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## Association of the use of Combination Therapy Self-Management of Prediabetes and Type-2 Diabetes Mellitus in Adults

Celestina Reed  
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# Walden University

College of Health Professions

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Celestina Reed

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Abstract

Association of the use of Combination Therapy Self-Management of Prediabetes and  
Type-2 Diabetes Mellitus in Adults

by

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MBA, American Intercontinental University, 2014

BA, Ghana Institute of Management and Public Administration, 2008

Dissertation Submitted in Partial Fulfillment

of the Requirements for the Degree of

Doctor of Philosophy

Public Health

Walden University

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## Abstract

Diabetes is a long-lasting chronic health condition that encompasses three types: Type 1, Type 2, and gestational diabetes. The disease affects how the body breaks down food into energy. It is an insulin-deficient disease and causes heart disease, vision loss, and kidney disease. Investigators of the Centers for Disease Control and Prevention and the American Diabetes Association evaluated patient treatment preferences to determine the upsurge in patient health-related quality of life (HRQOL) and optimum health. The literature revealed that patients' preferences consisted of therapies and achievable goal setting using the health belief model (HBM) framework. This quantitative research aimed to predict therapies in diabetes management measured by PROMIS 25 (instrument) for patients with Type 2 diabetes. The generated data were analyzed using Statistical Package for Social Sciences (SPSS, Version 24) *t* test, ANCOVA for significant differences in therapy groups with statistical significance set at  $p < 0.05$ , multivariate logistic regression analysis, Spearman's correlation for the strength and direction of monotonic association between two variables, and possible bivariate analysis to examine associations of concomitant factors. The outcomes from therapy preferences were analyzed using PROMIS 25 mean scores (i.e., managed confidence (Well-being),  $p =$  control symptoms of anxiety (HRQoL), across subgroups, assessed the individual self-efficacy of HRQoL, and Well-being probability, and in the same manner, of optimum and general health outcomes. Social change that increased the patient's willingness to participate in therapies that increased the HRQoL and well-being revealed in the HBM outcome increased patients' positive engagement in lifestyle behaviors that reduced risk.

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## Dedication

Firstly, I dedicate this dissertation to my God, who in His infinite mercies have equipped me with wisdom and strength. Secondly, to my beloved parents, Dr. Nana Opoku-Ampomah, and Regina Coffie, who in their brilliant pursuits made education a common enemy of poverty and human capacity development a family objective. By their exploits, they have encouraged me to achieve greater heights in education up to this level.

I also dedicate this dissertation to the wonderful people who have supported me to accomplish my academic dreams. These are Professor Kwadwo Ansah Koram, Dr. William Rogers, and Dr. Paul Crohmann, who supported my undergraduate education, and introduced me to the world of biomedical research and encouraged me to pursue higher heights academically.

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## Chapter 1: Introduction to the Study

Diabetes is a chronic health condition that encompasses three types: Type -1, Type-2, with exception to gestational diabetes class type A1 and A2. The disease affects how the body breaks down food into energy. It is considered as an insulin deficient disease that causes heart disease, vision loss, and kidney disease (Centers for Disease Control and Prevention [CDC], 2017). T1DM is an autoimmune reaction that halts the body from producing insulin in 5% of people with diabetes and is most often diagnosed in children, teens, and young adults. These individuals generally need to take daily insulin (CDC, 2017). Gestational diabetes develops in pregnant women; it poses a high risk to the baby and has the propensity to increase the risk of both the baby and mother developing type-2 diabetes mellitus later in life. Diabetes as a chronic disease that develops over time and is usually diagnosed in about 90% to 95% of adults (more in children, teens, and young adults) with T2DM. Diabetes generally develops over time, and it diagnosed through blood sugar testing after symptoms become evident (CDC, 2017).

Treatment and careful monitoring to retain a recommended blood glucose range could prevent short-term problems of hypoglycemia and long-term complication effects of the endocrine system due to malfunctioning of the immune, muscular, nervous, reproductive, respiratory, skeletal, and urinary systems (Global Diabetes Community, 2019; Lash et al. 2018). CDC and American Diabetes Association investigators evaluated patient treatment preferences to determine the upsurge of patient health-related quality of life (HRQOL), lifestyle behaviors of healthy eating patterns, and regular physical activity

(Brunisholz et al., 2014; CDC, 2017; Cooke et al., 2013; Deakin et al., 2005; Toobert et al., 2003). Individuals with diabetes are required to make several daily self-care decisions and perform complex care activities. Diabetes healthcare support provides people with diabetes the foundation to navigate these decisions and engage in activities known to improve health outcomes aligned with the current research position focused on people with type-2 diabetes treatment (Powers et al., 2017).

The American Diabetes Association found self-care education and support (DSME/S) as a process that facilitates knowledge, skills, and ability necessary for diabetes self-care implementation (Powers et al., 2017). The initial DSME and DSMS typically provided patients with ongoing support that could be provided by health professionals and a variety of community-based resources. These programs are designed to resolve the patient's health beliefs, cultural needs, current knowledge, physical limitations, emotional issues, family support, financial status, medical history, health literacy, numeracy, and other factors that impact each person's ability to meet the challenges of self-management (Powers et al., 2017).

The DSME and DSMS ensure integration of routine care and recommend all health care providers and systems-developed processes guaranteed to patients with T2DM services and adequate resources available in their communities as support (Wagner et al., 2005). The use of these diabetes education algorithms defines when, what, and how DSME/S should be provided for adults with T2DM (Powers et al., 2017; Wagner et al., 2005). The algorithm focuses on five principles: (a) guidance provision with emphasis on patient engagement, (b) shared information, (c) psychosocial, (d)



behavioral support integration with other therapies, and (e) coordinate care (Powers et al., 2017). Critical times to assess, provide, and adjust DSME/S support include (a) diagnosis of new incidence of T2DM, (b) annual health maintenance, and prevention of complications, (c) new complication factors that impact self-management, and transitions in care occurred (Powers et al., 2017). It is important to know that type-2 diabetes mellitus is a chronic condition, and a situation could arise at any time requiring additional attention to self-care needs. Patient's needs are continuous but also critical; time may be needed to intensify self-care, re-educate on planning, and provide support (ADA, 2015; Powers et al., 2017). The American Association for Diabetes Education seven self-care behaviors provide a framework that identifies topics that include healthy eating, being active, taking medication, monitoring, problem solving, reducing risks, and healthy coping (ADA, 2015).

The global view of patient self-care is central for chronic care through management programs (Bodenheimer et al., 2002). In the past decade the CDC, in collaboration with ADA, implemented patient-centered strategies as per patients' needs appropriate for treatment of chronic diseases in the United States (CDC & ADA, 2015). However, bringing self-care considerations into the management of chronic care can be challenging (Forlobs, 2011).

In the United States, the CDC and the ADA understanding of patient self-care for chronic disease treatment focuses on low participation and uses patient identified groups in diabetes self-care education to inform efforts that improve usage (Berry, 2019). T2DM is found in about 9.4% (30.2 million) of the U.S. adult population (aged 18 years) and

older (Berry, 2019), with almost a quarter of those not knowing they have the condition. Reflecting on the evidence of people living with T2DM in the 1990s, the figures more than tripled the number of new cases in 2010 (Berry, 2019). Amongst them were 4% (18 to 44 years), 17% (45 to 64 years) and 25.2% (65 years and over) of the people living with T2DM. The reasons for this increased risk of development with age and obesity due to combination of genetic and lifestyle factors (Berry, 2019). A quarter of all Americans with T2DM encounter retinopathy that causes vision loss, and blindness. Additionally, about 44% (50,000) of people with T2DM experienced kidney failure treatment and 60% (73,000) experience lower limb amputations. They also lost 113 days of productivity that amounted to \$90 billion (Berry, 2019). These numbers include the underserved individuals with T2DM risk surge concerns about mechanisms and programs success (Reyes et al., 2017) due to less and unavailable resource support. Patient empowerment through traditional programs for these patients has become a challenge in the United States. (Reyes et al., 2017).

Self-care has had several definitions. Godfrey et al. (2011) defined self-care as involving a range of care activities deliberately engaged throughout life to promote physical, mental, and emotional health; maintain life; and prevent diseases. Self-care is performed by the individuals on their own behalf, for their families, or communities, and includes care by others. In the event of injury, disability, or disease, the individuals continue to engage in self-care, either on their own or in collaboration with healthcare professionals (Godfrey et al., 2011). Self-care includes social support and the meeting of social, and psychological needs of individuals with T2DM. Self-care provides the

continuity of care that interactions between the healthcare system, and patients, enables an individual to manage their disease or disability, and maintain well-being as measured by Patient-Reported Outcomes Management Information Systems (Godfrey et al., 2011; PROMIS, 2017).

PROMIS (2017) revealed self-efficacy to manage chronic conditions as universal rather than disease-specific to include (a) perform daily management activities with confidence of daily living without assistance to assess exercise, sexual activities, and manage challenging situations; (b) manage emotions with confidence to manage/control symptoms of anxiety, depression, helplessness, discouragement, frustration, disappointment, and anger; (c) manage medications/treatment with confidence in medication schedules with different complexity as managing medication, and other treatments in challenging situations like travelling, when running out of medication, and when adverse effects are encountered; (d) manage social interactions with confidence in participating in social activities, getting help when needed by managing communication, and communicate with others, including health professional, about their medical condition; and (5) manage symptoms with confidence to keep symptoms from interfering with work, sleep, relationships or recreational activities.

### **Background**

Prevention of disease such as diabetes with the use of adequate therapeutic controls that are timely and evidence-based could reduce the patient burden that negatively impact the economic, financial, mental, emotional, and psychopathological aspects that increases diabetes-associated comorbidities, complications, and mortality in

minority groups. (CDC, 2016, 2017; Healthy People 2020; McEwen & Seeman 1999).

Patient access to treatment programs and access to health care services are less predictable in minority groups reducing improvement in T2DM prevention due to inadequate resource availability to the group (Li et al., 2010; Rodgers, 2018). Increase in financial burden due to out-of-pocket expense for treatment among minority diabetes patients can result in non adherence to antidiabetic medication use and eye exams that hinders T2DM risk reduction (Chou et al., 2014).

Multiple initiative treatment strategies to reduce diabetes-associated challenges to minorities with diabetes are required to lower undertreated and untreated diabetes that rapidly increases growth of diabetes-associated complications (Federally Qualified Health Centers, 2018; Hill et al., 2011; Saaddine et al., 2002). Making intervention of preventive programs and access to health care common reachable to minority groups with increased access to Medicaid/Medicare expansion and privately insured in a similar fashion are significant to public health (Polsky et al., 2015; Wherry & Miller, 2016). Building of primary care capacities and infrastructural support needs for self-care and strengthening minority underserved areas using probability data from the BRFSS noninstitutionalized household adults of the United States to observe effective therapies is optimistic to minority groups (Jackson et al., 2017; Johnson et al., 2015; Schneider et al., 2012).

I used the construct of self-care as my dissertation framework, predicting health behaviors when an individual is susceptible to chronic disease takes an action to perceive the susceptibility, severity, benefits, and barriers with readiness to perform the action to

reduce the risk. I examined three therapeutic strategies and support that literature had suggested for patients with diabetes to reduce their disease risk: (a) good food choices, (b) engaging in physical activity, and (c) taking medication and accessing health care services to monitor progress in minorities as effective intervention. This is part of new discovery evidence-based strategy when participation is timely and planned. It is rare to attain literature on all-inclusive strategies to improve minorities with diabetes health to the optimum level indicating a gap in knowledge (Powers et al., 2017).

Clinical implications that therapies are an effective intervention benefiting patients with diabetes can reduce complications as indicated in both experimental and observational studies. The wide-ranging literature revealed therapy to reduce dysfunction and organ damage (Powers et al., 2017). Hence, I aimed to add to public health practices on the all-inclusive therapeutic interventions that will add insights to newly discovered evidence, and benefits of self-efficacy that seeks to improve patients HRQoL, and optimum health because health belief parameters of patient's preference for treatment considered through self-care leads to prevent, and curtail diabetes progression (see Powers et al., 2017).

The research has enhanced understanding of these management strategies of all-inclusive therapy in chronic disease control like T2DM. The study has also added to the current knowledge of T2DM timely and effective management in contrast to other long-term chronic diseases such as cystic fibrosis (CF) that are not curable (see Zolin et al., 2018). CF is a hereditary chronic disease, with primary defect to the lungs, and digestive system, a condition that potentially threatens life span by shortening it. CF produces thick

and sticky mucus that can clog the lungs, and obstruct the pancreas (Zolin et al., 2018). Conversely, CF is comparable to T2DM with no cure and management of symptoms to improve health-related quality of life. The disease symptoms vary, and treatment plans are individualized as T2DM.

The literature on early detection of diabetes demonstrates that therapy in the treatment of T2DM meets clinical criteria of reducing risk to the vital organs in the body while also providing patients the flexibility to incorporate the symptoms into daily life. The use of diabetes self-management education and support DSME/S to administer therapy where they are mostly guided by health professionals and facilitators on timely planned achievable goals (Powers et al., 2017).

The aim of this research was to fill the knowledge gap whether there are any differences in therapies individually by themselves or collectively for effectively managing patient's groups of users against nonusers. Since a patient's response to treatment may differ relative to patient preferences to therapies, the current study is thus needed to enhance understanding on whether the outcomes of therapies improve HRQoL, and optimum health as measured by PROMIS 25 in patients with T2DM or chronic diseases.

### **Statement of Problem**

The research problem I addressed was the gap in literature related to the use of all four effective therapies. These consist of good food choices (e.g., vegetables, fruits, and protein), physical activity (e.g., jogging, biking, swimming, walking, running, and aerobics), medication (e.g., insulin, noninsulin, or alternative medication) and access to

health care service monitoring (routine check of A1C, diabetes self-management education DSME, and support DSMS) in minorities with T2DM to improve HRQoL and Well-being, as measured by PROMIS 25. Factors related to poor HRQoL consist of comorbidities, employment status, stress, multiple infections, and delay in T2DM diagnosis. Other factors related to improved HRQoL consist of home-based therapy, treatment comfort, flexibility, convenience, independence; short treatment duration with less disruption to activities of daily living (ADL) such as work, school, and social life, and satisfactory blood sugar levels (Ghazavi et al., 2015; PROMIS 25). Zhao, et al. (2018) showed below average number of patients with T2DM (19%,  $n=251$ ) were connected to self-care activities, stress, and exhaustion; however, women, compared to men, were more susceptible to stress, and anxiety, and people who had diabetes more than 5 years.

So far, the literature has not elaborated on changes in HRQoL and Well-being as dependent variables to include all therapies using PROMIS 25 instrument in a population of patient with T2DM. Factors affecting improved health in minorities with T2DM include delay in diagnosis, comorbidity, demographics, socioeconomics, psychological aspects, and psychosocial attributes. The above have been a challenge to minority groups in the United States (Brown, Ang et al. 2007). Overall, prevalence rate for most affected was higher in American Indians/Alaska Natives (15.1%), Blacks non-Hispanic (12.7%), Hispanic ethnicity (12.1%), Asians (8.0%) than in non-Hispanic Whites (NDSR, 2017). Globally, the rates of T2DM since 1980 have increased from 108 million to 422 million in 2014 (CDC, 2015). Mathers and Loncar (2006) projected that mortality arising out of

T2DM will be the seventh leading cause of death by 2030 for all ages. In 2015, 30.3 million people, or 9.4% of United States population had T2DM (CDC, 2015). Of these, 30.2 million cases were adults (18 years and older) affected by T2DM were 45-64 age group as the most affected. T2DM proportionately affect both men and women with approximately 15.3 million men and 14.9 million women with T2DM (CDC, 2015). This rate is projected to increase significantly by 2050, with an increase of 18 million cases among the fastest growing ethnic group, African Americans. Evident in the 2015 ADA report, prevalence rate increase for Black males by 363% and females 217% more than White males 148%, and females 107% from 2000 to 2015 (ADA, 2015) as shown in the ethnic demographic composition changes across race that included Whites non-Hispanic 7.4%, Asian Americas 8.0%, Hispanics 12.1%, Blacks non-Hispanic 12.7, and 15.1% American Indians/Alaskan Natives (ADA, 2015).

Taking control of T2DM to improve the health-related quality of life focuses on the need for additional support and new insights into therapies appropriate to an individual need. Although education, economics, new treatments, technology, research, and development have contributed to controlling T2DM in most individuals, the challenges of T2DM self-management are overwhelming for minorities (AHRQ, 2017). T2MD is a chronic disease for which controlling the condition demands on patients' ability to learn self-management skills, and practices like regular blood glucose levels monitoring, combination of therapies comprising healthy dietary and physical activities well as routine oral medications (ADA, 2018). However, minorities in America are underserved due to inadequate care resulting from limited health care access, health



insurance, and high-risk exposures from social, and environmental contributors (ADA, 2018; Saban et al., 2014; Spanakis & Golden, 2013). Generally, addressing T2DM health disparities in the United States. minority patients with T2DM frequently received fewer foot and ophthalmological examinations (ADA, 2018; Saban et al., 2014; Spanakis & Golden, 2013). Similarly, these individuals were less likely to receive other preventive health care services as Whites (Beckles et al., 1998; Thackeray et al., 2004). The future, however, requires investigations into predisposing risk factors of T2DM among minorities in the United States, the incidence of T2DM complications, and measures to improve self-management of T2DM, and inform policies on health professional practices, and health systems.

### **Purpose of Study**

Through this quantitative study, the mean differences in HRQoL and well-being as measured by PROMIS 25 for patients with T2DM who are using behavioral change lifestyle factors consisted of (a) good food choices, (b) physical activity, (c) medication, and (d) access to health care service monitoring were predicted. The dependent variables were PROMIS 25 instrument measures of anxiety and despair associated with HRQoL and participation in ADL's related to overall life satisfaction as a representation of well-being (see HealthyPeople.gov, 2017). The predominant purpose for this research was to encourage minority patients' participation in four inclusive therapies through self-care programs to obtain optimum HRQoL and well-being in day-to-day management of the chronic disease. The outcome of this research has the potential to increase the body of scientific knowledge supporting the patient reported outcomes of HRQoL and well-being

as effective contributions to new discovery insights of preventive self-care practices and inform CDC and ADA decision making in the health management system (see ADA & CDC, 2015).

### **Research Questions and Hypotheses**

RQ1: Is there a significant statistical association between decreased well-being proxy PROMIS score (managed confidence) for T2DM present that determines optimum health in ethnic groups who utilized combination therapy for self-care, controlling for age, gender, education level, income status, and ethnic group?

*H<sub>0</sub>1*: There is no significant statistical association between decreased well-being proxy PROMIS score “managed confidence” for T2DM present that determine optimum health in ethnic groups who utilized combination therapy for self-care.

*H<sub>a</sub>1*: There is significant statistical association between decreased well-being proxy PROMIS score “managed confidence” for T2DM present that determine optimum health in ethnic groups who utilized combination therapy for self-care.

The following were the independent variables for RQ1: Ethnic/race groups, age, gender, and therapies (e.g., total number of times T2DM patient made good food choices; ate vegetables, fruits, and protein; engaged in physical activity like jogging, biking, running, walking, swimming, and aerobics; medicated with insulin, noninsulin and/or alternative; and accessed healthcare services included routine checks and times seen by health professional for diabetes DSME, and DSMS). The dependent variable was the well-being proxy PROMIS score “Managed confidence” (Diabetes presence; have you ever been told that you have diabetes).

RQ2: Is there a significant statistical association between increased HRQoL proxy PROMIS score “Control Symptoms of Anxiety” for general health, and total number per day/week therapy is participated in controlling for age, gender, education level, income status, and ethnic group?

*H<sub>0</sub>2*: There is no significant statistical association between increased HRQoL proxy PROMIS score “Control Symptoms of Anxiety” for general health, and total number per week therapy is participated.

*H<sub>a</sub>2*: There is significant statistical association between increased HRQoL proxy PROMIS score “Control Symptoms of Anxiety” for general health, and total number per week therapy is participated.

The following served as the independent variables for RQ2: therapy participation (e.g., total vegetables consumed per day/week, fruits consumed per day/week, protein consumed per day/week, total physical activity per day/week, medication; non taking insulin/taking insulin/alternative medication, and times seen by health professional for diabetes DSME and DSMS), age, education level, gender, income status, and ethnic group. The dependent variable for RQ2 was the HRQoL proxy PROMIS score for “Control Symptoms of Anxiety” (General Health = Control Symptoms of Anxiety)

RQ3: Is there a significant statistical association between increased HRQoL proxy PROMIS score “Control Symptoms of Anxiety” for general health, and timely examined blood glucose levels, eyes and foot controlling for age, education level, gender, and income status, and ethnic group?

$H_03$ : There is no significant statistical association between increased HRQoL proxy PROMIS score "Control Symptoms of Anxiety" for general health, and timely examined blood glucose levels, eyes, and foot.

$H_a3$ : There is a significant statistical association between increased HRQoL proxy PROMIS score "Control Symptoms of Anxiety" for general health, and timely examined blood glucose levels, eyes, and foot.

The independent variables for RQ3 were examination time (how often check blood for glucose, foot, and eye), age, education level, gender, income status, and ethnic group. The dependent variable was the HRQoL proxy PROMIS score for "Control Symptoms of Anxiety" (General Health = Control Symptoms Anxiety)

### **Theoretical Framework for the Study**

The dissertation theoretical framework I used was Hochbaum, Rosenstock and Kegels's (1958) health belief model (HBM) that was created by social psychologists and from workers of public health in the United States to understand self-defeating health behaviors. The focus was on the attitudes and beliefs of individuals for the public health services by social scientists of the 1950s to understand peoples' failure to adopt disease prevention strategies or early detection of diseases through screening tests (Hochbaum et al., 1958). Later the HBM was used for patients' responses to symptoms, and medical treatment compliance (Glanz et al., 2015).

Hochbaum et al. (1950) proposed the HBM drives psychological, and behavioral theoretical bases of health-related behaviors: (a) desire to avoid ailment and (b) belief that a specific health action could prevent the ailment. Eventually, the proponents

suggested an individual's action is often dependent on the perceptions of benefits, and barriers associated with the health behavior. Overall, there are six constructs for the HBM. The initial four constructs were developed as the original tenets, and the last two were added as research evolved about the HBM. The original constructs included (a) perceived susceptibility of the disease, (b) perceived severity by the individual feelings of having the disease, (c) perceived benefits to reduce the disease threat with effective action, (d) and perceived barriers as hindrances to perform the recommended health action. Cue to action stimulates the need toward decision to accept recommended health action and self-efficacy promotes level of confidence to perform the behavior successfully (Glanz, et al., 2015; Hochbaum, 1958).

The framework helped me identify individuals' belief in the personal threat of an illness such as T2DM coupled with personal belief in the effectiveness of the recommended health behavior like good dietary choices, physical activity, medication, and access to health predicts the likelihood an individual will adopt the behavior by setting achievable goals. This framework aligned the study approach and was appropriate for the research questions about self-care with combination therapy founded on self-efficacy that predicts change in behavior in the target group (see Glanz, et al., 2015).

### **Nature of the Study**

A population study with a national outlook on participants from a noninstitutionalized stratified sampled data of the United States population households of 2017 annual surveillance system was evaluated. I reviewed a random sample of 15,000 to 20,000 individuals with emphasis on objective measurement of

statistics, and numerical analysis of the secondary data surveyed. The following variables were examined as independent variables: ethnic groups (American Indians/Alaska Natives, Blacks non-Hispanic, Hispanic ethnicity, Asians, and non-Hispanic Whites), therapies, total participation times for physical activity per week, fruits consumed per day/week; vegetables consumed per day/week, not taking insulin, times seen health professional for diabetes, examination time (how often the person checks blood for glucose), times feet check for sore/irritation, and last eye exam where pupils were dilated against the dependent variables through PROMIS scores of HRQoL (for symptoms control in-relation to therapy participation, and examination times) and wellness (through managed confidence in-relation to using all-inclusive effective therapies) that included the variables of optimum health (have you ever been told you have diabetes?) and general health. Factors such as age, gender, neighborhood, educational level, income status, and race, which may be potential confounders, were used as controlled factors. I used a cross-sectional design to attain the differences of effects that reflected the study population engaged.

