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Chinese Immigrants with Non-Insulin-Dependent Diabetes Mellitus: Nutritional Self-Management Approach

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Chinese Immigrants with Non-Insulin-Dependent Diabetes Mellitus:
Nutritional Self-Management Approach

Presented in Partial Fulfillment of the
Requirements for the Degree of
Doctor of Nursing Practice

Nova Southeastern University
Health Professions Division
Ron and Kathy Assaf College of Nursing

Winnie M. Wong
2017

**NOVA SOUTHEASTERN UNIVERSITY
HEALTH PROFESSIONS DIVISION
Ron and Kathy Assaf College of Nursing**

This project, written by *Winnie M. Wong* under direction of *Dr. Marcia Derby-Davis*, Project Chairs, and approved by members of the project committee, has been presented and accepted in partial fulfillment of requirements for the degree of

DOCTOR OF NURSING PRACTICE

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Certification

We hereby certify that this capstone project, submitted by Winnie Wong, conforms to acceptable standards and is fully adequate in scope and quality to fulfill the project requirement for the Doctor of Nursing Practice degree.

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Abstract

Background: Chinese immigrants (CIs) with non-insulin dependent diabetes mellitus (NIDDM) generally have poor control in their diet regimen. Due to the variation in body mass, physiology, and cultural differences as compare with the general American population, special attention must be conducted in treating diabetes in Cis, emphasizing culturally sensitive care and nutrition therapy that acknowledge the differences.

Purpose: The purpose of this project was to assess cultural challenges in self-management for CIs living with non-insulin dependent diabetes mellitus and evaluate the effectiveness of a diabetic nutritional self-management guide tailored to this population.

Theoretical Framework: Havelock's theory of change is a model emphasized for understanding and intervening of the possibility that people might be resistant to behavior changes.

Methods: Thirty-five foreign-born CIs were selected. The project was comprised of two phases to include pretest and posttest self-assessment questionnaires in addition to pretest and posttest A1C levels to evaluate the effectiveness of a custom meal plan.

Results: Result findings were non-significant. However, female CIs were noted to have superiority for diet management as compared with male CIs. The two groups had no significant difference in age and cultural characteristics.

Conclusion: The goal of the implementation of this project was to improve self-care for Chinese diabetic patients through behavior training and change in policy making. Social and cultural norms were identified that had great influence on an individual's overall health knowledge. Increasing health care providers' overall cultural competency was expected to promote better health outcome and ease the complexity of the acculturation

process. However, the management of the diet did not have a significant change for the improvement of A1c. Future recommendations include the exploration of the immensity of change in cultural diet and acculturation.

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Chapter 1: Nature of Project and Problem Identification

Diabetes is a chronic disease with a complex treatment, including both medical and behavioral modified interventions. These challenges will depend upon the degree to which the patient has acquired the new country's social and cultural norms as well as individual characteristics, such as age, education, and gender. In regard to nutritional interventions for non-insulin dependent diabetes mellitus (NIDDM), understanding adherence to therapy regimens in the long term will depend upon overall health literacy and cultural acceptance of the recommended diet (Kung et al., 2014). Diabetes may cause increased risk of serious medical conditions, such as heart disease, stroke, various circulation disorders, and vision complications (Barley & Lawson, 2016). Long-term complications from diabetes can develop gradually and damage blood vessels that supply blood to major organs (Bender, Arbuckle, & Ferris, 2017). All these health conditions can eventually add up to the ultimate complication, which is an early death. According to Tsan and Tsan (2015), diabetes ranks as the seventh leading cause of death.

Chinese immigrants (CIs) with NIDDM generally have poor control in their diet regimen. Due to the variation in body mass, physiology, and cultural differences as compare with the general American population, special attention must be conducted in treating diabetes in Cis, emphasizing culturally sensitive care and nutrition therapy that acknowledge the differences (Gao, Wang, Zhu, & Yu, 2013). Little attention has been focused to their unique cultural beliefs and practices regarding diabetes. This project

focused on cultural diversity and its effects on diabetes management in CIs as a minority and the challenges faced in adhering to the nutritional recommendations.

Dietary factors adversely affect the development and progression of NIDDM in the population of CIs (Yang et al., 2014). Identifying strategies for better diet control of this chronic disease are crucial to prevent complications and mortalities. Social-demographic identifiers are recognized significantly as the diet barriers for CIs with poorly controlled Type 2 diabetes. Cultural practices leading to population-specific needs should be considered in this minority population to cultivate adherence to lifestyle factors (Xu et al., 2013). Little attention has been directed to CIs' unique cultural beliefs and practices regarding diet control in diabetes self-management (Faber & Kruger, 2013).

Changes in overall health following immigration have been noted from decreasing health advantages over time and increasing prevalence of obesity related to metabolic diseases such as Type 2 diabetes. Adaptation to the new environment and culture are risk factors for diabetes. Despite significant growth in numbers of CIs and their exposure to acculturation and economic stress factors, little data has been explored about their health practices (Luo et al., 2015). Immigrants face obstacles to optimize treatment of complex chronic diseases due to many factors, such as lack of resources of interventions based on culture, may be a major barrier to optimal good health. Change is making something different from the way it was. One must deal with change every day. Change is often challenging as people can become stuck in their own traditional ways of doing things and dealing with life situations (Barley & Lawson, 2016). It is easier to stick with familiar routines than to accept the challenge to learn new information.

In general, the population of CIs encounter physical, economic, cultural, and political changes. As a NIDDM patient, a change that will benefit health outcomes is evidenced through attitudes, beliefs, values, and behaviors (Barley & Lawson, 2016). It is apparent that individual characteristics, such as age, gender, and socio-economic status in combination with the duration of stay in the original country highly affect the level of acceptance to the recommended diet management of diabetes. Culturally tailored, patient-centered intervention programs that acknowledge individual differences will allow for a more flexible diet management.

Problem Statement

Currently, 42.3% CIs with NIDDM do not adhere to the recommended nutritional management at a small primary internal medical clinic in South Florida. Ethnic minority populations have had higher prevalence of diabetes in which they encounter challenges in diabetic care to include limited health literacy and low capability to communicate their health need (Tsan & Tsan, 2015). CIs often struggle with conflicts between health-related information received from their health care providers (HCPs) and own cultural beliefs.

Purpose Statement

The purpose of this quality improvement project was to (a) assess existing knowledge and practices of HCPs for increasing nutritional self-management for non-insulin dependent diabetic CIs, (b) conduct a literature review to identify a standardized treatment guideline for CIs to increase patients' compliance in diabetes self-nutrition management, (c) develop a plan to educate these CIs for diabetes self-nutritional management, and (d) evaluate the effectiveness of the diet therapy guide for CIs.

Project Objectives

This project was guided by the following objectives:

1. Assess existing knowledge and practices of HCPs for increasing nutritional self-management for non-insulin dependent diabetic CIs.
2. Conduct a literature review to identify a standardized treatment guideline for CIs to increase patients' compliance in diabetes self-nutrition management.
3. Develop and implement a plan to educate these CIs for diabetes self-nutritional management.
4. Evaluate the effectiveness of the diet therapy guide for CIs.

Theoretical Foundation

A theoretical foundation demonstrates the significant relationship between theory, research, knowledge development, evidence, and practice (Faber & Kruger, 2013).

