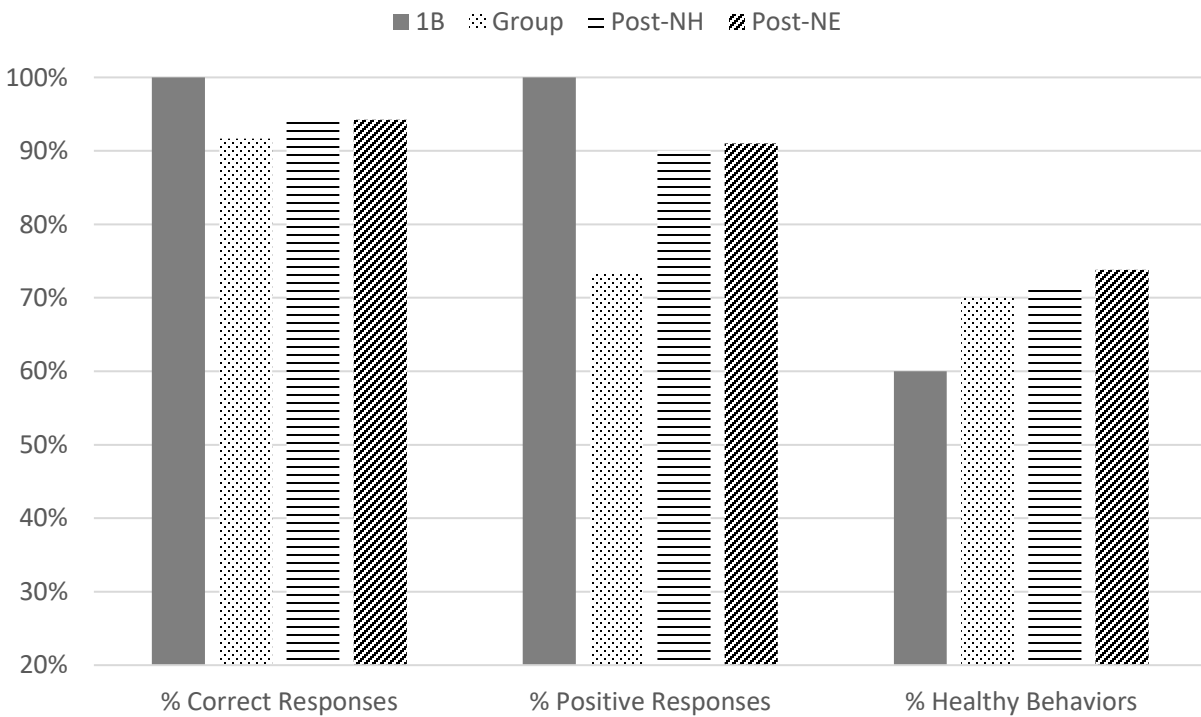


Figure 61. Post-Second SDSMP self-efficacy scores on the PAS for Patient 1B-f-60



**HbA1c%.** As a baseline, this patient was measured with HbA1c% of 7.6% in October 2016; 7.3% in November 2016; and 7.8% in February 2017, which was two months before the second SDSMP. In May 2017 she measured 8.0%, which was above the clinical target of 6.5%, and further intervention was warranted. Even after attending the second SDSMP, this patient still had a 0.2% increase in HbA1c% (See Figure 62).

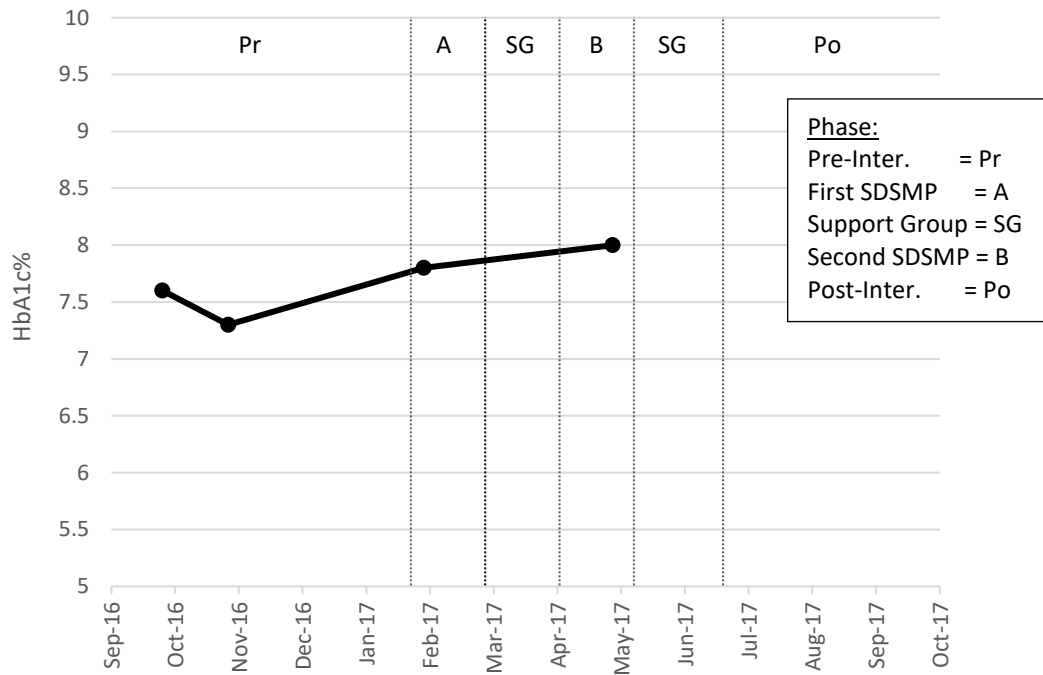


Figure 62. Changes in hemoglobin A1c percentage (HbA1c%) over time for Patient 1B-f-60

**Body mass index.** As a baseline, this patient’s BMI ranged from 40.53 in October 2016 to 40.71 in February 2017. After attending the second SDSMP her BMI remained around baseline level at 40.53. By July 2017, her BMI had decreased to 40.18 with no further follow-up data available at the six-month follow-up. Although attendance at the program may have contributed to a decrease of 0.60 in this patient’s BMI, she remained above the clinical target, and further intervention was warranted as she was in the obese range (See Figure 63).

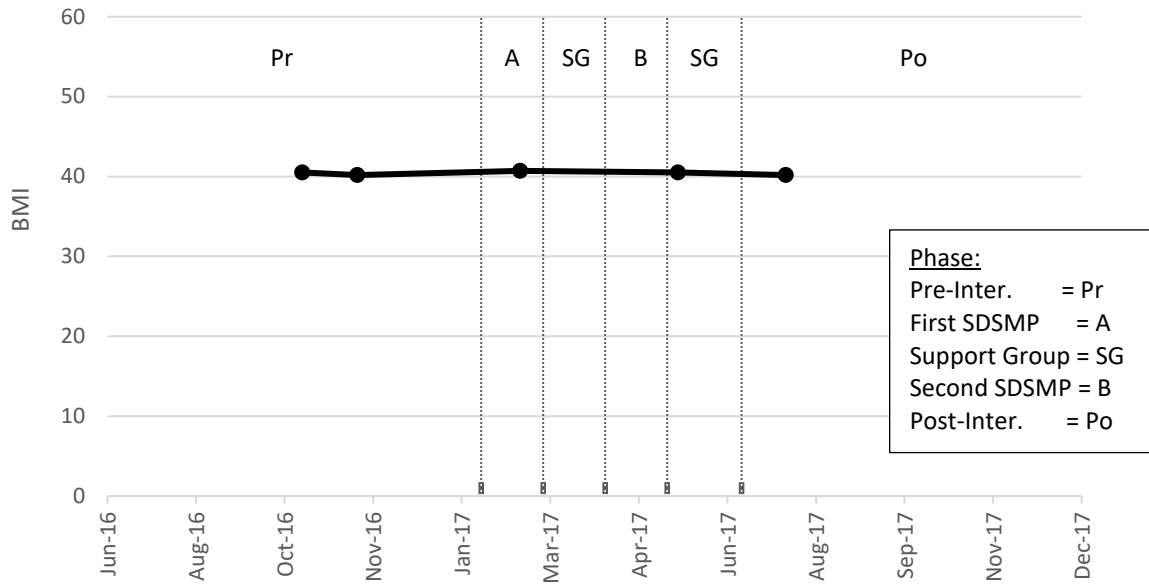


Figure 63. Changes in body mass index (kg/m<sup>2</sup>) over time for Patient 1B-f-60

**Case Summary: Patient 1B-f-60.** Although Patient 1B-f-60 fluctuated between mild to minimal depression and anxiety levels, it was unclear whether this was related to the program or the onset and resolution of a stressful life event. In terms of self-efficacy, she remained strong in Knowledge and improved in her Coping and Behaviors. She outperformed the group and regional norms in Knowledge and Coping but underperformed in Behaviors; however, she was above clinical target for all three. The patient also remained in the obese range on BMI and above the clinical target for her HbA1c%.

**Patient 2B-m-80.**

**Depression.** Patient 2B-m-80 was an 80-year-old, Caucasian male with Type 2 diabetes. Pre-Second SDSMP, his PHQ-9 depression score was 4, which indicated minimal to no depression. Post-Second SDSMP his depression score was 0, which indicated minimal to no depression. His depression score decreased by four points after the second SDSMP, which was not clinically significant. While the program may have resulted in a modest decrease in the patient’s depression, the change was not clinically significant (See Figure 64). Further

monitoring was still warranted as diabetes patients are at increased risk for developing depression.

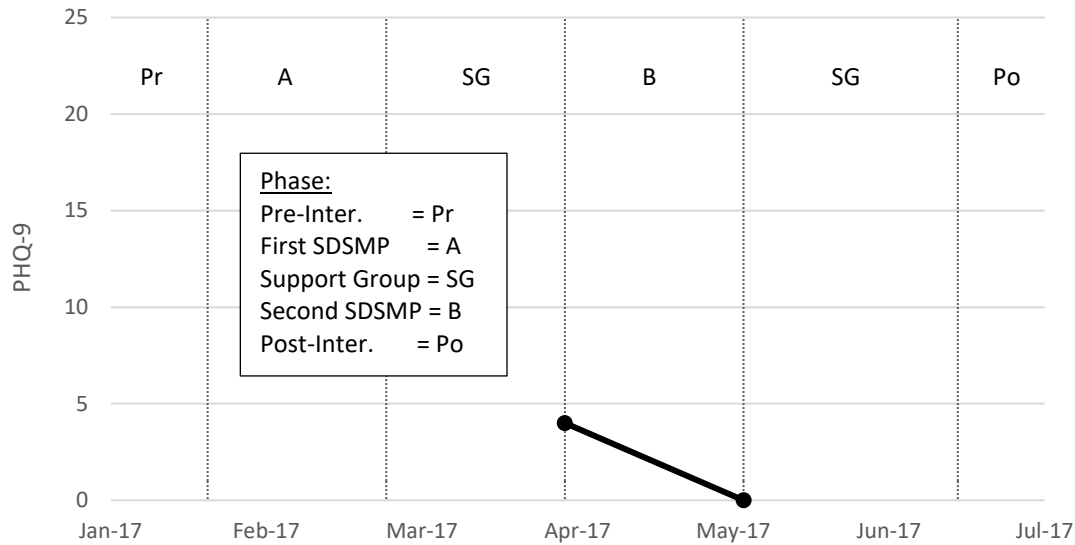


Figure 64. Changes in PHQ-9 depression scores over time for Patient 2B-m-80

**Anxiety.** Patient 2B-m-80 scored a 2 on the GAD-7 at Pre-Second SDSMP, which indicated moderate anxiety, and he scored a 0 at Post-Second SDSMP, which indicated minimal to no anxiety. His anxiety level remained in the minimal to no anxiety range throughout the study; however, it decreased by two points after the second SDSMP, which may have indicated the program contributed to a modest decrease in anxiety (See Figure 65). Further monitoring of patient anxiety levels was still warranted as diabetes patients are at increased risk for anxiety disorders.

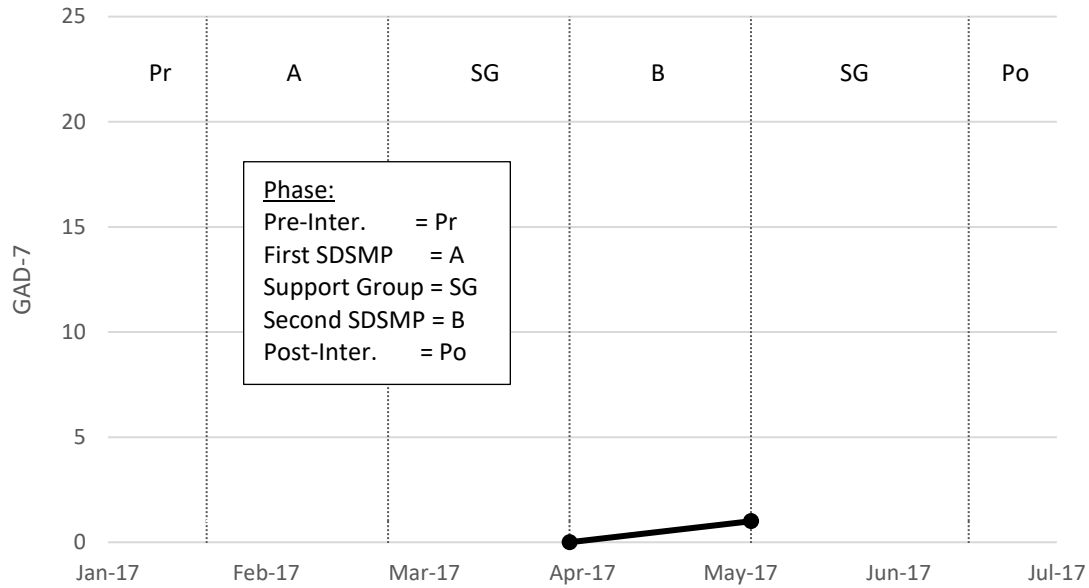


Figure 65. Changes in GAD-7 anxiety scores over time for Patient 2B-m-80

**Self-Efficacy.** On the Pre-Second SDSMP administration of the PAS, the patient scored 75% correct on Knowledge; 100% positive on Coping; and 100% healthy on Behaviors. Post-Second SDSMP, the patient scored 100% correct on Knowledge; 80% positive on Coping; and 100% healthy on Behaviors. After the second SDSMP, this patient improved in Knowledge, decreased in Coping, and remained strong in Behaviors. He remained above clinical target, group, and regional norms in all three areas except for Coping, where he underperformed relative only to regional norms (See Figure 66–67).