I used a logistic regression to analyze the data and statistical tools such as comparing means to assess the deductive logic of the differences in means of ethnic groups and therapy effect on T2DM impact on overall Well-being, times of participation, and physical examination impact on HRQoL. Analysis of variance (ANCOVA) statistical model was used to investigate the strength of the association between therapies, and T2DM risk as per PROMIS 25 in chronic disease patients (PROMIS, 2017). Meaningful and useful inference were drawn from scores of the BRFSS survey instruments,

measured, and the report results were analyzed, or I (a) validated the intended contents of measure, (b) predicted scores by criterion measure (if results correlate with other results), and (c) constructed validity (measure hypothetical constructs). The dependent variable was the PROMIS 25 instrument which measures HRQoL, and Well-being through managed confidence with therapy use, and control symptoms of anxiety by improving physical, social, and emotional Well-being, were adapted into the entire quantitation processes (see PROMIS, 2017; Spanakis & Golden, 2013; Tinker, 2018)

### **Definitions**

*Cue to action:* To instigate action when perceived susceptibility and perceived benefits are crucial to active internal symptoms, feeling and external recommendation from a physician during an office visit (Hochbaum, 1958). Otherwise, cues operate mainly through perceived threat (Strecher & Rosenstock 1997).

*Health-Related Quality of Life (HRQoL):* HRQoL tracks the health of individual patient, measure and allow for comparison across health conditions. Physical functioning, depression, and pain with one or more chronic disease are measured (Hanmer et al., 2015).

*Managed confidence:* Self-efficacy for managing chronic conditions.

*Managed daily activities:* Confidence to perform various daily living activities without assistance. This included items such as exercise, sexual activities and managing challenging situation activities.

*Managed emotions:* Confidence to manage/control symptoms of anxiety, depression, helplessness, discouragement, frustration, disappointment, and anger.

*Managed medications/treatment:* Confidence in managing medication schedules of different complexity. Managing medication and other treatment in challenging situations like when travelling, when running out of medications, and when encountered adverse effects.

*Managed social interactions:* Confidence in participating in social activities and getting assistance, when necessary, by managing communication with others about their medical condition, which includes health professional's communication.

*Managed symptoms:* Confidence to control/manage symptoms, to manage different settings and to keep symptoms from interfering activities of work, sleep, relationships, or recreation.

*Patient-Reported Outcomes Measurement Information System (PROMIS 25):* A universal self-efficacy banks of questions for adult respondent ages 18 years and older and have at least one chronic health condition. PROMIS is a National Institute of Health (NIH) modified toolbox on self-efficacy items. Self-efficacy is explained as confidence in one's ability to successfully perform specific behaviors or tasks.

*Perceived barriers:* Hindrances or obstacles to the action taken like negative consequences from an action. Consequences impede the action or subsequent engagement in the behavior. Obstacles may be cost or fear of screening procedure or psychological such as becoming anxious.

*Perceived benefit:* Patient beliefs about positive features or advantages about a recommended action to reduce the threat (combination of susceptibility and severity).



*Perceived severity:* Patient beliefs of the seriousness of contracting a disease or condition or leaving a condition untreated to include consequence such death, disability, pain, and social consequences on ability to work, maintain relationships with others or feel stigmatized.

*Perceived susceptibility:* Patient beliefs about the likelihood of getting a disease or condition and willingness to act through screening.

*Well-being:* Several dimensions that consisted of emotional Well-being (coping effectively with life and created satisfied in relationships) and physical Well-being (recognized the need for physical activity, healthy foods, and sleep; NCCIH & NIH, 2018).

### **Assumptions**

I made four assumptions in this study. Firstly, I assumed that the BRFSS sample obtained is representative of the chronic disease and conditions, health risk behaviors, access to health care, and use of preventive health services as well as the associated death and disability in the United States, whose treatment preferences inform CDC and ADA new-evidence discovery. Secondly, I made the assumption that lifestyle changes such as good food choices, physical activity, medication, and access to health care services collective approach for minority groups with willingness to engage inform optimum health, HRQoL/QALY, and affect total life satisfaction to optimize Well-being. Thirdly, I assumed treatment therapies are mutually exclusive in T2DM treatment as an effective strategy, and finally that PROMIS 25 measures are crucial to minorities with T2DM treatment to inform change in the group's behavior.

### **Scope of Study**

Diabetes affects both adults and children of United States households, the noninstitutionalized members surveyed for the BRFSS database. However, I incorporated only patients who were 18 years and over and fit the liberal definition selection of adults in the study. The rationale in support identifies with the sample size variation and evidence of the likelihood to develop the condition increases drastically with aging. With an emphasis on adults 45 years and older being prominent to have diabetes. In this study, adults 18 years and overrepresented 54 states of permanent United States households from noninstitutionalized information, facilitated on large sample size (BRFSS, 2018). Secondly, several therapies and support for treatment (ADA, 2015; CDC, 2015; Powers et al., 2017). This study captured only T2DM in the general heading of diabetes and without segment of subtypes.

### **Limitations**

Blome and Augustin (2016) proposed a subjective well-being (SWB) approach emphasized on the emotional component of subjective well-being to quantify recall bias for clinical trials, rather than HRQoL due to biases that exist when measuring patient-relevant treatment benefit either prospectively or retrospectively. My research was a retrospective study where exposures to suspected risk information was gathered by researchers and respondents are annually surveyed. Retrospective studies are subjected to recall bias respondent shift to reprioritized, reconceptualized, and recalibrated for which they have argued SWB as a measure of only recalibration than not reprioritized and A second aspect of bias relates to symptoms assessment in HRQoL. The inclination to

respond to symptoms in HRQoL for change pose differentiation difficulties between actual benefit and potential double counted benefits (Blome & Augustine, 2016). Blome and Augustine suggested retrospective study (recall bias) for patient reported outcomes over prospective study (response shift) to evaluate patient position on changes of treatment benefit; reconceptualized validity threat, and response bias from lack of data (Blome & Augustine, 2016).

### **Significance of the Study**

The attained information of the study could assist T2DM management education, and advocate communities to work changes in HRQoL and well-being parameters resulting from using all-inclusive effective therapies to perceive quality of life for populations with chronic condition in a more dynamic manner (ADA, 2018; CDC, 2017; Zurita-Cruz et al., 2018). For example, it will inform surveillance development with patient perceptions of effective treatments required, increase impact of health and social participation of behavioral lifestyle within their current environment, and improve rate of participation and safety practices. Once this information becomes available to the population, such insight could bring hope and promote engagement in therapy in the underserved population and become useful for refining treatment development conventions and safety practices in the future related to behavioral lifestyle changes. An extensive evidence-based discovery of combination therapy consisted of a healthy diet choice, physical activity, and effective medication through a self-participatory program, and access to health care services. Social change that increased the patient willingness to participate in therapies that increased the HRQoL and well-being. Thus, improved the

overall life satisfaction; reduce the disease physical impact, mentally, and socially, of the researched population (see Gebremedhin et al., 2019).

### **Summary and Transition**

Chapter 1 featured information about self-management with combination therapy. The role of individual willingness of action to participate in improving HRQoL and achieve optimum care were indicated as crucial to public health new evidence-based treatment for minority with diabetes. The next chapter reveals the fundamentals of the study concerning; existing literature, the gaps in the literature, and strategy of the literature search, theoretical framework; health belief model, other constructs, and literature review of the studies that used health belief model constructs, autoimmune disease management aspects of; the patient role, the role of disease control/advocate groups of the CDC and ADA, and the health system of the targeted population, treatment options; treatment outcomes, and patient therapy participation, patient-centered care, and patient reported outcomes; HRQoL, optimum health, and PROMIS.

## Chapter 2: Literature Review

The gap in literature relative to all-inclusive therapy through self-care problem is addressed in minority groups with T2DM. The literature revealed whether individual participation in healthy eating, physical activity, medication, and access to health care and monitoring could improve HRQoL and attain optimum health as measured by PROMIS 25, where the probability of managed confidence is equal to controlled symptoms of anxiety due to T2DM. My goal with this study was to determine the mean differences in HRQoL and Well-being of minorities in the United States measured by PROMIS 25 for patients with T2DM who participated in all-inclusive therapy that includes healthy eating, physical activity, medication, and access to health care services.

The literature review focused on the following areas:

- Literature search strategy
- Theoretical framework
  - Health Belief Model/ other Constructs
  - Literature review of Studies that Used Health Belief Model Constructs
- Autoimmune Disease
  - The Role of the Patient
  - The Role of the CDC and ADA
  - The Target Population and Health System
- Treatment Options
  - Treatment Outcomes
  - Patient Participation and Patient-Centered Care

- Patient Reported Outcomes: HRQoL and Optimum Health
- PROMIS
- Summary and Transition

### **Literature Search Approach**

I reviewed literature impartially with emphasis on an objective approach to biomedical study. A positive stance that suggested factual knowledge is gained through observation to include measurement as trustworthy (Collins, 2010), but then determination and voluntarism are strongly influenced by the management of patient's emotional problems that trigger action and behavior (Collins, 2010). Yet, it would be useful to consider psychosocial limits together with patient's subjective experience to growth of behavior (Wilson, 2000). The reviewed literature was conceptualized to establish a progressive paradigm shift that included patient's opinion of modernized biomedical study.

The literature search followed guidance that connects patient's disease and treatment with questions about how the patient identified with the disease as well as demographic and environment factors to reveal how some have improved through biomedical outcomes (e.g. explains how the patient perceived the disease condition due to severity with controlled symptoms of anxiety as evidence of treatment with managed confidence through self-efficacy) and psychosocial outcomes (e.g. tailored the patient to set achievable goals, participate lifestyle behaviors, and self-report the perceived benefit, barriers, and challenges) that reveals optimum health than others.

I searched for key words in the databases located under the Walden University Library, Health Sciences Research. The searched databases included MEDLINE with Full Text, CINAHL Plus with Full Text, PubMed, ProQuest Nursing & Allied Health Sources, Science Direct, and Thoreau. Keywords used included *chronic disease or chronic illness, autoimmune disorders AND prevention, optimum health AND self-care, effective lifestyle behaviors, disease burden AND behaviors, effective treatment preferences AND access to healthcare, self-management AND support, patient-centered, and patient-reported outcomes, and T2DM.*

I searched for peer-reviewed research on chronic disease prevention, treatment, and therapy published in the years 2015 and 2019, except for health news, and seminal literature included in the context of the review due to chronic disease such as T2DM disability-related, comorbidity, complications, and mortality. I excluded articles that solely focused on Type-1 diabetes, gestational diabetes of pregnant women, and children I left out incurable illness and psychological disorders due to the known biological cause of diabetes and lifestyle factors.

I used timely, nonscholarly transcripts of patient-centered collaborative work from the CDC and ADA as well as the Federally Qualified Health Centers preventive behavioral programs as means to clarify patient perceptions. These patient-centered programs are a series of public health efforts and education focused on lifestyle specific changes with patient involvement, family, health professionals, and advocacy institutional contributions that have further revealed understanding into life with chronic conditions, prevention options, treatments used, and anticipated studies, and future health promotions

(see CDC, 2017; ADA, 2018; FQHC, 2018). Those preventive techniques accounted for connections to the commonality, historic, and attempted efforts of treatments established. These materials have assisted to reshape thoughts of self-management education and self-management support discussions, questions that promote HRQoL and optimum health measures presented in the current study. Websites of advocacy organizations such as the National Institute of Diabetes and Digestive and Kidney Disease, NIH and the Endocrine Society's sources were accessed to expound the considered variables of the study. Finally, websites such as Agency for Health Research and Quality's, National Academy of Sciences Engineering Medicine (NAP), Kaiser Family Foundation, and ADA were searched as well.

### **Theoretical Framework**

The selected theoretical framework for the study was the health belief model. This framework asserts that prevention and treatment must involve the entire individual to include the biological, psychosocial, and social engagements (Hochbaum et al., 1958). The framework accounted for biological aspects (i.e., organ system, organs, vital signs, physical structure, mental membrane, kidneys, heart, eyes, blood vessels and nervous system), psychological (behaviors, emotions, and perceptions), and sociodemographic (places, and people who assist patients in their activities of daily life (ADLs) transitioned at home, work, doctors' office, places of worship, relationships, engagements, and groups). Self-care therapies such as dietary changes, physical activity, and medication, as well as access to health care and monitoring of progress, programs for T2DM education, and support programs developed and approved by CDC and ADA, through biomedical



studies by observation and clinical trials for safety and effectiveness informed treatment options. These biomedical studies included biological measures of molecular mechanisms that control blood sugar levels with dietary patterns, used transcripts of epigenomics, proteomics, metabolomics, and microbiomes, integrated from diverse omics technologies for the nutritional systems (Zhao et al., 2015). Similarly, the biological measures for physical fitness achieved through exercise buffer against stress-related diseases that optimize effects on hormonal stress responsive systems such as the hypothalamic-pituitary-adrenal axis, and the sympathetic nervous system (Silverman & Deuster, 2014). This blunting appears to reduce emotional, physiological, and metabolic reactivity as well as increase the positive mood, and Well-being (Silverman & Deuster, 2014). Another mechanism of regular exercise and/or physical fitness may confer resilience by reducing excessive inflammation (Silverman & Deuster, 2014).

The biological measures of medications and insulin therapy work to lower glucose production, stimulate the pancreas, secrete more insulin, and improve the body's sensitivity to insulin to slow digestion and assist lower blood sugar levels (Mayo Clinic, 2019). Patient support groups and advocates wanted to support studies intended to observe and estimate patient treatment response benefits with current treatment combination, and preferences that maintain healthy lifestyle, facilitates active behavior and lowered overeating (Blair, 2009; Galper et al., 2006; Goetzel et al., 2012; Kohl et al., 2012; Pratt et al., 2012; Shomali, 2012; Wen & Wu, 2012). The CDC and ADA pursues user decision making through biomedical contributions of clinical studies and patient reported outcomes collected during clinical trials and observational studies on T2DM management (Powers et

al., 2017). A search of the literature that showed research in the population with T2DM patient-reported treatment outcomes is presented in Table 1.

The disability, comorbidity, and complications were secondary framework I used to explain the potential association of independent and dependent variables. These help to explain the reasons behind an individual considered for observation in alignment with lower HRQoL relative to progressive malfunctioning of the immune, muscular, nervous, reproductive, respiratory, skeletal, and urinary systems sought self-care for a better HRQoL as compared with healthy individuals in a specific population (Global Diabetes Community, 2019).

### **Health Belief Model / Other Constructs**

Hochbaum et al. (1958) proposed the HBM as it drives psychological and behavioral theoretical bases of health-related behaviors: (a) desired to avoid illness and (b) belief in a specific health action could prevent the illness. Eventually, the proponents suggested an individual's action is often dependent on the perceptions of benefits and barriers associated with the health behavior. Overall, there are six constructs for the HBM. The initial four constructs were developed as the original tenets and the last two were added as research evolved about the HBM. The constructs include (a) perceived susceptibility of the disease, (b) perceived severity by the individual feelings of having the disease, (c) perceived benefits to reduce the disease threat with effective action, (d) perceived barriers as hindrances to perform the recommended health action (e) cue to action stimulates the need toward decision to accept recommended health action, and (f)

self-efficacy promotes level of confidence to perform the behavior successfully (Glanz, et al., 2015; Hochbaum, 1958).

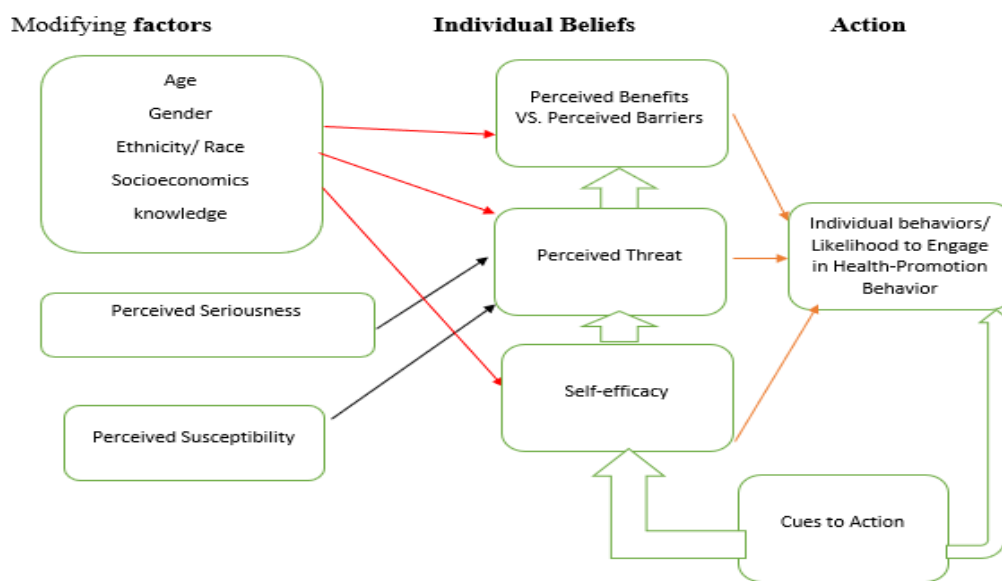
A framework that identified the individuals' belief in personal threat of an illness such as T2DM adds to the personal belief in the effectiveness of the recommended health behavior such as good dietary choices, physical activity, medication, and access to health care and predicts the likelihood that the individual will adopt the behavior by setting achievable goals (Hochbaum et al., 1958). Aligned to the study approach and appropriate for the research questions is self-care with combination therapy, founded on self-efficacy for the target group (Glanz, et al., 2015). The constructs of the HBM have been substantiated empirically on strength of prediction of health behaviors in cross-sectional and to some extent experimental intervention studies. It has proven to identify correlation of health behavior that may be crucial in motivating behavioral change and useful to inform intervention design and evaluation (Albarracin et al., 2005; Leventhal, et al., 2003).

The model illustrated in Figure 1 relays the pathways through which the constructs connect each other and to health behavior by showing the HBM tenets in relationship to the variables being studied in this dissertation. Operationalization of the HBM are the inputs of sociodemographic that includes age, sex, race, education, or socioeconomic concerns that may moderate relationships between health beliefs and health behaviors. For example, because T2DM is more prevalent in older individuals, the age of a person may moderate the relationship between perceived threat and diabetes prevention behaviors such as self-care through therapy (e.g., dietary, physical activity,

medication, monitoring, and access to health services support), with the outcome that older people may believe themselves to be at greater risk for T2DM and rate T2DM as a more severe disease than younger adults. The modifying factor acyclic graphs are indicators of potential confounders that may introduce conditional associations and minimize bias.

**Figure 1**

*Pathway Indicator of HBM*



*Note.* Adapted from Hochbaum G. M. (1958)

Chronic disease threatens the body with dysfunction that is restorable through medical, and/or physiological, and psychological interventions. Given type- 2 diabetes

typical condition, challenges with blood glucose levels and elevated A1C level may signal the need for medication change, meal plan or activity level. In addition to the A1C test, periodically followed measurements of blood pressure, blood and cholesterol levels, thyroid, liver, and kidney function as well as regular eye and foot exams are indicated. Chronic disease further confronts physiological life with reduction in participation, decision, planning, and socializing. Socioeconomically reduced productivity (i.e., less work time, household management, income, and hobbies such as hiking or gardening), that increases the disease threat psychologically to hurt (attitudes, emotions, affiliation, and despair) and then reduce ability to self-care (World Health Organization, 2015).

### **Literature Review of Studies that Used the Health Belief Model Constructs**

#### ***Program Participation and Goal Achievement***

The T2DM articles seen in the literature search used Health Belief Model, while other articles adopted; the Grief Model, illness appraisal, and coping model, Orem's self-care, and shift perception model to further reveal the individual reaction towards chronic disease presence. In addition, the literature illustrated the use of the models in clarifying the association of the dependent and independent variables of most chronic disease conditions. A summary of such literature is presented in Table 2. Glanz, et al. (2015), studied several behavioral theories' engagements that inform behavior change, for which this study addressed the individual patient reported level concerns in perspective of the health belief model, and related models in support of the main theory to explain the impact of chronic disease and benefit of treatment that surpasses barriers and challenges the individual encountered which include health behaviors that

impact his or her perceptions of the chronic disease threat. The severity of the illness, and consequence of perceived hindrances of their behavior change and beliefs about the benefits of the behavior change that improves HRQoL (Glanz, et al., 2015). Thus, the patient's initial belief of being at risk of the illness, and/or the complications prior to behavior change occurrence reduced the risk, the risk perception crucial role played in developing healthy behaviors, such as dietary changes, exercise, medication, and monitoring, and health care services access (Janz & Becker, 1984). Due to prevalence, comorbidity, complications, and mortality outcomes associated with diabetes, African Americans were disproportionately a subgroup of the minority (Chow et al. (2012); Janz & Becker, (1984)). They had found among the South Side communities, where many individuals with diabetes engaged in self-care, believed their risk for diabetes-related complications was expressively greater than reported (Chow et al., 2012; Peek, Ferguson et al., 2014).

Chow et al., (2012) argued intervention targeting disparity prevention in minorities defines anxiety and depression related to complications (i.e., blindness, amputations, kidney failure, heart attack, and stroke) from diabetes as inevitable psychosocial threats to patients experience with friends and family members, and economic burden on health care system and the individual. This research conventionally identified the related independent variables of the HBM, aspect of biomedical as (i.e. age, gender, race, socioeconomics, knowledge); psychological (i.e. proven anxiety and/or depression, mental health and professional doctor visits) aligned with perceived seriousness, and susceptibility that perceived the chronic disease threat,

socioeconomics (i.e. annual income, education level, marital status, and demographics); aligned with perceived barriers against the benefits, self-efficacy influence the belief to achieve the required behavior that promotes health outcomes from the cues of action. The dependent variables of T2DM that explains optimum health with therapy scores, managed confidence and controlled symptoms taken general health scores for HRQoL self-rated of health, and mental health status had inconsistently related stoical beliefs of majority of patient's "denial" as a coping strategy to deal with diabetes (Peek et al., 2009).

Although Peek, Ferguson et al. (2014) had studied the risk factor reduction and benefits of behavioral change and found the key objective of diabetes being a chronic disease as controllable, with risks of complications that could be significantly reduced by the individual's decisions, and behaviors. Nundy et al. (2014) promoted the insight of self-reported individuals with diabetes or condition through text messages designed to impact health beliefs, with program participants whose health beliefs had changed due to their perceived risk of long-term complications significantly at the program completion (Nundy et al., 2014).

To conclude, the approach of behavioral medicine with acknowledgement to complexities of behavioral change, which reflect the crucial use of multiple strategies, and systems, that support behavior change in individuals with T2DM is an effective intervention (Nundy et al., 2014; Peek, Ferguson et al., 2014). Nundy et al. (2014) noted that patients who made behavioral intervention central, needed significant time to identify strategies that modify health beliefs, enhance self-efficiency, and change

cultural norms of behavioral change (Nundy et al., 2014; Peek, Ferguson et al., 2014). Peek, Ferguson et al. (2014) noted that, individuals who lived in social communities with families, friends and peers, whose support had proved invaluable to patients initiated or sustained behavioral changes, and health systems as well as larger policy changes are now on the cutting edge of impacting the individual level behavior changes (Peek, Ferguson et al., 2014). The benefits of the 21st century South Side Diabetes Project use of a comprehensive approach support to behavior change in individuals with T2DM, and strategies that improve health behaviors as well as health outcomes of participants are presented in the consensus report of Marrero et. al., (2013). Evidence of the study revealed that the individual level participant benefited from the HBM, rather than social communities, health systems, and larger policy changes of the Ecological Model, makes the HBM appropriate for the current study (Nundy et al., 2014; Peek, Ferguson et al., 2014).

Peek et al. (2014) also distinguished lifestyle changes, education, and self-care as all necessary to T2DM patient, as well as the historical processes discussed in the clinical setting, or face-to-face in education programs or support groups (Peek, Ferguson et al., 2014). Peek, Ferguson et al., (2014), and Zrebiec & Jacobson (2001) emphasized technology permitted collaboration virtually through community, as an effective means of communicating about chronic disease management, which are mostly assessed through the internet for health information, preferring interactive exchanges of health information over static education information as crucial to health promotion (Peek, Ferguson et al., 2014; Zrebiec & Jacobson,2001). Brown, Lustria et



al. (2007) had found technologies that combine the broad reach of mass media with interactive abilities help patients, and providers to deal successfully with complexities of the disease improving the system of care, expanding the reach of interventions, and empowering patients to engage in self-care behaviors (Brown, Lustria et al., 2007).