Nursing theories greatly contribute to knowledge development, which may direct education, research, and practice. The framework of theories should lend itself to research testing, and this testing may lead to knowledge that guides practice (Kass, Taylor, Hallez, & Chaisson, 2015). It is vital for nursing theories to develop and lead practice. Theories contribute in enriching the general body of knowledge through research studies implemented to validate those data collected (Steed, Bamard, Hurel, Jenkins, & Newman, 2014).

Havelock's Change Theory

Havelock's theory of change is a model that emphasizes the understanding and intervention of the possibility that people might be resistant to behavior changes (Barley & Lawson, 2016). Change is a powerful and an inevitable part of a human's life (Barley & Lawson, 2016). Havelock's theory of change gives people one way of considering

change in a six-stage process that acknowledges resistance to change and the need to carefully plan for change (Barley & Lawson, 2016).

Model structure. Change is a vital part of having social success, growth, and success in managing care. In general, people can change either on their own or in response to the outside influences.

Model process. Havelock's theory of change has six stages that directly affect the plan and management of patient care (Steed et al., 2014). Stages consist of building relationship with the patient, diagnosing problem, obtaining pertinent resources and bringing plan to yield optimal outcomes, picking resolution for change project that is going to be implemented, establishing and accepting change, monitoring progress of the plan, and stabilizing it permanently (Steed et al., 2014). Havelock's theory of change supports the Doctor of Nursing Practice (DNP) project and the continued manage care of diabetes patients.

Outcomes. Change theory assists people to understand the purpose of a change for optimal health outcomes (Barley & Lawson, 2016). Making a change in diet as compared with their norm takes processes in a step approach. The goal is to allow for the change with adaptation and acceptance.

Application of theory. Diabetes self-management is central to diabetes care. Self-management involves individual behavior change, especially in cultural diet. However individual-level behavior change remains a challenge for many people with diabetes, particularly for a minority, such as the Chinese Americans who faced barriers to diabetes-related behavioral changes (Kung et al., 2014). In general, because people must deal with change at every level, Havelock's change theory formulated one widely studied

and accepted theory to assist in dealing with change (Steed et al., 2014). The six key aspects of the change theory were applied to this project by expanding and managing change in the diet control for CIs with diabetes through planning and monitoring. Through Havelock's theory of change, one can see the importance of planning an orderly process from recognition of the need for change in the behavior recognized as a self-care deficit to the person's ability to maintain a changed system (Steed et al., 2014). The change theory will help this population to realize the amount of work that is required to affect lasting positive change with diet control to compromise medical regimen. Many people can improve their health by managing their chronic conditions, such as diabetes, to engage in health promotion behavior (Barley & Lawson, 2016). Nurse practitioners can apply the change theory to promote responsibilities of the patients and their families to manage self-care through behavior changes. With the knowledge and expertise that the nurse practitioners possess, CIs will successfully manage their chronic conditions through overcoming negative emotions associated with diabetes and fulfill responsibilities to diet control.

Significance of the Project

Cultural and family challenges to diabetes management within the CI population living in United States (US) have demonstrated cultural concerns for balance and significant food rituals (Yang et al., 2016). The prevalence of diabetes in CIs has been gradually increasing and infrequent focus on this population has been observed. Barriers to health care for CIs include language barriers, lack of provider awareness of cultural health preferences, and lack of culturally adapted disease management program (Nie, Xie, Yang, & Shan, 2016).

Nursing Practice

Health care professionals, such as nurse practitioners, play a vital role in the management of diabetes through education as the key to improve compliance. Nursing practice has made a significant impact by identifying practical strategies to improve diet adherence, therefore, enhancing therapeutic outcome. Diet control in diabetic patients requires a great deal of teaching and support. Nurse practitioners assist to create guidelines to serve as a guide to planning and implementing diet education for the CIs.

The role of nurse practitioners in diabetes management may include diabetic educators and primary care providers. Nursing practice has caused a significant impact in today's health care through advanced education and training. The effectiveness of nurse practitioners in primary care to manage diabetic control has led to better care for those with diabetes.

Health Care Outcomes

Failure to adhere to healthy diabetic diet regimen is a crucial problem affecting the CIs as well as the entire health care system. Barriers to diet adherence must be addressed through the patient-provider interaction and communication. The concomitant effects of non-adherence to the diabetic diet regimen include wasting medications, disease progression, decreased function and mobility, lessened quality of life, and increased hospital readmissions, hence, increasing the financial burden of the United States health care system. Complications of diabetes include microvascular and macrovascular disease, which highly represents the major causes of morbidity and mortality (Zeng et al., 2014). Cardiovascular disease is the leading cause of mortality in

patients with diabetes and is the major cause of end stage renal disease, blindness, and limb amputations (Yang et al., 2014).

Poor adherence will lead to longer hospital stay and increase use of nursing facilities. The increased proportion of Chinese patients with diabetes has challenged today's health care system. High quality diabetes self-management has brought success in diabetic control using behavior strategies.

Health Care Delivery

For individuals and populations, optimal health can highly benefit from high quality health care services that are effectively synchronized with a powerful public health system (Zeng et al., 2014). HCPs must work continuously to reduce the burden of sickness and promote the overall health and physical function of the people in U.S. health care delivery system (Barley & Lawson, 2016). Health care administrators must address the problems with access to care, chronic disease management, and improve the potentiality of the delivery system to properly serve the population concerning cultural competency, quality of care, information technology, and preventative services (Barley & Lawson, 2016). Moreover, the health care delivery system should have a role within the public health system. It is rapidly evolving in ways that require multidisciplinary expertise to promote high quality, safe, and effective care.

Health Care Policy

Current policy makers must reassess the elements in health care of managing diabetes as a chronic illness. The impact of chronic disease in health care spending has called for remake of health care policy to increase the alertness of the importance in self-management of diet control for patients with diabetes. The associated comorbidities and

complications have suggested that policy reform needs to focus on the cost of health care in relation to the outcomes. Initiating policies to enhance the personal responsibility for health will influence the overall health care system in regard to the economic, social, and cultural resources.

Summary

Chapter one described the immediate need for a culturally tailored and patient-centered intervention program to recognize individuals' preferences and promote adherence to diet control. Few culturally appropriate interventions for CIs with NIDDM were available, and none addressed self-management with custom meal plans (Gao, Wang, Zhu, et al., 2013). The implementation of a culturally adapted meal-plan guide will enhance and support the efficacy of self-management of NIDDM. The problem and purpose statements of this project identified that more attention must be paid in treating diabetes in CIs with sensitive cultural care and custom nutritional therapy. Information gained from this project was expected to increase all health care providers' knowledge regarding this minority population.

Chapter 2: Review of the Literature

Type 2 NIDDM is the most common form of diabetes. Many risk factors for NIDDM include lifestyle modification, and diet control can be reduced significantly with time and effort in self-management. This chronic disease is increasingly prevalent. However, it is also largely preventable. According to Gao, Wang, Zhang, et al. (2013), one out of three adults was prediabetic, and there were more than 100 million people in the United States living with diabetes. Yang et al. (2016) also noted that diabetes rates nearly doubled in the past three decades due to increase in obesity and sugary diets.