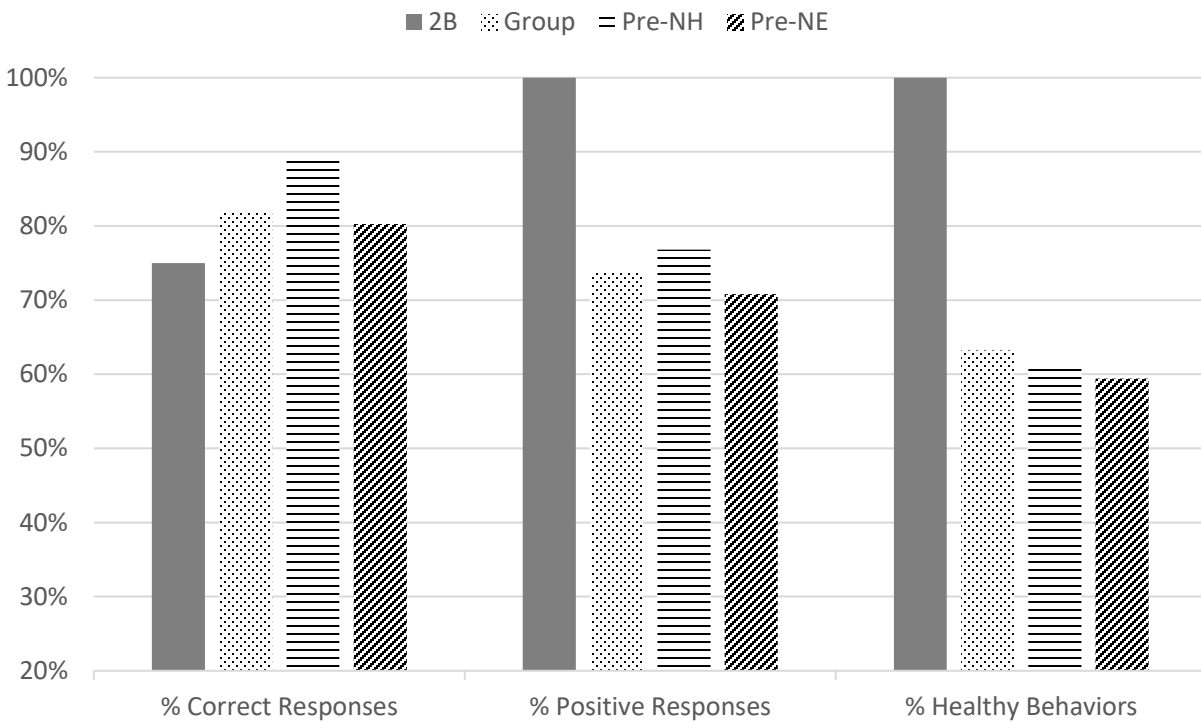


Figure 66. Pre-Second SDSMP self-efficacy scores on the PAS for Patient 2B-m-80

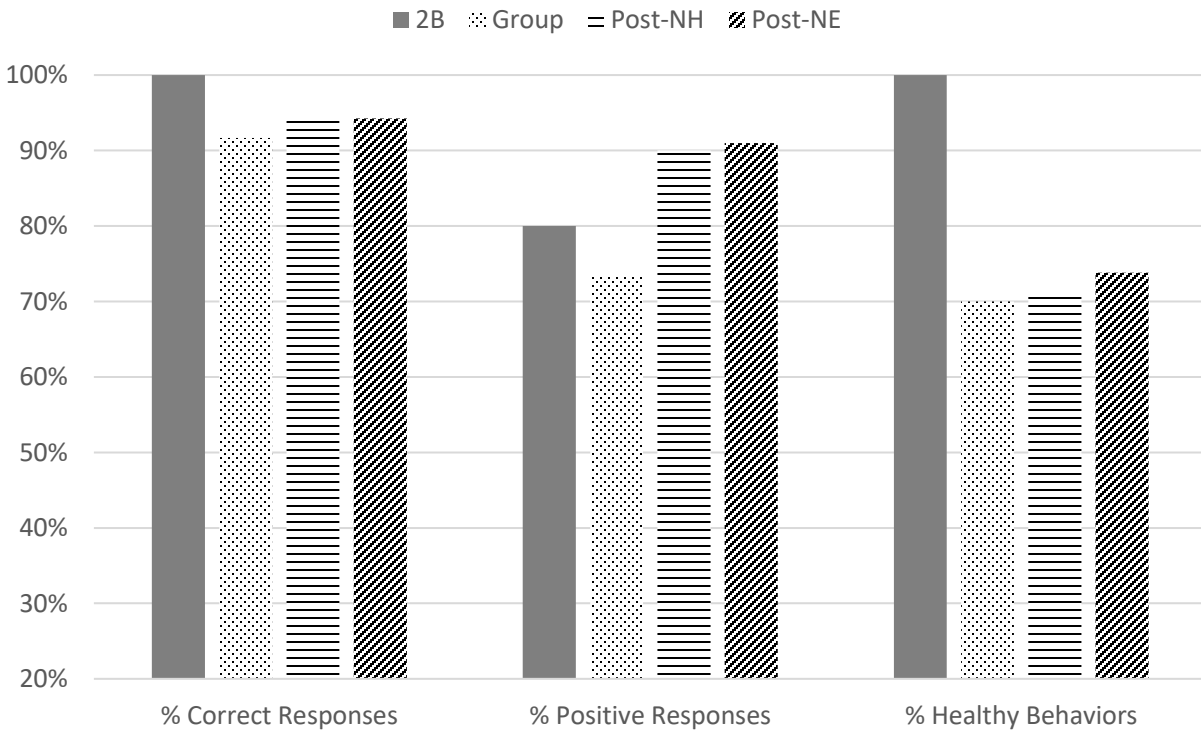


Figure 67. Post-Second SDSMP self-efficacy scores on the PAS for Patient 2B-m-80

*Case summary: Patient 2B-m-80.* Patient 2B-m-80's depression and anxiety remained in the minimal to no range. In terms of self-efficacy, he improved in Knowledge, decreased in Coping, and remained strong in Behaviors. He remained above clinical target, group, and regional norms in all three areas except for Coping, where he scored lower than regional norms.

### **Group Results**

**Depression.** Overall, eight of the 12 patients experienced a decrease in PHQ-9 depression scores after attending the SDSMP while 3 patients experienced an increase and one patient maintained the same score. The group experienced a one-point decrease in mean average depression scores after attending their SDSMP (see Figure 69). However, these depression changes were generally not sustainable over time as suggested by the follow-up PHQ-9 scores of the four interview participants. Patient 1AB-m-54 experienced an initial decrease after attending both SDSMPs but returned to baseline levels by the 11-month follow-up interview. Patient 7A-m-60's depression remained the same after attending the first SDSMP and support group; however, he experienced a clinically significant increase in depression by the time he was interviewed 11 months later, which was likely due to a significantly stressful health-related event. Patient 10A-m-49's depression increased significantly while attending, but his depression also decreased to previous levels by the 11-month follow-up interview. Of the interview participants, only Patient 8A-f-75 exhibited a net decrease in depression that was sustained until the 11-month follow-up interview (see Figure 69). Also, several other patients exhibited changes in their PHQ-9 depression scores that were assessed during the monthly support group. Final depression outcomes for all patients at the completion of the study period are depicted in Table 5.

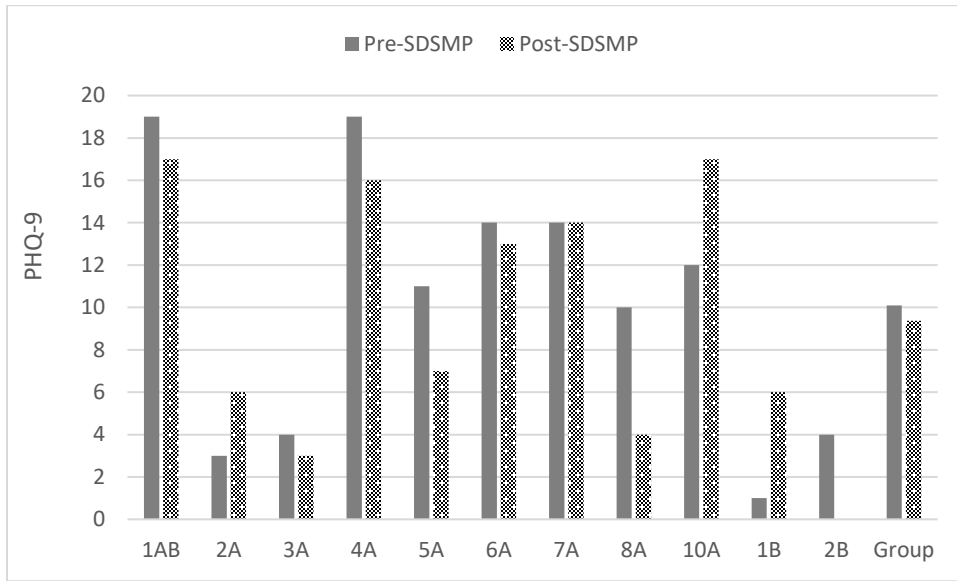


Figure 68. Changes in patient PHQ-9 depression scores after attending the SDSMP

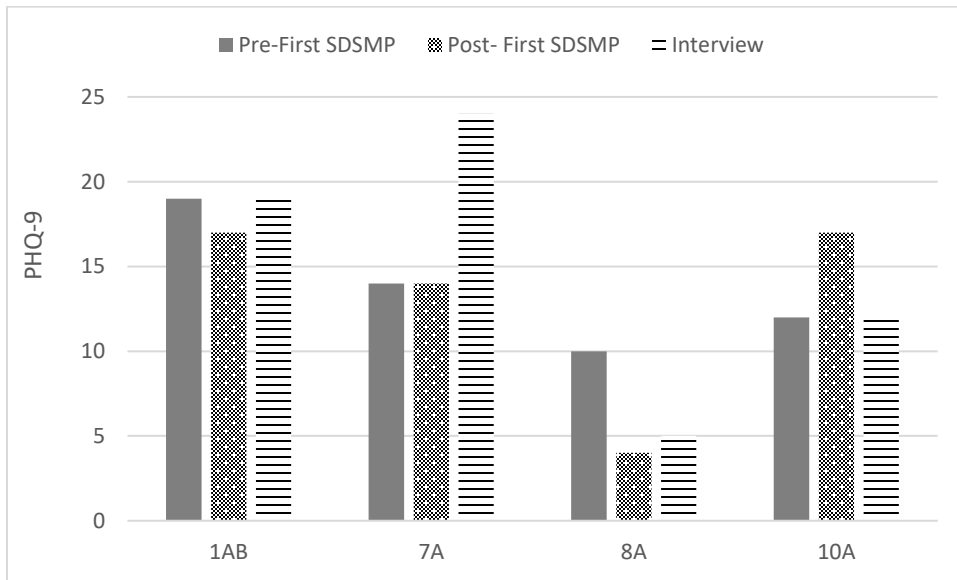


Figure 69. PHQ-9 depression scores over time for interview participants

**Anxiety.** Five of the 12 participants who completed the post-program outcomes measures experienced a decrease in their GAD-7 anxiety scores after attending the SDSMP; four participants experienced an increase in their anxiety scores and two patients remained the same. The group experienced a one-point decrease in mean average anxiety scores after attending the

SDSMP (see Figure 70). However, these results were generally not sustainable over time as suggested by the GAD-7 follow-up scores of the four interview participants (see Figure 71). Patient 1AB-m-54 remained the same score after attending the SDSMP twice, then his score increased further by the 11-month follow-up interview. Patient 7A-m-60’s score increased after the SDSMP, and then increased significantly at the follow-up interview due to a significant health-related event. Patient 10A-m-49 decreased after the SDSMP, and then decreased further by the interview. Patient 8A-f-75 decreased after the SDSMP, and then increased slightly by the follow-up. Also, several patients exhibited changes in GAD-7 anxiety scores, which were assessed during the monthly support group. Final anxiety outcomes for all patients are depicted in Table 5.

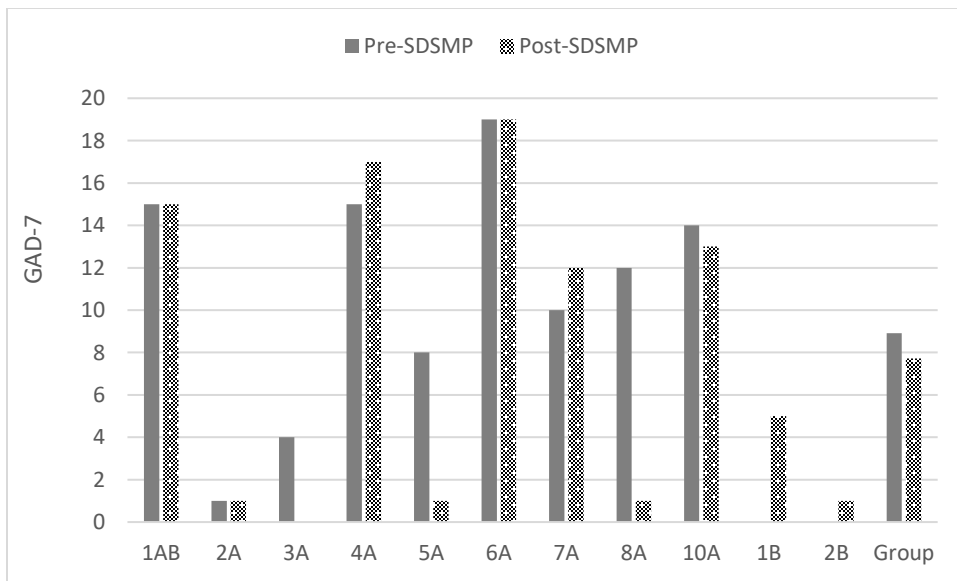


Figure 70. Changes in patient GAD-7 anxiety scores after attending SDSMP



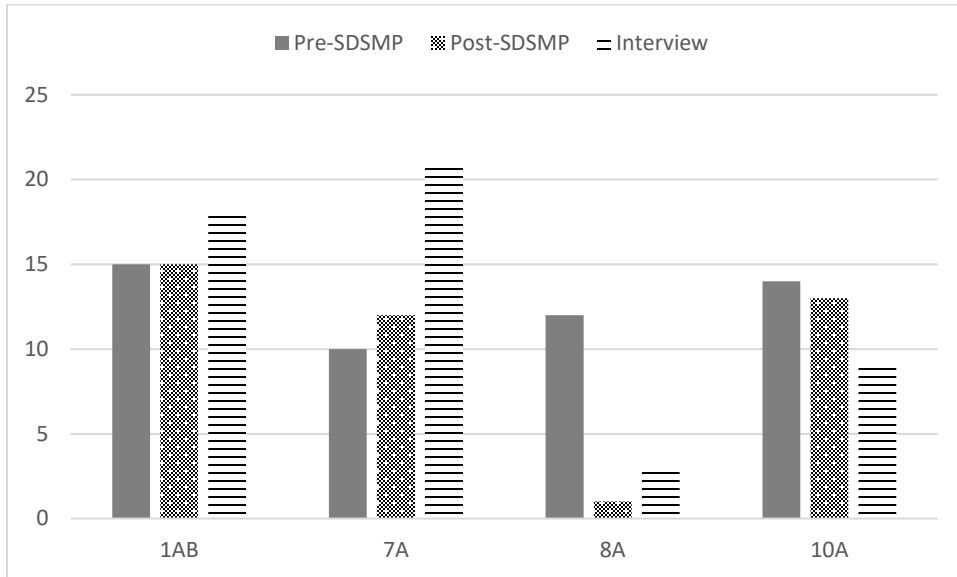


Figure 71. GAD-7 anxiety scores over time for interview participants

**Self-Efficacy.** Comparisons were made between group mean average scores on the PAS for Knowledge, Coping, and Behavior and the aggregated regional norms for 2016 SDSMP participants in the New Hampshire (NH) and New England (NE) areas to demonstrate whether self-efficacy in the study group improved to a similar degree. Pre-SDSMP, the group mean for Knowledge was 82% (89% NH; 80% NE); the score for Coping was 74% (77% NH; 71% NE); and the score for Behavior was 63% (61% NH; 59% NE). Post-SDSMP, the group mean score for Knowledge was 94% (94% NH; 94% NE); the score for Coping was 73% (90% NH; 91% NE); and the score for Behavior was 70% (71% NH; 74% NE). See Figure 72 and Figure 73 for Comparison of Mean Scores on the Patient Activation Survey Pre-SDSMP and Post SDSMP.