Brown, Lustria et al. (2007) highlighted interpersonal media provision increases a wide range of advantages over standard delivery modalities. The technical affordances of web delivery tailored appropriately, and timely to reinforce education messages, offered social support, improved feedback, and increased participation, and also correlated significantly to improved health outcomes. Bandura (1997) recapitulated self-efficacy as key component of HBM with sense of confidence of an individual ability to perform an activity as a crucial precursor to behavioral changes. Bandura (1997) portrayed self-efficacy from mastery experience, social persuasions, physiological factors, and social modeling. Mastery experience expresses the small success that increases individual's self-efficacy more likely than not believe they could do something continually if they have seen for themselves that could be done at least one time. Mastery experience was one of the main goals of the "South Side Diabetes Project" that provided opportunities for small success in diabetes self-care, and management through experimental learning. A typical practical example for a diabetes class included participants activity engaged in ordered food role, read food labels from local restaurant menus, engaged in chair-based exercises of jazz music, and participated in dialogue with physicians on recommended medications. The program allowed an individual opportunity to master the experience through a guided

shopping tour with budget options for healthy dietary, cooking demonstrations, and community cook-off events as well as “Question the Doctor” opportunities at community venues, for which communities engaged physicians on the research team, and inquired about general questions of health/health care, as element of self-efficacy (Skaff et al., 2003; Walker et al., 2003).

Aljaseem et al. (2001), and Peek, et al. (2014) views on self-efficacy sometimes included several models and could be defined as an individual’s judgement regarding his or her ability to execute, plan, and monitor activities daily. Self-efficacy has several empirical literatures in its association to health behaviors, specifically medication taking behaviors, physical activity, and dietary (Ajaseem et al., 2001; Peek, et al., 2014). Individuals with greater levels of self-efficacy were less likely to skip routine good dietary choices, regular physical activity, and doses of medication. Self-efficacy reveals 4% to 10% variation in diabetes self-care behaviors in 309 patients’ study with type-2 diabetes mellitus (Ajaseem et al., 2001; Peek, et al., 2014). Self-efficacy was found to be a significant predictor of adherence to diabetes treatment for insulin, and non-insulin dependent patients with T2DM. Self-efficacy has been revealed as a prognosticator of behavior change that is maintained over time (Ajaseem et al., 2001; Peek, et al., 2014). Kavanaugh et al. (1993) revealed self-efficacy as a significant predictor of later adherence to treatment of diabetes even after accounting for past levels of adherence to include the confidence level of the participants concerning adherence to a diabetes treatment regimen over eight weeks as determined behavior to change (Kavanaugh et al., 1993).

Peek, et al., (2014) noted goal achievement indicator as relevant to an individual predicted outcome on their effort to set goal, and the patient belief to attain the goal as explains (Self-efficacy). (Peek, et al., 2014) revealed self-efficacy as could be enhanced through role modeling or found models the individual identifies with, and as well with increased persuasive correspondence that could improve the individual's confidence (Peek, et al., 2014). Cues to action that motivates goals of achievement could either be generic in nature whereby the individual is determined to be healthy or specific to achieve lower A1C levels, could impact self-esteem, and group membership (Peek, et al., 2014).

**Table 1**

*Review of Patient-Reported Outcomes in Type-2 Diabetes Mellitus Treatment*

Reference	Objective and Population	Variables	Patient-Reported Outcomes by Measurement Instrument	Results
Trikkalinou, A., Papazafiropoulou, A. K., Melidonis, A. (2017).	T2DM patients' ways to perceive changes in different aspects of their quality of life. The Differences and similarities in study problems and caveats studies. Further studies on the effects of	T2DM patient awareness of complications:  Dietary knowledge, attitude, and lifestyle practices for better diabetes control  Stakeholders: health care providers, health facilities, and involved agencies  Appropriate self-care and better quality of life	Metabolic anomaly, the consequence of complications development or comorbidities coexistence lowering patient HRQoL.  Physical inactivity and lifestyle association increase T2DM risk in nondiabetic individuals.  T2DM patient knowledge	Physical activity increases skeletal contraction, enhances cell glucose uptake, muscle blood flow, and transportation of glucose into the muscle to reduce abdominal fat distribution and storage. The individual lifestyle and environmental factors are the primary causes of the extreme

	T2DM in family life or metabolic pathways between diabetes and dementia. Review of 1,950,000 articles of the last five years.	Unhealthy food intakes and physical inactivity and increase high risk of diabetes  Lack of therapy of healthy food choices, physical activity, and medication cause complications	requirement achieves better compliance with medical, dietary, physical therapies, and lifestyle.  T2DM association with high intake of carbohydrates, fats, sugars in a diverse population	increase in the T2DM risk. Receipt of T2DM education increase patient' awareness to improve the quality of life and reduce family burden.  T2DM patients encounter eating disorders and symptoms associated with psychological distress
Thent, Z. C., Das, S., & Henry, J. L. (2013).	Patient treatment with physical exercise impact T2DM and quality of life.  Randomized controlled trial and clinical cohort prospective Adults with T2DM $\geq 18$ years and older observed in 4500 individuals.	Exercise types, duration of exercise, and intensity of exercises  Aerobic and resistance training. 3 times/week 16 weeks 40 to 60 minutes  Combination therapy treatment effect with aerobic and resistance exercises in T2DM Treatment interference Therapy-related problems Therapy settings	Diabetes-related markers; blood lipids, relevant cytokines, and anthropometric, and hemodynamic indices  Aerobic exercise reduced blood glucose concentrations to a greater extent than resistance exercise, and both have a higher risk of exercise-induced hypoglycemia. Aerobic exercise improves physiological parameters, fasting blood glucose level, and lipid profile levels in T2DM patients.	Exercise had a positive effect on glycosylated hemoglobin (HbA1c).  65% Showed an exercise effect on T2DM. Resistance exercise showed a positive impact on patients with T2DM.  United States of America had a keen exercise interest in T2DM management for developing countries to adopt

Reiner, M., Niermann, C., Jekauc, D., & Woll, A. (2013).	Patient preferences concerning treatment and therapy participation regularly as the basis of; positive feelings during exercise, and exercise adherence. Comparative trainee groups of 41, 24 participants and 17 control groups	Positive emotions. pleasure and fun. Affective state of mind Work out time Exercise. Physical activity aerobics	Physical activity prevents age-related diseases, Physical activity reduces the rising health care cost for T2DM and CVD. The relationship between physical activity and Non-Communicable Disease incidence and health problems could get controlled in the long-term.	Exercise mediated the impact of the intervention on physical activity adherence. Exercise is relevant and beneficial to NCD with an impact on weight gain, obesity, and diabetes. Affective states during exercise can be systematically influenced to increase physical activity adherence. Lifestyle factors of a healthy diet, less alcohol consumption, and physical activity reduce non-communicable Disease.
Turan, Y., Ertugrul, B. M., Lipsky, B. A., & Bayraktar, K. (2015).	Physical therapy and rehabilitation improve outcomes for diabetic foot ulcers. Male and female average age 60 years of diabetic patients	Diabetes foot ulcer frequent and severe foot problems treatment. Surgical debridement, drainage, antimicrobial therapy for infected wounds, pressure off-loading wounds and advanced wound dressings	Check foot wood of diabetic patients, redness, swelling, increased warmth or pain, tenderness, numbness, skin breaks, blisters, peeling, ingrown toenails or nail deformity, and callus or skin dryness.	Foot ulcer rates overly 80% than 30% to 40% in patients with peripheral neuropathy with a ten year and 25 years history as 60% to 70%
Kern, D. M., Auchincloss, A. H., Stehr, M. F., Diez Roux, A. V., Moore, K. A., Kanter, G. P., & Robinson, L. F. (2018).	Healthy food prices association with unhealthy food and T2DM prevalence, incidence and	Individual average price of selected healthy foods Unhealthy foods and their ratio Individual residential address Region	Healthy and unhealthy neighborhood prices were positively related to insulin resistance treatment.	The social-economic status of deprived neighborhoods from available healthy foods and physical activity resources were consistent with

	treatment resistance from a multi-ethnic cohort of 2,353 to 3,408	Age Gender Race/ethnicity Family history of diabetes Income /wealth index Education Smoking status Physical activity Neighborhood socioeconomic status	The relationship score produced higher outcomes of treatment resistance.	treatment resistance.
Silverman, M. N., & Deuster, P. A. (2014)	The biological mechanisms were supporting the role of physical fitness in health and resilience. Quantity of aerobic fitness  Physical fitness attained by regular exercise and spontaneous physical activity reflects resilience. Induced positive psychological and physiological benefits, blunting stress reactivity, protects against potential adverse behavior and metabolic ramifications of stressful events, and	Age Gender Life events Genetic predisposition, Current fitness level Body composition/degrees of adiposity Nutritional status Existing psychological Physiological stress response systems Hypothalamic pituitary adrenal (HPA) axis autonomic nervous system immune system metabolic behavioral adaptation to stress	The acute exercise revealed physical challenge or stressor activates systems in a dose-dependent manner as the interaction between intensity and duration generates the magnitude of the stress response. Exercise at a lower intensity offers 50% of maximal capacity or less and at 70% of maximal capacity, markedly activates the HPA axis, sympathetic nervous, and immune systems at termination to regain homeostasis.  Physical fitness could protect against the development of chronic, stress-related disease and promote health and resilience by optimizing function and	The blunting contributes to reduced emotional, physiological, and metabolic reactivity as well as increased positive mood and Well-being.  Exercise and physical fitness confer resilience by minimizing excessive inflammation. Chronic psychological stress, physical inactivity, and abdominal adiposity are associated with persistent, systemic, low-grade inflammation that exerts adverse effects on mental and physical health. The anti-inflammation effects of regular exercise/activity could promote behavioral and metabolic resilience that

prevent several chronic diseases.

interaction of physiological stress-responsive systems and then minimized the prevalence of biological risk factors for disease.

protect against various chronic diseases related to systemic inflammation.

Other benefits of exercise get into the brain by enhancing growth factor expression and neural plasticity that improves mood and cognition.

**Table 2**

*Literature that Used HBM in Comparison with Interventions for Diabetes Patient*

Reference	Disease State	Comparison with literature on Diabetes Patient Intervention
Harvey, J. N. (2015)	Psychosocial intervention	Used the psychological framework to understand the relationship between patients' perceptions and their behavior. The health belief model suggests that patients develop their model that connects with their condition as diabetes patients. Like the HBM, the personal model (PM) made up of beliefs categorized under the identified symptoms and their meaning, causation to include blame, timeline or course, seriousness or consequences, and curability or controllability, which includes perceptions of treatment effectiveness and personal control. These PM tenets determine the patient adaptive coping strategies outcomes. Coping mechanisms that are adaptive to include acceptable, problem-focused, cognitive reappraisal, and seeking social support or maladaptive like avoidance or denial, expressive of anger, or turned to alcohol and illicit drug user. Harvey, 2015 included clinical and biochemical assessments, quality of life, and other psychosocial measures relevance to the goals of therapy. To set the inclusion of QoL questionnaire assessment of problem areas and further assist the discussion about Well-being.
Shabibi, P., Zavareh, M. S. A., Sayehmiri, K., Qorbani, M., Safari, O.,	Educational intervention	The study promoted self-care behaviors in type-2 diabetes mellitus patients through the Health Belief Model framework to reveal the productive relationship

Rastegarimehr, B., & Mansourian, M. (2017).		between educational intervention and self-care behaviors increase. Under the guidance of physicians, healthcare workers, and family members, with a continuous regular class held by health care professionals for diabetes patients. Shabibi et al., 2017 highlighted the health belief model indicators significant effectiveness in promoting the self-care behaviors in type-2 diabetes mellitus patients after the intervention. Identified the HBM construct indicators of self-efficacy, perceived barriers height to promote self-care behavior in type-2 diabetes mellitus patients.
Dehghani-Tafti, A., Mahmoodabad, S. S. M., Morowatisharifabad, M. A., Ardakani, M. A., Rezaeipandari, H., & Lofti, M. H. (2015).	Predictors of self-care	Used the Health Belief Model framework to understand the relationship between diabetes patients and self-care behaviors from the designing and implementation of educational interventions in diabetes control strategies. Dehghani-Tafti et al., 2015 aligned the HBM link with behaviors of regularly taking anti-diabetic medications weekly and checking inside of shoes weekly practices as more efficient than reporting about self-care behaviors. Also, the consumption of fruits and vegetables, followed by a healthy choice of the diet were predictive of the health belief model efficiency. Used the health belief model to predict better health outcomes of treatment regimen or general medical advice to glycemic control and cardiovascular risk factors than treatment beliefs. Self-reported adherence to therapy was relevant to the patient predictor of cardiovascular risk factors and glycated hemoglobin in diabetes patients. Lill-Brith et al., 2015 showed treatment adherence association with improved overall life satisfaction and self-rated health as more pronounced with wellness. To set to involve a personalized approach to diabetes care, which considers the identified indicators of poor adherence and quality of life to help improve outcomes of type 2 diabetes management in primary practices.
Lill-Brith, W-v. A., Helge, G., Søren, S. (2015).	Treatment beliefs and health behaviors predict diabetes health outcomes measured by glycated hemoglobin (HbA1c) level, blood pressure, and lipid profile.	

### Criticism of the Health Belief Model

Critics of Health Belief Model intimated that the model does not account for a person's attitudes and beliefs but rather dictates a person's acceptance of a health behavior. The model does not account for habitual behaviors, and thus may inform decision-making process to accept a recommended action, neither does it account for behaviors achieved for non-health related concerns such as social adequacy. HBM does



not justify environmental or economic factors that may hinder or encourage the recommended action. Rather, it assumed everyone has access to equal amounts of information on the illness or disease, as well as adopted cues to action are widely prevalent to inspire people to act, and that “health” actions are the core goal in the decision-making process (Glanz, et al., 2015).

### **Autoimmune Disease**

Chronic disease is a “condition of ill health produced by disease or disability that requires therapeutic intervention over an extended period and affected several aspects of an individual’s quality of life” (Whitter et al., 2008). The emergence of chronic disease has led to a slow progression, long in duration, and spontaneously resolving the void that mostly limits one's functional abilities of productivity and quality of life.

There has also been a focus of the chronically ill patients obtaining information on management of the disease, and competency in health care decision-making to learn strategies of self-management and therapies (NAP, 2012). Chronic disease has strengthened therapeutic approaches with corrective surgery, new approaches of analgesia, rehabilitation, physical and occupational therapy, improved nutrition management, and adaptation of home and community environments for functionality for impaired people (NAP, 2012). It is relevant to fathom the implications of chronic disease cognition as another form of cognition; namely, social, and economic welfare. Social cognition affects personal cognition of individual’s economic, quality of life and families as the main drivers of health care costs. The medical cost of care for

individuals with chronic illness increases medical care annual expense by 75% of \$2trillion in the U. S health care expense (Kaiser Family Foundation, 2010), and globally by 2030 will increase the economic burden by \$47 trillion (Bloom et al., 2011). The clinical and public health concepts in perspective of intervention, and policies to curtail chronic disease has been crucial to consider an individual's genetics, biology, and behaviors interaction with the cultural, physical environmental and social affects health outcomes (NAP, 2012). Chronic illness upsets the body and self-balance, disrupts one's whole body and self-sense. The duration of chronic situation turnout has mostly led into functioning and lifestyle changes of roles, plans of the future and self-esteem. (NAP, 2012).

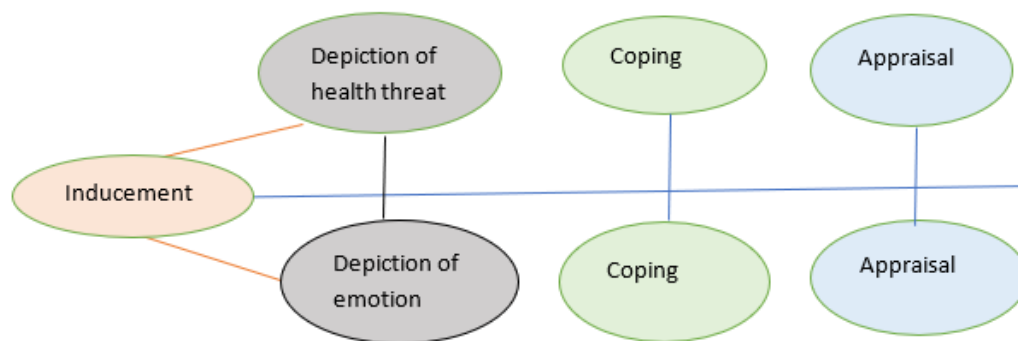
### **The Role of the Patient**

Type-2 diabetes mellitus cognition refers to disease depictions or perceptions of disease. Depiction of disease is defined relative to the belief of individuals due to involvement, prospects and intentions of the illness and health. Such depiction can make the decision of individuals to seek care, cope with behaviors of patients and compliant to medical advice (Kugbey et al., 2017). The individual's care to self is also affected by illness. Literature has shown intervention influences health related behaviors of patients and health belief that depicted the illness (Garcia-Pérez et al., 2013). The process is reflected in Leventhal and colleagues (year) appraisal, and coping of illness, that asserts illness depiction as the core constituent, cognizant to various facets of the influential factors that depicts the illness constructs. In Figure 2, the model proposes health and illness behaviors outcome as threats imposed on health,

given the coping processes faced by an individual to adapt the threats for which an illness depicts or influences both cognitive and emotions.

## Figure 2

### *Illustration of Illness Appraisal and Coping Model of Leventhal*



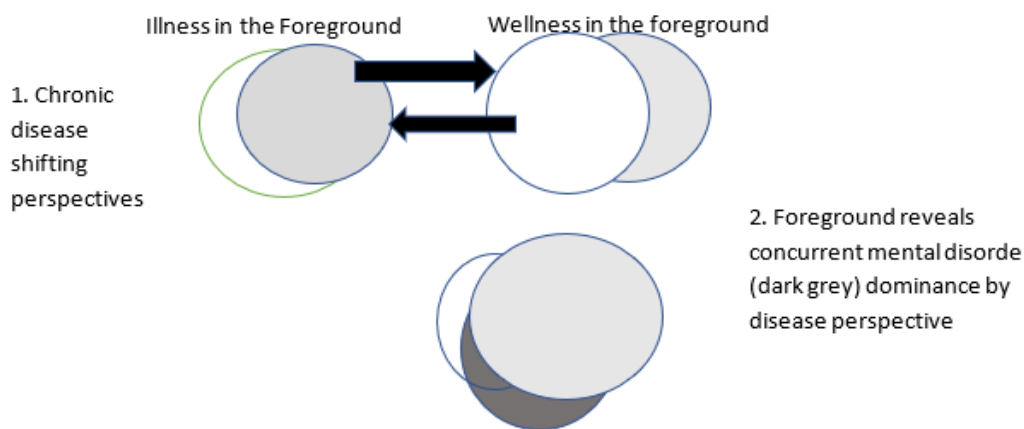
*Note.* Adapted from Leventhal, Nerenz, & Steele, (1984)

The emotional depiction pertains to illness depiction that demonstrate the distinctive experience of illness variation perspective of an individual and the next. Emotions like exasperation, rage, despair, and apprehension, stimulate the individual to participate in the health-related behaviors especially if the patient has a planned action of regimen of treatment (Leventhal et al., 1984). In absence of a planned action, an emotion may completely engulf the individual patient, and prevent the health-related behaviors (Leventhal et al., 1984). The predictive power of the model reflects some characteristics of adherence since the model emphasized the patient as a solver of problems that pertains to reality of health threat and has the potential to deal with the emotional threat. Both the cognitive and emotional factors could direct a patient to engage in self-managed behaviors (Leventhal et al., 1984).

The conceptualization of disease in relation to beliefs, discernment, prospects, defiance, and practices connects an individual with a chronic illness (Kristensen et al., 2018). A typical model of illness perspective, Shifting Perspectives Model of Chronic Illness (Figure 3), emphasizes the concept of a dynamic experience of chronic illness (Paterson, 2001). The perspectives of the disease empower an individual to reveal his or her ideological experience, awareness, and essentials (Paterson, 2001). The perspectives of illness and wellness depicted by the overlapped circles of the model, for which, at any point in time, identifies an individual perspective to achieve primacy over the other (Paterson, 2001). At the forefront of wellness, the individual identifies with his or her chronic illness as a chance to agree amid self-distinctiveness and illness distinctiveness, to determine change of his or her association with the environment and others in connection to the chronic illness (Kristensen et al., 2018; Paterson, 2001).

### Figure 3

*Illustration of the Shifting Perspective Model of Chronic Illness*



*Note.* Adapted from Paterson, B. L. (2001)

The patient is subjected to agree with these two identities, with a disclosure to the disease, and perceived to educate others on the disease, and advice individuals to repudiate inappropriate health behaviors. By integrating changes into all facets of their individual, public, work, life, home, and private to enable the individual to agree to be between being identified with the illness and maintain wellness. For the concealed patients to the illness engagement in the public, risky behaviors may impose damaging health consequences. Reconciled self to the illness, the self, and not the impact of the chronic illness on the body is identified as the source. To agree between the identities reflects one of the healthiest means to manage chronic disease (Kristensen et al., 2018; Paterson, 2001).

For the chronic disease patient, the body demands ways an individual function, and networks with others daily (Paterson, 2001). The body creates an aspect of the physical identity, as an identity to be accounted for as a patient (Paterson, 2001). Where the constrictions of the body, levied by the chronic illness are mostly therapeutic in nature, in a sense that society places these constraints on the patient, reducing interactions, and capabilities (Paterson, 2001). The twofold request of bodily existence and therapy must be reconciled for the chronically ill individual. Reconciling with the disease, the body could be distressed with the presence of symptoms that are not seen or felt (Paterson, 2001). As the patient carries out their daily activities with no cognizance to any change, the seriousness of the disease could be invisible (Paterson, 2001). Sometimes the medical view given by providers are not

consistent with the patient's interpretation of the illness in accordance with the condition of the body, specifically at instances when the patient physically indicates health irrespective of diagnosed disease (Paterson, 2001).

Chronic disease threatens individuals with self-veracity, and beliefs seen in previous assumptions on the association between the body and self, reflecting unbalanced distraction. Several patients with chronic disease construct in the latter identities of existing personalities, by visualizing self in the future, and set goals that associates with the future identity, despite the identity not being attainable (Chrmaz, 1987).

### **The Role of CDC and ADA**

Public health in 21st century achievements have had a paradigm shift in the disease focus from communicable to chronic diseases such as diabetes. As medicine has progressed scientifically as well as public health intervention for infectious diseases, there is upsurge in chronic diseases medical incidences. Globally, incidences for type 2 diabetes have shown that 422 million in 2014 are affected. In the United States alone, over 30.3 million people had type 2 diabetes in 2015 and 84.1 million had prediabetes, a number expected to increase by 18 million more in the rapidly growing ethnic group by 2050 in ages 18 years and older (ADA, 2015; CDC, 2015). This number in 2015 increased by 1.5 million new cases, which reached a high of 25.2% in older adults with more than half of the incidence being mainly adults between 45 to 64 years in both men and women in the most dominant group Black (9.0 per 1000 persons) and Hispanic (8.4 per 1000 persons) race compared to Whites (5.7 per 1000 persons). It is the seventh

leading cause of death by 2030 for all ages (Mathers & Loncar, 2006, National Diabetes Statistics Report, 2017). Diabetes mellitus is classified by the American Diabetes Association into two main categories: namely, type 1 and type 2 (National Diabetes Statistics Report, 2017). Beta cell destruction for type 1 identifies with complete insulin deficiency in the body. About 5% of adolescents and children are diagnosed with Type 1 (National Diabetes Statistics Report, 2017). The most common form of diabetes is Type 2 (90%-95%), a disease typically diagnosed in older adults and is more progressive and characterized as secretory insulin defect (National Diabetes Statistics Report, 2017). Complications arising out of diabetes include progressive dysfunction, and failure of several organs including the kidneys, nerves, heart, eyes, and blood vessels (National Diabetes Statistics Report, 2017). Other effects of diabetes affect the limbs, specifically the feet. These various complications of diabetes are the life-threatening events of hyperosmolar (nonketotic) and ketoacidosis coma from biochemical imbalance in the body (National Diabetes Statistics Report, 2017).

Opportunistic infections like pneumonia or influenza are also a concern to diabetes patients, as more are likely to die due to infection rather than individual without diabetes (National Diabetes Statistics Report, 2017).

Increased complications and co-morbidity have resulted in the use of therapies through self-management, a superlative daily practice of engagement as an effort to reduce the disease risk in the most affected group like minorities by the Diabetes Association (National Diabetes Statistics Report, 2017). In 2013, physical exercise was noted as effective on type 2 diabetes by 65%, with a strong association to the U.S.

population with diabetes through self-management, to recommend aerobics exercise as a common clinical practice of promise that requires knowledge expansion through global research on practice, particularly in the developing nations (Thent et al., 2013). The financial burden of diabetes and CVD risk relative to treatment cost to health systems was found to have reduced due to physical activity and positive long-term impact on all non-communicable diseases. Research that justifies the relationship between physical activity and NCD incidence in a larger adult group (Reiner et al., 2013) is pertinent. Serious complications of foot ulcers that usually affect over 80% diabetes patients due to long-term of 10 years (60%), and 25 years (70%) indicated a high wound healing with physical therapy. This requires further studies into use of physical therapy to minimize complication risk of diabetes mellitus (Turan et al., 2015).