Lack of Relevant Studies about Chinese Immigrants

Despite the rapid growth in the population of CIs in the US, their health care needs were not appropriately addressed as this issue became more visible as it continued to rise (Zeng et al., 2014). Most CIs were not invited in type II diabetes mellitus studies and other types of health research due to variety of reasons (Zeng et al., 2014). One of the reasons was the lack of knowledge in chronic disease within this population (Luo et al., 2015). Inadequate documented diabetes-related research about CIs indicated an emergent need for research on diabetes self-management in this specific growing population.

With today's everchanging health system, HCPs encountered difficulty in striving to keep the people with diversified backgrounds in healthy state (Zeng et al., 2014). Gao, Wang, Zhang, et al. (2013) found that there is a lack of studies about CIs with NIDDM. More often, miscommunication due to cultural differences and expectations can lead to dissatisfied care delivery (Gao, Wang, Zhang, et al., 2013). It is crucial to discover and

understand how environmental and social factors affect individuals' lifestyle choices and changes beyond diabetes disorder itself. One of the reasons for lack of studies in CIs with NIDDM was minimal sample size in a study in order to generalize the findings (Zeng et al., 2014). There needs to be enough studies to provide meaningful implications for medical needs and to understand cultural norms to custom care plan.

Search of the Literature

To explore scholarly articles on CIs currently living with NIDDM, the following key search words were used: diabetes mellitus, patient education, Chinese immigrants, behavioral change, and diet management. The search was broad to incorporate many related articles through future manual screening. Most of the studies were restricted to randomized controlled trials. The main studies that delivered outcomes of diabetes self-management education interventions for CIs were reviewed.

Literature searches in three databases included CINAHL, MEDLINE, and Nursing & Allied Health Collection. This paper included the contributing components that might affect diabetes self-management among CIs in the US and related health outcomes. This literature review examined the following topics: Havelock's theory of change, self-management in diabetes, culturally sensitive management, and diabetes self-management in CIs.

Havelock's Theory of Change

Havelock's theory of change is a model that emphasized the understanding and intervention of the possibilities that people might be resistant to behavior changes (Barley & Lawson, 2016). Change is a powerful and inevitable part of a human's life (Barley & Lawson, 2016). Havelock's theory of change had given one way of considering change in

a six-stage process that acknowledge resistance to change and the need to carefully plan for change (Barley & Lawson, 2016). Nie et al. (2016) studied diabetes self-management programs for CIs and found high coherence and statistically increased in glucose control and knowledge in diabetes. Luo et al. (2015) found that participants of CIs achieved better health outcome through diabetic education for diet control with emotional support from their families.

Self-Management in Diabetes

Optimal health outcomes derived from enhancing diabetes self-management for better diet control included general excellence of life, glycosylated hemoglobin (Hgb A1C), blood pressure, and other cardiovascular risk factors. Barley and Lawson (2016) noted behavior interventions can promote diabetes self-management by forming patterns and habits to improve health in general. Successful behavior changes benefit patients with diabetes by increasing health knowledge, problem-solving techniques, motivation, and capability to manage stress (Barley & Lawson, 2016).

Culturally Sensitive Management of Diabetes

According to Gao, Wang, Zhang, et al. (2013), increasing awareness for cultural sensitivity is essential to effective diabetes education with knowledge of cultural beliefs, values, language, and customs. Thus, cultural sensitivity can nourish a respectful and positive patient-provider relationship. Gao, Wang, Zhang, et al. (2013) noted individuals with diabetes will ultimately achieve desired health outcomes and promote quality of life. However, health needs vary from people living in different countries with their traditional health practices. Ethnic diversity created many challenges for practitioners to deliver competent care to improve diabetes self-management (Gao, Wang, Zhang, et al., 2013).

Diabetes Self-Management in Chinese Immigrants

Traditional culture of CIs is extremely diverse. Barriers to effective diabetes self-management include cultural attitudes, beliefs, and diet. Gao, Wang, Zhang, et al. (2013) found it difficult to measure direct outcomes or conduct a meta-analysis. Gao, Wang, Zhang, et al. (2013) found that in some literature reviews, the interview method was used to pinpoint specific interventions that were deemed successful or unsuccessful health outcomes. Variables are measured through data collection of Hb A1C levels, physical activity, and diet outcomes (Luo et al., 2015). Other measures were chosen based upon body mass index (BMI), total body fat, and dietary intake (Nie et al., 2016). Diet tailored to the Chinese culture was considered with an advisable change in caloric intake, dietary risk, amount of vegetable intake, fruit intake, fat intake, and cholesterol intake (Yang et al., 2016).

The impact of diabetes extends beyond physical health. Routine daily practices of cultural meal planning involve all family members of that household. The experience of daily living and the management of diabetes are molded by cultural beliefs and practices, family structure, and acculturation background (Gao, Wang, Zhu, et al., 2013). In a qualitative study of CIs with NIDDM, Luo et al. (2015) found that cultural beliefs about specific food and its meaning to quality of life and social relationships display a major challenge of making dietary changes. Participants from these studies noted that they had gained emotional support and skills in better management of their diabetes through the support of an education enhancement program (Zeng et al., 2014). CIs face challenges in diabetes self-management (Yan et al., 2016). Health literacy and the ability to receive then process basic health information may be limited (Yang et al., 2016). Barley and

Lawson (2016) found that some CIs have poor diabetes self-management due to multiple cultural and environmental barriers, which prevent them from reaching out for health care needs.

Conclusion

This chapter highlighted the significance of how culture highly affects an individual's health beliefs and perspectives, hence influencing Type 2 diabetes self-management behavior. It is vital to investigate holistically in Chinese culture, characteristic beliefs in illnesses, and family dynamics for dietary recommendation. A culturally diverse diabetes self-management support group for CIs facilitates interactions. Therefore, increasing knowledge in diabetes results in better glucose control and chronic disease management to prevent risks for associated complications. A holistic health program should be initiated to the CIs. The goal of treatment is to understand that specific food preferences play a vital part in traditional Chinese culture. Dietary preferences confer a major challenge in managing Type 2 diabetes within this population. Because many CIs are still following their cultural diet after they migrate to the US, diabetic consultants must understand their food preferences to alleviate difficulties in transition.

Chapter 3: Methods

NIDDM is a chronic disease that is highly manageable with medical treatment and diet self-management. This condition has a wide range of care options to include the most effective therapy as self-management (Xu et al., 2013). CIs residing in United States are considered a health disparity population (Yang et al., 2014). Diet control has been a challenge for many HCPs due to these patients' biological barriers and linguistic factors (Yang et al., 2014). The purpose of this project was to initiate a care program with custom meal plans tailored to the CIs to promote ultimate health outcomes with NIDDM.

Project Design

Description of Project

The project studied 35 foreign-born CIs in South Florida living with NIDDM. Initial level of glycosylated hemoglobin was measured from each participant to serve as a tool to make a comparison at the end of the study. Initially, each subject participated in a private meeting the first session to answer a brief pre-survey questionnaire, and a diabetic meal plan tailored to the Chinese culture was given. The meetings were designed not only to assess beliefs and practices about diabetes nutrition but also to increase their compliance with a diabetic diet by answering questions. Participants were returned for their second session in 2 weeks to follow up for how they were doing with the custom meal plan. The final session was held on Week 12 to return for a post-survey questionnaire in addition to measuring the level of A1C. All meetings were conducted in Chinese.

