

COMPLEMENTARY AND ALTERNATIVE MEDICINE USE  
BY NATIVE HAWAIIANS AND PART-HAWAIIANS WITH TYPE 2 DIABETES:  
A FEASIBILITY STUDY

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Keywords: Native Hawaiian, type 2 diabetes, diabetic peripheral neuropathy, CAM

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## ABSTRACT

In Hawai'i, type 2 diabetes is prevalent among Native Hawaiians and thus is a burden to their well-being, since there is an increased risk for health complications such as cardiovascular disease, kidney disease, and neuropathy. The terms "Native or Part Hawaiian" in this study refers to individuals who self identified one as their racial category. Individuals with type 2 diabetes should implement recommended daily self-management strategies to promote better health outcomes and possibly delay associated complications. The concept of self-management is found in chronic illness and Native Hawaiian health literature. The literature reveals that complementary and alternative medicine (CAM) serves to improve well-being through culturally accepted health and lifestyle practices. This study scrutinizes the process of recruiting and interviewing Native Hawaiians and Part Hawaiians with type 2 diabetes complication of diabetic peripheral neuropathy (DPN) and explores reasons these individuals use complementary and alternative medicine. A quantitative research method is conducted using two survey instruments: the CAM use survey and the SF-36 survey to assess reasons for CAM use, perceived general health, and bodily pain. A descriptive statistical analysis is performed to identify frequency data in a sample of 21 Native Hawaiians with DPN. The frequency data reveal factors that contribute to the use of CAM for diabetic peripheral neuropathy self-management, such as education, income, marital status, and religious beliefs. Knowledge and assessment of complementary and alternative medicine use may assist health care professionals in treating and caring for Native Hawaiians and Part Hawaiians with type 2 diabetes.

*Keywords:* Native Hawaiian, type 2 diabetes, diabetic peripheral neuropathy, CAM

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## **LIST OF ABBREVIATIONS**

### **CAM – Complementary and Alternative Medicine**

CAM is defined as “a group of diverse medical and health care systems, practices, and products that are not generally considered to be a part of conventional medicine” (NCCAM, 2012).

### **CSDPN - Chronic Sensorimotor Diabetic Peripheral Neuropathy**

Chronic sensorimotor diabetic peripheral neuropathy (CSDPN) is a common presentation compared to acute diabetic peripheral neuropathy (DPN) (Hartemann et al., 2011).

### **DPN – Diabetic Peripheral Neuropathy**

DPN is the loss of sensation in the periphery and progression in a symmetrical stocking-glove pattern with proximal progression (Lindsay, Rodgers, Savath, & Hettinger, 2010).

### **DPNP – Diabetic Peripheral Neuropathy Pain**

Diabetic peripheral neuropathy pain (DPNP) is exhibited by a discomfort of burning, tingling, or aching feeling with increased intensity at night (Barrett et al., 2007).

### **NH – Native Hawaiian**

“Any individual who is a descendent of the aboriginal people who, prior to 1778, occupied and exercised sovereignty in the area that now constitutes the State of Hawai’i” (U.S. Public Law 103-150, 1993, p. 1513).

### **T2D - Type 2 Diabetes**

Type 2 diabetes may be a combination of insulin resistance and insulin insufficiency (CDCP, 2014).



## **CHAPTER 1. INTRODUCTION**

Chapter 1 is an introduction and overview of a feasibility study assessing the background, significance, purpose, and summary of the research done on CAM use by Native Hawaiians with DPN. The general overview of DPN, a common problem, is reviewed highlighting the prevalence, treatment options, and quality of life burden. In Chapter 2, the literature reviews information on the evolving challenges a Native Hawaiian individual with type 2 diabetes may encounter with self-management. Native Hawaiian cultural values, social support systems, and distrust are topics found in the literature that could provide insight for health care professionals recommending conventional methods of treatment and self-management for diabetic peripheral neuropathy symptoms. Chapter 3 details feasibility research methodology conducted with insight for future Native Hawaiians studies, a population with poor health outcomes. The demographic racial categorical survey data selections reviewed were Native Hawaiian and Part-Hawaiian. Research results in chapter 4 attempt to answer the research questions (1) are Native Hawaiians and Part-Hawaiians with type 2 diabetes and DPN using CAM, (2) what are the reasons CAM are being used, (3) do Native Hawaiians and Part-Hawaiians combine CAM therapies, (4) are CAM therapies being used for type 2 diabetes self-management, and (5) What are the characteristics of Native Hawaiian and Part-Hawaiian CAM users. A discussion in chapter 5 compares research findings to relevant studies from the literature providing new knowledge for the potential improvement of Native Hawaiian well-being and health outcomes.

A common complication of type 2 diabetes is Diabetic Peripheral Neuropathy (DPN) and could result in chronic pain. This chronic pain contributes to changes in quality of life, mental health, and potential substance abuse. Chronic pain is difficult to manage and may impact physical, social, and economic aspects of an individual's life. Individuals with DPN may

experience anxiety, depression, and sleep disturbances (Bair, Robinson, Katon, & Kroenke, 2003; Gore, Dukes, Rowbotham, Tai, & Leslie, 2007; McDermott, Toelle, & Rowbotham, Schaefer, & Dukes, 2006). For more information on CAM treatment for DPN see Appendix A.

DPN is the loss of sensation in the periphery and progression in a symmetrical stocking-glove pattern with proximal progression (Lindsay, Rodgers, Savath, & Hettinger, 2010).