### **The Target Population and Health System**

Several studies have shown diabetes' disproportionate effect on minority ethnic groups like African Americans, Hispanics, Asian, Alaska Natives, and American Indians when compared to Caucasian majority taking account of overall rates of diabetes prevalence in the United States. In 2015, the American Diabetes Association reported American Indians and Alaskan Natives had the highest type 2 diabetes prevalence (15.1%), African Americans (12.7%) Hispanics (12.1%), and Asian Americans (8.0%), compared to Whites with the lowest rate of just 7.4% (ADA, 2015). Although, the estimates were adjusted on age differences in the population, the variations within the individual subgroups were unadjusted (ADA, 2015).



The causes of T2DM and the differences of effects on these subgroups has made it critical to be investigated. Recognized causes of diabetes among demographic composition indicates that neighborhood environment plays a greater role in determining culture, and ethnicity relationship to diet and exercise. Neighborhoods noted for higher food prices of healthy foods positively correlated with high unhealthy food consumption and are associated with high incidence of diabetes with no impact on improved diabetes outcomes (Kern et al., 2018). Although a genetic tendency to diabetes may increase an individual's chances of diagnosis, factors of diet and exercise reduce the chance. Just as diabetes differentially affects minority, we also see a variation in diabetes medication adherence within this population (Kern et al., 2018).

Other studies examined diabetes in minority in relation to race, poverty, and place to establish the odds of having diabetes as higher for Blacks than Whites. Poverty among individuals increased the chance of having diabetes and living in poor neighborhood for Blacks than poor Whites (Gaskin et al., 2014). Some studies have suggested further studies to determine Hispanics subgroupings, specifically Mexican Americans to Whites gradient (Gaskin et al., 2014). The disparity of diabetes economic burden in minority was noted as a 50-100% higher for illness and mortality from diabetes than Whites in America with attribute to unequal treatment and access. Reducing the impact to the group included suggestions of increased advocacy and role of health care providers in the combat of diabetes (Chow et al., 2012).

The literature on medication reports on adherence ranged from about 90-95% of the population with diabetes (National Diabetes Statistics Report, 2017). A likelihood

attribute to methods and measures of adherence detected a reduced adherence in patients with chronic conditions, like diabetes than those with acute episodes for demanded treatment illnesses (National Diabetes Statistics Report, 2017). Medication adherence perceived understanding to barriers, identified adherence to anti-diabetes medication diversity intervention and measurements in patients as 83.7%. With both patients and providers as low as 5.8% prevented impact on interventions associated with adherence to therapy (Sapkota et al., 2015). In general, adherence to anti-diabetes medication indicated a less than optimal adherence across patients from USA, Canada, Norway, UK, and other multiple countries (Sapkota et al., 2015). In the USA, adherence differed by subgroups of African American, Hispanics, Native Americans/American Indians, and Chinese Americans (Sapkota et al., 2015). Patients and provider adherence to treatment recommendations relate to consistent methods (Brundisini et al., 2015).

Barriers that hinder adherence are associated with several factors such as; (1) emotional experiences with positive and negative motivators to adherence; (2) intentional non-compliance; (3) patient-provider association, and correspondence; (4) information, and knowledge; (5) medication administration; (6) cultural, and social beliefs, and; (7) financial concerns for both providers, and their patients to reflect their different understanding of what patients required to achieve improvement and adhere even for clinical trials (Brundisini et al., 2015). An outcome that may assist providers on possible contributor effects of a specific patient's medication practices and encourage self-management with better understanding that promotes medication adherence in adult community with type 2 diabetes is shifted from traditional medical view compliance to

patient-centered concordance associated with other needs was ideal to new evidence-based studies (Brundisini et al., 2015). To minimize risk of nonadherence, some investigations had related higher adherence to improved glycemic control, lessened emergency department visits, reduced hospitalization, and lower cost to medication (Capoccia et al., 2016). There are also developed strategies and consideration of known factors that facilitates medication administration provision for ongoing support, and assessment at each visit (Capoccia et al., 2016). In order to positively achieve diabetes outcomes, Capoccia et al., (2016) has found adherence as an imperative suggestion explicit to valuation of adherence, and specific implementation of individual strategies to support diabetes care through self-management medication administration (Capoccia et al., 2016).

Kennedy-Martin et al. (2017) assessing health systems and medication barriers to effective diabetes care identified financial constraints, access to health services, and facilitators as major factors to reducing diabetes risk control and outcomes of medication adherence. Thereby, informed decisions on continuous research geographically on diabetes outcomes linked to health systems, variations in types, and rigor of research, and research topic gaps (Kennedy-Martin et al., 2017).

### **Treatment Options**

Swoboda et al. (2017) proclaims self-care therapies with set goal and achievement for type-2 diabetes mellitus patient promotes behaviors. Where goal setting defines accomplishments based on value, future, and status with emphasis on action. It is the basic motivation for, and provides purpose to behaviors (Swoboda et

al., 2017). There are several types of goals; namely, self-selected goals, goals set cooperatively, goals imposed by others, and assigned goal with the rationale to achieve and/or desired (Swoboda et al., 2017; Cullen et al., 2001). The moderate success attributed to variability intervention outcomes seen in lifestyle interventions, and diabetes self-care education program, for individuals with type-2 diabetes, as some behavioral goals get achieved (Pillay et al., 2015). Pillay et al., (2015) and Anderson et al., (2010) outlined achieved goal often used in diabetes self-care education for long-term disease management as successful goal setting. Challenges of goals setting specified has led to the greater likelihood of performance of the target behavior preferable to easy and vague goals that may overtime lead to greater behavioral change (Miller et al., 2014). Locke & Latham (2002) aligned successful goal setting to required four steps; (1) identifying the need for change as basis of expressive or distressing experience; (2) Goal establishment, determined by specificity, and difficulty; (3) Goal-associated activity monitoring, permitting changes in effort, planning or strategy of goal achievement, and (4) Self-rewarding of achieved goal to encourage setting other goals (Locke & Latham, 2002).

Knights and colleagues (2006) suggested behavioral change approaches must incorporate diabetes self-care education with or without clinical, behavioral, and psychosocial phase and lifestyle programs (Knights et al., 2006). Recommendations by health care experts for individuals with diabetes should include adopting and adhering to multiple self-care behaviors that included eating healthy, being active, monitoring, taking medications, solving problems, healthy coping and reducing risk (Knights et al.,

2006). Knowledge acquisition in-sufficiency promote behavioral changes. There is, therefore, the need for a traditional edifying shift from educational services to more patient-centered practices that includes interactive, problem solving, and other behavior approaches (Knight et al., 2006).

### **Treatment Outcomes**

The evidence of diabetes specific behavioral interventions can be effective, yet uncertain with combination of program components, and mechanisms of delivery in most effective interventions (Chodosh et al., 2005; Ellis et al., 2004; Fan & Sidani, 2009; Glazier et al., 2006; Norris, Lau et al., 2002). In moderating the effectiveness of multiple component behavioral programs for T2DM, a meta-analysis to identify the related factors of the program components and mechanisms of delivery were sorted and evaluated (Pillay et al., 2015). Results indicated that effective intervention included most lifestyle, “diabetes self-management education” (DSME), and support programs that are usually offering greater or equal to eleven contact hours led to clinically relevant improvements in glycemic control by  $\geq 0.4$  or 40% reduction in HbA1C (Pillay et al., 2015). Whilst “standalone” programs with ten or fewer hours contact particularly yielded less benefit with personnel delivery for DSME (Pillay et al., 2015).

Programs with in-person delivery was most often effective than inclusion of technology. Programs focused on lifestyles, which were usually structured with weight loss and physical activity interventions or on DSME achieved similar benefits relative to glycemic control, with lifestyle programs being ideal to reduce BMI (Pillay et al.,

2015). Behavioral programs showed benefits to persons with poor glycemic control or suboptimal more than those with good control. In addition, tailoring programs to ethnic minority groups, like inclusion of group interaction with peers seemed beneficial (Pillay et al., 2015). The outcome was a buildup on factors affecting intervention effectiveness for T2DM. This study concluded with the highest number of studies that focused on programs that met current recommendations of patient behavioral change (Ellis et al., 2009; Glazier et al., 2006; Norris, Lau et al., 2002; Norris, Zhang et al., 2004).

A 422 patient with T2DM study focused on objective determination of frequency and effectiveness of choices of goal in diabetes management used mail and telephone support over a six-month period (Estabrooks et al., 2007). The study hypothesized self-selection of goals and behavior as key to persistence enhancement of goals. Patients were allowed to make choices of goals. Those who chose goals that matched their needs mostly improved with results in a greater behavioral change (Estabrooks et al., 2007). Targeted goals included reduced fat intake <30% of calories consumed daily, increased fruit and vegetable per daily consumption five to nine times and increased physical activity weekly to 150 minutes to moderate-intensity physical activity (Estabrooks et al., 2007). Goals were chosen, hindrances were recognized and strategies to overcome hindrances through an interactive computer program were identified. Feedback on goal-related were offered during a counseling session by a trained medical assistant (Estabrooks et al., 2007). The study conducted a follow-up call after two weeks on progress and feedback. Results indicated about half of the

population chose activity goals, one quarter increased fruit and vegetable consumption and a quarter reduced fat intake (Estabrooks et al., 2007). The entire study participants reduced dietary fat, with higher decrease in those who selected that activity goal (Estabrooks et al., 2007). Fruits and vegetable consumption choice among participants significantly increased consumption, and as well increased physical activity goals (Estabrooks et al., 2007). Limitations of the study were narrowed goals selected due to only three goal choices, which may have limited the population and not representative of the goals for all diabetes patients (Estabrooks et al., 2007). The study uses of self-selection limited the number and scope of goals such as diet, and physical activity. An accurate self-selection process that would permit more goals that are specific would have been more effective (Estabrooks et al., 2007).

The goal setting literature reveals goal setting as effective to maintaining new behavior, and changes. Diabetes patients, whether newly diagnosed to change dietary, and lifestyle behaviors, or longtime patient struggling with condition management, goal setting may play a key role in self-management of their chronic condition (Estabrooks et al., 2007). Attributes of personality studied in diabetes individuals most often incorporates predicament of control, self-concept or self-esteem, and coping mode. Studies of self-concept have revealed positive self-esteem outcomes in better psychosocial adjustment to patient with diabetes. Positive self-concept is also correlated with adherence (Anderson et al., 1981; Jacobson et al., 1987).

Setting goals to self-manage behaviors increases the patient's self-efficacy. Managing health with goal setting support turned out to be helpful to patient's

decision to be responsible, and accountable (Langford et al., 2007). In addition, peer support reinforces goal-setting process. Feedback is a tool of relevance to the process of goal setting to improve patient self-efficacy (Cullen et al., 2001). Associating self-efficacy to goal setting level and achievement to individuals who set higher goals outperform the non-self-efficacious (Schwarzer, 1999). This in a meta-analysis of Locke & Latham (2002) found an effect size of  $r = .39$  of 14 studies evaluating the association.

Self-efficacy sometimes formulates the construct that incorporates several models that defines the individual judgement relating to their capability of monitoring, planning, and executing daily activities (Ajaseem et al., 2001). Health behaviors like medication taking behaviors associated with self-efficacy have much empirical support. Self-efficacy is associated with about 4 to 10% of the change in diabetes self-care behavior among 309 patients with type-2 diabetes mellitus (Ajaseem et al., 2001).

Due to the characteristics of self-efficacy and the ability to modifying an individual's self-efficacy, any intervention focused on self-efficacy improvement could have an incredible implication in refining health outcomes of the chronically ailed patients (Marks et al., 2005). Additionally, potential intervention that includes the use of therapeutic support in managing chronic diseases could improve self-efficacy in several ways. Some of the ways are observation of others for appropriate behaviors determination, as means to be responsive to others (Bandura, 1997). Self-efficacy played a role in behavior change for long, specifically changed, and maintained health. With effects on coping behaviors, and patient's persistence in



subjective aggressive activities like exercises reinforce self-efficacy as better than patients that held preventive behaviors immaturely (Bandura & Adams, 1977). Self-efficacy effects reveal how the patient perceive to choose behavior, and how much exhaustive effort they put in executing the process, and for how long they persisted the behavior irrespective of the hindrances (Bandura & Adams, 1977).

Other ways therapeutic groups promote self-efficacy concept is working with pragmatic learning communities. This had been found out to encourage the construction, application, and distribution of pragmatism insights for others to emulate. As such, individuals with a long-term chronic illness could gain pragmatic expertise in the illness management over time. Given that, the individual attained support from the program that improves self-management, with possible positive health benefits to physical and social functioning (Winkelman & Choo, 2003).

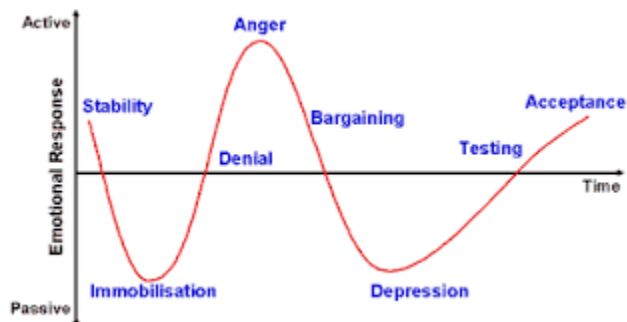
### **Patient Participation and Patient-Centered Care**

Reconciling both distinctiveness of disease and therapy is a way of incorporating the disease distinctiveness into the therapy distinctiveness. The model in figure 4 reveal how a patient perceives health and reject outcome of the disease from occurrence of diagnosis to varying degrees of acceptance, and denial that are aligned with diagnosed experience. This is reflected by Kubler-Ross (1969) in the five phases of emotional adjustment occurrences of the Grief Model shown in Figure 4, which identifies Denial, Anger, Bargaining, Depression, and Acceptance phases are essential to the model. Denial acclimates the mindfulness or insentient aspect that increases refusal to accept the disease as facts and evidence that associates the condition Kubler-Ross (1969).

The author demonstrated the natural defensive reaction of an individual who is perfectly fine. For which, if the demanded change of the condition is ignored, patients could remain in denial for a longer period according to Kubler-Ross (1969). Anger manifests in several ways. Where the individual is emotionally distressed with anger to self and/or with others, particularly the most closed to them from the traditional bargaining phases, the individual finds the attempt to bargain by negotiating compromise with the higher power Kubler-Ross (1969). Although, bargaining scarcely does not provide any justifiable solution, particularly when it is a condition of life or mortality. On the other hand, depression prepares grief with acceptance that adjunct emotion. To register reality of the disease or mortality, most often, the individual with disease establishes the state prior to family and friends, for whom they channel through their own patient conditions to deal with the disease.

#### Figure 4

*Kubler-Ross Stages of Grief Modal 4*



*Note.* Adapted from Kübler-Ross, E. (1969)

The focus of the model is directed to terminal patients, also transferable to personal changes and emotional distress resulting from non-mortal factors and dying, like diagnosis of chronic illness. Patients are usually stimulated and identified with Kubler-Ross's five stages of change as they learned to accept a chronic illness (Kubler, 1969; Folling et al., 2015). The transformational process uses the emotional change process of acceptance to denial of the chronic illness. With evidence of constant changes as the individual's illness, grows alongside learning of the illness outcomes (Kubler, 1969). This poses two thematic discussions to evaluate the transformation: by addressing the reformation of the experiences of the illness, and self. The reformation of the illness experience accounts for the cognitive changes about how the patient perceives the illness as a threat to health, and a challenge to be encountered (Kristensen et al., 2018). This indicates a genuine way of refocusing on the illness that integrates the confines of the illness with intended approaches to adapt and regain a sense of normality in one's life. While other patients use the option to non-normalize, as preventive way of creating a realistic distinctness for an illness (Kristensen et al., 2018). Whereby, the initial stage of reformation of illness experience starts with acceptances to self as a chronically ailed individual, use the control process to regain health (Liddy et al., 2014).

For many patients, gradual denial fades into acceptance when denial assume healthiness if the protective functions are safe for a short time (Kubler, 1969; Kenning et al., 2013, Nash, 2015). Denial outcome for the patient conflicts with how the illness will add to life. To make uncertainty an unorganized stage of the illness, it is important

to note the state of the patient's mind prior to confirmation of diagnosis of an individual's symptoms. In addition, makes retention of uncertainty after diagnosis a possible associate with meaning to the illness, effective treatment, affects the daily living with the illness, work, and relationships (Nash, 2015). Strategies to manage uncertainty are vast, with denial as one of them. The denial idea was born from the defense mechanisms of Freud in 1949 (Baumeister et al., 1998) where an individual uses a radical defense attempt to block the external events from awareness. By avoiding conditions of threats, for which the individual could either refuse to acknowledge the condition or do not acknowledge the feelings of the condition, with frequent use of defense mechanisms (Baumeister et al., 1998). Individuals could pursue other people with the illness from a network of others to accept the illness with acknowledgement, and initial experience of the illness by coming into terms with acceptance of the illness (Nash, 2015). Even if the state of the patient is anguish, support groups can be a beneficial network that could assist the individual progress through the stages of acceptance and motivate the individual to self-manage the disease (Nash, 2015).

The individual involvement in several activities by adopting healthy behaviors; not to smoke, eat healthy diets, take medications reveals the responsiveness of the individual with an action plan, to self-monitor, cope with emotions, manage disability and navigate the health care system. This explains the subjectivity of the individual to self-care (Osborne et al., 2011; Brady, 2012; Molton, & Yorkston, 2017). Objective aspect of self-care promotes control of the disease, symptom control, deterioration

prevention and variation of a condition pursued by an individual (Boger et al., 2015). To identify the indicators of self-care, Ruiz, et al. (2014) observed the main constructs of activeness and effective self-care of the condition. Outcome of the observation was divergent to responses that defines self-care to include multiple behaviors, and differences from general wellness behavior were non-reflective of chronic condition self-care such as resolution to lose weight or exercise (Boger et al., 2015).

While most responses observed showed action to manage chronic condition (Ruiz, et al., 2014) they also found out that goal setting and planning skills help transform individual to self-care “as a means to an end”, and “not the end itself”. The essence of self-care is an individual’s wise decision, recognition, and response to change circumstances, to adapt changes to the disease trend, tempo, and complicated realities of life with chronic disease (Lorig & Holman, 2003; Greenhalgh, 2009). Action taken applies to any chronic disease and condenses a range of activities of response to symptoms or conditions as they come up. Action reproduces personification, and conclusion that translates education, plans and daily life counseling with the overall knowledge of “taking action” to improve chronic situation (Hill-Briggs et al., 2007).

A study that examined programs components of provider, and patient communication strategies and skills, found self-care education determines individual’s behavioral change (Peek, Ferguson et al., 2014). Particularly, for dietary patterns and physical activity in minority group such as African Americans with diabetes through the South Side Diabetes Project known as “Improving Diabetes Care.” The outcome

indicated dietary and physical activities improved health, and reduced disparities in the group and largely the working class (Peek, Ferguson et al., 2014). They found programs tailored to health literacy, adult learning and cultural needs of the population modifies the evidence-based basics (Peek, Wilkes et al., 2012). Thus, identified the hindrances, cultural norms, and beliefs in the individuals such as African America's of low-income known in the past study (Peek, Ferguson et al., 2014) using collaborating techniques, role-play, testimonials, games, films, and hands-on-skill training support to behavior change (Peek, Quinn et al., 2008; Peek, Wilson et al., 2009; Peek, Odoms-Young et al., 2010). The study used "Prescription of Food, and Exercise" in collaboration with Walgreens, and Farmers Market that provided fresh fruits and vegetables to the community with provisions of expanded food options programs to included food shopping tours, community food pantries, skills training in healthy food preparation/ cooking, physical activity classes, provider workshops and mobile technology programs (Peek, Ferguson et al., 2014).

### **Patient Reported Outcomes: HRQoL and Well-being**

As pertained to traditional research, patient coping mechanisms and health outcomes of the process of acceptance, adaptation and positive outcomes is evident. Studies have suggested optimism or positive demonstrations as helpful to coping with anxiety from chronic disease diagnoses (Liddy et al., 2014). Nash (2015) posited acceptance or denial response to dealing with the chronically ill and diagnosis of diabetes as reflects patients' use of the stage model indicated responses of the disease characterized with denial or acceptance resulted in internalizing the stage and its

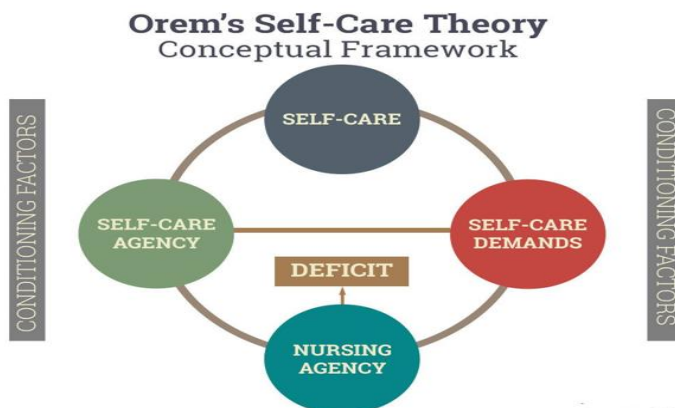
accompanied label Nash (2015). This emotion related to the stage negatively, fused with emotions may inhibit the restructuring of distinctiveness that allows self-management in dealing with the disease (Nash, 2015). However, quality of life (QOL) is relevant to the chronically ill patient due to the multidimensional effect of chronic illness to health, and physical functioning, mental health, social functioning, treatment satisfaction, future burden, and sense of Well-being of an individual. Where, QOL defines the individual's life position sensitivities in culture and value system of living, related to goals, expectations, standards, and issues. The overall feelings of life satisfaction of an individual revealed their mental alertness to life (Megari, 2013). Cella and Nowinski, (2002) had suggested a personal assessment of a variety of other distinct dimensions from which an entire range of experiences faced by a person including perceptions and spheres of thoughts about life, could result in both objective and subjective QoL (Patrick & Erickson, 1993). Among the factors influencing QOL include culture, physical, psychological, interpersonal, spiritual, financial, political, temporal, and philosophical values associated with an individual who is chronically ill (Patrick & Erickson, 1993).

Hypothetically, Quality of life affects the functional ability that encompass roles such as physical activities, and achievement of beliefs, degree, and social interaction quality, psychological Well-being, somatic sensations, happiness, life situations, life satisfaction and necessities of satisfaction from treatment/therapy of an individual who is chronically ill (Brown, Brown et al., 2004). QOL informed patient's performance and improvement, arising out of life satisfaction with effective treatment.

Godarzi et al. (2011) views on lack of awareness and proper functioning of the chronically ill patients, resulted from non-compliance with treatment to control the illness that requires self-care (Godarzi et al., 2011). Self-care could be effective, learned, informed, and be objective to activities, and behaviors of an individual who is chronically ill, use self or relations in resolving situations of life. Self-care aimed to regulate the factors that are effective to growth, and performance of an individual in association with life, health, and Well-being. Behaviors related to self-care impacts the total skill sets, and knowledge of the individual to use their practical efforts and makes self-care central, and valuable core of emphasis to the active role of the individual in their own healthcare. Self-care could be the best strategy by providers to reduce medical services cost (Craven, et al., 1992).

The concept of self-care as proposed by Orem (Self Care Model) is based on a good clinical planned guide, and implementation of a good self-care, which motivates the individual's core principle. It is the belief of Orem that human beings have the capability to take care of their lives. Whenever the capability is distorted, the individual required support from health providers like nurses to regain the capacity (Borji et al., 2017) by providing direct care and compensatory education (Meleis, 2011). According to Orem, the provider's role introduces facilitation as an agent of change to the individual who is chronically ill (Mamarian, n.d.).



**Figure 5***Orem's Self-Care Framework*

*Note.* Adapted from Fawcett, J., & DeSanto-Madeya, S., 2013:

Orem, D. E., 2001, p. 289

A multidimensional concept defines the patient as an individual recipient of care from a health care professional and multi-person unit. Orem reflects on the individual as one member of a multi-person unit who is the unit of service for nursing practices and the multi-person unit as more than one person, all as a whole of whom is assessed on required self-care.

Whose therapeutic self-care demand is continuously effective care of self as an individual or multi-person unit, and subject to universal self-care requisites common to all people at all stages of life, but adjusted for age, development, and the environment by eight tenets;

- Maintenance of a sufficient intake of air
- Maintenance of a sufficient intake of water

- Maintenance of a sufficient intake of food
- Provision of care associated with elimination processes and excrements
- Maintenance of a balance between activity and rest
- Maintenance of a balance between solitude and social interaction
- Prevention of hazards to human life, human functioning, and human well-being
- Promotion of human functioning and development within social groups in accord with human potential, known human limitations and the human desire to be healthy (Fawcett & DeSanto-Madeya 2013; Orem, 2001, p. 289).