Research Setting

This project took place in an internal medicine office in South Florida. The setting had two physicians, two nurse practitioners, two physician assistants, one diabetic educator, and two case managers. The office is open Monday to Friday from 8 a.m. to 6 p.m. Patients in this practice include a diverse population. The medical director of this office is a Chinese American immigrant who was born in Hong Kong. The location of this practice is situated in a low-income area, hence there are many patients with Medicaid and Medicare insurance coverage. This site was ideal for this quality improvement project due to many Chinese immigrants who come into this office for medical care.

Participants

Inclusion Criteria

The inclusion criteria for this DNP project included Chinese adults diagnosed with NIDDM for at least 1 year, age between 35 to 75 years, and identified as a Chinese American who immigrated to the United States from either mainland China or Hong Kong. The level of A1C of these candidates needed to be above 7.

Exclusion Criteria

The exclusion criteria for this DNP project included CIs with major diabetic complications, such as a stroke or heart attack in the past 12 months, kidney failure, and limb amputations.

Participant Recruitment

Recruitment and selection of participants had to be fair within the context of the study (Xu, et al., 2013). The recruitment of participants for this DNP project was

conducted in two phases. In the beginning of phase one, the subjects were identified who fit the inclusion criteria. The quality improvement team within the clinic identified a list of patients whose A1C levels were currently not controlled and needed dietary management. After receiving information, the first 35 candidates were selected to participate. In the second phase, these participants were educated about the purpose of this quality improvement project, and they were informed that participation was voluntary, and no incentives were provided.

Ethical Considerations

Confidentiality is an important component of research studies. Privacy must be maintained with the respect for others to be treated as a single, unique individual and given the right to autonomy, including the right for privacy (Faber & Kruger, 2013).

This project outlined a research translation project for CIs' educational purposes to fit within the practice scope of a nurse practitioner. The information was collected through individualized interviews in such a manner that their personal demographics were identified directly or through identifiers when it was time to present for academic purposes. Only the DNP candidate and the supervisory physician had access to the data. In addition, all interviews with the patients were conducted confidentially. Many CIs were uncomfortable with sharing their health information with non-relatives or friends. Confidentiality was assured by meeting with prospective participants away from the patient care area at the office. Study codes, such as letters assigned individually, were created to identify the participants. Volunteer participant information was de-identified and kept safe in a digital journal in the investigator's computer. The primary investigator

was the sole user of that computer. The password was protected and programmed to log off after 2 minutes of inactivity.

The Institutional Review Board (IRB) screened all applications for research involving human subjects (Kano, Getrich, Romney, Sussman, & Williams, 2015). The duty of the IRB was to approve applicants, monitor processes, and review biomedical research (Kano et al., 2015). This DNP project was approved by Nova Southeastern University (NSU) IRB.

Informed Consent

Informed consent is the process of participants learning the facts about a research before deciding whether to take part (Kass et al., 2015). Before obtaining informed consent, the participants were provided with a clear explanation of the project, objectives, their rights in research, potential risk, and how they met the inclusion criteria to participate in the project. The participants were also advised that the consent must be voluntary, and they were free to withdraw at any time without affecting their medical care.

Project Phases/Objectives/Timeline

This project occurred in several phases to meet each objective.

Phase 1

In Phase 1, existing knowledge and practices of HCPs were assessed for increasing nutritional self-management for non-insulin dependent diabetic CIs. The existing clinical policies and guidelines were reviewed, and a meeting occurred with the HCPs to discuss the process utilized to assist patients with diet management and referrals. By the end of Week 1, Objective 1 was met.

Phase 2

In Phase 2, a literature review was conducted to identify a standardized treatment guideline CIs to increase health care providers care congruency in diabetes self-nutrition management. Scholarly articles, books, and other resources were surveyed on nutritional self-management for non-insulin dependent diabetic CIs. DNP project implemented in March 2018 with IRB approval.

Phase 3

In Phase 3, the DNP candidate collaborated with medical director and diabetic educator to develop a plan to educate these CIs about diabetes self-nutritional management and design a general plan to incorporate evidence-based practice (EBP) guidelines from the literature review. The DNP candidate obtained approval from the medical director of the research practice site and the NSU IRB. Thirty-five volunteer participants who meet inclusion and exclusion criteria signed informed consents. A list of assessment questions established preliminary A1C levels that were initiated, and a healthy meal plan was distributed that was tailored to the cultural needs of CIs. By week 4, all 35 participants were selected with informed consents signed. First and second sessions with proposed pre-survey questionnaire were completed. Custom meal plans were given to all participants. Volunteers were scheduled to return on Week 12 for the post-survey and to measure A1C level.

Phase 4

The DNP candidate evaluated the effectiveness of the diet therapy guide for CIs by repeating A1C level and utilized a final assessment questionnaire to evaluate behavior changes regarding diet control. The DNP candidate presented the project with initial

perspectives, findings, and modified recommendations using a pretest/posttest evaluation process prior to implementation of quality improvement project. The interprofessional team reviewed and supported the project for acceptance and/or remodification. All final assessments from post-survey were completed on all 35 participants. Meal plans were modified according to the recommendations through using a pre/post evaluation survey.

Resources and Budget

Gathering funds for a research project is competitive and challenging. This project took place in a primary clinic and utilized the interview method as a tool to collect important data. The total cost for this DNP project was estimated at \$496. Details are shown in the table below. The clinical site provided transportation assistance as the office had its own van to transport those who were in need. The on-site parking area was free. The interdisciplinary team consisted of two physicians, two nurse practitioners, two physician assistants, a diabetes educator, and two case managers.

Table 1
Project Resources and Budget

Resource	Item	Expense
Office supplies	Pens, poster boards, markers	\$23
	Papers/copies of interview questionnaire	\$50
	Papers/copies of educational handouts	\$100
Travel expenses	Gas (30 miles/day x 2 per week x 12 weeks)	\$175
	Toll (\$2/day x 24 days)	\$48
Goods for office staff	Food & beverages (\$25 x 2 occasions)	\$50
Miscellaneous		\$50
Total		\$496

The main goal of a quality improvement project was to produce outcomes and knowledge that assist with the development and approval of new treatment remedies. With the high prevalence of Type 2 diabetes in CIs, a research project focuses on evaluating and improving self-management is essential to the general population.

Culturally specific dietary changes contributed to optimal health outcome in relation to their eating habits. Today's ever-changing health care system encourages the process of incorporating research results and best practices into everyday practice, hence support continuous learning.

Outcome Measures

The outcome of this project was evaluated using the measures listed below.

Additional information on these outcomes are discussed in Chapter 4.

Objective 1

Assess existing knowledge and practices of health care providers for increasing nutritional self-management for non-insulin dependent diabetic CIs. This outcome was measured through the ongoing process of communication with the providers regarding the expected health outcome of the CIs diagnosed with diabetes.

Objective 2

Conduct a literature review to identify a standardized treatment guideline for CIs to increase patients' compliance in diabetes self-nutrition management. This objective was accomplished by examining the cultural beliefs of CIs with diabetes through a critical analysis of current scholarly research reports related to CIs.