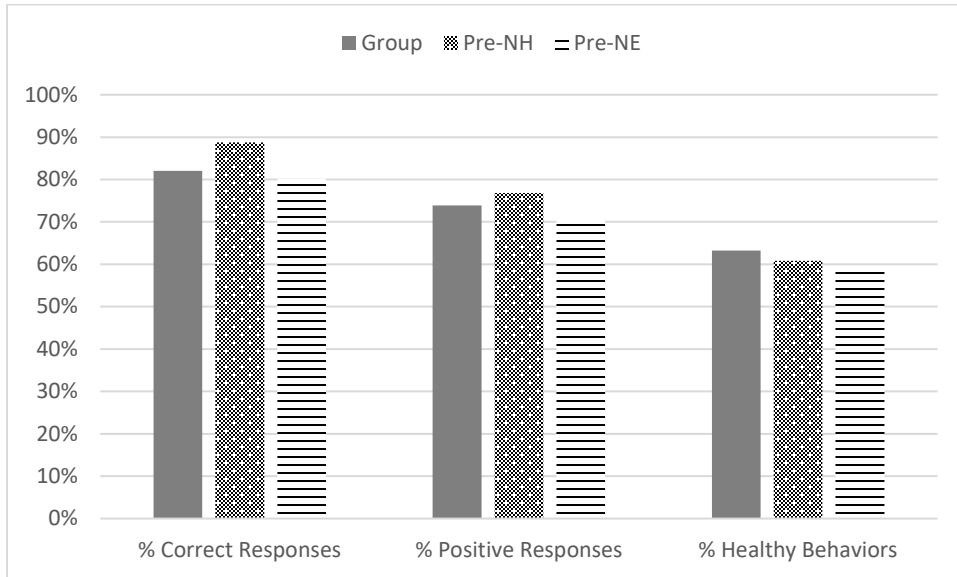


Figure 72. Comparison of group mean scores on the PAS at Pre-SDSMP

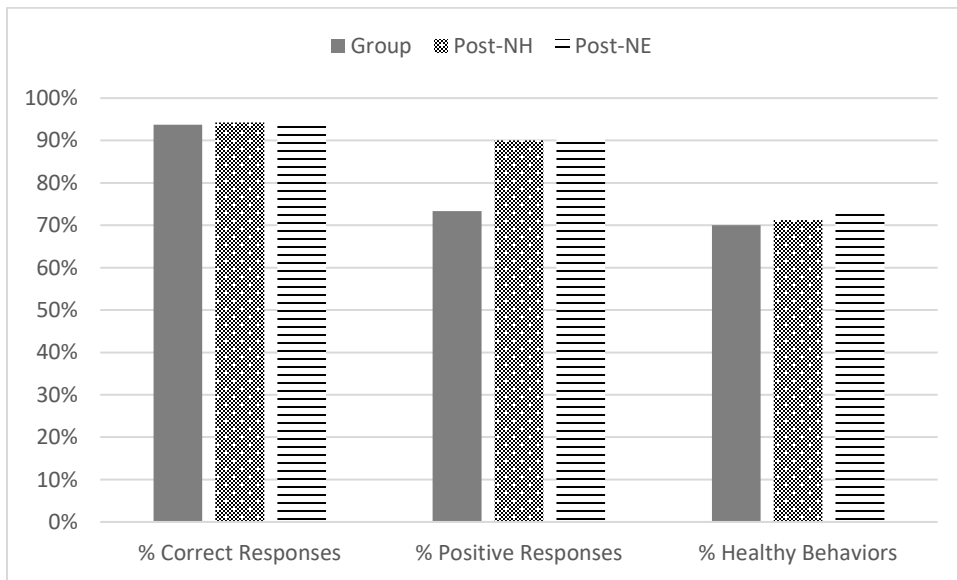


Figure 73. Comparison of group mean scores on the PAS at Post-SDSMP

**Summary of Quantitative Findings**

Table 5 summarizes the changes or lack of changes in the various psychological and medical outcomes variables for each patient. The table also indicates which variables require further intervention for that patient (See Table 5). The key defines the meaning of the three numbers (-1, 0, 1), noting whether the variable improved (1), whether there was no change (0),

or whether a negative change (-1) was measured at the final outcomes assessment that each patient completed. The marker (x) following a number indicates that further intervention was warranted for the patient in this variable. If there is no marker (x), then the variable met the clinical treatment target. If a marker (x) appears alone in the table, the patient did not complete a post-program measure, but their previous assessment indicated this variable was not within the clinical treatment target. Blank cells (-) indicate there was no measurement available for the patient for that variable.

### **Conclusion**

In conclusion, this section presented the results of the study. The psychological outcomes and diabetes lab results were reported as available, using the multiple single case format. Symptom severity levels and clinical cutoff scores were noted, as well as whether and to what extent the patient improved in each variable. Each section concluded with a case summary of notable changes for that patient. In addition, qualitative findings from follow-up interviews were integrated in the summaries of those four participants.

## Discussion

This section discusses implications of a program evaluation study. The study is reviewed in its adherence to its research framework and goals. Participant outcomes evidenced whether psychoeducation in diabetes management was effective for improving psychological and medical outcomes in diabetes patients, as shown by graphs and tables on patient data; the extent to which the program answered the study's research questions; the trends that were noted in patients' psychological and medical functioning, as assessed by the PHQ-9, GAD-7, Patient Activation Survey, and their BMI and HbA1c% lab results; and the themes that emerged from post-education patient interviews. Implications of the results are discussed, limitations of the study are reviewed, and recommendations are made for future research regarding diabetes behavioral healthcare in primary care.

The purpose of the study was to evaluate the implementation of a diabetes management program in a primary care setting in Nashua, New Hampshire. The program consisted of two administrations of an evidenced-based diabetes management program, known as the Stanford Diabetes Self-Management Program (SDSMP), and a monthly diabetes support group formed by the two SDSMP leaders with several but not all SDSMP participants. The program was carried out under the auspices of a Graduate Psychology Education (GPE) grant and utilized a population-based research approach (Halpern & Boulter, 2000) and the biopsychosocial conceptual model (Engel, 1980). The program occurred in the co-located primary care and mental health clinics of the federally-qualified health center, Harbor Care Health and Wellness Center.

The diabetes management program was evaluated using Practice-Based Participatory Research (Fauth & Tremblay, 2011) and analyzed using a multiple single case design (Mertens,

2010). A mixed methodology consisted of quantitative psychological outcomes measures and diabetes medical data and qualitative 11-month follow-up interviews with four program participants. Results included the mental health and medical data across SDSMP program time for participants. In addition, the diabetes management program was evaluated in its ability to fulfill the program goals of Harbor Care Health and Wellness Center and the GPE grant.

### **Program Effectiveness for Individual Patients**

The following section interprets the psychological and medical outcomes for each participant who attended the diabetes management program. Addressing the research questions of the study, interpretations are made as to how, why, and to what extent each participant improved or did not improve; and whether four patients, who were interviewed, reported having sustained these improvements approximately one year later. Results are compared with the results of similar studies. Explanations are given for the study's contribution to research gaps, as noted in the Significance of the Study section.

**Individual Outcomes.** The following section presents a discussion of individual patient outcomes after the program. Possible explanations for the outcomes are provided.

***Patient IAB-m-54.*** Overall, Patient 1AB-m-54 remained the same in most variables, but worsened slightly in HbA1c% and BMI. Further intervention was indicated for his depression, anxiety, diet, physical activity, and BMI due to his clinical severity levels remaining above target. The patient attended both SDSMP programs. Later, Patient 1AB-m-54 reportedly attended two additional SDSMP programs with a new doctoral student program leader. This attendance occurred prior to his 11-month follow-up, which indicated that four SDSMP programs led to no beneficial clinical outcomes for Patient 1AB-m-54.

One positive result was that Patient 1AB-m-54 continued to portray strong diabetes coping skills as measured by the Coping scale on the Patient Activation Survey, despite his numerous reported health challenges and poor scores on other variables. His interview also suggested several possible explanations for why he did not improve in most areas. First, Patient 1AB-m-54 described his learning style as being “visual and hands-on,” and he criticized the workshop for not adapting to his abilities. He also spoke proudly of his achievements as an auto mechanic, which emphasized his identification with a hands-on process. In some respects, Patient 1AB-m-54’s responses suggested that he possesses certain types of knowledge, skills, or abilities that were not utilized by the SDSMP. Therefore, it might be a mistake to view this patient as difficult or “failing to improve” after attending the SDSMP four times. What is revealed, rather is that the SDSMP utilizes a traditional classroom style of teaching. Patient 1AB-m-54’s evaluation comments provide valuable feedback for the treatment team at Harbor Care Health and Wellness Center and for the SDSMP in general, which may wish to provide experiential learning that utilizes various sensory modalities.

Second, other barriers to successful treatment were revealed in Patient 1AB-m-54’s interview. He spent several minutes speaking candidly about his diet, which had not changed in over 10 years and consisted of foods high in starch, animal fat, and protein that diabetes patients are recommended to minimize. With such a diet and an HbA1c% that was barely below the clinical target, that Patient 1AB-m-54 is likely taking medication that keeps his blood sugar under control. Whether the patient can continue with his current dietary behaviors for the rest of his life without any further consequence to his diabetes was a subject of debate with Patient 1AB-m-54 throughout the study. Certainly, his eating habits may increase his risk for developing heart disease as his preferred foods are also high in saturated fat and cholesterol.

Third, Patient 1AB-m-54 reported not having a romantic partner, living alone, and not being able to afford healthy groceries (i.e., fresh vegetables). He viewed these factors as obstacles to his maintaining a healthy diet. He stated he often felt lonely. Living alone also influenced his motivation, as he stated that a romantic partner would prepare his meals for him. There was an undertone of hopelessness in his belief that self-care was not worth it because he was alone, which might have been reflected in Patient 1AB-m-54's high depression score. Finally, this patient frequently complained of severe chronic back pain due to a previous work injury. He stated that the pain prevents him from exercising and losing enough weight to maintain a healthy BMI.

Despite the numerous health challenges and other barriers, Patient 1AB-m-54 demonstrated perseverance and a desire to improve through his attendance at four SDSMP programs. Perhaps repeated program attendance reflected a certain character strength he alluded to as a hands-on learner. Interestingly, Patient 1AB-m-54's suggestion during the interview was that the workshop be offered in a one-on-one format to better match to his abilities. Some personalized individual education may be essential to this patient's long-term healthcare.

***Patient 2A-f-57.*** Overall, Patient 2A-f-57 remained the same in most variables but worsened slightly in diet, physical activity, and depression scores. Further treatment was warranted for her depression. As no post-program diabetes lab results were available for the patient's HbA1c% and BMI, there is no evidence if she benefited medically after attending the SDSMP. Also, as her biomarkers were above the clinical target at baseline, further assessment was warranted. The patient might have begun receiving her diabetes care at another clinic or she was delinquent in attending the recommended quarterly diabetes medical check-up, which would explain why her follow-up data were not available.

**Patient 3A-f-67.** Overall, Patient 3A-f-67 improved in her depression and anxiety but decreased slightly in diabetes coping skills; yet she still remained above clinical targets in all these variables. This patient may have benefited psychologically from the program as her depression and anxiety decreased. Further monitoring was advised regarding her HbA1c% and BMI as lab results were not available. As the patient may have been attending diabetes medical care at another clinic, there is no evidence whether the SDSMP led to any medical benefit or whether her diabetes was well-managed.

**Patient 4A-f-39.** Overall, Patient 4A-f-39 showed improvements in depression, diabetes coping skills, diet, and physical activity level. She remained strong in her diabetes knowledge but her anxiety increased. It is unclear whether the SDSMP benefited her psychologically as her depression decreased, but keeping in mind as well that her anxiety increased. Despite improvements in diabetes coping skills, diet, and physical activity, there was no evidence whether the patient's diabetes was sufficiently managed. As the patient was attending diabetes medical care at another clinic, no lab results were available, and there was no evidence that the SDSMP led to any beneficial behavior change that improved her HbA1c% or BMI.

**Patient 5A-f-57.** Overall, Patient 5A-f-57 showed improvements in depression, anxiety, diabetes coping skills, diet, physical activity level, HbA1c%, and BMI. She also remained strong in diabetes knowledge. The patient's mental health may have improved, and her self-efficacy may have increased while attending the program. This patient also appeared to have adopted successful behavior changes and coping skills that may have resulted in beneficial decreases in her HbA1c% and BMI. Despite these improvements, further intervention was warranted for Patient 5A-f-57's depression and her BMI as they remained above clinical targets.



**Patient 6A-m-54.** Overall, Patient 6A-m-54 showed improvements in depression, diabetes knowledge, diet, physical activity level, BMI, and HbA1c%. The SDSMP may have contributed to beneficial behavior changes that helped decrease his BMI and bring his HbA1c% below the clinical target. This patient may have benefited psychologically from the program; however, further interventions were warranted for his depression, anxiety, and diabetes coping skills as his score were not below clinical targets.

**Patient 7A-m-60.** By the end of the study, Patient 7A-m-60 showed increases in depression, anxiety, and BMI. However, his depression and anxiety scores fluctuated during the SDSMP, which suggested that he received temporary psychological benefit while attending. During the interview, this patient stated he appreciated the social support offered in the group setting. The modest psychological benefits he exhibited suggested that he might benefit from attending an ongoing diabetes support group. Also, during the interview, Patient 7A-m-60 reported experiencing a significant health-related event, which might have explained his increased depression and anxiety scores at the 11-month follow-up interview. He also reported that his ability to care for his diabetes had decreased since the SDSMP because of his current health condition; however, this decrease was not consistent with his scores on the Patient Activation Survey, which indicated that the patient remained strong in his diabetes knowledge, diet, and physical activity level. As his depression and anxiety both increased over this time period, it may be that this patient's self-efficacy had diminished in aspects not captured by the Patient Activation Survey while his actual behaviors remained adequate. Also, his improved scores on diet, physical activity, diabetes knowledge, and coping skills were not sufficient to decrease his BMI, which remained high at the end of the study. Only one measurement of his Hba1c% was available, so it was unclear whether the SDSMP benefited him medically.

*Patient 8A-f-75.* Overall, Patient 8A-f-75 showed improvements in depression, anxiety, and diabetes knowledge and coping skills, but by the end of the study, her gains in knowledge and coping had decreased to pre-SDSMP levels. Her diet, physical activity, and diabetes knowledge and coping skills scores also remained above clinical target. Further interventions were warranted around her diabetes knowledge as well as her depression as she had reached the minimum score to be considered mildly depressed. As the patient was attending diabetes medical care at another clinic, no lab results were available, and there was no evidence that the SDSMP contributed to any medical benefits. During the interview, Patient 8A-f-75 reported experiencing a significantly stressful life event, which might have led to the relapse to mild depression at the end of the study. Her scores in diabetes knowledge and coping skills had also decreased by that time; however, the patient's attitude seemed generally upbeat during the interview and she reported experiencing several benefits from the SDSMP, including dietary changes even though these were not accounted for by her Patient Activation Survey score at the time. Additional diabetes education programs of a similar modality may further benefit this patient, especially if administered on an ongoing basis. This patient was a regular participant of the diabetes support group, which suggests that the modest benefits she received might be sustained with ongoing social support.

*Patient 9A-m-62.* By the end of the SDSMP, Patient 9A-m-62 showed modest improvements in his BMI score, but he worsened considerably in his HbA1c%. Further intervention was warranted for his HbA1c% and BMI as both were above clinical target. With no post-SDSMP assessment, there was no evidence whether he benefited psychologically from attending the workshop; however, he was clinically depressed at the pre-SDSMP administration of the PHQ-9, so further intervention was warranted. Conversely, his self-efficacy measured at

the highest levels at pre-SDSMP, but we do not know whether his self-efficacy changed during the duration of the program, and if it did, if this change coincided with the dramatic increase of his HbA1c% over the next few months post-SDSMP. During the program, the patient reported he was experiencing a significantly stressful life event, which, it stands to reason, may have affected his ability to care for his diabetes, leading to an increase in HbA1c%.

***Patient 10A-m-49.*** Overall, Patient 10A-m-49 showed improvements in his anxiety, diabetes knowledge, diet, and physical activity level; however, these improvements in knowledge, diet, and physical activity were lost at the 11-month follow-up interview. Further intervention was also warranted for his depression and anxiety. Despite measurable increases in diabetes knowledge, this patient stated during the interview that he had not “learned anything new,” having attended similar classes before. The patient described an elaborate exercise routine he was currently maintaining, which he said resulted from his increased motivation and learning how to set specific lifestyle goals during the workshop. The patient also reported receiving social support from the group, which may have contributed to his lower depression and anxiety scores post-SDSMP. He also spoke glowingly of Harbor Care Health and Wellness Center and his care team there. Patient 10A-m-49 verbally requested his medical data not be used in the study, so there was no evidence whether his reported changes in diet and physical activity made an impact on his medical health.

***Patient 1B-f-60.*** Overall, Patient 1B-f-60 showed improvements in depression, diabetes coping skills, diet, and physical activity level, and she remained strong in her diabetes knowledge. Additional assessment and intervention were warranted for her HbA1c%, and BMI. As her latest HbA1c% was taken before she completed the SDSMP, there was no evidence on whether the increases in her diabetes coping skills, diet, and physical activity benefitted her

medically. Also, the patient's HbA1c% had been gradually increasing during the study, which warranted further monitoring. During the SDSMP the patient reported experiencing a stressful life event, which might explain the temporary increases in her depression and anxiety scores that decreased by the time she attended the support group one month later.