The Orem's model examined the ability and defects of the individual, and designed nursing interventions for self-care in accordance with the needs of the individual seeker (Orem, 2001, p. 289). The application process begins with an initial assessment of how the individual's ability matches his or her demographic characteristics and self-care specific needs (Orem, 2001, p. 289). This should be in conformity to health including medical information, past medical history, diagnoses, medications, allergies, expectations, and general care subject to body systems, the daily life usual patterns of health, and perception of social interactions, and the health needs relative to diagnosis test (Borji et al., 2017). The above should be done before an appropriate plan that fits the individual could be designed, developed, and implemented (Borji et al., 2017).

Attitudinal change and responsibility of the individual to connect with providers could occur through support, and motivation mechanism of health care providers, diabetes support groups, and chronic disease researchers. Results of Orem's Self Care

Model improves the QOL of individuals in experimental study in all aspects, with exceptions to general health and emotional role (Borji et al., 2017).

Ghanbari and Kazemnezhad (2009) illustrations of the Orem's self-assessment of patient's physical aspect individually are more pronounced to accept self-care needs of health in its entirety. Patient's expression of less need to address psychological health, social or spiritual concerns attributed to insufficient knowledge emphasis to improve health condition on admission played a role (Ghanbari & Kazemnezhad 2009). Implementation of Orem's self-care scores in five aspects that included diet, physical activity, blood glucose monitoring, medicine (Alternative medication), orthodox medication and diabetic foot care showed significant increase (Ghafourifardet & Ebrahimi, 2015).

Shahbaz and colleagues (2016) reviewed Orem's self-care model indicated that implementation of the model promoted self-care behaviors in diabetic foot ulcers. Whilst Shahbodaghi et al. (2014) identified self-care implementation program for diabetes, and complications with regulatory protocol of diastolic blood pressure after intervention. This study was based on previous study findings that indicated that before intervention QOL for most patients were moderate (Shahbodaghi et al., 2014). About 60% of diabetic patients who had a poor quality of life (Ghanbari & Kazemnezhad, 2009) were attributed to chronic nature and undesirable prognosis. The results showed QOL of patients in the control group were not significant before and after intervention. With Orem's Self Care model, enhanced quality of life for patients

in the experimental group were noticed with exceptions to general health and emotional role (Borji et al., 2017).

### **PROMIS Instrument**

The instrument of PROMIS were set to standardize and validate questionnaire elements used for the measurement of QoL. The National Institute of Health had developed as Roadmap Initiative that can be used for series of chronic disease conditions to include autoimmune disease (Hanmer et al., 2015; PROMIS, 2017).

### **Summary and Conclusions**

This chapter introduced the fundamental basis for this study, significant changes in HRQoL and Optimum Health for patients with T2DM who use therapies, healthcare access, and monitoring with consideration of patient treatment options, specifically healthy eating, physical activities, medication, monitoring, and access to health care, health systems impact and disease impact response to lifestyle changes overtime. It is, therefore, imperative an individual and therapy could be used in behavioral studies to better reveal understanding that underpin factors of physical health and chronic illness (William et al., 1999).

Self-care attributed about 95% of management to Individual patients with type-2 diabetes. Hence, it is pertinent to educate diabetes patients after diagnosis to manage their own conditions effectively. Diabetes self-management education programs that are known by the American Diabetes Association with focus on goal setting in the process of self-management becomes an ideal intervention (Sprague et al., 2006). Thus, education assists patients with diabetes to expand their knowledge base and to

assume a more active role in self-management by becoming more motivated to achieve the set goals of self-management (MacPherson et al., 2004).

Effective self-management support needs to be harmonized with services and support to individual patients between outpatient and office visits. Peer support was one of the solutions to the inadequate support problem identified, to permit self-care support reaching many patients with less or no costs to the individual. Telephone support groups could provide support to patients from providers by assisting their goal setting and goal achievement drive (Piette, 2002; Pillay et al., 2015). The above provided a viable alternative for most care-management programs with no funding and facilitators for proactive provision of day-to-day support to individuals with diabetes (Piette, 2007; Pillay et al., 2015).

The literature reviewed revealed evidence on the collective effects of therapy on individuals with diabetes especially self-care for which individuals with diabetes could be motivated through self-efficacy by identifying with the illness, therapies, set goals, and achieve the goals (Piette, 2002; Pillay et al., 2015). However, approach to diabetes management may not be a viable option for most care managing programs that are financially, and personnel constrained to offer proactively daily support to individuals with diabetes (Piette, 2007; Pillay et al., 2015).

The literature was limited with conclusive evidence on the nature of the association between constructs that explain the illness recognition, effective collective therapies, goals setting and achievement. Research on support programs did not recognize the impact of the disease on the target group, irrespective of individuals

with type-2 diabetes, and providers' attitudes about the group having meaningful benefits was non-conclusive. Most research often did not use standardized measurement tools for objective outcomes, rather used subjective measure of gratification as the ideal measure of success for the group.

The findings indicated that some researches were not adequately empowered, and consequently the attained outcome was insignificant. The length of the research could also be a concern, as several research did not evaluate the long-term impact of therapy support groups. These therapy support groups most often found in research are not always representative of the patient population, given majority of group members being white middle-class women. Thus, making generalization of research findings difficult. Methodological flaws of not using control groups and randomization of individuals to conditions were common across most research. Most research were limited on time for longitudinal assessment and after intervention period. The research did not continue regardless of demonstrated significant benefits, which were invariably beyond the period of the intervention. When support is not continuous, and individual patients are not directed to other support sources, there could be greater ramifications for discontinuity of support.

It is, therefore, necessary to conduct further studies that evaluates these associations and add clarity to insights with better understanding on the implications of self-care with combination therapy in chronic condition. This study thus assessed the reasons underlying self-care challenges, hindrances, and risk especially for the neediest such as minority population with T2DM.

### Chapter 3: Research Method

The purpose of this study was to examine whether patient incorporation of four therapeutic treatment into T2DM control and management results in optimum health. The latter refers to the Well-being of a chronic patient overall life satisfaction and his or her general health in relation to functional limitation due to vision loss, mobility or intellectual disability, life expectancy, as well productive life, and good quality life that defines HRQoL. Patients' therapy determination of treatment for T2DM through statistical tools like regression analysis provides outcomes on physical activity, dietary choices, medication, routine checks for access to health care, and monitoring with data developed to identify chronic diseases, and treatments aimed at patient self-care experience as measured by the scores of optimum health (Well-being) and general health (HRQoL). The patient therapeutic treatment also informs the CDC and ADA in their evidence-based discovery decision making. The latter accounts for biomedical aspects of physical health in relation to patients' safety from muscular-skeletal system injuries of the bones, joints, muscles, ligaments, and tendons, overheating and dehydration, metabolism (binge eating disorders, bulimia, anxiety and stress), and medication (low blood sugar, upset stomach, skin rash, itching, weight gain, kidney complications, tiredness or dizziness, metal taste, gas, bloating, and diarrhea). It also includes psychosocial aspects of the individual patients' daily life satisfaction and overall quality of life. Through the literature review process, the following were identified: (a) HRQoL and well-being for patients with T2DM is highly related to positive psychological outcomes nationally; (b) patients with T2DM investigated for

treatment of emotional distress, social activities and roles show several positive benefits to reduced chronic disease risk being measured with instruments of HRQoL such as participation; (c) HRQoL advocates use of a series of therapies on electronic system of collected self-reported information from diverse populations assessed indicate positive emotions impact, reduced risk of disease, illness, injury, and better immune functioning, speedier recovery, and increased longevity.

This chapter focuses on the T2DM population studied, study design, sample size determination, and methods for establishing a sample and data analysis. The PROMIS 25 survey instrument reliability and validity have been established with supporting literature provided in the last chapter.

### **Research Design and Rationale**

I used a cross-sectional study to evaluate whether therapy participation by T2DM patients attained from the literature revealed differences in HRQoL and well-being of minority patients with T2DM, especially those who used physical activity, diet, medication, and access to health monitoring to achieve optimum health (reduce the diabetes anxiety) and improve general health (control symptoms of diabetes). The independent variables were ethnic/race groups, examination time, and therapy time. Emphasis was on the different therapies used and reported by individual patients at the time of the data collection. Patient groups were divided into categories: those who engaged in therapies against each of the variables under study and those who did not engage in any therapy. Consequently, patients who were reported to have used less than two therapies or no therapy were compared with patients who were reported to have used



more than one therapy. Similarly, patients who reported to have used therapy were compared with patients who reported used therapy which did not involve a longer time monitoring. The PROMIS 25 score mean for HRQoL such as managed emotions (anxiety, depression, helplessness, discouragement, frustration, disappointment, and anger) and Well-being managed symptoms (perform various daily living activities without assistance/managed confidence). For items such as access to exercise, participation in social activities, and social interaction with others to include health professionals were compared. Patient therapy category was determined by the therapy engaged and reported using the data collection time.

The bigeminal demonstration of the two groups and the phraseology of the research questions showed conducting a *t* test. In-addition, other statistical analyses were conducted as dictated by the data. For example, additionally to PROMIS 25 mean score differences for the bigeminal therapies, I considered the possible value in ascertaining which factors were available from the dataset that influenced the PROMIS 25 score. Further analysis such as correlation and multiple regression analyses, and/or analysis of covariance were planned, had the data better met the assumptions of the statistical test, to assess the plausible contributed variables like gender, income status, education level, neighborhood, and ethnic group to the PROMIS 25 scores in relation to other potential covariates.

A literature search revealed the chronic disease burden imposed by treatment routine has an impact on Well-being and HRQoL. I used PROMIS instrument measures for Well-being and HRQoL. The measurement proxy for Well-being was “perform

various daily living activities without assistance/managed confidence”, and the proxy measurement for HRQoL were “Anxiety” and “Depression”, as well as all others of the PROMIS measurements were dependent variables (HealthyPeople.gov, 2015; PROMIS 25, 2017). The possible confounding variables such as age, gender, education level, income status and neighborhood status related to HRQoL have been studied in patients with T2DM (Shamshirgaran et al., 2018).

## **Methodology**

### **Population**

The randomly selected adult in a household self-reported health-related quality of life, health care access, exercise, and chronic health conditions data of the CDC identified demographic variations in health-related behaviors for program designing, implementation, and public health evaluations purposed to address emergent, critical health issues of the noninstitutionalized population and mitigated health risk.

The population risk factor data I used in the study consisted of all patients who had managed their chronic conditions with therapies of good food choices, physical activities, medication regime (oral and insulin), were being observed or oriented by health professionals through access to health, and who were using lifestyle behavior therapies. Also, included in the criteria are those who had consented and responded to the PROMIS 25 instrument questions via the BRFSS, developed, tested, and added to the National Health Interview Survey to address the multidimensional domains related to physical, mental, emotional, and social functioning. This was a collaboration between NIH/National Cancer Institute and National Center for Chronic Disease Prevention and

Health Promotion. The institutions added the evaluation and improvement of HRQoL, and Well-being as a public health priority as well as the Healthy People 2020 who monitored the evaluation measures in the United States (Healthy People 2010; NHIS, 2010; PROMIS, 2019). As of April 12, 2017, the total population included were 450,016 patients. Any patient who met the criteria for completion of the BRFSS relative to the PROMIS 25 instruments was eligible, considered, and included in the research.

### **Sampling and Sampling Procedure**

The population used for the study were extracted from a computer-assisted telephone interview of the noninstitutionalized national household survey data set of a secondary data consisted of chronic disease patients that included diabetes patient's annual health related perceptions on access to health care, therapies, goal setting, goal achievement, and outcome monitoring of the 2017 BRFSS (2018). In the sample selection, I considered the four-criterion power analysis : power, significance criterion ( $\alpha$ ), sample size ( $n$ ), and effect size (ES) where a fixed value of any one is a function of the other three (see Cohen, 1965), obtained through G\*Power to ascertain differences between two independent means, a priori to the sample size selection based on a higher level of effect size 0.10 or more, an alpha of 5% or 0.05 at the confidence level of 95% for the selection of a larger sample size enough to attain enough power of 90% to enable the detection of enough statistically significant difference predictive of the null hypothesis to be rejected or accepted (Faul et al., 2009). Since my study was a population study, I used a large random sample of all cases (224,931) of the eligible individual participants meeting the inclusion criteria from 450,016 population at a set of alpha 0.05

amongst those who engaged in the 2017 BRFSS survey. The purpose was to draw comparisons on attributes common between those who engaged and completed the PROMIS 25 related survey as possible means to make a generalization of HRQoL and well-being results.

### **Data Analysis Plan**

I address the research question I planned on two statistical methods. I planned two-tailed  $t$  tests for independent samples to determine statistically significant difference in unrelated groups using Spearman's correlation to measure the strength and direction of monotonic association between two variables. The second method was regression analyses that consisted of multivariate logistic regression for predictor variables (continuous and discrete) to model a binary outcome with only two possible values (0=yes, 1=no) for categorical dependent variables. I also contemplated the possibly of analysis of covariates (ANCOVA) to remove any effects of covariates in the direction to examine the difference between means presented in Table 3 and ran predictive models that imputed encoded missing data (i.e., 9 or 99 or 999) while controlling for age, gender, ethnic group, education level, and income status. The supported assumptions were that the data used were homogeneity of variance, normally distributed covariates, and a dependent variable at each level of independent variable are linearly related. I assumed it was homoscedastic of dependent variable for each value of independent variable and the covariate and the independent variable would not interact. Consequently, these attributes could be tested by parametric statistics to determine the outcome of the research questions posed.

**Table 3***Assessment of Indicated Connection Between Patient Treatment and Therapies*

Patient Treatment, with Literature reference	Therapeutic Groups	Outcome
Therapies (good dietary choice, medication, physical activity, and monitoring) Hagley et al. (2018)	No changes in non-Insulin regimen and carbohydrate intake. Reductions in basal insulin doses. Other medication beside insulin. Older adults increase cardiovascular complications	Exercise related hypoglycemia.  Mitigates nocturnal hypoglycemia risk. Increase exercise related hypoglycemia. Avoid heat related sickness due to exercise
Colberg et al. (2016, p. 2071) Fahey et al. (2012, p. 2072) Koh et al. (2010)	Lack of medication and exercise	At 6 months for 6 minutes' walk test distance were not indifferent for Intradialytic exercise, +14%; home-based exercise, +11%; usual care, +5% and pulse wave velocity (intradialytic exercise, -4%; home-based exercise, -2%; and usual care+%

**Research Questions and Hypotheses**

The predominant question is whether addressing patient treatment with therapy, healthcare access monitoring results in better outcomes from psychosocial, and physiological perception, and whether any of these outcomes might be influenced by age, ethnicity, gender, education level, income status and neighborhood. Fairchild and McDaniel (2017) asserted mediation as a third-variable effect that explains how or why the two variables relate. The authors used a path diagram definition to describe the indirect effect of independent (X) variable on dependent variable (Y) connects with a mediator (M). They relayed the notion of mediation as accounts for the impact of an intervening variable, given an example mediator (M effect), that postulated to transmit

the impact of an independent variable (X), onto an outcome (Y); and moderating variables as those that revealed understanding into the circumstance for which the independent, and dependent variables are connected (Fairchild & McDaniel, 2017). Fairchild and McDaniel (2017) defined a confounding variable as one that is connected to both the independent and dependent variables to changing the effect between the two, and covariates, which could connect to either or both the independent and dependent variable and yet would not impact changes to their association once controlled attenuates. In this current study, gender, age, ethnic group, education level, and income status may explain the circumstance to which patients attained a higher sense of total life satisfaction, and less sadness or felt ill (HRQoL and well-being) to engage in therapy pertained to patient-reported outcome. These variables could be connected to a specific therapy. Consequently, gender, age, ethnic group, education level, income status, and neighborhood could be moderated as confounded variables. Other potential confounding variables were thought about with availability of data fields of the secondary data set used. The initial variable primarily, connected to the active disease present, and physiological complications reported during the PROMIS 25 related patient assessments. Trikkalinou, et al. (2017) relayed the patient experience with active disease, and physiological complications reduced HRQoL scores in comparison with the non-active disease patient. Consequently, through the literature, disease present and physiological complications are connected to the current study dependent variables to be measured for HRQoL, and Well-being. The study results could be confounded at different levels of active disease and physiological complications for all independent

variables (therapies). Secondly, the next possible confounded variable examination was therapy participation related effects connected with Musculo-skeletal, and BMI, and influence on HRQoL and Well-being. Engagement via non-professional DSME and DSMS, and resources tend to create confined impacts of pain, soreness, and inflammation which also could impede a patient's health beliefs, cultural needs, current knowledge, physical limitations, emotional concerns, family support, financial status, medical history, health literacy, numeracy and other personal inability challenges that increase the disease risk (Powers et al., 2016). Nevertheless, these non-professional engagements could create both limited, and/or broad impacts on the patient. However, when dependent variables of HRQoL of therapy participation duration are compared to independent variables, the outcome could be confounded by the associated treatment symptoms, and adverse occurrences (AE), since AEs are directly associated with care, and services of the different therapy groups. The therapies are homogeneous across the four treatments. Consequently, therapy practices by patients across the different treatments are related to their specific individual needs, and health professional recommendations (Hagley et al., 2018). The current study facilitated therapies used by the patients during the survey in relation to PROMIS 25.

RQ1: Is there a significant statistical association between decreased well-being proxy PROMIS score (managed confidence) for T2DM present that determines optimum health in ethnic groups who utilized combination therapy for self-care, controlling for age, gender, education level, income status, and ethnic group?

$H_01$ : There is no significant statistical association between decreased well-being proxy PROMIS score “managed confidence” for T2DM present that determine optimum health in ethnic groups who utilized combination therapy for self-care.

$H_a1$ : There is significant statistical association between decreased well-being proxy PROMIS score “managed confidence” for T2DM present that determine optimum health in ethnic groups who utilized combination therapy for self-care.

The following were the independent variables for RQ1: Ethnic/race groups, age, gender, and therapies (e.g., total number of times T2DM patient made good food choices; ate vegetables, fruits, and protein; engaged in physical activity like jogging, biking, running, walking, swimming, and aerobics; medicated with insulin, noninsulin and/or alternative; and accessed healthcare services included routine checks and times seen by health professional for DSME, and DSMS. The dependent variable was the well-being proxy PROMIS score “Managed confidence” (Diabetes presence; have you ever been told that you have diabetes).

RQ2: Is there a significant statistical association between increased HRQoL proxy PROMIS score “Control Symptoms of Anxiety” for general health, and total number per day/week therapy is participated in controlling for age, gender, education level, income status, and ethnic group?

$H_02$ : There is no significant statistical association between increased HRQoL proxy PROMIS score “Control Symptoms of Anxiety” for general health, and total number per week therapy is participated.



*H<sub>a2</sub>*: There is significant statistical association between increased HRQoL proxy PROMIS score “Control Symptoms of Anxiety” for general health, and total number per week therapy is participated.

The following served as the independent variables for RQ2: therapy participation (e.g., total vegetables consumed per day/week, fruits consumed per day/week, protein consumed per day/week, total physical activity per day/week, medication; non taking insulin/taking insulin/alternative medication, and times seen by health professional for diabetes DSME and DSMS), age, education level, gender, income status, and ethnic group. The dependent variable for RQ2 was the HRQoL proxy PROMIS score for “Control Symptoms of Anxiety” (General Health = Control Symptoms of Anxiety)

RQ3: Is there a significant statistical association between increased HRQoL proxy PROMIS score “Control Symptoms of Anxiety” for general health, and timely examined blood glucose levels, eyes and foot controlling for age, education level, gender, and income status, and ethnic group?

*H<sub>03</sub>*: There is no significant statistical association between increased HRQoL proxy PROMIS score "Control Symptoms of Anxiety" for general health, and timely examined blood glucose levels, eyes, and foot.

*H<sub>a3</sub>*: There is a significant statistical association between increased HRQoL proxy PROMIS score "Control Symptoms of Anxiety" for general health, and timely examined blood glucose levels, eyes, and foot.

The independent variables for RQ3 were examination time (how often check blood for glucose, foot, and eye), age, education level, gender, income status, and ethnic group. The dependent variable was the HRQoL proxy PROMIS score for “Control Symptoms of Anxiety” (General Health = Control Symptoms Anxiety)

**Table 4**

*List of Variables*

Variable	Description	Variable Type	Code
<b>Independent Variables</b>			
Therapy 1; FRUIT2 (Good Food Choice)	How often did you eat fruit? (Fresh, frozen or canned fruit, and not including dried fruits and juices)?	Continuous	101-199 = times per day (once or more) 201-299 = times per week (once or more) 301-399 = times per month (once or more) 401-499 = times per year (once or more)
		Continuous	777 = Don't know/Not sure 888 = Never 999 = Refused/missing
FVGREEN1 (Good Food Choice)	Not including lettuce, potatoes and rice, how often did you eat other vegetables: Include tomatoes, green beans, carrots, corn, cabbage, bean sprouts, collard greens, and broccoli to include raw, cooked, canned, or frozen vegetables and protein		101-199 = times per day (once or more) 201-299 = times per week (once or more) 301-399 = times per month (once or more) 401-499 = times per year (once or more) 777 = Don't know/Not sure 888 = Never 999 = Refused/missing
Therapy 2: INSULIN Medication	Are you now taking insulin	Categorical	0 = yes 1 = no
Therapy 3 BLDSUGAR; Monitoring diabetes	How often do you check for glucose or sugar	Continuous	101-199 = times per day (once or more) 201-299 = times per week (once or more)

			<p>301-399 = times per month (once or more)</p> <p>401-499 = times per year (once or more)</p> <p>777 = Don't know/Not sure</p> <p>888 = Never</p> <p>999 = Refused/missing</p>
Therapy 4: EXEROFT1	During the past month, other than regular job, did you participate in any physical activities or exercises such as running, walking, jogging, or swimming for exercise	Continuous	<p>101-199 = times per week</p> <p>201-299 = times per month</p> <p>777 = don't know/Not sure</p> <p>999 = Refuse/missing</p>
IMPRACE	Imputed race/ethnicity	Categorical	<p>1 = White, non-Hispanic</p> <p>2 = Black, non-Hispanic</p> <p>3 = Asian, non-Hispanic</p> <p>4 = American Indian/Alaskan native, non-Hispanic</p> <p>5 = Hispanic</p> <p>6 = Other race, non-Hispanic</p>
CHKHEMO3 Access to health care	Times seen health professional for diabetes (About how many times in the past 12 months have you seen a doctor, nurse, or other health professional for your diabetes	Continuous	<p>1-76 = Number of times (1-76 or more)</p> <p>88 = None</p> <p>98 = Never heard of "A one C" test</p> <p>77 = Don't know/Not sure</p> <p>99 = Refused/missing</p>
EYE EXAM	Last time you had an eye exam in which the pupils were dilated	Categorical	<p>1 = within the past month (anytime &lt;1 month ago)</p> <p>2 = within the past year (1 month but &lt; 12 months ago)</p> <p>3 = within the past 2 years (1 year but &lt; 2 years ago)</p> <p>4 = 2 or more years ago</p> <p>7 = don't know/Not sure</p> <p>8 = never</p> <p>9 = Refused/missing</p>
FEETCHK2	Times feet check for sores and irritations	Continuous	<p>101-199 = times per day (once or more)</p> <p>201-299 = times per week (once or more)</p> <p>300-399 = times per month (once or more)</p> <p>401-499 = times per year (once or more)</p> <p>555 = no feet</p>

Dependent Variables			
PROMIS 25: Managed confidence (DIABEDU)	A domain in the PROMIS 25 validated tool in this study being used as a proxy for Well-being. Have ever taken a course or class in how to manage your diabetes yourself.  Satisfaction with life or Well-being (LSATISFY); 1=very satisfied 2=satisfied 3=dissatisfied 4=very dissatisfied 7=don't know/not sure 9= refused/missing	Dichotomous	777 = don't know/Not sure 888 = never 999 = Refused/missing  0 = yes Taken course or class; Satisfaction with life; 3 or 4, 1 = no Not taken course or class; Satisfaction with life; 1, or 2 or 3, 7 = Don't know/Not sure 9 = Refused/missing
PROMIS 25: Diabetes present (DIABETE3)	Have you ever been told by a doctor or other health professional that you have prediabetes or borderline diabetes	Dichotomous	0 = yes Diabetes present 1 = no No diabetes or prediabetic or borderline diabetes 7 = Don't know/Not sure 9 = Refused/missing
PROMIS 25; Anxiety (EMTSUPRT)	A domain in the PROMIS 25 validated tool in this study being used as a proxy for HRQoL; Emotional support and life satisfaction  GENHLTH (General Health; 1=excellent 2=very good 3=good 4=fair 5=poor 7=don't know/not sure 9=refused)  1 = always 2 = usually	Dichotomous	0 = Yes (Emotional support and life satisfaction; 4 & 5 and General health; 4 or 5) 1 = No (Emotional support and life satisfaction; 1, 2, & 3 and General health; 1 or 2 or 3 ) 7 = don't know/ not sure 9 = refused

3 = sometimes  
 General health; 4 or 5  
 4 = rarely  
 5 = never  
 7 = don't know/ not sure  
 9 = refused  
 General health; 1 or 2 or  
 3

## Moderating Variables

AGE_G (Age group)	Six-level imputed age category		1 = 18 to 24 2 = 25-34 3 = 35-44 4 = 45-54 5 = 55-64 6 = 65 or older
HOWSAFE1	Neighborhood safe from crime	Categorical	1 = extremely safe 2 = safe 3 = unsafe 4 = extremely unsafe 7 = don't know/not sure 9 = refused
SEX	Patient reported Gender	Dichotomous	0 = male 1 = female 9 = Refused /missing
EDUCAG (Education level)	Level of education completed (1=never attended school or only kindergarten 2=grade 1 through 8 (Elementary) 3=grades 9 through 11 (some high school) 4=grade 12 or GED (High school graduate) 5=college 1 year to 3 years (Some college or technical school) 6=college 4 years or more (College graduate) 9=Refused)	Categorical	1 = did not graduate high school (Education level; 1 or 2 or 3) 2 = graduated high school (Education level; 3) 3 = attended college or technical school (Education level; 5) 4 = graduated from college or technical school (Education level; 6) 9 = don't know/not sure/missing
INCOMG (Income categories)	Annual household income from all sources	Categorical	1 = <\$15,000 (INCOME2 = 1 or 2)

(INCOME2;1=<\$10,000 (No code zero)	2 = \$15,000 to <\$25,000 (INCOME2 = 3 or 4)
2=<\$15,000 (\$10,000 to <\$15,000)	3 =\$ 25,000 to <\$35,000 (INCOME2 = 5)
3 = <\$20,000 (\$15,000 to <\$20,000)	4 = \$35,000 to <\$50,000 (INCOME2 = 6)
4 = <\$25,000 (\$20,000 to <\$25,000)	5 = \$50,000 or more (INCOME2 = 7 or 8)
5 = <\$35,000 (\$25,000 to <\$35,000)	9 = don't know/not sure
6 = <\$50,000 (\$35,000 to <\$50,000)	
7 = <\$75,000 (\$50,000 to <\$75,000)	
8 = \$75,000 or more	
77 = don't know/Not sure	
99 = refused	

### **Instrumentation**

PROMIS 25 is the general instrument intended for individuals aged 18 years and older self-efficacy for managing chronic disease. This instrument used eight response option for each of the seven domains of self-efficacy to managed chronic disease symptoms: anxiety, depression, fatigue, pain interference, mobility or physical function, peer relationships (social status), and one's response on a pain intensity item and for physician-rated severity. For each response within the social status domain, the individual could select a value 1-8. Subsequently, in the emotions, management score table for the chronic disease of the PROMIS 25, the lowest raw score in any 8A domain is 8, and the highest score is 40 for the questions based on the *t*-score (PROMIS, 2018).