Objective 3

Develop a plan to educate CIs about diabetes self-nutritional management. This objective was achieved by providing basic information for the participants in addition to the materials of self-management and included standardized policies regarding proposed amount of educational sessions for each CIs with diabetes and a standard guideline protocol to guide each health care provider.

Objective 4

Evaluate the effectiveness of a diet therapy guide for CIs following standardized policy using professional organizations evidence-based recommendations for diabetes nutritional self-management. A post-assessment questionnaire was administered to the CIs to evaluate behavioral changes in diet control following the nutritional educational program.

Summary

Failure to adhere to healthy diabetic diet regimen is a crucial problem affecting CIs as well as the entire health care system. Barriers to diet adherence must be addressed through patient-provider interaction and communication. The concomitant effects of non-adherence to the diabetic diet regimen include wasting medications, disease progression, decreased function and mobility, lessened quality of life, and increased hospital readmissions, hence, increasing the financial burden of the United States health care system. Complications of diabetes include microvascular and macrovascular disease, which represents the major causes of morbidity and mortality (Zeng et al., 2014). It was expected that the implementation of a culturally adapted meal plan for CIs would enhance their self-management, improve glycemic control, and improve health outcomes. However, the meal plan had a minimal effect on the self-management so that the findings were insignificant.

Chapter 4: Results and Discussion

Chinese immigrants are prone to have increased risk of uncontrolled chronic diseases, such as NIDDM (Kung et al., 2014). Substantial risk factors for uncontrolled NIDDM in this minority group include nutritional alteration from traditional cultural diet and acculturation pressure (Kung et al., 2014). Diet control in diabetes demands effective self-management. However, cultural beliefs and differences in addition to language barrier predispose HCPs to many challenges in care management of CIs. The goal of the proposed project was to assess the degree of adherence with a custom meal plan tailored to the CIs. Project outcome was measured by pretest and posttest dietary questionnaires in addition to pretest and posttest A1C levels.

Results of Data Analysis

There were 35 Chinese participants ($n = 35$) with 17 females ($n = 17$) and 18 males ($n = 18$). Each CI was evaluated for a glycosylated hemoglobin level at Week 1 and Week 12. A custom meal plan was given at the initial dietary interview. All participants returned between Week 11 and Week 12 for a repeat A1C level. A two-tailed t test was used to compare the results of initial and final A1C levels from two different time frames. A p value of less than .05 was considered statistically significant.

In terms of the participants, 85% of all participants were born in China with 15% born in Hong Kong, and 80% reported non-English speaking. Average age for male CIs was 62 and female CIs was 58. Adherence to diabetes treatment was highly related to patients' behavior (Zeng et al., 2014). A1C level served as a crucial assessment tool to

evaluate glycemic control (Zeng et al., 2014). Data were analyzed for 35 CIs participants with NIDDM. The mean score of the initial A1C level was 8.85 with standard deviation of 1.6076, and the final mean score of A1C level was 8.22 with *SD* of 1.1263 of the sample group. A *t* test was performed to measure the difference between pretest and posttest A1C level mean score for the two variables. The findings were non-significant with a *p* value of less than .05. The mean of the two separate A1C level tests was not significantly different; hence, there was no statistical evidence to determine if there was a true difference (see Table 2).

Table 2
Comparison of Week 1 and Week 12 A1C Levels

Descriptive Statistics			
	Mean	Standard deviation	<i>n</i>
Week 1 A1C	8.8514	1.6076	35
Week 12 A1C	8.2171	1.1263	35

An independent sample *t* test was conducted to determine if there were a difference between the two separate A1C level tests. The mean score of the A1C level in Week 1 ($m = 8.85$, $SD = 1.6076$) was not significantly different from the mean score of the A1C level in Week 12 ($m = 8.22$, $SD = 1.1263$). As a result, the findings were not significant with a *p* value of less than .05 (see Table 3).

Table 3
Independent Samples t-Test

Independent samples <i>t</i> test		
<i>t</i> statistic	1.9117	Result
Degrees of freedom	68	Do not reject the null hypothesis
Critical value	1.9944	Conclusion
95% confidence interval	-0.6037 1.8722	Week 1 was not significantly different from Week 12 $t(68) = 1.9117$, $p > .05$

Comparison of A1C findings of female and male participants indicated that female CIs were superior with diet management based on the reduction of the final A1C levels. A custom meal plan was given to each participant to assess for diet adherence. Data collection consisted of pretest and posttest dietary questionnaires in addition to pretest and posttest A1C levels that were collected accordingly. There were no significant differences between the age of female CIs as compared with the male CIs. The mean age for male CIs was 62 and female CIs was 58. Initial mean A1C level for female CIs was 9.13 with *SD* 1.8654, and final mean A1C level was 8.08 with *SD* 1.2804. Male CIs had an initial mean A1C level of 8.59 with *SD* 1.3204, and final mean A1C of 8.35 with *SD* 0.9775. As noted, female CIs had a higher mean A1C level of 9.13 at the beginning of the project as compared with 8.59 of male CIs. Furthermore, female CIs were found to have a -1.0 reduction in final mean A1C level as compare with male CIs with a -0.2 reduction within 12 weeks of the project (see Table 4).

Table 4
Comparison of A1C Levels in Female and Male CIs

Descriptive statistics			
<u>Female</u>			
	Mean	Standard deviation	<i>n</i>
Week 1 A1C	9.1294	1.8654	17
Week 12 A1C	8.0765	1.2804	17
<u>Male</u>			
Week 1 A1C	8.5889	1.3204	18
Week 12 A1C	8.35	0.9775	18

Discussion of Findings

Each project objective was completed according to the timeline and is discussed in its entirety.

Objective 1

Assess existing knowledge and practices of health care providers for increasing nutritional self-management for non-insulin dependent diabetic CIs.

Action steps. The provider's existing knowledge for nutritional information that was provided to patients for self-management through nutritional referrals and appointments was assessed. A diet recommendation guide was initiated for those CIs who were not adhering to the diabetes diet therapy. In addition, a plan was set with standardized clinical guidelines for these participants to follow up routinely with the goal of diet adherence by Week 4.

Outcome. The objective was met. A custom meal plan was given to each project participant to assess for diet adherence. Three focused dietary consultations were scheduled on week 1, 3, and 12. Data collection consisted of pre and post dietary questionnaires in addition to pre and post A1C levels were collected accordingly. A tailored diet recommendation guide based on theories from clinical research, calories and portion control, and individualized preferences may improve overall diabetes self-management in CIs (Yang et al., 2016).

Objective 2

Conduct a literature review to identify a standardized treatment guideline for CIs to increase patients' compliance in diabetes self-nutrition management.

Action steps. A literature review was conducted to identify a standardized treatment guideline for CIs to increase health care providers' care congruency in diabetes self-nutrition management.

Outcome. The objective was met. A literature review matrix was reviewed, and several scholarly articles were selected to support the significance in promoting diabetes

self-management education for CIs in outpatient clinics. The literature review findings indicated poor adherence to diet management that may cause complications from diabetes and increased morbidity and mortality (Yang et al., 2016).

Objective 3

Develop a plan to educate these CIs on diabetes self-nutritional management.

Action steps. Explored The existing institution's practice and policy was explored for increasing nutritional self-management for non-insulin dependent diabetic Chinese-immigrant patients.