*Patient 2B-m-80.* Overall, Patient 2B-m-80 showed mixed results regarding his psychological health and diabetes self-management. His depression score decreased, but he worsened slightly in his anxiety. He showed improvements in his diabetes knowledge and remained strong in his diet and physical activity, but he worsened in his diabetes coping skills. As he was attending diabetes medical care at another clinic, no lab results were available for the study, so there was no evidence that the program benefitted him medically. This patient made a remarkable statement during the last meeting of the SDSMP. He stated that he had eaten a “vegetarian dinner” the night before and discovered the following morning his blood sugar measurement was dramatically reduced. Eating low starch vegetables was a contrast to his normal diet that he described as “meat and potatoes.” With mixed results on psychological outcomes measures and the lack of diabetes lab results, this patient's realization about the benefit of a low-starch diet in controlling his blood sugar was the only evidence of him changing as a result of attending the SDSMP.

**Group Results.** The SDSMP appeared to be overall a positive psychological experience. Group means on PHQ-9 depression scores and GAD-7 anxiety scores decreased by one point each (see Figures 68 and 70). Seven of the 12 participants showed improvements in their PHQ-9 depression scores, and four showed improvements in their GAD-7 anxiety scores. Two patients became more depressed afterwards (7A and 2A), but at least one of these occurrences may have been due to the onset of a new health problem. The other patient appeared to benefit

psychologically from the SDSMP temporarily. Three patients experienced increased anxiety afterwards (4A, 7A, and 2B), but one of those occurrences might have been due to the new health problem, and the other patients showed mild increases. Also, all four patients who attended the interview endorsed social support as one of the primary benefits from attending the SDSMP. Added psychological benefits of social support may not have been demonstrated by the pre- and post-SDSMP assessments as social support was not queried by any of the measures. How social support affects diabetes patients may be an area for future research regarding group psychoeducation about diabetes self-management.

The group as a whole also showed improvements in their diabetes knowledge, diet, and physical activity level. Group means on the Knowledge scale of the Patient Activation Survey increased by 12%, demonstrating improvements in patient knowledge about their diabetes. Group means on the Behaviors scale of the Patient Activation Survey also increased by 7%, demonstrating improvements in patient diet and physical activity level. Conversely, the group mean score on the Coping scale of the Patient Activation Survey decreased by 1% between pre-and post-SDSMP measures, which indicated a slight decrease or no change to the group's diabetes coping skills. This suggested that the program did not benefit the group as a whole regarding their ability to emotionally cope with their diabetes, an important aspect of patient self-efficacy.

Insufficient data were available to demonstrate whether the SDSMP benefitted the group medically. Only two patients (5A and 6A) showed improvements in diet and physical activity level that coincided with improvements in their post-SDSMP workshop BMI and HbA1c% lab results. Conversely, two patients (1AB and 9A) showed unhealthy increases in their BMI and HbA1c% several months post-SDSMP, but these occurrences might be explained by the

adherence to a high-starch diet and a significantly stressful life event for these patients, respectively.

### **Adherence to the Research Framework and Goals**

The following section evaluates the study's adherence to the research framework, questions, and program goals, as defined by myself and Harbor Care Health and Wellness Center.

**Practice-Based Participatory Research.** The study adhered to the framework and goals of Practice-Based Participatory Research (PBPR; Fauth & Tremblay, 2011). The goal of PBPR is to adapt evidence-based treatment models to the clinical population of a healthcare clinic. In this study, the SDSMP was the evidenced-based treatment program that uses psychoeducation about diabetes self-management to improve psychological and medical outcomes in diabetes patients. PBPR also follows a population-based approach where the specific needs of a clinical population are assessed, and programs are designed based upon resource availability and its ability to fulfill population needs. The SDSMP is designed to be peer-based, and the training for the program leaders and the education itself were pro bono, which made attendance affordable for the low-income population of Harbor Care Health and Wellness Center. Instead of allocating paid employees, the SDSMP was led by two doctoral students attending their practicum training year at the site, which amounted to additional cost-savings for the site.

The clinical population had a significant number of diabetes patients with co-occurring depression and anxiety disorders; therefore, it was important to evaluate the merits of the SDSMP for improving depression and anxiety. The study also conformed to the phases of PBPR, which are Planning, Pilot, Discovery, and Quality Improvement. Planning and Pilot consisted of

selecting and administering the educational tools, while the latter two phases of Discovery and Quality Improvement comprised the program evaluation study.

**Diabetes Program Goals at Harbor Care Health and Wellness Center.** Five interrelated program goals were identified for the diabetes self-management program by me and Harbor Care Health and Wellness Center to:

1. Administer an effective behavioral health program for diabetes patients;
2. Improve coordination of care delivery between medical and behavioral health providers through greater collaboration and consultation about diabetes patients;
3. Initiate a longer-term behavioral health program for complex diabetes patients with comorbid mental health issues;
4. Pilot a model of integrated healthcare delivery for patients with chronic diseases at the site; and
5. Evaluate the effectiveness of the diabetes management program using medical, psychological, and behavioral outcomes measures.

**Goal 1.** For goal 1: an effective diabetes program, the program appeared to benefit several patients in terms of psychological and medical outcomes. The four participants at the 11-month follow-up interview described the program as beneficial for the social support offered by the group setting. In addition, several participants showed modest improvements on their depression and anxiety scores. While not all of these benefits were sustained over time, even temporary symptom relief may warrant offering an ongoing diabetes self-management education program or support group at the site. Such a program might be cost-effective if it were led entirely by doctoral students attending their practicum training year at Harbor Care Health and Wellness Center.

**Goal 2.** For goal 2: improving coordinated care, the SDSMP may have increased the quality of collaboration between behavioral health and medical practitioners at the site. Near the end of my practicum training year, I was told by the Vice President of Operations at Harbor Care Health and Wellness Center that “The clinic has become more integrated since you arrived” (Personal Communication, Carol Furlong, June 29, 2017). In addition, one of the physicians at the clinic requested she be allowed to read my dissertation upon its completion, and she offered to let me present my project during a future clinic meeting (Personal Communication, Graciela Silvia Sironich-Kalkan, June 28, 2017). Several other primary care providers consulted with me regularly regarding their patients’ progress during the SDSMP and said that they received positive feedback about the program from their patients.

**Goals 3 and 4.** For goals 3 and 4: initiating a long-term behavioral health program and piloting an integrated healthcare delivery model, the SDSMP may have achieved these goals. Several clinic practitioners reported being pleased with the program and requested that the next doctoral student attending practicum training year at the site continue administering the SDSMP. The new practicum student administered two additional SDSMPs during her training year. In addition to having several new patient participants, three previous SDSMP participants from the present study attended the program with the new doctoral student. Group diabetes education seemed to be well-liked by clinicians and patients at the clinic. This suggested that the SDSMP may be well-suited for the clinical population and the Nashua, New Hampshire region, which is similarly comprised of working-class, low income, and homeless individuals. Finally, goal 5: evaluating the program was fulfilled by the completion of this program evaluation study.

**Multiple Single Case Design.** There were several advantages to using a multiple single-case design. First, the moderate duration of the study and increased frequency of



patient-researcher interactions allowed for multiple administrations of psychological outcomes measures. Multiple measurements helped to demonstrate whether educational benefits were sustained over time. Second, single case studies may be congruent with clinical practice, as diabetes patients must have symptoms monitored continuously throughout their lives. Symptom monitoring is typically administered by a care manager at the site, per the collaborative care model, and the care manager tracks individual progress around symptoms in a patient registry. Third, individual factors and treatment barriers (see Individual Risk Factors section) impact the individual outcomes in a study. Observing patients at weekly meetings and at the 11-month follow-up interview revealed many of the factors affecting their outcomes that may have gone unobserved in a randomized control trial study. Any factors that were unaddressed by the SDSMP also illuminated potential treatment targets for future programs as well as unmet healthcare needs. The failure of the SDSMP to benefit all patients equally in all variables highlighted areas of future improvement for developing culturally-informed patient-centered psychoeducation programs in community mental health centers and hospitals (Zane, Bernal, & Leong, 2016). This goal of fulfilling all healthcare needs of all patients is consistent with the philosophy of patient-centered medicine.

*Answering research questions.* The following research questions were proposed at the onset of the study:

- How effective was the SDSMP program at increasing patient-reported self-efficacy in diabetes management?
- How effective was the SDSMP program in reducing depression and anxiety symptoms between pretest and posttest self-report measures?

- How effective was the SDSMP program, at increasing basic patient knowledge of diabetes, as determined through pretest and posttest measures?
- How effective was the SDSMP program at increasing patient-reported use of self-care practices?
- How effective was the SDSMP program at improving patient attendance to routine diabetes follow-up appointments?
- How effective was the SDSMP program at improving patient biomarkers related to diabetes management, including HbA1c% and BMI at routine follow-up exams?
- What aspects of the SDSMP program were most effective?
- What aspects of the SDSMP program should be modified or added?
- What behavior changes and medical and psychological outcomes were sustained or achieved by participants at the 11-month follow-up interview?

The moderate/partial effectiveness of the SDSMP was supported by some results of the multiple single case analyses of scores. Six patients showed small improvements and one patient showed a clinically significant improvement on their Patient Health Questionnaire-9 scores for depression, while four patients showed small improvements on their Generalized Anxiety Disorder-7 scores for anxiety. On the Patient Activation Survey, two patients showed improvements in diabetes knowledge, three showed improvements in their diabetes coping skills, and four showed improvements in their diet and physical activity levels. For patient lab results, two showed improvements in hemoglobin A1c percentage (HbA1c%) and two showed improvements in their body mass index (BMI; kg/m<sup>2</sup>) over the course of the one-year follow-up. Of the four interview participants, Patient 8A-f-75 sustained small improvements in her depression (PHQ-9) and anxiety (GAD-7) and Patient 10A-m-49 sustained a small improvement

in his anxiety (GAD-7), which coincided with their attendance at the SDSMP. None of the interview participants sustained improvements in PAS self-efficacy scores. Whether psychological improvements were sustained by any of the other SDSMP participants is unknown as they did not participate in the 11-month follow-up interview and psychological outcomes assessment.

A comparison of mean averages on Knowledge, Coping, and Behavior scales in the Patient Activation Survey was utilized to address several of the research questions. As demonstrated by Figures 72–73, the patients scored similarly to the regional norms on all three PAS scales at Pre-SDSMP and showed similar degrees of improvement at Post-SDSMP on their Knowledge and Behavior scores; however, they scored significantly below regional norms for Coping. The lower Coping score may be explained by the smaller number of research participants creating a negative skew and a lack of normative sampling of the patient population. Another explanation may be the clinical acuity levels of the target population. Nine participants completed the SDSMP with clinically significant depression scores on the PHQ-9; and five of the 12 participants completed the SDSMP with clinically significant anxiety scores on the GAD-7. Such symptom severity may have interfered with their ability to emotionally cope with diabetes successfully, which would reduce their Coping scores post-SDSMP.

The lower Coping scores in the group may also have been caused by an outside variable that was not considered by the study, such as how diabetes coping skills are affected by comorbidities. Several of the patient participants suffered from multiple chronic illnesses like hypertension and chronic pain that further complicated their diabetes and may have inhibited their ability to cope. Also, the lack of improvement in the group mean for Coping scores may be a statistical outlier due to the small sample size. A larger sample size of patients from the

diabetic population is needed to demonstrate whether any local or regional differences are statistically significant.

The symptom acuity and relatively lower socioeconomic status of the research participants was representative of the typical patient profile at Harbor Care Health and Wellness Center. As their recent UDS report (2016) indicated, 1,017 of the 2,194 total patients (46%) carried a diagnosis of depression in their medical record, and 1,649 of the total patients resided somewhere on the spectrum of homelessness, including living in a shelter, in affordable housing, or on the street. The combined challenge of managing co-occurring diabetes, depression, and sometimes other chronic illnesses while living in poverty may explain the study group's lack of response to the SDSMP in their diabetes coping skills when compared to regional norms.

**Research Hypotheses.** The following hypothesizes were made regarding the previously-stated research questions:

1. The program will result in an increase in patient diabetes knowledge, diabetes coping skills, and diet and physical activity scores on the Patient Activation Survey between pretest and posttest questionnaires. These results will be maintained at the 11-month follow-up.
2. The program will result in a decrease in patient depression and anxiety between pretest and posttest scores on PHQ-9 and GAD-7 questionnaires. These results will be maintained at the 11-month follow-up.
3. The program will result in an improvement in important diabetes medical biomarkers at follow-up visits for each patient over a six-month period, including HbA1c% and BMI.
4. The program will result in an increase in each patient's attendance of routine follow-up appointments over an 11-month period.

Hypotheses 1 and 2 were partially correct. Certain individuals, as well as the group as a whole, showed improvements in depression, anxiety, diabetes knowledge, and diet and physical activity at posttest; however, not all participants in the SDSMP showed similar results and the group as a whole did not show improvements in their diabetes coping. Also, based on limited participation at the 11-month follow-up interview, only two of the four interviewees were shown to sustain their improvements for depression and anxiety. Whether similar improvements were sustained by other patients who benefited psychologically from the SDSMP could not be determined.

Hypothesis 3 was also only partially correct. Only two patients showed improvements in their HbA1c% and BMI lab results when attending their routine diabetes check-ups during the 11-month follow-up visit. Because many participants in the study receive primary care for their diabetes at clinics other than Harbor Care Health and Wellness Center, lab results and attendance at their diabetes check-ups during the 11-month follow-up were not available. Regarding Hypothesis 4, Harbor Care Health and Wellness Center patients who attended the SDSMP did not increase attendance for routine diabetes check-up every three months as recommended by the American Diabetes Association (2016). In fact, these patients only show record of attending one diabetes appointment in the entire 11-month period. However, the study only considered medical appointments where diabetes labs were drawn; therefore, some patients may have received diabetes care during appointments where diabetes was not the primary concern, or the recommended measures were not taken. Attendance records of diabetes patients receiving primary care at other clinics were also not available.

**Comparison to similar studies.** Several patients in the program achieved similar results to previous studies. Patient 5A-f-57 achieved an 11% reduction in her HbA1c% and Patient

6A-m-54 a 19% reduction. This compared to results of  $d = 0.10$  (Lorig et al., 2016), and a mean difference of -0.4% using the Spanish version of the SDSMP (Lorig, Ritter, Villa, & Piette, 2008). Seven patients in this study also improved in their depression scores within a range of one to six points. In previous studies, the group mean average reduction in depression scores were one point (Lorig et al., 2016) and 1.4 points (Lorig et al., 2009). Similar group mean differences in post-program depression and anxiety scores were found for the present study, as noted above. As different measures for self-efficacy, diabetes coping, and behavior change (e.g., diet and physical activity) were used in the previous studies, and because insufficient information was provided about measures used by the previous studies, no direct comparisons can be made for self-efficacy. The Patient Activation Survey is also a proportional measure, which further complicates statistical comparison with Likert-type and other scales. Previous studies did not consider anxiety as a variable, and only one study utilized patient bodyweight but not BMI.

### **Fulfillment of Research Gaps**

The study contributed to the literature on serving low-income, homeless, and some older adult diabetes patients through psychoeducation for diabetes management, but many future research opportunities remain. The study appeared to be the first of its kind to target these specific underserved populations and that also performed a program evaluation. While participants in the study were either low-income, working-class, or on the spectrum of homelessness, none of the participants were homeless in the traditional sense (i.e., living in a shelter or on the street). The study also contributed to the literature on diabetes management a comprehensive description of the target population and its use of a psychoeducation program, which was recommended by Norris et al. (2001), as well as its application of biopsychosocial theoretical conceptualization, and its utilization of a population-based approach (Prochaska,

2005). More research is warranted with traditionally homeless diabetes patients for whom treatment adherence maintenance is difficult (Hulton et al., 2015), diabetes patients from diverse racial, ethnic, and immigrant backgrounds (Kim & Lee, 2016), and obese older adults with chronic diabetes (Gómez-Ambrosi et al., 2011).

**PBPR at Harbor Care Health and Wellness Center.** The study succeeded in its application of Practice-Based Participatory Research (PBPR). The research framework utilized the four phases of PBPR garnering feedback in the form of psychological and medical outcomes, along with direct feedback from the participants who gave post-SDSMP interviews. In utilizing a population-based approach, the patient feedback served as future guidance for organizational leaders at Harbor Care Health and Wellness Center for educating diabetes patients in the Nashua New Hampshire region. Though only two out of 12 participants improved medically in relation to their diabetes, one patient achieved a clinically significant decrease in their PHQ-9 depression score, and several patients benefited with modest or temporary reductions in their depression and anxiety. Ongoing monitoring of the psychological health of diabetes patients was warranted, and such endeavors may help demonstrate whether these modest benefits can be maintained over time. A pro bono diabetes management program like the SDSMP that is administered on an ongoing basis by doctoral practicum students may be cost-effective for the site.