For the variable anxiety, and depression, (inversely worded), for the lowest *t*-score was better than average *t*-score. Also, for the variable peer relationships (positively worded) for the lowest *t*-score is impaired than average. The average *t*-score

was based on the United States population at a normalized score of 50.0 (PROMIS, 2018).

### **Data Handling**

Upon the receipt of the institutional review board (IRB) approval from Walden University, I followed up with the submission of the pre-existing data synopsis from CDC through the Behavioral Risk Factor Surveillance System. This body of information, in line with PROMIS 25 related patients' data of 2017, generally taken from states specific data on health risk behaviors, chronic diseases and conditions, access to health care, and use of preventive health services associated to the leading causes of death, and disability in the United States. It included factors such as; alcohol consumption, chronic health conditions, breast-and-cervical, prostate, colorectal cancer screening, exercise, health status, healthy days/health-related quality of life, health care access, inadequate sleep, oral health, tobacco use, e-cigarettes, immunization, falls, seat belt use, drinking and driving and HIV/AIDS knowledge. The data and code book were downloaded onto a personal computer and laptop, non-coded and extracted into an SPSS version 24. Data files were stored on a personal OneDrive.

### **Protection of Human Subjects**

The obtained data for this research were taken from the Centers for Disease Control and Prevention survey data and documentation annual survey data, which had already been de-identified.

### **Dissemination of Findings**

The presentation of research findings to the Walden University was in partial fulfillment of academic requirement for a doctorate in public health. Even though not requested, these findings could be disseminated to the ADA and CDC and their patients, caregivers, and advocate membership. The outcomes of this research might be presented for publication in peer-reviewed journals such as BMJ Public Health and Epidemiology.

### **Threats to Internal Validity**

Internal validity threats included the listed biases that could be present in the populations I studied, namely, patients with chronic condition of T2DM who responded in the BRFSS in line with PROMIS 25 survey and those who fall out of the PROMIS 25 survey. The biases included: (1) recall bias (2) response to survey bias (e.g., those with the tendency for several positive or several negative responses to survey about health responses) (3) selection – historic bias of patients’ use of therapy might differ among individual respondents and (4) selection- maturation of patients who previously engaged in survey (for which CDC implored for completion twice annually). The above may differ from those for whom have not previously taken PROMIS 25 survey, or patients who have used multiple types of therapies against those who have not (Blome & Augustine, 2016).



### **Threats to External Validity (Generalizability)**

The patient population with T2DM is randomized. Subsequently, the population consented to take the PROMIS 25 related instrument could represent patients in CDC's BRFSS survey. Similarly, patients with T2DM in BRFSS survey data, with whom my patients were a subset of the broader population, could be represented in the whole population of patients with T2DM globally. Eventually, the aim was to be able to generalize across all patients with T2DM. Next to data analysis, identified possible external validity threats by comparing dataset of persons in BRFSS survey data patients who completed the PROMIS 25 related survey with those who did not for consistency.

### **Summary**

In this chapter the methodology for understanding possible associations between patient preferences for treatment (for therapies; good food choice, medication or alternative medicine, physical activity, and monitoring through access to healthcare) served as the fundamentals of patient well-being (given once ability to peer relationships and HRQoL (anxiety and depression) were presented. A synopsis of all BRFSS from Centers for Disease Control and Prevention participants who consented to complete the PROMIS 25 related survey of a randomized population was 17,858 participants in the three accessible years of 2018-2020. A synopsis identical to BRFSS from 2010-2020 randomized population of 450,016 participants was available for comparison. In the next chapter, statistical methods used for analyses of data and the outcome and meaning of the data will be discussed. Additionally, the illustrated transformations made on how the

therapies were optimized following examination of the data and how the patient's therapies categorized will be espoused.

## Chapter 4: Results

The purpose of this research dissertation was to discover whether the use of combined therapeutic treatment consisted of behavioral change lifestyle factors resulted in the predicted mean changes in HRQoL and well-being for patients as measured by the PROMIS 25 survey instrument. The behavioral change factors assessed were (a) good food choices, (b) physical activity, (c) medication, and (d) access to health care service monitoring and self-management of T2DM. I used a secondary dataset from the CDC to answer the research questions. The three formulated research questions variables had the following outline:

Good food choice: Is X statistically different between patients with T2DM who reported used of good food choices (fruits and vegetables) as part of combination therapy within a certain period of time as patients and those who reported used combination therapy (e.g., good food choice, physical activity, medical, eye exam, feet check) and access to health care monitoring (blood glucose and glycosylation hemoglobin check) therapies overtime (day, week, month, once a month, month/year)?

Medication: Is X statistically different between patients with T2DM who reported used medication as therapy within a certain period of time as part of combination therapy within a certain period of time as patients and those who reported used combination therapy (e.g., good food choice, physical activity, medical, eye exam, feet check) and access to health care monitoring (blood glucose, and glycosylation hemoglobin check) therapies overtime (day, week, month, once a month, month/year)?

Physical activity: Is X statistically different between patients with T2DM who reported used physical activity as therapy within a certain period of time as part of combination therapy within a certain period of time as patients and those who reported used combination therapy (e.g., good food choice, physical activity, medical, eye exam, feet check) and access to health care monitoring (blood glucose and glycosylation hemoglobin check) therapies overtime (day, week, month, once a month, month/year)?

Access to health care monitoring: Is X statistically different between patients with T2DM who reported used access to health care monitoring as part of combination therapy within a certain period of time as patients and those who reported used combination therapy (e.g., good food choice, physical activity, medical, eye exam, feet check) and access to health care monitoring (blood glucose and glycosylation hemoglobin check) therapies overtime (day, week, month, once a month, month/year)?

Eye exam: Is X statistically different between patients with T2DM who reported used eye exam as therapy within a certain period of time as part of combination therapy within a certain period of time as patients and those who reported used combination therapy (e.g., good food choice, physical activity, medical, eye exam, feet check) and access to health care monitoring (blood glucose and glycosylation hemoglobin check) therapies overtime (day, week, month, once a month, month/year,)?

Feet check: Is X statistically different between patients with T2DM who reported used feet check as therapy within a certain period of time (s) as part of combination therapy within a certain period of time as patients and those who reported used combination therapy (e.g., good food choice, physical activity, medical, eye exam,

feet check) and access to health care monitoring (blood glucose and glycosylation hemoglobin check) therapies overtime (day, week, month, once a month, month/year)?

Where X is (a) The Well-being proxy PROMIS 25 score for “Managed confidence” taken course or class due to diabetes present to increase their total satisfaction with life; (b) The HRQoL proxy PROMIS 25 score for “Control symptoms of Anxiety”, required emotional support and life satisfaction to improve general health; or (c) The HRQoL proxy PROMIS 25 score for “Control symptoms of despair”, required emotional support and life satisfaction to improve general health. Additionally, self-care with combination therapy was defined as range of care activities deliberately engaged throughout life to promote physical and emotional health, maintain life, and prevent disease (Godfrey et al., 2011). Also, I included five algorithm guidance principles that emphasized patient engagement, shared information, psychosocial, and behavioral support integrated with therapies, and coordinated care as allowed by DSME and DSMS (see Powers et al., 2017). Thus, a patient adapting lifestyle behavioral therapies over lifetime increased their general health, satisfaction with life and quality of life, and prevent or reduces T2DM risk.

### **Hypotheses and Variables**

The null and alternative hypothesis per question, and the independent and dependent variables were successively stated as:

H<sub>0</sub>: There is no significant statistical association between the mean differences

H<sub>a</sub>: There is significant statistical association between the mean differences

Independent variable: Therapies

Dependent variable: PROMIS score (Legacy scale mean)

Analysis of data was undertaken between 12 February – June 2021 preceding the receipt of Walden IRB approval on 13 January 2020 (approval number January-13-2021-0564670). The remaining sections of this chapter focuses on dataset preparation for analysis, results presentation, and summary.

### **Data Collection**

I updated the dataset from 2016 to 2017 collected from the CDC to have access to PROMIS 25 related data inclusive for 2017 issuance of the survey. Furthermore, I attained a dataset of individuals 18 years and older who had/not completed a PROMIS 25 survey and were noninstitutionalized. This was similarly included in the Chapter 3 planned outlined on purpose for noted similarities and differences (See Table 4) among individual patients in the secondary dataset who had not completed PROMIS 25 related survey, and those who had.

### **Inclusion/Exclusion**

The individuals of the dataset who had/not completed the PROMIS 25 related survey annually for the year 2017 included 224,931 participants. Among these were therapy recipients and those who did not include good dietary choices, physical activity, medication, and monitoring through access to healthcare services. There were no concessions for individuals who completed or did not complete a PROMIS 25 survey from the research questions data analysis. I retained the total number of participants in the analysis of my research questions.

The dataset of participants surveyed for PROMIS 25 reported and those who did not consist of 224,931 individuals. The age range of participants included was 18 years and older. With this considerable number of participants, there is the expectation that the precision of the predictor(s) of PROMIS 25 dependent variables will provide enough certainty in the analysis.

### **Therapies Categorical Values Context**

The adequacy to predict Well-being and HRQoL with the initial plan was to use four therapies instead of one or two. As such, to determine the therapy insulin sufficiency was not enough for the operationalization of medication therapy decision. However, as the analysis progressed with the dataset, I realized that patient time to medicate was a vital indicator of impact and that needed deeper examination. Consequently, any patient who used insulin could account for the time interval, not per day, week, month, and year against the therapy's specific administrative tool to achieve optimum health. Similarly, if a patient takes insulin daily per duration of allowable clinical dosage time, sufficiency of medication care will match therapy efficient daily, and not weekly, monthly, and yearly. The dataset reveals patients who reported insulin intervals reported hourly intervals of 1:12, 1:15, 1:41 to 3:05 minutes daily. Thus, participants provided intervals of insulin administration time that could be categorized with allowable clinical dosage time information. In this manner, the therapy could align with the research question statement with the dataset per the therapy definition, but not sufficient without oral medication.

Furthermore, concerning the management of insulin, the required time daily through annually indicated administration time variation across patients. Consequently, in view of the lack of precise data regarding individual patient's time of administration, the categories were grouped by those who use and those who did not use insulin medication therapy.

### Demographics

The dataset comprised of the entire population of people who may have and have not taken the PROMIS 25 gauged through the BRFSS. Nevertheless, this population of PROMIS 25 survey participants is a subset of some chronic noninstitutionalized patients in the CDC patient documented information. To support the generalizability of the entire population the assessment of the available data was common to all researchers in the information document as well as to enable the prediction of those who engaged in PROMIS 25 survey, and those who did not. Table 5 shows demographics of participants in the survey information segment of those engaged and not engaged in the PROMIS 25 survey.

**Table 5**

*Demographics of Therapy-Engaged Patients Versus Nonengaged Patient*

	PROMIS 25 (M-Class) <i>N (%)</i>	Non PROMIS 25 (M-Class) <i>N (%)</i>	PROMIS 25 (E- Support) <i>N (%)</i>	Non PROMIS 25 (E-Support) <i>N (%)</i>
Sex	8671(100%)	10457(100%)	1765(100%)	8128(100%)
Male	4076(47.1%)	4571(52.9%)	957(20.9%)	3614(79.1%)
Female	4589(43.8%)	5879(56.2%)	808(15.2%)	4514(84.8%)
Refused	6(46.2%)	7(53.8%)	-	-



Race	8671(100%)	10457(100%)	1756(100%)	8128(100%)
American Indian/Alaska Native	223 (42.6%)	301(57.4%)	41(27.5%)	108(72.5%)
Asian, non-Hispanic	119(56.4%)	92(43.6%)	43(29.9%)	101(70.1%)
Black, non-Hispanic	1203(44.1%)	1524(55.9%)	109(37.7%)	180(62.3%)
Hispanic/Latino	846(51.6%)	794(48.4%)	129(32.3%)	271(67.8%)
Other, non-Hispanic	244(46.8%)	277(53.2%)	40(28.4%)	101(71.6%)
White, non-Hispanic	6036(44.7%)	7469(55.3%)	1403(16.0%)	7369(84.0%)
Age	8671(100%)	10457(100%)	1756(100%)	8128(100%)
18-24	28(40.0%)	42(60.0%)	110(18.3%)	492(81.7%)
25-34	129(46.2%)	150(53.6%)	1819(17.7%)	840(82.3%)
35-44	377(46.7%)	430(53.3%)	216(18.1%)	978(81.9%)
45-54	1092(45.9%)	1285(54.1%)	308(19.3%)	1289(80.7%)
55-64	2270(44.8%)	2793(55.2%)	399(17.7%)	1858(82.3%)
65 or older	4775(45.3%)	5757(54.7%)	551(17.1%)	2671(82.9%)
Education Level	8671(100%)	10457(100%)	1765(100%)	8128(%)
Did not high school graduate	13596	884(39.4%)	171(41.4%)	242(58.6%)
Graduated high school	(0.6%)	3125(50.1%)	589(23.6%)	1907(76.4%)
Attended college or tech school	3117(49.9%)	3285(60.4%)	559(18.8%)	2420(81.2%)
Graduated from college or tech	2151(39.6%)	3135(60.9%)	430(10.8%)	3534(89.2%)
Don't know/Not sure	2014(39.1%)	28(48.3%)	16(39.0%)	25(61.0%)
	30(51.7%)			
Income	8671(100%)	10457(100%)	1765(100%)	8128(100%)
<\$15,000	1286(51.6%)	1208(48.4%)	224(40.7%)	327(59.3%)
\$15,000-<\$25,000	1772(48.5%)	1881(51.5%)	308(25.9%)	879(74.1%)
\$25,000-<\$35,000	912(45.6%)	1089(54.4%)	215(24.3%)	669(75.7%)
\$35,000-<\$50,000	1017(43.3%)	1332(56.7%)	258(20.2%)	1017(79.8%)
\$50,000 or more	2059(39.3%)	3181(60.7%)	473(10.1%)	4190(89.9%)
Don't know/Not sure	1625(47.9%)	1766(52.1%)	287(21.5%)	1046(78.5%)
Safety	1709(100%)	2306 (100%)	1757(100%)	8107(100%)
Extremely safe	664(41.1%)	952(58.9%)	571(12.1%)	4166(87.9%)
Safe	929(43.1%)	1225(56.9%)	1008(21.2%)	3752(78.8%)
Unsafe	78(48.1%)	84(51.9%)	123(47.5%)	136(52.5%)
Extremely unsafe	17(50.0%)	17(50.0%)	24(52.2%)	22(47.8%)
Don't know/Not sure	21(48.8%)	22(51.2%)	22(47.8%)	24(52.2%)
Refused	-	6(100%)	9(56.3%)	7(43.8%)
Insulin Administration	8671(100%)	10457(100%)	234(100%)	788(100%)
Yes, Insulin	2036(32.4%)	4241(67.6%)	92(25.8%)	265(74.2%)
No, Insulin	6616(51.6%)	6206(48.4%)	142(21.4%)	522(78.6%)
Refused	19(65.5%)	10(34.5%)	-	1(100%)

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*Note:* The values represent the percentage of the fraction of engaged respondents, 8671 of the totals for PROMIS 25(Taken Class to Manage Diabetes) and 10457 for the non-engaged (non-PROMIS 25). M\_class, 1765 of the totals for PROMIS 25 (How Often

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get Emotional Support Needed) and 8128 for the non-engaged respondents (non-PROMIS 25) with no missing values for those who Often get Emotional Support Needed. Missing values for both Well-being and M\_class were not included.

### **Gender, Others, and Race**

Participants groups by gender was near equal predictor for male and female engaged than the nonengaged of PROMIS 25(Well-being & HRQoL) (47.1% male/43.8% female) versus (20.9% male /15.2% female) and (52.9% male/56.2% female), versus (79.1% male/84.8% female), though the nonengaged and engaged in PROMIS 25 were less balanced for PROMIS 25 (Well-being & HRQoL) in the survey. Age and race indicated same pattern between minority and majority engaged in class to manage diabetes (Well-being) and needed emotional support (HRQoL) reported 42.6% American Indian/Alaska Native, 56.4% Asian, 44.1% Black, 51.6% Hispanic/Latino, 46.8% other, 44.7% White, and 27.5% American Indian/Alaska Native, 29.9% Asian, 37.7% Black, 32.3% Hispanic/Latino, 28.4% other, 16.0% White nonengaged class and support showed 57.4% American Indian/Alaska Native, 43.6% Asian, 55.9% Black, 48.4% Hispanic/Latino, 53.2% other, 55.3% White, and 72.5% American Indian/Alaska Native, 70.1% Asian, 62.3% Black, 67.8% Hispanic/Latino, 71.6% other, 84.0% White. While other demographics reveals same pattern of near equals for the engaged against nonengaged, there was less balance for age, education levels, income levels, and safety.

I performed a chi-squared test of independence on sex, education, and income levels, race/ethnicity, and safety to check for any uniformity in distribution of PROMIS 25 and non-PROMIS 25 participants in the BRFSS 2017 data. The outcome of the chi-

square test of independence between PROMIS 25(Well-being, HRQoL) and sex revealed all expected cell counts as less than five. The derived statistically significant association makes the null hypotheses for sex and PROMIS 25 (Well-being, HRQoL), for participants engaged or nonengaged in the survey to reject null hypothesis  $\chi^2_{(class, support)} = 20.776, p < .005$  and  $55.544, p < .005$  at a Cramer's  $V = .033$  and  $.075$  that indicated an irrelevant nonassociation. Sex revealed unequal distribution in the population between PROMIS 25 and sex variables.

The chi-square test of independence between PROMIS 25 (Well-being, HRQoL) and race/ethnicity revealed all expected cell counts as less than five. A statistically significant association derived revealed the null hypotheses as nonassociative for race and PROMIS 25 (Well-being, HRQoL) for participants engaged or non-engaged in the survey to reject the null hypothesis  $\chi^2_{(class support)} = 30.612, p < .005$  and  $188.962, p < .005$  at a Cramer's  $V = .040$  and  $.138$ . This indicates an irrelevant nonassociation. The relationship between race/ethnicity and PROMIS 25 is attributed to an uneven distribution and chance in the population.

The chi-square test of independence between PROMIS 25 (Well-being) and neighborhood safety revealed all expected cell counts as less than five. There is a non-statistically significant difference for safety and PROMIS 25 (Well-being) for participants engaged or non-engaged in the survey to fail to reject the null hypothesis  $\chi^2_{(class)} = 2.440, p > .05$ , at a Cramer's  $V = .025$ .

However, difference between safety and PROMIS 25 (HRQoL) for participants whether engaged or non-engaged in the survey statistically significantly led to reject the

null hypothesis  $\chi^2_{(\text{support})} = 245.231, p < .005$ , at a Cramer's  $V = .158$  for safety and PROMIS 25 (HRQoL). Although, the association is small for Well-being, this may align HRQoL outcome with chance and Well-being with non-random cause that could impact PROMIS 25. Neighborhood safety revealed uneven distribution and differences of effect in the population for Well-being and HRQoL of PROMIS 25 and between the expected variables.

The chi-square test of independence between PROMIS 25(Well-being, HRQoL) and age revealed all expected cell counts as less than five. The null hypotheses derived a non-statistically significant association to make the null hypotheses associative for age and PROMIS 25, for participants engaged or non-engaged in the survey, to refuse to reject null hypothesis  $\chi^2_{(\text{class})} = .369, p > .005$  and  $\chi^2_{(\text{support})} = .066, p > .005$  at a Cramer's  $V = .004$  and  $.003$ . This indicates a weak association, with attributes to some non-random cause. The Age and PROMIS 25 relationship revealed a poor uneven distribution in the population, which could impact PROMIS 25.

The chi-square test of independence between PROMIS 25 (Well-being, HRQoL) and education levels revealed all expected cell counts as less than five. A statistically significant association derived makes the null hypotheses a nonassociative for education level and PROMIS 25 for participants engaged or non-engaged in the survey to reject  $\chi^2_{(\text{class, support})} = 238.672, p < .005$  and  $163.258, p < .005$  at a Cramer's  $V = .112$  and  $.128$ . This indicates a weak nonassociation with attributes to chance. The relationship between education level and PROMIS 25 is uneven distribution in the population.

The chi-square test of independence between PROMIS 25 (Well-being, HRQoL) and income revealed all expected cell counts as less than five. A statistically significant association derived makes the null hypotheses a nonassociative for income and PROMIS 25 for participants engaged or non-engaged in the survey to reject the null hypothesis  $\chi^2$  (class, support) = 44.504,  $p < .005$  and 227.114,  $p < .005$  at a Cramer's V = .048 and .167. This indicates an irrelevant nonassociation with attributes to chance. The relationship between income and PROMIS 25 is uneven distribution in the population (Wagner, 2017).

### **Therapy**

Therapy assessed among the participants reporting of whether engaged in insulin or non-insulin recipients (i.e., medication), of the population of PROMIS 25 (Well-being, HRQoL) survey related partakers. The engaged in insulin and non-insulin recipient taking class to manage diabetes split into 32:68 and 52:48. Insulin recipients and non-insulin recipient who engaged and non-engaged in emotional support split into 26:74 and 21:79 followed by those who did not engage in PROMIS 25 (Well-being, HRQoL) as majority against minority users. Even though all participants who engaged in PROMIS 25 (Well-being) reported survey, the 205,803 (Class) and 223,909 (Support) missing values for the non-reported of the PROMIS 25 survey could distort the outcomes to tilt the effect towards the non-engaged prediction of insulin on PROMIS 25.