Outcome. The objective was met. The evidence-based practice guidelines and policies were retrieved from the diabetes self-management education (DSME) file according to clinical guidelines from American Diabetes Association (ADA). The clinic protocol was revised to meet the CIs population's distinct need.

Objective 4

Evaluate the effectiveness of a diet therapy guide for CIs following standardized policy using professional organizations evidence-based recommendations for diabetes nutritional self-management.

Action steps. Evaluated The effectiveness of the diet therapy guide for CIs following standardized policy using professional organizations evidence-based recommendations for diabetes nutritional self-management was evaluated.

Outcome. The objective was met. The pretest and posttest dietary questionnaires were designed to assess participants' knowledge before and after using the custom meal plan. A professional translator for validity verified these questionnaires with a total of 14 open-ended questions related to CIs' individual dietary practice. Moreover, the Week 1

A1C level established the baseline to compare with the posttest A1C results. The American Diabetes Association recommends an A1C goal for Type 2 diabetes of less than 7 (ADA, 2018). Although the participants of this project did not achieve A1C level of 7, there was a reduction in the final A1C levels of the female CIs with a mean score of 8.08 with SD 1.2804, whereas the final mean score of the male CIs was 8.35 with SD 0.9775. However, these findings indicated that the mean final A1C levels of all participants was greater than 7.

Expected and Unexpected Findings

Of the 35 participants, 79% ($n = 28$) of the participants reported they received less information about diabetes self-management due not speaking English. Moreover, CIs stated that there were insufficient health educational materials in the Chinese language with specific diet practices. Project participants verbalized concerns in the understanding of information given for meal substitution list as compared with their usual meal. Other expected findings included that CIs were not aware of their responsibilities in self-management of diabetes. Although some participants utilized diabetes educational materials given in addition to custom meal plan during dietary interviews, several CIs claimed that they were not actively participating in diet adherence. Yang et al. (2016) found many CIs were not volunteering to look for health information; hence, they were not aware of available resources for diabetes self-management. Moreover, project participants reported that they tried not to be a burden for their families and felt worried about affecting the traditional family meal ritual. Social support was another factor that can highly influence self-management and health outcomes (Kung et al., 2014).

According to Kung et al. (2014), the strong feeling of avoidance to become a burden highly affected CIs' desire to verbalize their concerns with diet control to their families.

Surprisingly, a better glycemic control in female participants was noted in comparison with male participants. Female CIs had a -1.0 reduction in final A1C level, and male CIs only had a -0.2 reduction within 12 weeks of the project. The findings suggested a gender difference with female CIs dominance in diet adherence. Female CIs may receive remarkable improvement in diabetes self-management from interventions focused on psychosocial aspects.

Strengths

This evidence-based DNP project showed a low level of health knowledge of diabetes within this CI population. However, participants were found to willingly accommodate a culturally tailored meal plan and were able to adjust their cultural diet practices. Participants reported that they were not offered guidance from health care providers about how to balance their diabetic diet according to cultural beliefs and practice. During Week 3, CIs were invited to return for a dietary consultation to answer questions and alleviate concerns. Appropriate diabetes educational materials in Chinese were given to promote health literacy. Although this project had a small sample, it was consistent with the literature in promoting health outcome with sustainable DSME. The data collected displayed a positive influence on glycemic control.

Limitations

Several imitations of this project were noted. The anticipated sample of 35 participants was small, hence not able to generalize result findings. Some factors regarding social support and ability to obtain health information were not readily

available. Findings may only represent CIs in certain geographic area and were not able to be generalized to the overall population. However, the non-significant findings of this project had not shown if there were a correlation between provider-patient communication and diabetes care self-management. Yet, it is interesting to find a culturally tailored meal plan did not result in a significant improvement in glycemic control, hence an indication that a gap continues to underlie health literacy and effective interventions.

Implications

Nursing Practice

Nursing plays a crucial role in educating CIs about self-management of diabetes. Patient education is the cornerstone to better health outcomes. Health care providers are sole educators for patients and health care staffs. Educating staff in an outpatient clinic promotes a team approach to patient care. The conclusion of this project identified positive findings from increasing awareness with diet management in NIDDM. Participants learned new knowledge in recognizing unwanted consequences from non-compliance for proper self-management in diet control. DSME programs must be developed to emphasize behavioral changes to support sustainability to promote efficacious diabetes management.

Health Care Outcomes

Promoting health literacy and diabetes self-management are the keys to optimal health outcomes. Studies to address diet preferences of CIs must be used to explore effective diabetes education relevant to the culture (Xu et al., 2013). Culturally tailored dietary recommendations may enhance self-management in this population (Zeng et al.,

2014). Diabetes educational programs focus on diet, physical activity, and medication management. Integrating cultural beliefs and practice can potentially yield the highest health care outcomes (Steed et al., 2014). Nursing practice assumes a unique position to manipulate many strategies for follow-up care and education for behavioral goals to sustain the continuous effect with self-management.

Health Care Delivery

The purpose of this evidence-based DNP project was to create a learning experience and provide an opportunity to design an improvement tool to promote diabetes self-management in CIs. Preventing comorbidities from diabetes will further reduce financial and economic burdens in United States (Steed et al., 2014). Behavior programs in DSME may decrease hospital admissions of CIs and expanding resources available will promote health literacy. According to Zeng et al. (2014), economic burden from diabetes had escalated cost of health care twice in the amount as compared with other chronic illnesses.

Health Care Policy

Developing a culturally sensitive DSME for CIs is crucial. HCPs must be highly trained to ensure competency in cultural diversity. The incorporation of a self-management program tailored to this minority group may promote optimal care practice. The custom meal plan in this project might serve as a guide for patient education to evaluate CIs' understanding of the disease process in NIDDM and ultimately address any concerns. New policies are needed to dispense more resources to this specialty group for future access to translated diabetes educational materials. This approach will promote health literacy in diabetes knowledge and foster better health outcomes.

Future Research

Project findings about dietary behaviors in CIs accentuate future recommendations. Future research should involve studies for valid and accurate measures of dietary intake. It is crucial to investigate how acculturation may affect lifestyle changes and alter health behaviors that can affect risk reduction for complications from diabetes. Interventions, such as a diabetes educational program with multilingual health services, will expand the accessibility of diabetes education materials in Chinese (Tsan and Tsan, 2015). A demand to increase fundamental knowledge is crucial for diabetes self-management, and competency in English-speaking is one of the most commonly known attributes of acculturation (Zeng et al., 2014). Training health care providers to ensure culturally sensitive, deferential, and equality health care is crucial to promote diabetes compliance and health outcomes among CIs. Future recommendations are suggested for self-management programs for this minority group to change health behavior through the sensitivity of cultural concerns. It is important to understand that certain cultural characteristics and family dynamics affect self-management behavior among CIs with NIDDM. Kung et al. (2014) found that components concerning family dynamic were not commonly explored in diabetes management of certain ethnic population. Every CI's family is somehow structured differently. Traditionally, male CIs are the head of household, and female CIs prepare meals for the entire family. Future research is needed to explore the immensity of changes in cultural diet and acculturation. CIs face many challenges living with diabetes. Diabetes is a chronic disease that depends highly on self-management involving behavior training. Cultural adaptability of the

recommended custom meal plan in this project focused on acculturation and its influence on diet self-management in CIs as a minority group.