### **Limitations of the Study**

There were multiple methodological, data gathering, design, and feasibility limitations to the study. As mentioned, the small sample size ( $N = 12$ ) and lack of a control group and normative population sampling created low statistical power and prevented the administration of a randomized control trial study. Also, the application of a traditional single-case controlled study (Mertens, 2010) was not feasible for a community-based behavioral health study utilizing

psychoeducation in a group format at a federally-qualified health center. The SDSMP was also designed to be administered over six weekly meetings to groups of 7–17 patients. This rendered the multiple phase changes and alternating treatment-withdrawal stages inherent to single-case design infeasible, and thus limited the study's ability to demonstrate that any benefits resulted entirely from the program (i.e., cause and effect outcomes).

Program attendance and dosage schedule can also affect the validity of the within-case analysis. Individual program attendance varied over the six-week duration. For example, one participant, a cab driver, arrived late and left early on two separate occasions due to his busy work schedule. Another participant skipped one meeting to attend a medical appointment. Another participant was absent from one meeting due to an unspecified illness. Three participants reported being ill or unable to start the program until the second meeting due to unspecified reasons. Attendance variability brings up issues of treatment fidelity making any conclusion less valid that the program resulted in changes of the dependent variables. Stanford University stipulates that attendance of four out of six classes qualifies as completion of the program; however, it could be argued that patients attending all six classes received a higher “dose” of the program, which might have altered their individual outcomes.

One solution for program attendance problems might be offering the SDSMP at different times of day or days of week to accommodate scheduling needs. Also, by allowing drop-ins and offering the program on a continuous basis with a new series of classes starting every six weeks, patients could make up missed classes during the next series. Patients might also repeat any classes they wished and complete the program at their own pace. However, there may be additional benefits to completing the program with an established peer group. The four interview participants reported receiving beneficial social support, and a therapeutic rapport between



participants attending weekly was observed. Such benefits may be unavailable to participants dropping in periodically, and rapport would have to be reestablished weekly when new participants arrive. Attending weekly meetings for six consecutive weeks also constitutes a difference “dosing schedule” than attending meetings once per month for six months. Ultimately, a program schedule that maximizes attendance might be different than a schedule that maximizes program efficacy. Individual sites will need to consider which schedule is the best suited for their clinical population.

Another weakness specific to the multiple within-case analyses was the lack of well-established baseline measures for the dependent variables. The program began as a population health project under a GPE grant, and only pre- and post-program assessments were administered. Ideally, patients would have completed multiple administrations of the PHQ-9, GAD-7, and Patient Activation Survey prior to attending the SDSMP to a steady baseline. Lack of established baseline scores threatens the validity of changes in dependent variables as resulting from the program because the pretest score may have reflected a fluctuation and not the patient’s actual baseline. Other factors may confound assessment of psychological outcomes and lab results. While several of the patients showed improvements in their diet and physical activity, it was unclear how concurrent treatments, such as diabetes medication (e.g., Metformin) might have contributed to improvements in HbA1c%. Psychiatric medications and seasonal changes not accounted for in the study may have also affected patient depression and anxiety scores. Other personal factors, such as life stressors, family events, and medical complications, or historical factors, such as important social, cultural, and political events might have affected the psychological and medical health of participants at any given time.

Patient attendance of routine diabetes check-ups was inconsistent over time (e.g., every three months, six months, no-showing, etc.) as patients attended their routine check-ups on different appointment dates both before and after the program. This was likely due to factors beyond control of the study, including personal needs around scheduling and appointment availability. Similar individual and historical factors due to the passage of time may have confounded pre- and post-program diabetes lab results. While medical biomarkers (i.e., HbA1c% and BMI) are likely to fluctuate over time based on various individual factors affecting patient health (e.g., diet, lifestyle, etc.; see Etiology and Symptoms section), the HbA1c% is considered one of the more reliable diabetes biomarkers. As a measurement of the average patient blood sugar level over the last three months, HbA1C% endures over time and is less prone to such fluctuation, which is why it is considered the “gold standard” for a diabetes medical diagnosis (ADA, 2016).

Another threat to the validity of the within-case analyses was instrumentation bias. The psychological outcomes measures were self-report surveys, and participants knew they were attending a diabetes program. Participants may have presented with a positive testing bias or “placebo” on post-program measures believing they “felt better” than they actually did because they had received a diabetes treatment. As program leader and researcher of the present study, participants may have also wished to “please” me by distorting their self-report questionnaires in a positive direction to demonstrate that they improved as a result of the program. A larger participant sample might have helped account for “faking good or faking bad” biases (i.e., malingering); however, with no control group and a lack of double-blindness, there was also no way to control for positive bias or placebo effect.

Stronger organization and foresight might have helped overcome gaps and inconsistencies in the data set. For instance, medical data were not available for patients receiving primary care at clinics other than Harbor Care Health and Wellness Center. Researchers might acquire proper releases of information in advance preparation for a study with patients from outside clinics. Future studies might also request in-house patients to attend their diabetes check-up pre- and post-program at set intervals to overcome time and other confounding historical variables. Such a practice would also be congruent with the care manager role per the collaborative care model (Cretin et al., 2004) and with best practices of the American Diabetes Association (2016), both which recommend that diabetes patients attend check-ups every three months.

Some of these potential biases were attended to some degree. Using a third-party interviewer for the 11-month follow-up interview may have reduced some of the positive bias in participant feedback about the program because the interviewees may have felt more comfortable speaking candidly to a third party. Patient medical data also provided an objective countermeasure to positive testing bias for self-efficacy to some degree. For example, any marked increase in patient self-efficacy scores, such as healthy diet and physical activity would likely have been accompanied by improvements in BMI and HbA1c%. Any lack of consistency between the two outcomes would have revealed a positive testing bias on the part of a participant; however, no such inconsistency was identified.

There were feasibility issues within the assessment process due to the nature of the illness under study. Survey exhaustion was apparent within participants, which was understandable for patients with diabetes who often experience fatigue as part of their symptomology (see Etiology and Symptoms section). Also, only four participants were able to attend the 11-month follow-up

interview and complete the follow-up assessment of psychological outcomes and self-efficacy, so it was unclear if any benefits were sustained over time for the other participants. Additional follow-up assessments might have occurred during routine diabetes check-ups to provide continuous measurement post-program and to work around the apparent participant survey exhaustion.

There were also questions regarding the Patient Activation Survey as an accurate measure for self-efficacy. The PAS breaks down into three domains: (a) Knowledge, (b) Coping, and (c) Behavior. Per Bandura (2006) self-efficacy is domain-specific (i.e., specific to challenges for particular behaviors), and questions should be phrased in terms of “I can.” The Coping scale adheres to these criteria and responses are gauged along a Likert-type scale. As proportional “yes/no” measurements, the Knowledge and Behavior scales may not be sensitive outcomes measures for self-efficacy. Responses on these scales are all or nothing and may not reveal variability in self-efficacy scores, and thus they are unsuitable for continuous measurement. I was also unable to locate evidence regarding the validity and reliability of the PAS within the diabetes literature, so it is unclear to what extent the PAS is an accurate representation of self-efficacy. Measures used in previous studies by Lorig et al. (2009), such as the Self-Efficacy for Diabetes Survey or the *Patient Activation Measure* pose a thorough range of questions that are domain-specific and reflect proper phraseology of language regarding self-efficacy assessment, per Bandura (2006); however, Stanford University stipulates the use of the PAS, and other measures were excluded to avoid survey exhaustion on the part of participants.

Additional considerations should be made for measuring behavioral change in diabetes management. On the PAS, a positive response of “most of the time” or higher on the Coping scale and “3 days per week” or higher on the Behavior scale is considered the clinical target.

Based upon existing literature, it is unclear why these responses were deemed the clinical targets by SDSMP developers; for example, whether eating three or more servings of fresh fruits and vegetables on three or more days per week is sufficient to control blood sugar in a diabetes patient. Further research is needed around whether the PAS is a medically-appropriate tool for assessing behavior change in diabetes patients.

Other potential measures include using patient diet and physical activity logs.

Concomitantly, weekly participant verbal reports to the group about accomplishment of goals for the prior week could be recorded and tracked by researchers. A large-scale correlational study assessing patient dietary and exercise behaviors alongside their HbA1c% and BMI might help determine the correct “dose” of low-starch vegetables and exercise required to regulate blood sugar in diabetes patients. Future studies might focus on a thorough investigation of changes in other more specific domains of self-efficacy and behavior change that are linked to beneficial medical outcomes, such as patient confidence in speaking to their physician about their illness. This could ultimately lead to the creation of a biopsychosocial assessment tool designed for continuous measurement of behavioral change in diabetes patients that is correlated with clinical symptom targets in the medical management of diabetes.

Self-efficacy-based programs and assessment measures may be biased against patients with physical disabilities. This bias is inherent to the language of self-efficacy measures and in how differences in patient abilities are not accounted for during the program. Again, per Bandura (2006), assessment questions concerning self-efficacy in a given skill domain should be phrased in “I can” statements. For example, on the Patient Activation Survey, a question reads “Do you feel you can make a plan with goals that will help control your diabetes?” As two of the primary self-care behaviors taught in the program were proper diet and exercise, physically disabled

diabetes patients may be more limited in their ability to adhere to recommended behavioral changes, such as exercising three times per week or standing for long periods while shopping for or preparing meals. Physically disabled patients may have less mobility, and therefore, they may face greater hardship when traveling to areas where grocery stores with fresh produce are located. Assessment of self-efficacy may have been biased against such patients because the SDSMP presumes they were physically able to carry out these given tasks or modify them appropriately.

Self-efficacy-based programs and assessment measures may also be biased against low-income and working-class individuals. Participants who could not afford healthy food ingredients or who lived in urban areas where fresh groceries were not readily available may have been more disadvantaged than patients from affluent communities where these resources are abundant. These participants may have scored themselves lower on their self-perceived ability to comply with recommended dietary changes due to socioeconomic and geographic factors rather than psychological self-efficacy. Ideally, diabetes programs should account for such differences and offer solutions or modifications appropriate to their ability and income levels (Mertens, 2010). Assessment measures should also account for how external obstacles factor into self-efficacy scores. Participants may respond differently in their self-evaluation of “I can” when external variables like affordability are not controlled for.

Additional limitations to the study were the cultural competencies of the program. The collaborative care model aspects of the program (i.e., program leaders serving as “care managers”) were previously tested on samples comprised primarily of patients with a Caucasian background (Huang et al., 2013). Regional statistics for the SDSMP were also undifferentiated by race, gender, ethnicity, education level, and socioeconomic status (New England Quality

Innovation Network–Quality Improvement Organizations, 2016). Therefore, it was not possible to account for individual differences when comparing participant outcomes in the study sample to regional norms. While most of the program participants in the study were of European American descent (with one African American), it is incorrect to assume that values are consistent across all demographic regions and between the various European American cultural groups in a given region. There also may be variations in outcome on diabetes lab results due to individual differences arising from biological differences between ethnic groups and the intersectionality of race, gender, ethnicity, and socioeconomic status, which were not accounted for by the research literature or in the present study.

Another important consideration for quality improvement was how to make the program more inclusive of people of color. Although the SDSMP was originally developed for Latino/a diabetes patients (Lorig et al., 2008), the two Latino/a participants who had originally signed up for the study dropped out before the first meeting. One of those individuals, a 28-year-old Latino father, stated that the program meeting times conflicted with his work schedule. The other participant, a 64-year-old Puerto Rican grandmother, stated she was due to be admitted to the hospital for an unspecified medical treatment during the six-week program period and could not attend. Even if these events occurred by chance, future program leaders at Harbor Care Health and Wellness Center must consider how to include the Latino/a population within their program in a culturally-sensitive manner, especially since diabetes disproportionately affects this particular ethnic group (Woodward-Lopez & Flores, 2006). One solution might be offering the program during evening hours so working-class Latino/a families can attend. Outreach might also be enhanced by offering the program materials, outcomes measures, and program paperwork in Spanish, conducting the program in a local Latino neighborhood community center or church,

and having the program administered by a Spanish-speaking provider.

Another area for future research is programming for patients with comorbid diabetes and depression and/or anxiety disorders. As noted in the Depression section of this paper, these disorders may adversely affect the treatment adherence of diabetes patients, and diabetes patients have increased susceptibility to developing either or both disorders. The lack of improvement in diabetes coping skills and the high prevalence of psychological distress in the study's patients suggested that depression and anxiety may have somehow interfered with the SDSMP's enhancement of self-efficacy and diabetes coping. Future studies might focus entirely on outcomes for patients with these specific comorbidities, the role of depression and anxiety as moderators for diabetes coping, and of increasing diabetes coping strategies as a mediator to relieving depression or anxiety in diabetes patients.

### **Evaluative Comments for Future Programs in Diabetes Management**

There are considerations for future program leaders and clinic stakeholders wishing to assist their diabetes patients. Sites interested in diabetes self-management education programs (DSME) focusing on patient self-efficacy to increase coping and healthy behaviors in diabetes patients might consider the type of evidence-based program that is best suited for their population. The SDSMP has a highly-structured and semi-scripted format. Program leaders follow a script but are "saying it in their own words." This format is suitable for research purposes as the curriculum can be replicated consistently, which has allowed for large-scale data aggregation by Stanford University. As a result, the SDSMP is empirically validated and ideal for a site desiring a pre-developed program with robust evidentiary support. It is also designed to be peer-based so it is not necessary for a credentialed health professional to lead the program, which could save considerable costs for hosting sites.



One drawback to the SDSMP and other DSME programs is that a considerable amount of meeting time is devoted to lecture around important topics in diabetes care. While participatory activities like brainstorming exercises and menu planning are interspersed, participants with a lower level of literacy or shorter attention span may have difficulty absorbing the significant amount of information delivered through lecture. The performance of Patient 1AB-m-54 exemplified this difficulty. After taking the SDSMP four times, he still only marked 50% of the answers correctly on the Knowledge scale of the Patient Activation Survey even after he chose the correct answer to the same questions in previous assessments. Patient 1AB-m-54 also discussed how the course did not match his learning style during the 11-month follow up interview. Learning diabetes knowledge may be an ineffective mechanism of change for similar patients of a lower literacy level.

Sites desiring a less-structured program, or for sites that wish to design a curriculum for their population based on the knowledge and expertise of their local practitioners might consider how social support was deemed an important element by participants in the study. As several SDSMP participants attended the diabetes support group or attended the SDSMP again with the next doctoral student, the implication is that social support may be crucial for certain patient populations. Conducting support groups would also be appropriate use of clinical psychology students' therapy skills. A more unstructured program format with less time devoted to lecture could increase the opportunity for social interaction, especially when delivering the program on an ongoing basis. Though not examined by the study, I posit that social support engendered by the diabetes education program may have been a mediating protective factor for modest benefits with regard to patient depression and anxiety. Some sites might enhance social support factors even further by hosting community events centered around diabetes and other chronic illness

management, hosting diabetes cooking classes, exercise classes, or serving healthy community meals to homeless diabetes patients. A program like the SDSMP could offer an educational opportunity for those desiring it, but an entire social network for diabetes patients could be built around something as curative as diabetes support groups.

Another limitation to self-efficacy-based programs is its emphasis on psychological change. The goal of DSME is to increase the patients' beliefs that they "can" perform specific prescribed behaviors fundamental to diabetes self-management, including changing their diet and increasing physical activity levels; however, the major dilemma is that a patient may feel confident that they *can* perform the correct behaviors, but they still fail to follow through. Such phenomena reflect the difficulty many physicians face in successfully helping their diabetes patients, but in this case of patient non-compliance can become an impetus for the biopsychosocial model and for psychologists to shed light on the underlying barrier towards diet and lifestyle transformation. It is suggested that individual counseling may be needed in a primary care setting to motivate patient commitment to change. While Bandura (2006) does point out that increasing self-efficacy may be a precursor to performing a behavior, (as it will make a patient more likely to repeat that behavior), becoming confident at performing a certain behavior still falls short of actually doing the behavior. This is exemplified in the study in patients who improved on the Patient Activation Survey but did not actually improve on their HbA1c% or BMI. However, Bandura's (1977) social learning theory could be applied to individual counseling sessions that focus on motivating commitment to change.