A chi-square test of independence carried out between PROMIS 25 (Well-being, HRQoL) survey related and insulin administration revealed all expected cell counts as less than five. However, different for those using class to manage diabetes and those who

needed emotional support for therapy. PROMIS 25 (Well-being) outcome indicated the presence of a statistically significant association between the survey participants relative to insulin therapy or non-insulin users.

The null hypotheses to assert therapy as nonassociative with PROMIS 25, among the engaged or non-engaged lead to reject the null hypothesis  $\chi^2_{(class)} = 626.944, p < .005$  at a Cramer's  $V = .181$  and non-statistically significant difference and associative for emotional support to fail to reject the null hypothesis  $\chi^2_{(support)} = 2.567, p > .005$  at a Cramer's  $V = .050$ . An indication of an uneven relationship between PROMIS 25 (Well-being, HRQoL) with attributes to chance and weak association distribution across the population for class management, with attributes to some non-random cause for emotional support needed (HRQoL).

**Table 6**

*Revealed Therapy Engaged Participants Versus Nonengaged Patients*

	PROMIS 25 (M-Class) <i>N</i> (%)	Non PROMIS 25 (M-Class) <i>N</i> (%)	PROMIS 25 (E- Support) <i>N</i> (%)	Non PROMIS 25 (E- Support) <i>N</i> (%)
Last Eye Exam Within Past Mon Yes/No, anytime <1 month	3476(100%) 1402(40.3%)	3476(100%) 2074(59.7%)	200(100%) 44(22.0%)	200(100%) 156(78.0%)
Last Eye Exam Within Past Yr Yes/No, anytime <12 mon	10105(100%) 4239 (41.9%)	10105(100%) 5866(58.1%)	611(100%) 123(20.1%)	611(100%) 488(79.9%)
Last Eye Exam Within Past 2Yr	2452(100%)	2452(100%)	115(100%)	115(100%)

Yes/No, anytime <2 years	117(47.9%)	1277(52.1%)	27(23.5%)	88(76.5%)
Last Eye Exam 2 or More Years	2169(100%)	2169(100%)	68(100%)	68(%)
Yes/No, anytime ≥ 2 years	1267(58.4%)	902(41.6%)	29(42.6%)	39(57.4%)
Last Eye Exam, Don't Know	318(100%)	318(100%)	9(100%)	9(100%)
Yes/No, anytime	197(61.9%)	121(38.1%)	-	9(100%)
Last Eye Exam, Never	582(100%)	582 (100%)	19(100%)	19(100%)
Yes/No, anytime	376(64.6%)	206(35.4%)	11(57.9%)	8(42.1%)
Last Eye Exam, Refused	26(100%)	26(100%)	-	-
Yes/No, anytime	15(57.7%)	11(42.3%)	-	-

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The outcome shown in Table 6 above indicates the participants who engaged in last eye exam with dilated pupils and survey takers of PROMIS 25(Well-being, HRQoL). The engagement time against the non-engaged in PROMIS 25 (Well-being, HRQoL) revealed majority participation for less than 12 months therapy duration as high against minority of one month early, two and more years, and less than two years. This was followed by those who did not know of eye exam or had never taken eye exam and refused to participate. The population showed delay eye exam for Well-being and HRQoL pattern that did not differ significantly from each other at the .05 level.

A chi-square test of independence carried out between eye exam therapy and PROMIS 25 survey revealed all expected cells counted at less than five. The outcome

proportion in eye exam and takers of class to manage diabetes and PROMIS 25 (Well-being) indicated the presence of a statistically significant association. The null hypothesis establish therapy as nonassociative of PROMIS 25 Well-being, in the engaged and non-engaged to reject the null hypothesis  $\chi^2_{(class)} = 362.376, p < .005$  at a Cramer's  $V = .138$ . This was different between PROMIS 25 (HRQoL) and eye exam therapy. Two cells (16.7%), for the therapy of eye exam in the engaged and non-engaged, have expected count of less than five. Rana, R., & Singhal, R. (2015) noted if the expected cell counts are not less than five, there are no cells with zero count makes the values adequate in a sufficiently large sample drawn from a random population, avoids type II error (Yates et al., 1999; Yates et al., 1934). The results revealed emotional support needed (HRQoL) and eye exam therapy as statistically significant association that is mutually exclusive to reject the null hypothesis  $\chi^2_{(support)} = 33.641, p < .005$  at a Cramer's  $V = .181$ . An indication of an uneven relationship between PROMIS 25 (Well-being) with attributes to chance and weak association for distribution across the population for PROMIS 25 (HRQoL).

**Table 7**

*Revealed Therapy Engaged Patients Versus Nonengaged Patients*

PROMIS 25 (M-Class) Yes	Non PROMIS 25 (M-Class) NO	PROMIS 25 (E-Support) Yes	Non PROMIS 25 (E-Support) No



Fruit	18,225	18,225	9,893	9,893
N	8,199	10,027	1,765	8128
Mean Rank	9,395.47	8,882.05	5,448.71	4,838.05
Vegetables	18151	18151	9,893	9,893
N	8160	9991	1,765	8128
Mean Rank	9348.13	8853.74	5,417.11	4,844.92
Physical Activity	5689	5689	4,753	4,753
N	2201	3488	620	4,133
Mean Rank	2905.74	2806.67	2,625.14	2,339.78
Blood Glucose Monitoring	19,128	19,128	1,022	1,022
N	8,671	10,457	234	788
Mean Rank	10,208.13	9,030.80	522.62	508.20
Glycosylated Hemoglobin	19,128	19,128	1,022	1,022
N	8671	10,457	234	788
Mean Rank	9,766.39	9397.09	550.00	500.07

The outcome of Table 7 above revealed the mean rank and total number of participants who completed the PROMIS 25 (Well-being, HRQoL) related survey and those who did not complete the BRFSS. A Mann-Whitney U test was performed to ascertain differences in prediction between those who engaged in the PROMIS 25 (Well-being, HRQoL) survey and those who did not. Therapy (ies) values examined were not similar in the distribution. Therapy engaged values and PROMIS 25 (Well-being, HRQoL) takers surveyed for the engaged in therapies were highly statistically significantly than those who did not take survey and engaged in the therapies, fruits, vegetable, physical activity, blood glucose monitoring, feet exam and glycosylated

hemoglobin monitoring. Except for blood glucose and PROMIS 25 (HRQoL) non-statistically significant was retained. Those who engaged ranked higher to predict effect on PROMIS 25 against the non-engaged surveyed. Fruit and PROMIS 25 (Well-being, HRQoL) mean rank (9,395.47, 8,882.05), and mean rank (5,448.71, 4,838.05), at  $U$  (38,784,986.5, 38,784,985.5),  $z = 6.641, 8.274$ , and  $p < 0.001$ . Vegetable mean rank (9,348.13, 8,853.74), and mean rank (5,417.11 vs 4,844.92), at  $U$  (38,542,729, 38,852,729),  $z = 6.356, 7.670$ , and  $p < 0.001$ . Physical activity mean rank (2,905.74, 2,806.67), and mean rank (2,625.14, 2,339.78) at  $U$  (3,704,847, 1,127,383),  $z = 2.227, 4.861$ ,  $p \leq .026, .001$ . Glycosylated hemoglobin mean rank (9,348.13, 8,853.74), and mean rank (550, 500.07),  $U$  (38,542,729, 83,187.5),  $z = 6.356, 2.345$ ,  $p \leq .001, .019$ . Feet check mean rank (10,224.76, 9,017.01), and mean rank (543.82, 501.90),  $U$  (39,611,183.5, 84,633),  $z = 16.126, 2.032$ ,  $p = .019, .042$ . Blood Glucose check mean rank (10,208.13, 9,030.80), and mean rank (522.62, 508.20),  $U$  (39,755,431, 89,595),  $z$  (14.871, .663),  $p < 0.001$ , and  $p = .507$ . Two of four Mann-Whitney U test assumptions was not met. *Assumption one*: The dependent variable was neither continuous nor ordinal, instead dichotomous. *Assumption two*: The independent variable(s) was not in two category groups, instead continuous. *Assumption three*: Independent observation was determined to retain the test. *Assumption four*: The two variables were not normally distributed, the distributions had same shape to retain the test.

The mean of increase managed confidence (Well-being/total satisfaction of life) and Control Symptoms of Anxiety (HRQoL) (I defined as the difference between the mean of therapy (ies) engagement with type-2 diabetes mellitus present and the mean of

increase (Well-being and HRQoL) skewed towards takers of PROMIS 25 survey who most of the time engaged in therapy more than those who did not take the PROMIS 25 survey. Finally, to increase life satisfaction and optimize your HRQoL relative to increased time of therapy engagement indicated a greater proportion of individuals who use therapy than those who did not participant in PROMIS 25. The groups showed the data as supportive for the proportion of individuals who took PROMIS 25 survey and engaged in combination therapy frequently.

### **Predictive Models: Assessment of Covariates in Research Questions 1-3**

The overall outcome between PROMIS 25 (well-being) and covariates; age, education level, ethnicity/race, income, and safety revealed Block 0 base rate decision statistics of selected cases 59.1% of the population who did not have T2DM or not prediabetic, 40.9% predicted to increase PROMIS 25 (well-being) by taken class to manage diabetes or manage confidence. Variables in the equation indicated a predicted observed odds ratio of 1.349 of covariates in PROMIS 25 by the Exp (B).

Block 1 of the Omnibus tests of Model Coefficient chi-square of  $\chi^2 = 52.242$  on 5 degrees of freedom (*df*), significant  $p < .001$ , indicated the null hypothesis that inclusion of covariates to the model has significantly increased the ability to predict the individuals in the population decision to manage confidence. Model summary 5424.4630 -2 Log likelihood, by adding the covariates reduce the -2-log likelihood statistic by 5476.872 - 5424.630 = 52.242, given the chi-square  $\chi^2$  value, makes the model a good fit. The Cox and Snell (.013) as well Nagelkerke *R* squared (.017) indicate the variation of covariates

in PROMIS 25 from a minimum of zero (0) to a maximum approximation of 1 of the relationship between the baseline log likelihood and the adjusted.

The odds ratio predicts an individual participant with T2DM of a given age group, education level, ethnicity/race, gender, and income by 40.9% likely to increase well-being given covariates to achieve total life satisfaction that increases general health, which will not occur in 59.1% of the population without T2DM (Wuensch, 2021).

Overall outcome between PROMIS 25 (HRQoL) and covariates; age, education level, ethnicity/race, income, and safety revealed Block 0 base rate decision statistics of selected cases to 82.2% of the population who did not have T2DM or not prediabetic. About 17.8% predicted to increase PROMIS 25 (HRQoL) in those who often get emotional support needed or control symptoms of anxiety to increase health related quality of life that improves optimum health. Variables in the equation indicated a predicted observed odd ratio 4.614 in PROMIS 25 (HRQoL) by the Exp (B).

Block 1 of the Omnibus tests of Model Coefficient chi-square of  $\chi^2 = 537.910$  on 5 degrees of freedom (*df*), significant  $p < .001$ , indicated the null hypothesis that inclusion of covariates to the model significantly increased the ability to predict the individuals in the population decision to control symptoms of anxiety. Model summary 8705.339 -2 Log likelihood, by adding the covariates to reduce the -2-log likelihood statistic by  $9243.249 - 8705.339 = 537.910$  by the chi-square  $\chi^2$  value, makes the model a good fit. The Cox and Snell (.053) as well Nagelkerke *R* squared (.087) are indication of the variation of covariates in PROMIS 25 (HRQoL) from a minimum of zero (0) to a

maximum approximation of one, of a relationship between the baseline log likelihood and the adjusted.

The odds ratio predicts that an individual participant with T2DM of a given age group, education level, ethnicity/race, gender, and income is 17.8% likely to increase the HRQoL with covariates to increased optimum health, will not occur in 82.2% of the population without T2DM (Wuensch, 2021).

### **Predictive Models for Binary Regression of Research Questions**

#### **Binary Regression Analysis of Research Question 1**

Overall predictive outcome between PROMIS 25 (well-being) covariates; age, ethnicity/race, and safety, and therapies (fruits, glycosylated hemoglobin, vegetables, physical activity, and insulin) revealed by Block 0 base rate decision statistics of selected cases to 60.7% of the population who did not have T2DM or not prediabetic. About 39.3% predicted to increase PROMIS 25 (well-being) by taking class to manage diabetes or manage confidence to boost general health. Variables in the equation indicated a predicted observed odds ratio of PROMIS 25 (Well-being) 1.543 by the Exp (B) from predictors of therapies and covariates.

Block 1 of the Omnibus tests of Model coefficient chi-square of  $\chi^2 = 123.177$  on 11 degrees of freedom (*df*), significant  $p < .001$ , indicated the null hypothesis that inclusion of covariates and predictors to the model has significantly increased the ability to predict the individuals in the population decision to manage confidence or increase well-being. Model summary statistic 3002.490 -2 Log likelihood, addition of the covariates reduces the -2-log likelihood statistic by  $3125.667 - 3002.490 = 123.177$  to the

chi-square  $\chi^2$  value, this small  $-2\log$  makes the model a better fit. The Cox and Snell (.051) as well Nagelkerke  $R$  squared (.070) indicated the variation of covariates in PROMIS 25 from a minimum of zero (0) to a maximum approximation of one of the relationships between the baseline log likelihood and the adjusted.

The odds ratio predicted that an individual participant with T2DM of a given age group, education level, ethnicity/race, gender and income is 39.3% likely to increase the well-being with therapies good food choices such as (fruits, vegetables and protein), physical activities, insulin (medication) and glycosylated hemoglobin (access to healthcare services by DME/DMS ) to achieve total life satisfaction that increases general health, that will not occur in 60.7% of the population without T2DM (Wuensch, 2021).

### **Binary Regression Analysis of Research Question 2**

Overall predictive outcome between PROMIS 25 (HRQoL), therapies (fruits, vegetables, protein, physical activities, insulin, glycosylated hemoglobin, and covariates; age, education level, ethnicity/race, gender, and income revealed Block 0 base rate decision statistics of selected cases to 82.3% of the population who did not have T2DM or not prediabetic, 17.7% predicted to increase PROMIS 25 (HRQoL) in those who often get emotional support needed or control symptoms of anxiety to increase health related quality of life or overall life satisfaction that improves optimum health. Variables in the equation indicated a predicted observed odd of the  $\text{Exp}(B)$  4.655 for PROMIS 25 from predictors therapies and covariates.

Block 1 of the Omnibus tests of model coefficient chi-square of  $\chi^2 = 66.454$  on 12 degrees of freedom ( $df$ ), significant  $p < .001$ , indicated the null hypothesis that

inclusion of covariates to the model has significantly increased the ability to predict the individuals in the population decision to control symptoms of anxiety. Model summary of 513.973, and -2 Log likelihood, by adding the covariates to reduce the -2-log likelihood statistic by  $580.427 - 513.973 = 66.454$  of the chi-squares  $\chi^2$  value, this smaller -2 log makes the model a good fit. The Cox and Snell (.101) as well Nagelkerke *R* squared (.167) are indication of the variation of covariates in PROMIS 25 (HRQoL) from a minimum of zero (0) to a maximum approximation of one, of a relationship between the baseline log likelihood and the adjusted.

The odds ratio predicts that an individual participant with T2DM of a given age group, education level, ethnicity/race, gender and income is 17.7% likely to decide to increase the HRQoL with therapies good food choices such as (fruits, vegetables, and protein), insulin (medication), physical activities, and glycosylated hemoglobin (access to healthcare services DME/DMS) to achieve optimum health, which will not occur in 82.3% of the population without T2DM (Wuensch, 2021).

### **Binary Regression Analysis of Research Question 3**

Overall predictive outcome between PROMIS 25 (HRQoL), therapy (blood glucose, foot check, eye exam, and covariates such as age, education level, ethnicity/race, gender, and income revealed by Block 0 base rate decision statistics of selected cases to 77.1% of the population who did not have T2DM or not prediabetic, 22.9% predict to increase PROMIS 25 (HRQoL) in those who often get emotional support needed or control symptoms of anxiety to increase health related quality of life or overall life satisfaction that improves optimum health. Variables in the equation indicated

a predicted observed odd of the  $\text{Exp}(B)$  3.368 for PROMIS 25 from predictors therapies and covariates.

Block 1 of the Omnibus tests of Model Coefficient chi-square of  $\chi^2 = 84.434$  on 10 degrees of freedom ( $df$ ), significant  $p < .001$ , indicated the null hypothesis that inclusion of covariates to the model has not significantly increased the ability to predict the individuals in the population decision to control symptoms of anxiety. Model summary of 1015.279 and -2 Log likelihood, by adding the covariates to reduce the -2-log likelihood statistic by  $1099.713 - 1015.279 = 84.434$  by the chi-square  $\chi^2$  value. The Cox and Snell (.079) as well Nagelkerke  $R$  squared (.120) are indication of the variation of covariates in PROMIS 25 from a minimum of zero (0) to a maximum approximation of one, of a relationship between the baseline log likelihood and the adjusted.

The odds ratio predicts that an individual participant with T2DM of a given age group, education level, ethnicity/race, gender, and income is 22.9% likely to decide to increase the HRQoL with therapies such as blood glucose (access to healthcare services DME/DMS), foot and eye exam to achieve optimum health, which will not occur in 77.1% of the population without T2DM (Wuensch, 2021).

### **Analysis of Research Hypothesis**

In Chapter 3, I indicated the use of a two-tailed independent  $t$  test to evaluate my research questions. I planned further to use Analysis of covariates (ANCOVA) to evaluate potential covariates such as age, educational level, gender, income, and neighborhood safety. Analysis of Covariates (ANCOVA) will remove any effects of covariates in the direction to examine the difference between means as shown in Table 4



and run predictive models to observe covariates variations in the outcome variable.

During the data analysis, I discovered the data fell short of meeting some requirements of outliers, normality, and homogeneity of variances, despite data transformation performed for the continuous variables such as log10 and re-coded into different variables for discrete/ dichotomous variables. Thus, for each question formulated when the assumptions were unmet, alternative measure was used.

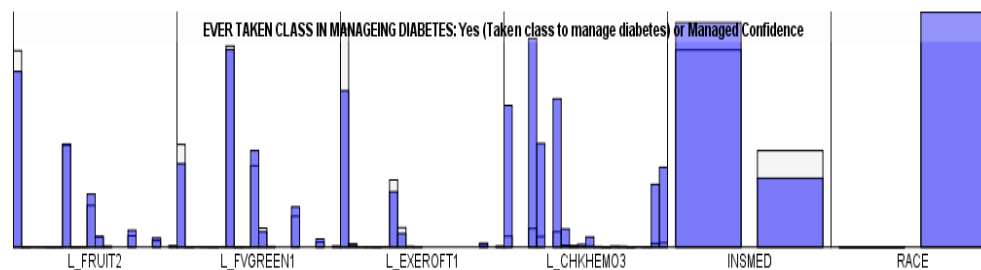
### **Hypothesis 1 – Therapy and Well-being (Managed Confidence) with T2DM**

The null hypothesis for research question 1, there is no significant statistical association between decreased PROMIS 25 (Well-being) and combination therapy with T2DM present to achieve optimum health through self-care in ethnic groups.

There were participants groups of therapy users/or engagers of; good food choices; fruits (8198), vegetables and protein (8160), physical activity (4307), medication (insulin) (2036), and glycosylated hemoglobin check (8671) through access to health care services (DME/DMS) in six categories of ethnic/race groups of 8671 individuals. I performed an independent two-tailed *t* test to ascertain association in mean of managed confidence (Well-being) among those taken class to manage T2DM and combination therapy for optimum health. The Asymmetric display reveals the presence of outliers in Figure 6 of the data for all therapies except for race examined by the inspection of histograms. Hence, I performed a chi-square and cross tabulation, Mann-Whitney U test, and non-parametric test.

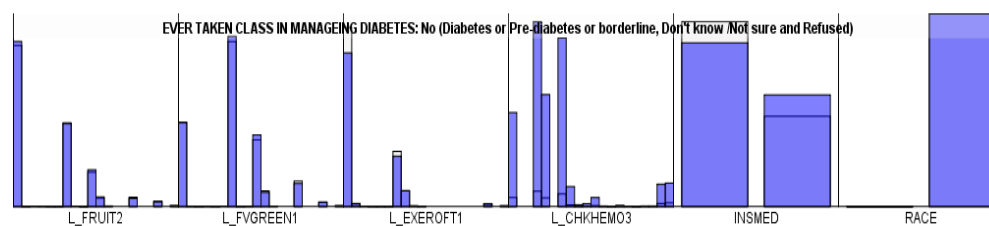
### **Figure 6**

*Histogram of Well-being Yes (Manage Confidence or Taken Class to Manage Diabetes) and Therapies and Ethnic Groups*



**Figure 7**

*Histogram of Well-being No (Manage Confidence or Taken Class to Manage Diabetes) and Therapies and Ethnic Groups*



The percentage of the proportion of PROMIS 25 score for Well-being (3.9%, 4.6%), skewed left from fewer to many who did not take class to manage type-2 diabetes with manage confidence, revealed skewness and kurtosis outcome for Well-being; -.188, and -1.965, for values between  $\pm 1$ , by inspection of the histograms. Homogeneity of variance assessed significantly revealed same variances for the engage and non-engage significantly by the levene's test for equality of variance ( $p < .001$ ) for non-normally distribution.

The individual participants independent  $t$  test revealed therapy (ies) users of; fruits, vegetables, physical activities, and glycosylate hemoglobin check statistical values for null hypotheses with equal variances across groups, for all predictors significantly to

decrease Well-being with  $p$  values less than  $p < .001$  of a two-tail test, which violates the assumptions of the homoskedasticity. Therefore, occurrence of type-1 error, hence, used a non-parametric test.

### **Hypothesis 1.2 – Therapy and Well-being (Managed Confidence) with T2DM**

Total Life Satisfaction (Well-being) predictor(s) statistics revealed for the presence of T2DM and managed confidence:

Fruit ( $M = 205.50$ ,  $SD = 149.47$ ),  $d = 21.13$ , 95%  $CI [17.096-25.166]$ ,  $t(18223) = 10.26$ ,  $p < .001$

Vegetable ( $M = 235.76$ ,  $SD = 142.43$ ),  $d = 19.44$ , 95%  $CI [15.486-23.403]$ ,  $t(18149) = 9.63$ ,  $p < .001$

Physical Activities ( $M = 150.71$ ,  $SD = 106.12$ ),  $d = 3.88$ , 95%  $CI [-.004-7.758]$ ,  $t(10448) = 1.96$ ,  $p < .050$

Glycosylated hemoglobin ( $M = 18.09$ ,  $SD = 32.18$ ),  $d = 9.05$ , 95%  $CI [8.288-9.818]$ ,  $t(19126) = 9.053$ ,  $p = .055$

In addition, the Mann-Whitney U test, of PROMIS 25 (Well-being) for those who engaged in therapies ranked higher to predict effect on PROMIS 25 (Well-being) than the non-engaged mean score for good food choices; fruit, vegetables and protein, physical activities, and monitoring through access to health care services the glycosylated hemoglobin. The differences were significant for participants who ever took a class in managing diabetes than those who did not take class to manage diabetes by the higher rank for the engaged than the non-engaged in predicting PROMIS 25 (Well-being). Fruit mean rank (9,395.47, 8,882.05), at  $U(38,784,986.5)$ ,  $z = 6.641$ , and  $p < .001$ . Vegetable

mean rank (9,348.13, 8,853.74), at  $U(38,542,729)$ ,  $z = 6.356$ , and  $p < .001$ . Physical activity mean rank (2,905.74, 2,806.67), at  $U(3,704,847)$ ,  $z = 2.227$ ,  $p \leq .026$ .

Glycosylated hemoglobin mean rank (9,348.13, 8,853.74), at  $U(38,542,729, 83,187.5)$ ,  $z = 6.356$ ,  $z = 2.345$ ,  $p < .001$ .

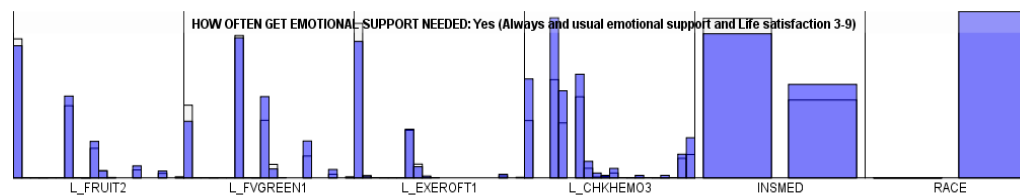
### **Hypotheses 2. Therapies and HRQoL (Control Symptoms of Anxiety) with T2DM**

The null hypothesis for research question 2, there is significant statistical association between increased PROMIS 25 (HRQoL) and combination therapy to achieve general health and total number per day/week combination therapy participated through self-care in ethnic groups.