Summary

The purpose of this evidence-based DNP project was to analyze the immensity of change in cultural diet and acculturation. Cultural adaptability of the recommended custom meal plan in this project focused on acculturation and its influence on diet self-management in CIs as a minority group. Although this DNP project resulted in non-significant findings, social and cultural norms were identified to have great influence on an individual's overall health knowledge. Despite the limitation of this project, the result findings have important implications for health care organizations and outpatient clinics in the delivery of diabetes self-management strategies. Health care leaders must propose new policies to meet the unique needs and conquer barriers challenging this immigrant population. Future studies will be appreciated to address the need of cultural consideration for the treatment of NIDDM for CIs to promote adherence to treatment therapy. Furthermore, increased HCP overall cultural competency may promote better health outcomes and ease the complexity of the acculturation process. The implementation of a culturally appropriate DSME may serve as a mainstay in the management of NIDDM.

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Appendix A

IRB Approval Letter

To: WINNIE M WONG, MSN

From: Vanessa A Johnson, Ph.D., Center Representative, Institutional Review Board

Date: April 23, 2018 Re: IRB #: 2018-206; Title, “Chinese Americans with Non-Insulin-Dependent Diabetes Mellitus: Nutritional Self-Management Approach”

I have reviewed the above-referenced research protocol at the center level. Based on the information provided, I have determined that this study is exempt from further IRB review under 45 CFR 46.101(b) (Exempt Category 2). You may proceed with your study as described to the IRB. As principal investigator, you must adhere to the following requirements:

1) CONSENT: If recruitment procedures include consent forms, they must be obtained in such a manner that they are clearly understood by the subjects and the process affords subjects the opportunity to ask questions, obtain detailed answers from those directly involved in the research, and have sufficient time to consider their participation after they have been provided this information. The subjects must be given a copy of the signed consent document, and a copy must be placed in a secure file separate from de-identified participant information. Record of informed consent must be retained for a minimum of three years from the conclusion of the study.

2) ADVERSE EVENTS/UNANTICIPATED PROBLEMS: The principal investigator is required to notify the IRB chair and me (954-262-5369 and Vanessa A. Johnson, Ph.D., respectively) of any adverse reactions or unanticipated events that may develop as a result of this study. Reactions or events may include, but are not limited to, injury,

depression as a result of participation in the study, life-threatening situation, death, or loss of confidentiality/anonymity of subject. Approval may be withdrawn if the problem is serious.

3) AMENDMENTS: Any changes in the study (e.g., procedures, number or types of subjects, consent forms, investigators, etc.) must be approved by the IRB prior to implementation. Please be advised that changes in a study may require further review depending on the nature of the change. Please contact me with any questions regarding amendments or changes to your study.

The NSU IRB is in compliance with the requirements for the protection of human subjects prescribed in Part 46 of Title 45 of the Code of Federal Regulations (45 CFR 46), revised June 18, 1991. Cc: Lynne Bryant, EdD Vanessa A. Johnson, Ph.D.

Appendix B

Letters of Support and Consent

Title of Study: Chinese Immigrants with Non-Insulin-Dependent Diabetes Mellitus:

Nutritional Self-Management Approach

Primary Investigator:

Nova Southeastern University

Winnie M. Wong, APRN

Co-investigator:

Institutional Review Board

Description of Study: This individual interview study will research on 12 foreign-born Chinese immigrants aged 35-75 years old and currently living in South Florida living with NIDDM. Hosting six interviews with each patient individually in a private session to assess for beliefs and practices regarding diabetes. Interviews will be conducted in Cantonese or Mandarin. Thereafter the contexts will translate into English.

Risks/Benefits to the Participant: This research study involves minimal risk to the participants. To the best of our knowledge, participants will have no more risk of harm than they would have in everyday life.

There are no risks of psychological or physical injury associated with the participants' participation in this study. I will attempt to preserve the participants' private information by assigning a special code number to their medical information and will remove personal identifiers (name, social security number, medical record number, etc.) from information stored. Access to any identifiable information about the participants that will

be contained within the research and will limit to me as the researcher associated with this study and my office staff.

The researchers will be taking steps to minimize the known or expected risks.

The possible benefit of the participants being in this research study is to improve blood sugar control therefore decrease risks for complications associated with diabetes. There is no guarantee or promise that the participants will receive any benefit from this study. I hope the information learned from this research study will benefit other people with similar conditions in the future.

Cost and Payments to the Participant: Participants will not be given any payments or compensation for being in this research study.

There will be no cost to the participants for their participation in this research study.

Participants will still be responsible for all of the costs related to their medical care, which will be billed to their insurance companies. Participants will also be responsible for any copays, deductibles, and co-insurance associated with medical care, just as they would be for any costs billed to their health insurance outside of this study.

Confidentiality: Information learned in this research study will be handled in a confidential manner, within the limits of the law and will be limited to people who have a need to review this information. Access to the identifiable medical record information contained within this research will be limited to researchers associated with this study and their research staffs. Organizations that may review and copy information include the Institutional Review Board and other representatives of this institution. If the results of the study published in a scientific journal or book, participants will not be identified. All

confidential data will be kept with the primary researcher at a secured location. All data will be kept for 36 months and destroyed after that time by the shred utility.

Participant's Right to Withdraw from the Study:

I have read this letter and I fully understand the contents of this document and voluntarily consent to participate. All of my questions concerning this research have been answered. If I have any questions in the future about this study, they will be answered by the investigator listed above or his/her staff.

If you have any questions about your rights as a participant, you can also contact the NSU IRB at 954-262-5369

I understand that the completion of this survey implies my consent to participate in this study.

Appendix C

Informed Consent

NSU Consent to be in a Research Study Entitled

Chinese Immigrants with Non-Insulin-Dependent Diabetes Mellitus: Nutritional Self-Management Approach

Who is doing this research study?

College: Nova Southeastern University College of Nursing

Principal Investigator: Winnie M. Wong, MSN, APRN

Chairs of Capstone Project Committee: Dr. Marcia Derby-Davis

What is this study about?

This is a research study, designed to test and create new ideas that other people can use. The purpose of this research study is to explore, assess, conduct, develop, and evaluate the effective of the diabetic nutritional self-management policy through a prospective review of provider's nutritional referrals and nutrition appointments. A healthy diet may just be the best medicine in the treatment for patients with diabetes. The findings will benefit Chinese immigrants with diabetes to achieve blood sugar control and lower the risk for serious health conditions from heart disease to cancer.

Why are you asking me to be in this research study?

You are being asked to be in this research study because you have been diagnosed with diabetes, which is being studied and you are a foreign born in China or Hong Kong who immigrate to the U.S.

This study will include about 12 people.

What will I be doing if I agree to be in this research study?

While you are taking part in this research study, each interview session will take approximately 15 minutes, once every other week, for 12 weeks.

Research Study Procedures - as a participant, this is what you will be doing:

- You will be schedule for consult on diabetic nutritional meal planning one time every other week for 15 minutes each session. You will be educated on the better choice for self-management of diet control.
- Patient has to be diagnosed with T2DM for at least one year, being aged 35-75 years, and identify self as a Chinese American immigrated to the United States from either Mainland China or Hong Kong.
- Patient has major diabetic complications such as a stroke or heart attack in the past twelve months, kidney failure, and limb amputations are excluded from this research study. Due to the purpose for this project is to study Chinese immigrants who were in their earlier stages of the disease process in order to benefit from behavioral and diet interventions.
- You will continue to receive your routine provider consult as appropriate to your current therapy.