Ultimately, the emphasis in diabetes research may need to shift towards the measurement of patient behavior. As diabetes is a "disease of the lifestyle" with a physiological basis, the bottom line is that if the patient's behavior does not change (i.e., eating more low-starch fruits

and vegetables) their diabetes will never improve. Lorig et al. (2009) exemplified this shift in emphasis from the Self-Efficacy for Diabetes Survey to the current Patient Activation Survey in which one third of the questions comprise a Behavior scale. Diabetes program leaders need not forgo self-efficacy as a desirable goal for diabetes patients; rather it is up to researchers and program developers to identify which programs are most ultimately most effective for creating sustainable changes in patient behavior.

Other considerations for future leaders are logistical. Recruitment for the program took a considerable amount of time and organization yet produced encouraging results as a pilot project. With 116 diabetes patients attending primary care at Harbor Care Health and Wellness Center, 12 patients completed the program, which is almost 10%. Recruitment began with a list of 32 referrals from Harbor Care Health and Wellness Center practitioners. This pre-screening for likely participants may have saved time for program leaders who would otherwise be cold-calling every diabetes patient at the clinic. Similarly, hosting the program at a medical clinic may be more desirable than advertising the program to the general public to find diabetes patients. Perhaps, however, both methods—community announcement and medical referrals—may increase the number of voluntary participants, heterogeneity, social energy, and sustained utilization. After recruitment, several patients dropped out due to work and scheduling concerns. This suggests that the meeting schedule needs to be communicated clearly, or that programs should be offered in the evening or on the weekends for working adults.

Another consideration when forming groups may be the individual readiness of different patients. Participants who enjoyed the social influences of the group, a construct promoted by Bandura (1977), attended multiple programs and the diabetes support group. These participants might make excellent future organizers and peer leaders. They helped increase attendance

numbers for programs with fewer participants and helped the diabetes program continue almost a year after the study concluded. They may have helped build a sense of community and belonging in the group that was not captured by the study that started the diabetes education project.

Conversely, a few interview participants complained about certain colleagues as shown by the Social Hindrance subtheme, suggesting that additional work may need to be done to screen out potential participants who might hinder the group experience. Also, the lack of behavioral change to lifestyle modification in a majority of participants suggests there are different degrees of readiness for change on an individual level. While there were too few participants to conclude anything broadly about the program's appropriateness of fit for different demographic groups, such as age, income, and resource availability, these factors of health disparity certainly apply and should be taken into consideration when adapting a program for a clinical population.

### **Conclusion**

In conclusion, this section presented the discussion of the results from the study. The results of the multiple single cases were discussed as well as the extent of improvement and the various reasons why patients did or did not improve. Comparisons were made between the individual patients, the regional norms, and expectations per the results from previous studies. Similar comparisons were made for the study's sample group. The study's adherence to the Practice-Based Participatory Research framework, questions, and goals, as well as the goals of Harbor Care Health and Wellness Center were discussed. Research gaps in diabetes management programs, limitations to the present study, future areas of research, and best practices for program leaders were discussed.

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## Tables

Table 1

*Summary of clinical trials of the SDSMP and associated variables*

| <b>Name</b>        | <b>Sample Size</b> | <b>Format &amp; Design</b> | <b>Variables</b>  | <b>Follow-ups</b>   | <b>Statistically significant Improvements</b>   |
|--------------------|--------------------|----------------------------|---|---------------------|---|
| Lorig et al., 2008 | 761                | Online<br>Control group    | Self-efficacy<br>Patient activation<br>Depression<br>Health distress<br>Activity limitation<br>Exercise (min./wk.)<br># physician visits<br>HbA1c%  | 6-month<br>18-month | 6m: HbA1c%, self-efficacy, patient activation, health distress, activity limitation, and # physician visits<br><br>18m: Self-efficacy and patient activation  |
| Lorig et al., 2009 | 345                | Classroom<br>Control group | Self-efficacy<br>Patient activation<br>Health care utilization<br>Depression<br>Fatigue<br>Exercise<br>Glucose monitoring<br>Communication with physician<br>Healthy eating<br>Reading food labels<br>HbA1c%<br>BMI | 6-month<br>12-month | 6m: Depression, Hypoglycemia, communication with physician, healthy eating, and reading food labels,<br><br>12m: depression, communication with physicians, healthy eating, patient activation, and self-efficacy |

|                    |                           |                                |  |                     |   |
|--------------------|---------------------------|--------------------------------|--|---------------------|---|
| Lorig et al., 2010 | 567<br>(Spanish-speaking) | Classroom<br>Control group     | Self-efficacy<br>Activity limitation<br>Fatigue<br>Health distress<br>Self-rated health<br>Exercise<br>Glucose monitoring<br># Physician visits<br># ER visits<br># Days in hospital<br>HbA1c%   | 6-month<br>18-month | 6m: Self-efficacy, HbA1c%, health distress, and symptoms of hypo- and hyperglycemia<br><br>18m: Self-efficacy, HbA1c%, health distress, self-reported health, and symptoms of hypo- and hyperglycemia., ER visits, physician visits, and exercise |
| Lorig et al., 2016 | 1242                      | Online/Classroom<br>Comparison | HbA1c%<br>Depression<br>Self-rated health<br>Illness intrusiveness<br>Medication adherence<br>Hypoglycemia<br>Exercise<br>Fatigue<br>Sleep problems<br>Communication with physicians<br>Attendance of eye, foot, cholesterol, kidney exams | 6-month             | HbA1c%<br>Depression<br>Self-rated health<br>Medication adherence<br>Illness intrusiveness<br>Fatigue<br>Hypoglycemia<br>Communication with physicians<br>Attendance of exams   |

Table 2

*Definitions of Qualitative Themes and Subthemes*

| Theme/Subtheme  | Definition   |
|---|--|
| Workshop Feedback   | Patient feedback about the workshop structure, content, format, or schedule; as well as requests made about future workshops.  |
| Perceived Barriers  | Obstacles or barriers the patient perceived in their lives that hindered them from receiving adequate care or properly managing their diabetes.  |
| Health Factors:   | Various patient-reported health problems or life factors that may have hindered diabetes self-management.  |
| <i>Unmet Care Needs</i>                                     | An unmanaged illness or condition or another unmet healthcare need.  |
| <i>Personal Obstacles to Change</i>                         | Individual factors-physical or psychological-that the patient perceived were preventing them from receiving proper care or from employing the necessary skills to manage their diabetes. |
| Practitioner Feedback:                                      | Patient feedback about the program leaders, their healthcare team at Harbor Care Health and Wellness Center, or about the clinic in general  |
| <i>Program Leaders</i>                                      | Patient feedback about the workshop leaders  |
| <i>Harbor Care Health and Wellness Center Practitioners</i> | Patient feedback about specific members of their healthcare team   |
| <i>Harbor Care Health and Wellness Center Clinic</i>        | Patient feedback about the organizational systems of Harbor Care Health and Wellness Center  |
| Social Influences:  | Factors related to learning in a group environment   |
| <i>Social Support</i>                                       | Various Social Influences of the group setting that assisted individual learning or the patient's diabetes self-care   |
| <i>Social Hindrance</i>                                     | Various Social Influences of the group setting that hindered individual learning or the patient's diabetes self-care   |

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|                                |   |
|--------------------------------|---|
| Positive Changes:              | New skills the patient learned or ways they benefited from the workshop regarding their diabetes self-care. |
| <i>New Skills Learned</i>      | Various self-care or coping skills the patient learned during the workshop.                                 |
| <i>Benefits from Attending</i> | Other benefits the patient reported resulted from the workshop.   |

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|   |   |
|---|---|
| Negative Effects:   | Any negative effects the patient reported experiencing after attending either the workshop or after receiving care at Harbor Care Health and Wellness Center. |
| <i>Negative Effects from Workshop</i>                               | Any negative physical or mental health effects the patient reported experiencing from the workshop.   |
| <i>Negative Effects from Harbor Care Health and Wellness Center</i> | Any negative physical or mental health effects the patient reported experiencing after receiving care at Harbor Care Health and Wellness Center.              |

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|                       |  |
|-----------------------|--|
| Self-Efficacy:        | Areas of personal strength, attitudes, and areas of proficiency the patient perceived having within themselves |
| <i>Self-Efficacy</i>  | Skills or areas where the patient reported having confidence or proficiency.                                   |
| <i>Motivation</i>     | Patient’s reported personal motivation for attending the workshop or improving their diabetes care             |
| <i>Learning Style</i> | Patient’s reported perception of their own learning style  |

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|                          |   |
|--------------------------|---|
| Lifestyle:               | Patient’s discussion about various aspects of their current lifestyle relevant to managing diabetes |
| <i>Diet</i>              | Patient’s description of their current diet   |
| <i>Physical Activity</i> | Patient’s description of their current physical activity level or exercise routine                  |
| <i>Self-Care</i>         | Patient’s reported use of self-care or other coping skills for diabetes self-management             |

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Table 3

*Themes with Sub-themes and Illustrative Responses*

| Workshop Feedback  |   | Perceived Barriers  |  |
|--|---|---|--|
| <p>I would like to see more people that have type 1 diabetes in the program because it just seems like most people that I know have type 2—and if they would lose a ton of body weight and eat right they wouldn't even be diabetic—and for people that are type 1, it's not an elective thing in that same regard.</p>  |   | <p>I will admit—being on my own—I cheat. You know, everybody does. But, like, have I got a girlfriend or wife to go home to that's got the meal already prepared and sit down and blah-blah-blah? You know? I go home and got to fend for myself, so you know I'll look at what's in the cabinets and stuff and say “well heck with this I'm just going to order a pizza!”—you know versus cooking something.</p> |  |
| Health Factors   |   |   |  |
| <i>Unmet Care Needs</i>  |   | <i>Personal Obstacles to Change</i>   |  |
| <p>My blood pressure is going out of control, so I've been put on new medication and that's been bumped up three times now. And besides that, I just have other changes like some meds—and it's probably going to be more changes down the line—but I want to get off the meds, not add more. I mean right now I'm up to eighteen. Eighteen prescriptions.</p> |   | <p>Do I follow a menu? No. My A1C is around 6, 6.7 to 7 now. I mean- I still ate everything I did nine years ago: hot dogs, French fries, hamburger, shepherd's pie, sloppy joes, spaghetti and meatballs, kielbasa—you know the nice good honey sauce on rice? I mean I eat everything that I did ten years ago.</p> <p style="text-align: center;">"</p>  |  |
| Practitioner Feedback  |   |   |  |
| <i>Program Leaders</i>   | <i>Harbor Care Health and Wellness Center Practitioners</i>   | <i>Harbor Care Health and Wellness Center Clinic</i>  |  |
| <p>Samuel was a good man, easy to listen to. Sometimes there are other people that we're doing it that we're not as easy as Sam. Yeah, Sam was easy to listen to. You know. Pleasant. He was a people person and to have just people persons doing it is the only thing that they should always focus on because non-</p>                                      | <p>What they could do is keep the good employees employed—here—that's how they helped me, such as Dr Sylvia, Shannon, and Molly. Those people are—have—Dr. Sylvia saved my life. This goes back years . . . that's the bottom line. I'd be dead. My blood sugar was 609—I was put in the hospital. When I</p> | <p>When I first got diabetes I'd never seen a needle or syringe before and this place was kind enough to let me come in when I was shooting 5 times a day—three times fast-acting, two times slow-acting insulin—and they would let me come in here and shoot it with me. No doctor's office</p>  |  |

people people make it hard for someone to sit there.

first got diagnosed I couldn't even walk. I couldn't move. I was dead. I was in ketoacidosis. So—yeah—keep their employees that care.

in the freaking country would be willing to do that and this place has some really awesome things about it that no one else has, and that can never change.

Social Influences

*Social Support*

Sometimes I tend to bury feelings instead of sharing them. And then when somebody would be sharing something that was pertinent to their life or their day, it just allowed me to open up more.

*Social Hindrance*

Individuals that didn't care about being there that were there anyway. Because they probably—for whatever reason—I would ask people to leave that don't really want to be there. They're there for whatever reason they're there but don't really care about diabetes or their health or their weight or what they put in their body.

Positive Changes

*New Skills Learned*

...they'd say "make an action plan and see if you can follow through with it." It's not something I did prior to that—yeah, that was one thing that stood out.

*Benefits from Attending*

What I want to eat now I always leave something extra on the plate. I don't need the whole thing and I'm eating fruit for a snack in the afternoon, popcorn, and I eat whole wheat bread which I didn't eat before.

Negative Effects

*Negative Effects from Program*

For people who've been working for many years to keep their diabetes in check, it's frustrating to listen to some hooper (sic) that doesn't give a---but is still sitting there.

*Negative Effects from Harbor Care Health and Wellness Center*

. . . and then the meds they put me on—I mean I've never taken such strong opioids in my life. I mean—it's one thing to take Oxycodone, but Dilaudid is one hundred times more powerful than morphine is!

Self-Efficacy

*Self-Efficacy*

Change comes hard but you have to be willing, you know? Personally, I find it exciting to—I’ve always liked to cook and I’ve always been a good cook.

*Motivation*

Not working is depressing. You don’t realize how much of what you are is what you do until you’re not doing it.

*Learning Style*

In my school, I had to have the oral test. I couldn’t do a written test because I’d be misinterpreting the questions and putting wrong answers down. But when they actually read and I verbally answered, I was passing it.

Lifestyle

*Diet*

I’m just more conscious of what I’m eating—like I don’t need something sweet. I go to something different.

*Exercise*

Basically, I take care of my garage for a little bit or sit downstairs in my room and watch TV for a while- watch a couple movies. I try to avoid going up and down stairs constantly. Might go out and run some errands, but the majority, I usually sit in my room watching TV.

*Self-Care*

I do all of the things (doctor recommendations) on a regular basis and I pretty much always have. I mean foot care was important when I was in the service.

Table 4

*Frequency of Interview Themes per Participant*

| Theme/Sub-theme                             | Participant | Frequency | Total |
|---|-------------|-----------|-------|
| Workshop Feedback                           | 1AB         | 7         | 19    |
|   | 7A          | 6         |       |
|   | 8A          | 2         |       |
|   | 10A         | 4         |       |
| Health Factors: <i>Personal Obstacles</i>   | 1AB         | 5         | 17    |
|   | 7A          | 5         |       |
|   | 8A          | 4         |       |
|   | 10A         | 3         |       |
| Lifestyle: <i>Self-Care</i>                 | 1AB         | 3         | 17    |
|   | 7A          | 3         |       |
|   | 8A          | 6         |       |
|   | 10A         | 5         |       |
| Social Influences: <i>Social Support</i>    | 1AB         | 2         | 16    |
|   | 7A          | 9         |       |
|   | 8A          | 2         |       |
|   | 10A         | 3         |       |
| Perceived Barriers                          | 1AB         | 8         | 15    |
|   | 7A          | 3         |       |
|   | 8A          | 3         |       |
|   | 10A         | 1         |       |
| Self-Efficacy: <i>Self-Efficacy</i>         | 1AB         | 5         | 15    |
|   | 7A          | 7         |       |
|   | 8A          | 0         |       |
|   | 10A         | 3         |       |
| Positive Changes: <i>New Skills Learned</i> | 1AB         | 3         | 12    |
|   | 7A          | 5         |       |
|   | 8A          | 2         |       |
|   | 10A         | 2         |       |
| Self-Efficacy: <i>Motivation</i>            | 1AB         | 0         | 10    |
|   | 7A          | 8         |       |
|   | 8A          | 1         |       |
|   | 10A         | 1         |       |

|   |     |   |    |
|---|-----|---|----|
| Lifestyle: <i>Physical Activity</i>   | 1AB | 2 | 10 |
|   | 7A  | 3 |    |
|   | 8A  | 2 |    |
|   | 10A | 3 |    |
| Practitioner Feedback: <i>Harbor Care Health and Wellness Center Clinic</i>           | 1AB | 3 | 8  |
|   | 7A  | 3 |    |
|   | 8A  | 1 |    |
|   | 10A | 1 |    |
| Positive Changes: <i>Benefits from Attending</i>                                      | 1AB | 1 | 8  |
|   | 7A  | 4 |    |
|   | 8A  | 3 |    |
|   | 10A | 0 |    |
| Lifestyle: <i>Diet</i>  | 1AB | 0 | 8  |
|   | 7A  | 3 |    |
|   | 8A  | 3 |    |
|   | 10A | 2 |    |
| Social Influences: <i>Social Hindrance</i>  | 1AB | 2 | 6  |
|   | 7A  | 1 |    |
|   | 8A  | 0 |    |
|   | 10A | 3 |    |
| Self-Efficacy: <i>Learning Style</i>  | 1AB | 3 | 6  |
|   | 7A  | 2 |    |
|   | 8A  | 0 |    |
|   | 10A | 1 |    |
| Negative Effects: <i>Negative Effects from Harbor Care Health and Wellness Center</i> | 1AB | 1 | 5  |
|   | 7A  | 4 |    |
|   | 8A  | 0 |    |
|   | 10A | 0 |    |
| Health Factors: <i>Unmet Care Needs</i>   | 1AB | 3 | 4  |
|   | 7A  | 1 |    |
|   | 8A  | 0 |    |
|   | 10A | 0 |    |
| Practitioner Feedback: <i>Program Leaders</i>   | 1AB | 1 | 2  |
|   | 7A  | 0 |    |
|   | 8A  | 0 |    |
|   | 10A | 1 |    |

|  |     |   |   |
|--|-----|---|---|
| Practitioner Feedback: <i>Harbor Care Health and Wellness Center Practitioners</i> | 1AB | 0 | 2 |
|  | 7A  | 1 |   |
|  | 8A  | 0 |   |
|  | 10A | 1 |   |
| Negative Effects: <i>Negative Effects from Program</i>                             | 1AB | 0 | 1 |
|  | 7A  | 0 |   |
|  | 8A  | 0 |   |
|  | 10A | 1 |   |

*Note.* Frequency indicates the number of responses per participant that fell under that theme or subtheme.