There are participants groups of therapy users of; good food choices; fruits (9893), vegetables and protein (9893), physical activity (4753), medication (insulin) (234), and glycosylated hemoglobin check (1022) through access to health care services (DME/DMS) in six categories of ethnic/race groups of 1756 individuals. I performed an independent two-tailed  $t$  test to ascertain association in mean of control symptoms of anxiety (HRQoL) among those who often get emotional support needed and combination therapy for general health. The Asymmetric display reveals the presence of outliers in (Figure 8) of the data for all therapies except for race examined by the inspection of histograms. Hence, I performed a chi square, and cross tabulation, Mann-Whitney U test and non-parametric test.

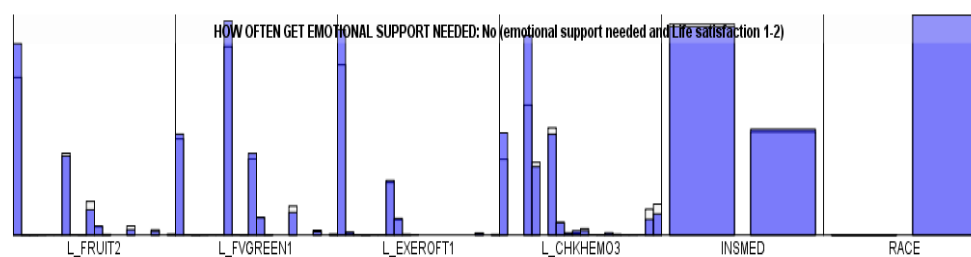
### **Figure 8**

*Histogram of Well-being No (Manage Confidence or Taken Class to Manage Diabetes) and Therapies and Ethnic Groups*



**Figure 9**

*Histogram of HRQoL Proportion (Control Symptoms of Anxiety or Often Get Emotional Support Needed), Therapies and Ethnical Groups*



The percentage of the proportion of PROMIS 25 score for HRQoL (.8%, 3.6%), skewed left from fewer to many who often get support needed to control symptoms of anxiety, revealed skewness and kurtosis outcome for HRQoL; -1.680, and .823 for values between  $\pm 1$ , by inspection of the histograms. Homogeneity of variance assessed significantly revealed same variances for the engage and non-engage significantly by the levene's test for equality of variance ( $p < .001$ ) for non-normal distributions.

The individual participants independent  $t$  test revealed therapies users of; fruits, protein, and vegetables, physical activities, and glycosylate hemoglobin check statistical values for the null hypotheses with equal variances across groups. All predictors significantly increased HRQoL with  $p$  values less than  $p < .001$  of a two-tail test, which

violates the homoskedasticity assumptions, therefore occurrence of type-1 error (false positive), hence, used a non-parametric test.

### **Hypothesis 2.2 – Therapy and Health Related Quality of Life (Control of Symptoms of Anxiety) with T2DM**

Health Related Quality of Life (HRQoL) predictor(s) statistics revealed for the presence of diabetes and control symptoms of anxiety:

Fruit ( $M= 2.23$ ,  $SD=.24$ ),  $d = .07$ , 95%  $CI [.056-.079]$ ,  $t (9891) = 11.81$ ,  $p <.001$

Vegetable ( $M= 2.37$ ,  $SD = .23$ ),  $d =.06$ , 95%  $CI [.052-.073]$ ,  $t (9891) = 11.58$ ,  $p <.001$

Physical Activities ( $M= 2.13$ ,  $SD=.18$ ),  $d =.02$ , 95%  $CI [.014 - .034]$ ,  $t (7323) = 4.75$ ,  $p <.001$

Glycosylated hemoglobin ( $M= .56$ ,  $SD = .56$ ),  $d =.10$ , 95%  $CI [.027- .169]$ ,  $t (1020) = 2.72$ ,  $p<.007$ .

In addition, the Mann-Whitney U test, of PROMIS 25 (HRQoL) for those who engaged in therapies ranked higher to predict effect on PROMIS 25 than the non-engaged mean score for good food choices, fruit, vegetables and protein, physical activities, and monitoring through access to health care services the glycosylated hemoglobin. The differences were significant for participants who control symptoms of anxiety with T2DM than those who did not control symptoms of anxiety by the higher rank of the engaged than the non-engaged in predicting PROMIS 25 (HRQoL). Fruit mean rank (5,448.71, 4,838.05), at  $U (38,784,985.5)$ ,  $z = 8.274$ , and  $p<001$ . Vegetable mean rank (5,417.11 vs 4,844.92), at  $U (38,852,729)$ ,  $z =7.670$ , and  $p<001$ . Physical activity mean

rank (2,625.14, 2,339.78) at  $U(1,127,383)$ ,  $z = 4.861$ ,  $p < .001$ . Glycosylated hemoglobin mean rank (550, 500.07), at  $U(83,187.5)$ ,  $z = 2.345$ ,  $p < .019$ .

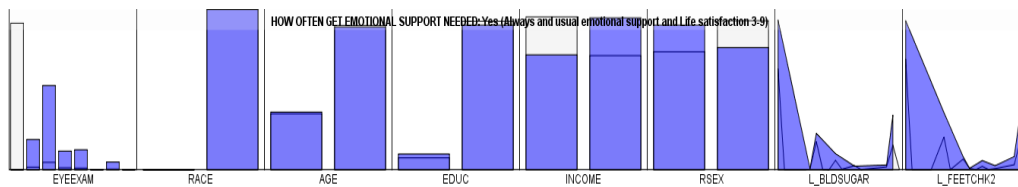
### **Hypotheses 3.1. – Monitoring and examining extremities and HRQoL (Control Symptoms of Anxiety) with T2DM**

The null hypothesis for research question 3, there is no significant statistical association between increased PROMIS 25 (HRQoL=Control Symptoms of Anxiety), timely examined of the feet, eyes, and blood glucose monitoring to achieve general health as part of combination therapy participated through self-care in ethnic groups. Extremities check indicated a statistically significant association, and non-significant statistical association for blood glucose.

A total number of participants groups monitored and examined extremities such as; feet (234), and blood glucose (234) through access to health care services (DME/DMS) in six categories of ethnic/race groups of 1756 individuals. I performed an independent two-tailed  $t$  test to ascertain association in mean of control symptoms of anxiety (HRQoL) in those who often get emotional support needed to perform the exercise to improve their general health. The Asymmetric display reveals the presence of outliers in (Figure 10) of the data for all therapies except for race examined by the inspection of the histograms. Hence, I performed a chi square, and cross tabulation, Mann-Whitney U test and non-parametric test.

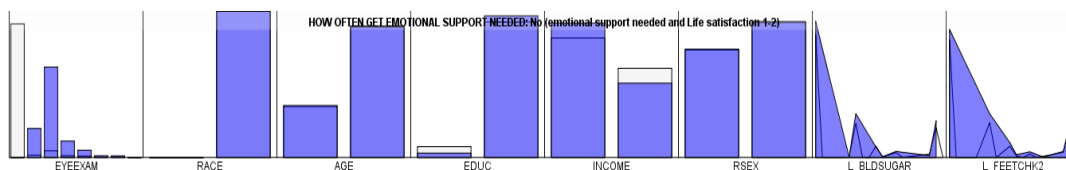
### **Figure 10**

*Histogram of HRQoL Proportion (Control Symptoms of Anxiety or Often Get Emotional Support Needed), Therapies and Ethnic Groups*



**Figure 11**

*Histogram of HRQoL Proportion (Control Symptoms of Anxiety or Often Get Emotional Support Needed), Therapies and Ethnic Groups*



PROMIS 25 (HRQoL) score indicated a non-normal distribution, skewness and kurtosis statistics (1.156, -.172, for blood glucose) and (1.030, -.496, for feet check) that skewed left from fewer to many who often get support needed to control symptoms of anxiety between  $\pm 1$ , indicated by the inspection of the histogram. Homogeneity of variance was present by assessing the levene's test for equality of variance  $p < .051$  respectively for feet check and  $p > .150$  barely for blood glucose.

Furthermore, individual participants who use feet check (Mean =2.33, SD=.378) had a statistically significant independent  $t$  test that revealed therapy users of; feet check, and blood glucose monitoring statistical values for the null hypotheses with equal variances across groups for feet check with exceptions to blood glucose. Some predictors significantly increased HRQoL with  $p$  values less than  $p < .051$  of a two-tail test, which



violates the homoskedasticity assumptions, therefore the possibility of occurrence of a type-I error (false positive) and committing a type II error with  $p = .129$  of the two-tailed tests in violation of the homoscedastic assumption was revealed. Hence, used a non-parametric test.

### **Hypotheses 3.1. – Monitoring, examining extremities and HRQoL (Control Symptoms of Anxiety) with T2DM**

Health Related Quality of Life (HRQoL) predictor(s) statistics revealed for the presence of diabetes and control symptoms of anxiety:

Feet check ( $M= 2.32, SD=.38$ ),  $d = .05$ , 95%  $CI [-.000-.108]$ ,  $t (359) = 1.96, p <.051$

Blood glucose ( $M= 2.29, SD = .38$ ),  $d = .04$ , 95%  $CI [-.014-.094]$ ,  $t (355) = 1.44, p =.150$

In addition, given the Mann-Whitney U test, of PROMIS 25 for those who engaged in feet check therapy ranked higher to predict effect on PROMIS 25 than the non-engaged mean score for feet checks. There was a significant difference for participants who control symptoms of anxiety with T2DM than those who did not control symptoms of anxiety for feet check by the mean rank (543.82, 501.90),  $U (84,633)$ ,  $z = 2.032, p =.042$ . Blood Glucose monitoring by the mean rank (522.62, 508.20),  $U (89,595)$ ,  $z (.663)$ ,  $p = .507$ .

### **Assessment of Covariates**

I performed Binary Logistic Regression Analysis to predict the variation in the outcome that reflects the adjustment to the mean differences of the PROMIS 25 measures attributed to covariates for PROMIS components Well-being and HRQoL by handling age, education level, ethnicity/race, income, gender, and safety.

The odds ratio predicts an individual participant in each age group, education level, ethnicity/race, gender, and income in the examined population. The Hosmer-Lemeshow showed the decision to increase PROMIS 25 (HRQoL and Well-being) considering combination therapies good food choices; fruits, vegetables, and protein, insulin (medication), physical activity, and access to healthcare services monitoring blood glucose, and glycosylated hemoglobin. Inspection of the bar charts revealed by the non-linear relationship between the PROMIS 25 measures and combination therapy was evident by the asymmetric pattern of the histograms. The homogeneity assumption was met. Also, concurrently measured by the Levene's test was not met. A regression that is evidence of the statistically significant outcome.

Most measures did not show standardized residuals greater than  $\pm 3$  for the standard deviations. However, after the adjustment of the model for therapies and covariates were performed, there were significant statistical association difference in the PROMIS 25 mean values for individual participants decision to increase HRQoL and Well-being with combination by the predictive models, given the association between the  $p$  value and the chi-square values, established on addition of covariates to predictors in the model.

The low statistical measure of the model summary between PROMIS 25 (Well-being, HRQoL) and the covariates revealed good prediction of the model in the population examined and hence the decision to manage confidence and control symptoms of anxiety to achieving general and optimum health. Whereas the higher statistical

measure of the model summary between PROMIS 25, covariates and therapies poorly predicted the model.

### **Summary**

In conclusion, individual participants examined on therapies, good food choices; fruits, vegetables, and protein, insulin (medicine), physical activity, foot and eye check and access to healthcare services by DME/DMS monitoring blood glucose and glycosylated hemoglobin indicated differences in mean of HRQoL and Well-being as measured by the PROMIS 25 survey. As a result, the null hypothesis of association between the two components was rejected. Overall, individual participants had equal chance to engage in therapies to increase their Well-being and Health Related Quality of Life. Consequently, individual participants with some HRQoL and Well-being with therapies were equally likely to be more or less engaged in a class to manage confidences and required emotional support to control symptoms of anxiety. Therefore, individual participants showed differences in HRQoL and Well-being for their general and optimum health for the therapies used at a given period when they engaged in the PROMIS 25 survey.

Assessment of the common parameters indicated all individual participants in the behavioral risk factor surveillance system (BRFSS) proved that those who engaged in the PROMIS 25 related survey and those who did not were similar in health improvement distribution. Hence, the differences in the groups in aspects such as age, educational level, ethnicity/ race, gender, income, and safety distributions, and predictions. Moreover, there are differences in groups of chronic disease condition parameters such as diabetes

and complications. These differences make it obvious to make a generalization of the research question findings to apply to the entire population of individuals in the BRFSS.

The implications of the findings in relation to the literature reviewed in Chapter 2 have been analyzed in Chapter 5 to determine gaps and identify possible areas for further research.

## Chapter 5: Discussion, Conclusions, and Recommendations

In this quantitative dissertation, I assessed the prediction of HRQoL and Well-being of therapies and access to healthcare services through monitoring and examination of extremities by analyzing PROMIS 25 scores/values due to the presence of T2DM. I used PROMIS 25 domain “Managed Confidence” as a proxy for well-being, and the domains of “Control Symptoms of Anxiety” as a proxy for HRQoL. As revealed in Chapter 1, Well-being projects how population perceive quality of life associate with negative emotions that reduces the overall life satisfaction thus affecting the general health, while HRQoL is associated positively to symptoms of improved general health.

I used statistical methods to predict the means to measure association differences in the PROMIS 25 scores/values according to the category of therapies, monitoring, and examination. In most situations, the null hypothesis was rejected meaning that there are mean difference and at other instances that failed to reject the null of no associative difference. The latter was to determine generalizability among the (Class=8, 671, Support=1,765) individual participants who engaged and those who did not engaged (Class=10,457, Support=8,128) in the PROMIS 25(Well-being, HRQoL) in the BRFSS. I predicted common attributes such as age, education, ethnicity/race, gender, income, and safety to achieve optimum and general health, of levels of therapies such as good food choices (fruits, vegetables, and protein), physical activity, insulin (medication), and access to healthcare service through monitoring of blood glucose, glycosylated hemoglobin, and examination of extremities (feet and eyes). Statistical analyses showed significant association differences in the populations of all aspects predicted, with

exception to blood glucose levels. Consequently, it is fair to generalize to the whole population in the BRFSS for there was also mean difference in HRQoL and Well-being as measured in the PROMIS 25 survey.

### **Interpretation of Findings**

The core idea of the research questions is that T2DM patients' behavior changes with combination therapy and access to healthcare services by monitoring blood glucose, glycosylated, and examination of extremities to reduce the risk of chronic disease progression and complication. Therefore, increased patient's positive engagement behaviors would have a higher mean well-being and a higher mean HRQoL. Consequently, the null hypothesis that there would be no significant statistical association could be rejected. There may possibly be a couple of justifications for this , such as (a) patients' willingness to engage in combination therapy was not prominent, that patients were somewhat already engaged in some therapies without optimized health before taken the PROMIS 25 survey; (b) statistical power to detect the association could be present; (c) other factors distributed in the groups were less influential; and (d) treatment effect difference. Preferences in overall satisfaction of HRQoL and Well-being, which are seemingly different in constructs, might be similar enough that their measurement involved generating secondary data that require more specific link to the questions between therapies and the PROMIS 25 survey questions such as duration of therapy, oral medication, and alternative or holistic practices.

Study findings presented in Chapter 4 are not unique. For instance, while most studies showed statistically significant association or changes in HRQoL and Well-

being due to the presence of T2DM not all studies have. Goh et al (2015) and In Wee et al (2006) both found statistical difference between T2DM and HRQoL per measured scores as reduces in ethnic groups of Asians/Indians and Malays with attributes to differences in diet. They revealed ethnicity as vital factor influencing quality of life in people with T2DM. In contrast, other research found differences between impaired glucose tolerance and overt diabetics outcome to reduce HRQoL for T2DM patients (e.g., Rubin & Peyrot, 1999; Stewart et al., 1989). While some found older and poorer controlled T2DM patients to reduce HRQoL scores (e.g., Vinamäki et al., 1995), others found HRQoL score reduce with ageing, which they attributed to the combination macrovascular and microvascular complications. Notably, anxiety and depression might increase and then decrease with age (Redekop et al., 2002).

Coffey et al. (2002), as cited in Trikkalinou et al. (2017) found self-administered quality of well-being for T2DM patients' score reduced in female and obese patients as well as comorbidity patient victims than their male with controlled diet, nonobese diabetic with no microvascular, neuropathic complications. Trikkalinou, et al. discovered self-care and better quality of life score as increases with therapy, healthy food choice, physical activities, and medical support to reduce diabetes mellitus risk that appropriately determine lifestyle behavioral change. Overall, the metabolic anomaly of the consequence of developed complications or the coexistence of comorbidities reduces patient HRQoL score overtime.

Lack of therapy of healthy food choices, physical activity, and medication lead to complications that reduces the score of HRQoL. Both Trikkalinou et al., (2017) and

Thent et al., (2013) found physical activity score increases when the skeletal contraction that enhances the cell glucose uptake, muscle blood flow and transportation of glucose to the muscle to reduce abdominal fat distribution and storage get exposed to the positive impact of exercise on glycosylated hemoglobin (HbA1c). The authors found (DME/DMS for T2DM patient as necessary to increase awareness that improves quality of life and reduce family burden and psychological relief of distress as boost to compliance of medical, dietary, physical therapies. and lifestyle. In their opinion, an individual patient receiving therapy of aerobic and resisting training performed three times per week, for 16 weeks and 40 to 60 minutes could generally achieve 65% effect. While Reiner et al. (2013) connected an individual patient's physiological and metabolic reactivity of positive emotions was derived from the patient's treatment preference and regular therapy engagement as basis of positive feelings, better state of mind that increases the quality of life and well-being score attained from pleasure and fun of work out, and adherence to exercise such as aerobics over time. Therefore, there is potential for increased therapies and duration of therapy over a longer period increase impact. However, the proportion of participants who took the PROMIS 25 related survey using combination therapy were more likely to have detected the differences. For example, the 8,671 and 1,765 (PROMIS 25 class, Support) individuals with chronic disease for insulin therapy revealed 2,036 and 253 participants who engaged, respectively.

The study findings collaborated with existing literature. The current study could affirm or add to evidence-based discovery of those studies. There is a significant



statistical association in HRQoL, and well-being reflected by most of the therapies used. Insulin was nonstatistically significant to increase HRQoL and Well-being could exist among individual patients who optimize in combination therapy use. Lastly, the significant statistical association could be disguised in availability of statistical power and a larger number of participants engaged in combination therapy. The sympathetic nervous and immune systems at termination to regain homeostasis of an individual could influence the frequency of engagement in therapies and, the period for an impact to be felt. Thus, some researchers had discovered that a clinical condition relative to the number and severity of condition, comorbidities such as neurological functioning is a greater influence on HRQoL due to behavioral adaptation to stress relative to parameters of therapy (Silverman & Deuster 2014). They found higher HRQoL, and well-being associated with chronic disease patient self-controlled stressors and inadequate bodily damage (Silverman & Deuster 2014). Additionally, Silverman and Deuster, (2014) found acute patients' interaction between intensity and duration of therapy generates magnitude of the stress response. According to Silverman and Deuster, those who reported using lower therapy intensity gain 50% to 70% maximal capacity that activates the hypothalamic pituitary adrenal sympathetic axis. The findings are in line with the health belief model framework objective of associating patients with treatment preferences that optimizes their general health as discussed in Chapters 1 and 2.

The research findings now, with further studies, may indicate the ultimate objective of associating patients with treatment preferences that optimizes their

HRQoL, and well-being are achievable by this population of individuals with chronic conditions. For instance, studies that found patients' treatment satisfaction correspond with therapy received and positive impact on quality of life (Reiner et al., 2013). Further, satisfaction with treatment was associated with DME/DMS to increase awareness. Individuals who engaged in combination therapy increased their lifestyle behavior that optimize quality of life and reduced family burden. The requirement of knowledge that pertains to patients with T2DM have enabled achievements of better compliance of medical, dietary, physical therapies and lifestyle (Powers et al., 2017; Trikkalinou et al., 2017). The availability of DME/DMS as an aspect of therapy allowing more preferential choice of when and where the patient could possibly receive diabetes mellitus education/support and duration of therapy could shift the purpose for which patient attained treatment satisfaction as many patients start the use of education and support tools on more effective manner. In Chapter 1, emphasis was laid on treatment and careful monitoring to retain the target blood glucose range that could prevent short-term hypoglycemic problems and complications effects in the long-term of the endocrine system due to malfunctioning of immune system as mentioned in the literature (Global Diabetes Community, 2019). Brunisholz et al. (2014) and CDC (2017) revealed treatment preferences of therapies such as healthy dietary patterns and regular physical activity as epitome of an optimum patient HRQoL and lifestyle behaviors. These studies urged the need to ensure self-care decisions and performance of complex care activities in patients with T2DM to achieve a quality of life increase. In this research, I used the health belief theoretical framework to predict health behaviors

via the PROMIS 25 survey on HRQoL and Well-being that are already proven and accepted according to clinical outcomes in individuals with T2DM to reduce risk and complications.

### **Limitations of Study**

I used a secondary dataset where the data collected were not tailored to the research questions considering therapies with good food choice; fruits, vegetables, protein, physical activities, medication, monitoring, and examination of extremities overtime. This allowed patient-specific preference for the engaged and non-engaged in lifestyle behaviors. For all chronic patients who did and did not report therapy, I extracted the information from the 2017 Behavioral Risk Factor Surveillance System published questionnaire and codebook<sup>17</sup>. Regarding duration of engagement and therapy labeling, some therapies did have time and others did not have for each patient and therapy. In addition, I inferred the 2017 Behavioral Risk Factor Surveillance System published questionnaire and codebook<sup>17</sup> for this information. Nevertheless, there might have been a significant level of unpredictability within my study population within the parameters of therapy categorization and labeling. There could also be possible confounding factors for which data were unavailable; for example, the time of patient receiving therapy (insulin) and patient response to therapy. Limitations associated with PROMIS 25 survey related amongst those mentioned in Chapter 1 and Chapter 3 about selection bias, recall bias, and survey response bias affected the studies.

### **Recommendations**

Patient-reported outcomes such as treatment preferences, treatment satisfaction, facets of treatment that lead to increase HRQoL and Well-being are essentially natural. For instance, Silverman & Deuster (2014) asserts people with type-2 diabetes mellitus biological measures for physical fitness obtained from exercise protect against stress-associated diseases that improve effects on hormonal stress response systems such as the hypothalamic-pituitary-adrenal axis, and the sympathetic nervous system to reduce the emotional, physiological, and metabolic reactivity and increase the positive mood, and well-being. Patients with chronic disease always are on the lookout for daily management as a tradeoff to cure. For example, the biological measures of medications, and insulin therapy works to lower glucose production, accelerates the pancreas, to discharge more insulin that improves the body's sensitivity to insulin that slows digestion and support lower blood sugar levels (Mayo Clinic, 2019). Hence, patient-reported outcomes are a formidable tool to help better understand patients. The HBM demands patients desire to avoid illness and belief in a particular health action that prevents illness, given the individual action dependent on benefits perceptions, and barriers associated with the health behavior. Gathering primary data to further study patient-reported outcomes using the Health Belief Model conceptual framework would expand the evidence base for combination therapy and for policy decision-making.

### **Positive Social Change Implications**

This is the first research that used the Health Belief Model conceptual to predict whether patients use of combination therapy of four therapies and physical examination

to translate an increase in HRQoL and Well-being when measured by the PROMIS 25 survey related for patients with type-2 diabetes mellitus. Studies aimed at studying patient physiological, psychology, and biomedical perspectives has the potential impact at the individual level and at the societal/policy level due to the provision of an evidence base of therapies acceptance, approval, and engagement. Implications for positive social change include effective therapy combination that improves patients' belief, behavior and lifestyle that optimizes overall satisfaction of life, beyond biomedical parameters and clinical boundaries and its availability to patients and ethnic groups.

This dissertation provides a guide as to how a theoretical conceptualized framework such as the Health Belief Model could be utilized along with the PROMIS 25 survey related information to achieve patient reaction and to evaluate therapies made in response to patient reaction for type-2 diabetes and other state of chronic diseases that affects the immune system.

### **Conclusions**

The study findings revealed that patients with type-2 diabetes mellitus are generally equal in terms of HRQoL and Well-being over the variety of therapies. Some of the prior studies reviewed support the findings. Consequently, the study would be greatly beneficial if it is repeated using questions specifically aimed to connect patient treatment preferences with PROMIS 25 survey, and as more data become available especially the recent CDC PROMIS information in addition to the Behavioral Risk Factor Surveillance System.

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