Are there possible risks and discomforts to me?

This research study involves minimal risk to you. To the best of my knowledge, the things you will be doing have no more risk of harm than you would have in everyday life.

There are no risks of psychological or physical injury associated with your participation in this study. I will attempt to preserve your private information by assigning a special code number to your medical information and will remove personal identifiers (name, social security number, medical record number, etc.) from information stored. Access to any identifiable information about you that is contained within the research will be limited to me as the researcher associated with this study and my office staff.

What if a research-related injury occurs?

I have taken steps to minimize the known or expected risks. However, you may still have problems or get side effects, even though the researchers are careful to avoid them. In the event of a research-related injury or if you have a bad reaction, please contact Principal Investigator right away. See the contact section at the end of this form for phone numbers and more information.

If you sign this form, you do not give up your right to seek additional compensation if you are harmed because of participation in this study.

What happens if I do not want to be in this research study?

You have the right to leave this research study at any time, or not be in it. If you do decide to leave or you decide not to be in the study anymore, you will not get any penalty or lose any services you have a right to get. If you choose to stop being in the study, any information collected about you **before** the date you leave the study will be kept in the research records for 36 months from the conclusion of the study, but you may request that it not be used.

Are there risks related to withdrawing from the study early?

If you decide to stop being in the study before it is over, please talk to the principal investigator about why you don't want to be in the study any more.

There is no risk to you if you do not complete the final withdrawal procedures and you can choose not to participate in them.

What if there is new information learned during the study that may affect my decision to remain in the study?

If significant new information relating to the study becomes available, which may relate to whether you want to remain in this study, this information will be given to you by the investigators. You may be asked to sign a new Informed Consent Form, if the information is given to you after you have joined the study.

Are there any benefits for taking part in this research study?

The possible benefit of your being in this research study is to improve your blood sugar control therefore decrease risks for complications associated with diabetes. There is no guarantee or promise that you will receive any benefit from this study. We hope the information learned from this research study will benefit other people with similar conditions in the future.

Will I be paid or be given compensation for being in the study?

You will not be given any payments or compensation for being in this research study.

Will it cost me anything?

There will be no cost to you for your participation in this research study. You will still be responsible for all of the costs related to your medical care, which will be billed to you or

your insurance company. You will also be responsible for any copays, deductibles, and co-insurance associated with medical care, just as you would be for any costs billed to your health insurance outside of this study.

Ask the researchers if you have any questions about what it will cost you to take part in this research study (for example bills, fees, or other costs related to the research).

Will clinically relevant research results be shared with me?

The study investigators plan to share certain research results with people who are in the study if they think they are important for you to know. The results will be shared with you in an individualized format, meaning that the results apply to you. The study team will share these results by your primary provider during a consult three months after the completion of the study to include a description of the results to be shared and the reasons why they are clinically relevant.

How will you keep my information private?

Information we learn about you in this research study will be handled in a confidential manner, within the limits of the law and will be limited to people who have a need to review this information. Access to your identifiable medical record information contained within this research will be limited to researchers associated with this study and their research staffs. Organizations that may review and copy your information include the Institutional Review Board and other representatives of this institution. If we publish the results of the study in a scientific journal or book, we will not identify you. All confidential data will be kept with the primary researcher at a secured location. All data will be kept for 36 months and destroyed after that time by the shred utility.

A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

Will my biological specimens be used in future research studies?

The research team will not re-use or share your study data and/or specimens for use in future research studies.

Whom can I contact if I have questions, concerns, comments, or complaints?

If you have questions now, feel free to ask us. If you have more questions about the research, your research rights, or have a research-related injury, please contact:

Institutional Review Board

Nova Southeastern University

(954) 262-5369 / Toll Free: 1-866-499-0790

IRB@nova.edu

You may also visit the NSU IRB website at www.nova.edu/irb/information-for-research-participants for further information regarding your rights as a research participant.

Research Participants Rights

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Research Consent & Authorization Signature Section

Voluntary Participation - You are not required to participate in this study. In the event you do participate, you may leave this research study at any time. If you leave this research study before it is completed, there will be no penalty to you, and you will not lose any benefits to which you are entitled.

If you agree to participate in this research study, sign this section. You will be given a signed copy of this form to keep. You do not waive any of your legal rights by signing this form.

SIGN THIS FORM ONLY IF THE STATEMENTS LISTED BELOW ARE TRUE:

- You have read the above information.

<u>Adult Signature Section</u>		
I have voluntarily decided to take part in this research study.		
_____	_____	_____
Printed Name of Participant	Signature of Participant	Date

- Your questions have been answered to your satisfaction about the research.

Appendix D

Diabetic Questionnaire

[Enter Post Title Here]

1. When were you first diagnosed with diabetes?

Year _____ Age _____

2. Do you exercise regularly?

Yes _____ No _____

3. Have you ever received diabetes education before?

Yes _____ If so, with who _____ No _____

4. How would you rate your understanding of how food affects your blood sugar?

_____ Very good _____ Good _____ Fair _____ Sometimes
_____ Never

5. Who usually does the cooking and food shopping in your home?

Self _____ Other _____ If so, who? _____

6. Do you ever skip meals?

Yes _____ No _____

7. How many meals do you usually eat per day?

8. How many snacks do you usually eat per day?

9. Give a sample of your meals for a typical day:

Time: _____

Breakfast _____

Time: _____

Lunch _____

Time: _____

Dinner _____

Time: _____

Snack _____

10. Do you get up during the night to eat or drink (other than water)?

Yes _____ **If so, what type?** _____ **No** _____

11. Do you use artificial sweeteners?

Yes _____ **If so, what type?** _____ **No** _____

12. Do you use any meal replacement products such as Ensure, Boost, Glucerna?

(Yes/No) Which ones and how often?

Yes _____ **If so, which one?** _____ **How often?** _____

No _____

13. What special food plan or diet do you follow (cultural/religious diet)?

14. Do you have any food allergies or intolerance?

Appendix E

Diabetic Meal Plan (English version)

1500 Calories

Breakfast

1 cup Grain (25) Example: Oatmeal, whole grain muffin, whole grain cereal

1 Carbohydrates (15) Example: 1 Slice whole wheat bread

1 teaspoon Soft Margarine (0)

1 Protein (0) Example: Egg white

½ cup Milk (6) Example: Fat free milk, soy milk, almond milk

Snack

1 small Fruit (15) Example: Strawberry, blue berry, black berry, grapes, grapefruit, kiwi, cherry

Lunch

1 cup Carbohydrates (40) Example: Buck wheat noodles, spinach noodles, egg noodles

2 ounce Protein (0) Example: Lean beef, lean pork, chicken breast

1 cup Cooked Vegetables (5) Example: Any green leafy vegetables (steamed, broiled or stir-fry)

1 teaspoon Oil (0) Example: Olive oil, vegetable oil (no butter or peanut oil)

Snack

1 small Fruit (15) Example: As above

Dinner

1 cup Carbohydrates (45) Example: Brown rice, long grain rice (basmati rice)