Table 5

*Summary of Patient Outcomes and Further Intervention Indicated*

|            | 1AB | 2A  | 3A | 4A  | 5A | 6A |
|------------|-----|-----|----|-----|----|----|
| Depression | 0x  | -1x | 1  | 1x  | 1x | 1x |
| Anxiety    | 0x  | 0   | 1  | -1x | 1  | 0x |
| Knowledge  | 0   | 0   | 0  | 0   | 0  | 1  |
| Coping     | 0   | 0   | -1 | 1   | 1  | 0x |
| Behavior   | 0x  | -1  | 0  | 1   | 1  | 1  |
| HbA1c%     | -1  | x   | -  | -   | 1  | 1  |
| BMI        | -1x | x   | -  | -   | 1x | 1x |

|            | 7A  | 8A | 9A  | 10A | 1B | 2B |
|------------|-----|----|-----|-----|----|----|
| Depression | -1x | 1x | x   | 0x  | 1  | 1  |
| Anxiety    | -1x | 1  | -   | 1x  | 0  | -1 |
| Knowledge  | 0   | 0x | -   | 0   | 0  | 1  |
| Coping     | 0   | 0  | -   | 0   | 1  | -1 |
| Behavior   | 0   | 0  | -   | 0   | 1  | 0  |
| HbA1c%     | x   | -  | -1x | -   | x  | -  |
| BMI        | -1x | -  | 1x  | -   | 0x | -  |

Key:

1 = improvement

0 = no change

-1 = negative change

x = further intervention indicated

*Note.* If a marker (x) appears alone in the table, the patient did not complete a post-program measure, but their previous assessment indicated this variable was not within the clinical treatment target. Blank cells (-) indicate there was no measurement available for the patient in that variable.

Appendix A

Consent for Release of Information

Reprinted from "Consent for Release of information: Authorization to release protected health information," 2016, Harbor Care Health and Wellness Center, Incorporated. Used with permission (see Appendix I: Copyright Permissions).

HARBOR CARE HEALTH AND WELLNESS CENTER, INC
AUTHORIZATION TO RELEASE PROTECTED HEALTH INFORMATION

I, \_\_\_\_\_ (Patient/Client), DOB \_\_\_\_\_,
whose address is \_\_\_\_\_,

authorize Harbor Care Health and Wellness Center, Inc. to disclose to and/or obtain my protected health information described below from:

\_\_\_\_\_
for the following purpose: \_\_\_\_\_ ("at patient request" is sufficient).

Dates of care: \_\_\_\_\_

Description of Information to be Disclosed (Patient/client must initial each item to be disclosed):

- \_\_\_ Copy of complete medical record
\_\_\_ Discharge Summary
\_\_\_ Initial Evaluation
\_\_\_ Medications
\_\_\_ Other (specify) \_\_\_\_\_
\_\_\_ Medical reports
\_\_\_ Laboratory reports
\_\_\_ Psychiatric Evaluations
\_\_\_ Psychotherapy Notes

If my initials appear here, \_\_\_ I specifically authorize release of drug/alcohol abuse and or psychiatric records. Federal law 42CFR Part 2 prohibits those receiving information on drugs or alcohol treatment from re-disclosing it unless further disclosure is expressly permitted by written consent of the person to whom it pertains, or is otherwise permitted by 42CFR Part 2.

If my initials appear here \_\_\_, I specifically authorize release of my HIV test results for the purpose set forth above. My signature below indicates I have read this form, have asked all the questions I have about the reason for the release of my identity, the results of my HIV test and I agree to the release of information to the above named party.

If my initials appear here \_\_\_, I specifically authorize release of my records that contain information about my diagnosis or treatment for AIDS or ARC, or contain some other reference to my identity as an AIDS or ARC patient for the purpose set above.

I understand that I have the right to revoke this authorization, in writing, at any time by sending notification to Harbor Care Health and Wellness Center, Inc. at 45 High Street, Nashua, NH 03060. I further understand that a revocation of the authorization is not effective to the extent that action has been taken in reliance on the authorization.

I further understand that Harbor Care Health and Wellness Center, Inc. will not condition my treatment on whether I give authorization for the requested disclosure. However, it has been explained to me that failure to sign this authorization may have the following consequences: I understand that I might be denied services if I refuse to consent to a disclosure for the purposes of treatment, payment, or health care operations, if permitted by state law. I will not be denied services if I refuse to sign this form for a disclosure for other purposes.



Unless you have specifically requested in writing that the disclosure be made in a certain format, we reserve the right to disclose information as permitted by this authorization in any manner that we deem to be appropriate and consistent with applicable law, including but not limited to, verbally, in paper format or electronically.

I understand that I may inspect or copy the protected health insurance described in this authorization.

I understand that there is the potential that the protected health information that is disclosed pursuant to this authorization may be redisclosed by the recipient and the protected health information will no longer be protected by the HIPAA privacy regulations, unless a State law applies that is more strict than HIPAA and provides additional privacy protections.

I understand that by authorizing this release of my medical information, I also release the care provider from all legal responsibility or liability that may arise from the release of this medical information.

EXPIRATION: This authorization will expire on (date/event) \_\_\_\_\_. If no date or event is specified, the authorization shall expire six months from the date it was signed. A photocopy of this authorization shall be considered as effective and valid as the original. A copy of this authorization shall be provided to the consumer or representative when signed.

Signature of Patient Client:

Date:

\_\_\_\_\_

\_\_\_\_\_

Signature of Parent/Guardian or Personal Representative:

Date:

\_\_\_\_\_

\_\_\_\_\_

If you are signing as a personal representative of an individual, please describe your authority to act for this individual (power of attorney, healthcare surrogate, etc.)

\_\_\_ Check here if patient/client refuses to sign authorization.

Signature of Staff Witness:

Date:

\_\_\_\_\_

\_\_\_\_\_

## Appendix B

**Psychological Outcomes Assessment Measures****Patient Health Questionnaire- 9 (PHQ-9)**

Adapted from “The PHQ-9: A new depression diagnostic and severity measure” by K. Kroenke, R. L. Spitzer, and J. B. Williams, 2001, *Journal of General Internal Medicine* 16(9), 606-613. In the public domain.

**Generalized Anxiety Disorder-7 (GAD-7)**

Adapted from “A brief measure for assessing generalized anxiety disorder: The GAD-7,” by R. L. Spitzer, K. Kroenke, J. B. Williams, and B. Löwe, 2006, *Archives of Internal Medicine*, 166(10), 1092-1097. In the public domain.

**Alcohol Use Disorders Identification Test (AUDIT)**

Adapted from “Development of the alcohol use disorders identification test (AUDIT): WHO collaborative project on early detection of persons with harmful alcohol consumption-II,” by J. B. Saunders, O. G. Aasland, T. F. Babor, J. R. De la Fuente, and M. Grant, 1993, *Addiction*, 88(6), 791-804. In the public domain.

**Primary Care PTSD Screen (PC-PTSD)**

Adapted from “The primary care PTSD screen (PC-PTSD): Development and operating characteristics,” by R. P. Cameron, and D. Gusman, 2003, *Primary Care Psychiatry*, 9(1), 9-14. In the public domain.

## Appendix C

**Qualitative Interview Questions**

1. How have things changed for you since the workshop?
2. How well have you been able to maintain those changes?
3. What does your current physical activity level look like? How much/often do you exercise during the week?
4. How many servings of fresh fruit and vegetables are you eating per day?
5. How often do you eat bread, pasta, potatoes, and other starches/complex carbohydrates?
6. What did you get most out of the workshop?
7. What would you like out of the program in the future?
8. What did you not like about the program?
9. If you could do the program again, what changes would you make?
10. What- if anything- do you still need from Harbor Care Health and Wellness Center to help you get your diabetes under control?
11. What sort of programs or groups would you like to attend in the future?

## Appendix D

### **Informed Consent to Interview and Answer Questionnaires**

You are invited to participate in an interview about your education in the Stanford Diabetes Self-Management Program at Harbor Care Health and Wellness Center in Nashua, NH. Your interview and responses to three questionnaires will contribute to Samuel Collier's dissertation study at Antioch University New England, Keene, NH, where he is a doctoral student in the clinical psychology program. Samuel Collier also conducted the diabetes management education that you attended. The answers you provide will help Samuel evaluate the program.

#### **Participation in the Interview**

For the interview, you will answer questions about your experience in the program. Topics covered will include what you liked about the program, how you benefited, and what you might want in a future program. The interview will take approximately 30 minutes and will be conducted in a private office at Harbor Care Health and Wellness Center in conjunction with a medical appointment you have so that you don't have to make a separate trip to Harbor Care Health and Wellness Center. Or if you prefer, you could interview over the telephone.

#### **Participation is Voluntary**

You are free to choose to interview, decline to interview, or stop the interview at any point. Whether you do the interview or decline to do so, you will continue to receive services at Harbor Care Health and Wellness Center.

#### **Who is the Interviewer?**

The interview will be conducted by a therapist at Harbor Care Health and Wellness Center. The instructor of the diabetes management program, Samuel Collier, also the evaluator of the program, will not be the interviewer. You are encouraged to answer the interview questions honestly and completely. The interview will be audio-recorded and transcribed into written form, so that Samuel Collier can analyze the interviews.

#### **Answering Three Questionnaires**

After the interview, you will answer three questionnaires on your emotions and beliefs about being able to manage your diabetes. The questionnaires will take 20 minutes to answer. If you're doing a phone interview, the questionnaires will be read to you on the phone, and the interviewer will note your answers. You are free to choose to answer the questionnaires, decline to do so, or stop answering the questionnaires at any point. You may skip any questionnaire item that you wish. However, you're strongly encouraged to complete the questionnaires. Whether you answer the questionnaires or decline to do so, you will continue to receive services at Harbor Care Health and Wellness Center.

#### **Confidentiality**

All information you disclose will be kept confidential. Other than the evaluator and the therapist doing the interview, no one will have access to your interview and questionnaire information. Your name and other identifying information will be omitted from the transcript, the evaluator's dissertation, and publications or presentation of the study. Your name will be replaced with an

ID number. Audio-recordings will be deleted after being transcribed. The transcripts and answered questionnaires will be stored in a password-protected computer and their hard copies kept secure in a locked filing cabinet in the evaluator's home. After the completion of the dissertation, computer-stored information will be deleted and hard copies will be destroyed.

**Risks and Benefits**

Participation in the study involves no more than minimal risk. You may feel some discomfort when evaluating your diabetes education and answering questions on your emotions. However, this experience is expected to be within the normalcy of everyday feelings. If you have a negative experience, the interviewer, who is a therapist, will be there to help you. Other diabetes patients at Harbor Care Health and Wellness Center may benefit from the results of the study as your feedback will guide future directions of the program. You may gain modest personal benefit in the form of a sense of achievement or accountability for maintaining healthy behaviors.

**Your Rights as a Research Participant**

If you have any questions about your rights as a research participant, please contact Dr. Kevin Lyness, Chair of Antioch University New England IRB at XXXX, or Dr. Barbara Andrews, Interim Provost and CEO, Antioch University New England, at XXXX.

**Consent for Release of Information**

Doing the interview and answering the questionnaires are both voluntary. Your signature on this form indicates you have read this form and understood what the researcher has communicated to you and that you have had all your questions answered. You willingly agree to release the interview and answered questionnaires to Samuel Collier for his use in his dissertation study.

---

**Participant Signature**

---

**Date**

---

**Interviewer Signature**

---

**Date**

---

**Researcher Signature**

---

**Date**

## Appendix E

**IRB Application****1. Name and mailing address of PI:**

Samuel B. Collier, M. S.  
XXXX  
XXXX

**2. Academic Department:** Clinical Psychology

**3. Department Status:** Doctoral Candidate

**4. Phone Number:** XXXX

**5. Name of Research Advisor:** Gargi Roysircar, Ed. D.

**6. Name and email address(es) of other researcher(s) involved in this project:** None

**7. Title of Project:**

Diabetes Management for Low-Income Patients: Within-Case Analyses in Primary Care

**8. Federal Funding?** No

**9. Expected start date for data collection:** December 15, 2017

**10. Anticipated completion date for data collection:** February 15, 2017

**11. Project Purpose(s): (Up to 500 words) Describe: 1) the question or phenomenon you are investigating, 2) the project purpose, and 3) how the research will be disseminated or used.**

Diabetes is the seventh leading cause of death in the United States and the number of patients diagnosed with diabetes both nationally and in the New Hampshire area has been increasing year by year. The proposed study seeks to evaluate the implementation of an evidence-based diabetes intervention program at Harbor Care Health and Wellness Center, a Federally-Qualified Health Center in Nashua, New Hampshire that serves a broad spectrum of low-income, homeless, and impoverished individuals and families. The intervention program, the Stanford Diabetes Self-Management Program, consists of a six-week workshop shown to increase patient knowledge, self-efficacy, and use of important self-care behaviors (e.g., healthy eating and monitoring blood sugar) that are shown to help patients manage their diabetes symptoms.

The researcher addresses the following research questions:

- How effective was the intervention at improving patient-reported self-efficacy in diabetes management, depression, and anxiety between pre-and post-intervention self-report measures?
- How effective was the intervention at increasing basic patient knowledge of diabetes as determined through pre-and post-intervention measures?
- How effective was the intervention at increasing patient-reported self-care behaviors?
- How effective was the intervention at improving patient attendance to routine diabetes medical exams at a 6-month follow-up?
- How effective was the intervention at improving important patient biomarkers related to diabetes management, including A1C measures, blood pressure, LDL, HDL, cholesterol, eye/feet exams, and bodyweight at routine 6-month follow-up diabetes exams?

The investigator will disseminate relevant information gained from the study in his dissertation and to relevant managers and clinicians of Harbor Care Health and Wellness Center, Nashua, New Hampshire, the setting of the intervention program.

**12. Describe the proposed participants- age, number, sex, race, or other special characteristics. Describe criteria for inclusion and exclusion of participants. Please provide brief justification for these criteria. (Up to 500 words)**

Participants in the study were attendees of the diabetes intervention program at Harbor Care Health and Wellness Center. The program was available to any clinic patient previously diagnosed with any type of diabetes or prediabetes, or who was considered at risk of developing diabetes. While most participants had type II diabetes, two patients had type I diabetes and one participant was considered “at-risk” of developing diabetes by her medical provider. Of those participants who fully completed the intervention ( $N=12$ ), six were male and six were female. Their ages ranged from 25 years to 70 years old. Five participants had physical disabilities, three were retired, two unemployed, and two self-employed. Four lived in affordable housing units while three lived in a family-owned home; two rented their apartment, and one owned their own home. One participant was African-American, the rest were Caucasian. Eight participants were previously diagnosed with mental health disorders, including Bipolar I Disorder (2), Major Depression (4), Alcohol Use Disorder (1), Posttraumatic Stress Disorder (1), and Generalized Anxiety Disorder (1). Education levels ranged from a high school diploma to a master’s degree. The exclusion criteria were presence of a severe medical or mental health condition that might present a barrier to patients’ completion of the program and any condition that might cause a disruption for the group, such as acute psychosis or a severe personality disorder. No patient met these exclusion criteria.

**13. Describe how the participants are to be selected and recruited. (Up to 500 words)**

Participants in the study were attendees of the diabetes intervention program at Harbor Care Health and Wellness Center. Recruitment for the program was conducted primarily through referrals from medical providers at Harbor Care Health and Wellness Center, who flagged the names of potential participants on the electronic medical record for the intervention leaders to contact. Flyers were also placed around the clinic, which resulted in one patient contacting the intervention leaders. “Word of mouth” in the community resulted in one participant reaching out

from a primary care clinic outside of Harbor Care Health and Wellness Center. All potential participants were contacted by telephone and offered a half-hour sign-up appointment with the intervention leaders to discuss the program. At that appointment, the program format, curriculum, and meeting schedule were explained to the patients, all patient questions were answered, and brief elements of motivational interviewing were employed to gauge patient interest or assess level of readiness as necessary. If the patient wished to sign up, they completed several documents, including the Patient Information Sheet (Appendix B) and consent for release of information form (Appendix A). This paperwork constitutes the routine consent paperwork stipulated by both Harbor Care Health and Wellness Center and the Stanford Program.

The ten participants ( $N=10$ ) who completed the Stanford Program with the researcher will be contacted by telephone and offered the opportunity to participate in a follow-up interview and to answer the three psychological questionnaires (PHQ-9, GAD-7, Patient Activation Survey) that were previously administered at pre-intervention and post-intervention. The recruitment for the interviews and the interviews themselves will be conducted by a third party, a current practicum student at Harbor Care Health and Wellness Center or a research-trained doctoral-level therapist.

The participants will be informed about the purposes of the follow-up interview and questionnaires and that participation is voluntary. To avoid placing additional hardship on the participants, the interviews will be booked in conjunction with another medical appointment. Additionally, the participant may elect to complete the interview over the phone. The same third-party interviewer will be administering both the follow-up interviews and questionnaires.

**14. Do you have a prior or current relationship, either personal or professional, with any person who will be involved with your research?**

The researcher was a practicum student at Harbor Care Health and Wellness Center during the third year of his doctoral program in clinical psychology and was the recipient of a stipend from a Graduate Psychology Education grant. The researcher was also one of the intervention leaders who led program. Beyond becoming certified to lead the diabetes program, the researcher has no relationship with Stanford University, and has no specific bias regarding the results of the intervention. The researcher had never met most of the participants who signed up for the program; however, three of the participants were therapy patients of the researcher. These three therapy patients had initially expressed interest in the program, but dropped out before the second meeting of the class. The third-party conducting the follow-up interviews will be a current practicum student at Harbor Care Health and Wellness Center or a research-trained doctoral-level therapist and may be a classmate of the researcher.

**14b. Describe how you will manage personal bias caused by these relationships and protect the validity of your data against the perception that you may be biased (For example, you will not recruit anyone who works directly for you or in your direct team.)**

The patient relationships with the researcher, who conducted the diabetes management program, terminated at the completion of his practicum in July 2017. The researcher believes that he holds no specific bias towards the results of the study in relation to the patients, Stanford University, or Harbor Care Health and Wellness Center. The interviews will be conducted by a third party who



is not expected to hold any bias about the outcomes of the study. The interviewer will ask the given questions with minimal prompts and deliver the audio-tapes of the interviews to the researcher. The interviewer will not take part in the transcription of the tapes or in their qualitative data analysis.

**15. Describe the process you will follow to attain informed consent.**

During the sign-up appointment, all incoming participants were requested to grant permission for the researcher to use their archived medical and mental health data for the evaluation purpose of his dissertation and help improve diabetes interventions at Harbor Care Health and Wellness Center. Participants were informed that granting this permission was voluntary, and if they chose to decline, they could still participate in the program. No participant declined and they all signed the consent form granting release of their psychological, medical, and demographic information to the researcher. Harbor Care Health and Wellness Center stipulates use of a specific consent form, designed by them and determined to be HIPAA compliant. This release form was modified for use in the study. See Appendix A for this Harbor Care Health and Wellness Center consent form used for the study.

Another consent for release of information form will be signed for the post-intervention interviews, granting permission to use patient interviews for the study. If the patient elects to conduct the interview over the phone, the same release will be mailed along with a self-addressed, postage-paid return envelope. See Appendix E for the Informed Consent for Patient Interviews and Answering of Questionnaires.

**16. Describe the proposed procedures, (e.g., interview surveys, questionnaires, experiments, etc.) in the project. Any proposed experimental activities that are included in evaluation, research, development, demonstration, instruction, study, treatments, debriefing, questionnaires, and similar projects must be described. USE SIMPLE LANGUAGE, AVOID JARGON, AND IDENTIFY ACRONYMS. Please do not insert a copy of your methodology section from your proposal. State briefly and concisely the procedures for the project. (500 words)**

To evaluate effectiveness of the program, the researcher will analyze three sets of data: 1) archived psychological data from outcome measures on depression, anxiety, and self-efficacy; 2) archived medical data on important biomarkers of diabetes obtained at routine medical check-ups; and 3) post-intervention interviews with participants.

The first set of data will be obtained from: The Patient Health Questionnaire- 9 (PHQ-9; Kroenke, Spitzer, & Williams, 2001) and the Generalized Anxiety Disorder-7 (GAD-7; Spitzer, Kroenke, Williams, & Löwe, 2006). These measures were used to determine whether the program offered any psychological benefit with reduction of depression and/or anxiety symptoms. These measures were administered on the first day and last day of the intervention. See Appendices B for these measures that are available in the public domain. The Patient Activation Survey was administered at the same intervals to demonstrate whether the intervention increased participant self-efficacy. Self-efficacy refers to the patient's level of confidence that they can perform a certain behavior and their belief that this behavior will help

them manage their diabetes symptoms (Bandura, 2006). See Appendix D for the Patient Activation Survey.

Two additional measures, the Alcohol Use Disorders Identification Test (AUDIT; Saunders, Aasland, Babor, De la Fuente, & Grant, 1993) and the Primary Care Posttraumatic Stress Disorder Screen (PC-PTSD; Cameron & Gusman, 2003), were administered as part of screening procedures for patients of Harbor Care Health and Wellness Center. Screening data will be included to describe each patient case, but will not be used to assess outcomes for the study.

Other data will consist of archived medical data from routine diabetes medical check-ups in primary care, occurring up to six months before and up to six months after the intervention program. These data are patient biomarkers of diabetes health: A1C levels, blood pressure, LDL, HDL, cholesterol, attendance of eye/feet exams, and bodyweight. The purpose of examining medical data is to help determine whether attendance of the intervention program corresponded with positive health effects in diabetes medical care.

In addition, follow-up interviews will be conducted to assess participants' experience of the intervention and which aspects of the program, if any, were to be beneficial. See Appendix D for a list of interview questions. The interview will provide an opportunity to re-administer the same psychological outcomes measures for depression, anxiety, and self-efficacy to examine whether any benefits persisted after six months. Attendance of the interview will be voluntary and conducted at a time and date concurrent with another medical appointment to avoid placing an additional burden on the patients.

Demographic information was obtained through the Patient Registration Form when participants signed up for the workshop. See Appendix A.

**17. Participants in research may be exposed to the possibility of harm — physiological, psychological, and/or social—please provide the following information: (Up to 500 words)**

***a. Identify and describe potential risks of harm to participants (including physical, emotional, financial, or social harm).***

No physical, emotional, or social harm was reported by the participants when they attended the diabetes intervention program or after its completion. The six-month post-intervention qualitative interview will be conducted during normal clinic hours and at a regular medical appointment. It will query information around topics that are non-sensitive in nature (Title 45 CFR 46.111 (a)(1)). Participation in the study involves no more than minimal risk, as defined by the Federal Code of Regulations, where “the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests” (Title 45 CFR; Part 46 Protection of Human Subjects Section 46.102i).

***b. Identify and describe the anticipated benefits of this research (including direct benefits to participants and to society-at-large or others)***

Participation in the diabetes management education program, which will be evaluated by the proposed study, might be beneficial to diabetes patients. Participation in the post-intervention interview may bring modest benefit to participants. The questions will ask patients to reflect on their participation in the diabetes program, their current healthcare needs and goals, and some sense of accountability over whether they are managing their illness effectively. Patients' opportunity to give feedback about services at Harbor Care Health and Wellness Center may also provide them a sense of buy-in or other positive emotions if patients perceive their participation will help other patients.

Results of the study may benefit society-at-large by adding to the research literature on diabetes interventions. The study considers the application of an evidence-based intervention program for underserved diabetes patients, including those who are low-income or on the homeless spectrum. Harbor Care Health and Wellness Center may also receive useful feedback about how they can modify future programs for their diabetes patient population.

***c. Explain why you believe the risks are so outweighed by the benefits described above as to warrant asking participants to accept these risks. Include a discussion of why the research method you propose is superior to alternative methods that may entail less risk.***

Use of archived medical data will pose little to no risk for participants and may offer some benefit to Harbor Care Health and Wellness Center and society-at-large. The interview may offer modest benefit to participants because they may gain self-knowledge and insight about their health practices. A study of archived data accompanied with subsequent qualitative interviews is warranted because the focus of the study is on tailoring a diabetes management program to the local NH treatment context of Harbor Care Health and Wellness Center. Using a different research framework, like randomize clinical trials, would be expensive, long-term, and would require large sampling. These features of traditional medical research are less relevant, given the immediate local need to deliver effective diabetes education to patients of Harbor Care Health and Wellness Center.

***d. Explain fully how the rights and welfare of participants at risk will be protected (e.g., screening out particularly vulnerable participants, follow-up contact with participants, list of referrals, etc.) and what provisions will be made for the case of an adverse incident occurring during the study.***

Participation was entirely voluntary in the intervention program. The program format, curriculum, and schedule were fully explained during the initial screening appointment and all participant questions and concerns were addressed. Feasibility issues were discussed with each participant, including attendance, transportation, participation, and physical and psychological ability to sit through a two- to three-hour class comfortably. As previously indicated, no patient presented at the initial sign-up appointment with exclusion criteria. The program took place during normal working hours of Harbor Care Health and Wellness Center, so regular support staff was available in the event of an emergency. Healthy snacks were provided should any diabetes patient experience low blood sugar. Patients with chronic pain were invited to stand or move around and stretch at any point during the program. Multiple breaks were taken throughout, and patients could leave any time if they felt ill or needed to use the restroom.

Telephone reminders were made each week to remind patients about upcoming classes and to check in.

Post-intervention, participants of the program will be contacted by phone and invited to attend a follow-up interview. These interviews will also be conducted during regular business hours at Harbor Care Health and Wellness Center and at scheduled medical appointments. Regular support staff will be available in the event of an emergency. Participants unable to attend the interview in person will be given the option to complete the interview over the phone.

**18. Explain how participants' privacy is addressed by your proposed research. Specify any steps taken to safeguard the anonymity of participants and/or confidentiality of their responses. Indicate what personal identifying information will be kept, and procedures for storage and ultimate disposal of personal information. Describe how you will de-identify the data or attach the signed confidentiality agreement on the attachments tab (scan, if necessary). (Up to 500 words)**

To protect patient privacy, all data will be stored securely and kept confidential by the researcher. Participants attended the diabetes intervention program led by the researcher; therefore, identities and general health information of these patients are already known to the researcher. Individual archived patient data will be stored securely and kept confidential by the researcher. The researcher will compile data from the electronic medical records of patients who participated in the program. To protect confidentiality, each set of patient data (medical data, psychological data, interview transcripts) will be assigned a participant number and stored in a password-protected Excel document by the researcher before it is removed from Harbor Care Health and Wellness Center. The Excel document containing the data will be stored in a flash drive and locked in a desk in the researcher's home office. All data files and transcripts will be deleted after completion of the dissertation study.

**19. Will audio-visual devices be used for recording participants? Will electrical, mechanical (e.g. biofeedback, electroencephalogram, etc.) devices be used?**

The qualitative interview will be recorded with an electronic audio recording device for transcription purpose with the permission of Harbor Care Health and Wellness Center and participants. See letters from Harbor Care Health and Wellness Center included with the application giving me permission to interview participants and use the interview data for the study. The audio files will be transcribed by the researcher and then deleted.

**20. Type of Review Requested (Click one): Exempt, expedited or full.  
Please provide your reasons/justification for the level of review you are requesting.**

Expedited

Participation in the diabetes management intervention program and in post-intervention interviews involves no more than minimal risk, as defined by the Federal Code of Regulations as circumstances in which the "probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or

during the performance of routine physical or psychological examinations or tests” (Title 45 CFR; Part 46 Protect of Human Subjects Section 46.102i).

The pre-post intervention data from the education program are archived and will be securely stored by the researcher to protect confidentiality, as required by Title 45 CFR 46.101(b)(4). As defined under Title 45 CFR 46.111 (a)(1), the nature of questions and information sought in the brief post-intervention follow-up interview are not considered sensitive (see Appendix D). The questions will focus primarily on the participants’ perspectives of how they benefited or did not benefit from the program and on their use of self-care behaviors (e.g., diet, exercise, foot exams, etc.). Although the participants are from an economically-disadvantaged population, with several having moderate physical disabilities, they may receive modest benefit through their participation in the interview.

### **Attachments section**

***Informed consent and/or assent statements, if any are used, are to be included with this application. If information other than that provided on the informed consent form is provided (e.g. a cover letter), attach a copy of such information. If a consent form is not used, or if consent is to be presented orally, state your reason for this modification below. \*Oral consent is not allowed when participants are under age 18.***

***If questionnaires, tests, or related research instruments are to be used, then you must attach a copy of the instrument at the bottom of this form (unless the instrument is copyrighted material), or submit a detailed description (with examples of items) of the research instruments, questionnaires, or tests that are to be used in the project. Copies will be retained in the permanent IRB files. If you intend to use a copyrighted instrument, please consult with your research advisor and your IRB chair. Please clearly name and identify all attached documents when you add them on the attachments tab.***

***Add all clearly labeled attachments for this application below (e.g. confidentiality agreement(s), questionnaire(s), consent / assent forms, etc.).***

The following are the titles of attachments included:

1. Consent for release of information
2. Patient Health Questionnaire- 9 (PHQ-9)
3. Generalized Anxiety Disorder- 7 (GAD-7)
4. Brief Qualitative Interview Questions
5. Informed Consent for Patient Interviews and Answering Questionnaires
6. Patient Activation Survey

7. Participant Registration Form
8. SDSMP Curriculum Overview
9. Letter of permission from Harbor Care Health and Wellness Center to utilize archived data for my dissertation
10. Letter of permission from Harbor to conduct follow-up interviews and use the interview data for my dissertation study.

Appendix F

Copyright Permissions

Harbor Care Health and Wellness Center, Incorporated (2016). Consent for Release of information: Authorization to release protected health information.

Antioch.edu Mail - Permission to Publish Harbor Care Consent for Relea... https://mail.google.co



Samu

Permission to Publish Harbor Care Consent for Release o

4 messages

Samuel Collier <[redacted]>
To: Susan Vonderheide <[redacted]>

Hi Susan,

Thank you so much for being on my committee. I wanted to follow up and verify the Harbor Care Consent for Release of Information that I included in my appendices in we discussed this several months ago and that the document is not copyrighted, but going to be okay as the paper will appear on several library databases.

Thanks so much,

Samuel

Susan Vonderheide <[redacted]>
To: Samuel Collier <[redacted]>
Cc: "s.misra" <[redacted]> <s.misra@[redacted]> "j.brown" <[redacted]>

Hi Samuel,

Please ask Dr. Misra and Jonathan Brown to confirm that this is okay! I am shortly. I have cc'd this email to them; contact them directly also if you do week.

Great job, by the way!

Susan

Sarthak B. Misra <[redacted]>
To: Susan Vonderheide <[redacted]> Samuel Collier <[redacted]>
Cc: Jonathan Brown <[redacted]>

Wed, Nov 7, 2016

Yes that's totally fine