Diabetic peripheral neuropathy pain (DPNP) is exhibited by a burning, tingling, or aching discomfort feeling with increased intensity at night (Barrett, Lucero, Robinson, Dworkin, & Chappell, 2007). Individuals with DPN may experience pain and loss of sensation with impact on their functional status, mood, and sleep pattern (Lindsay et al., 2010). Clinical findings such as type of pain (burning sensation, electric shock-like sensation, and aching coldness in the lower limbs), time of occurrence (at rest or at night), and abnormal sensations (tingling and numbness) assist in the diagnosis of painful diabetic neuropathy (Hartemann et al., 2011)

Symptoms diabetic individuals with DPNP may experience are limited mobility, extreme discomfort, and numbness (Barrett, Lucero, Robinson, Dworkin, & Chappell, 2007). These symptoms present activity limitations for those with diabetes to maintain an active lifestyle and functional status. In addition to activity limitations there are challenges to maintain quality of life and adhere to recommended diabetic treatment regimens.

Quality of life (QOL) domains are altered by DPN. In one study, health related QOL domains (energy, sleep, pain, physical mobility and emotional reactions) presented lower scores for those with painful DPN (Benbow, Wallymahmed, & MacFarlane, 1998). Van Acker et al. (2009) found painful symptoms of DPN affected the physical and mental aspects of QOL associated with age, body mass index, diabetes duration, female gender, and smoking. In

contrast, painless Chronic Sensorimotor Diabetic Peripheral Neuropathy (CSDPN) had no significant impact on QOL (Hartemann et al., 2011).

Prevalence and incidence estimates of DPN vary based on select study criteria and population (Hartemann et al., 2011). Centers for Disease Control and Prevention (2011) estimates DPN as one of the most prevalent complication of diabetes mellitus at 60-70%. Painful diabetic peripheral neuropathy affects approximately 10-20% of patients with type 2 diabetes (Lindsay et al., 2010) and five percent in patients with type 1 diabetes (2011). Constant daily pain was experienced by 53% of diabetic neuropathy patients (Galer, Gianas, & Jensen, 2000).

Treatment of diabetic peripheral neuropathy is conventional treatment options established and recommended by national guidelines to manage pain. The American Society of Pain Educators provide a consensus guideline for DPN treatment with a collaborative plan between patient and provider to discuss pharmacological therapies to reach a goal of decreased pain, increased functional measures and quality of life (Argoff et al., 2006). Conventional pharmacological therapies are antidepressants, anticonvulsants, opioids, topical agents, and other therapies such as spinal cord stimulation, frequency-modulated electromagnetic neural stimulation, acupuncture, transcutaneous electrical nerve stimulation, and magnetic insoles (Argoff et al., 2006). Individuals and providers should consider comorbidities, other medication, treatment goals, potential side effects, drug interactions, cost, and availability of conventional DPNP treatment (Argoff et al., 2006).

These individuals with painful DPN may not achieve adequate pain management, functionality, and quality of life with conventional treatment. They may choose to explore other therapies, such as CAM. Complementary alternative therapies may provide pain relief, eliminate

potential side effects from conventional treatment, increase function, and improve quality of life for those with DPN. There is a need for healthcare providers to assess types of CAM treatments for DPN to provide more complete care (Lindsay et al., 2010).

CAM therapies are unconventional therapeutic options used independent of traditional treatments or as an adjunct therapy. The National Center for Complementary and Alternative Medicine (NCCAM) used the term “complementary and alternative medicine” to describe unconventional medicine (NCCAM, 2008). According to NCCAM (2012), therapy used in conjunction with conventional medicine was termed “complementary medicine” and a therapy used instead of conventional medicine was “alternative medicine”. CAM use was the implementation of diverse medical and health care systems, practices, and products that are not a part of conventional medicine (NCCAM, 2012). In 2014, NCCAM’s name was changed by congress and signed by President Obama to National Center for Complementary and Integrative Health (NCCIH) (NCCIH, 2014). This new name represents data from large population based surveys that the use of complementary therapy was used in combination with conventional treatment (NCCIH, 2014). The use of CAM as an element of self-care was increasing (Canaway & Manderson, 2013).

CAM includes natural products, mind and body medicine, manipulative and body-based practices, and other CAM practices. Approximately 40% of Americans use nonconventional health care for general well-being or a particular condition. It is common for complementary therapies to be used together with conventional medicine rather than the complete replacement of conventional therapies with alternative therapies (NCCAM, 2012).

The purpose of CAM is to promote health and well-being through body, mind, and environment. Types of CAM are alternative-medical systems (acupuncture, Ayurveda medicine,

homeopathic, naturopathy), biologically-based therapies (chelation, folk medicine, herbal, special diets, and megavitamins), manipulative/body-based therapies (chiropractic and massage), biofeedback, relaxation, hypnosis, yoga, tai chi, qi qong, and prayer (NCCAM, 2012). See Appendix A for samples of CAM types for treatment of DPNP.

A variety of complementary alternative therapies found in the literature were initially used by specific cultures. For example, acupuncture implemented by the Chinese culture was an option for diabetic peripheral neuropathy pain relief (Tong, Guo, & Han, 2010). Historical cultural CAM practices and purposeful cultural assessment may provide healthcare providers with insight to an individual's CAM preferences and uses.

The benefits from the use of complementary alternative therapy for DPN in other cultures may be applicable to Native Hawaiian diabetic individuals in Hawai'i. The review of the literature explores the use of complementary alternative therapy and the ability to translate benefits for DPN through cross-cultural connections. There is a need for healthcare providers to be culturally competent and increase their awareness of complementary alternative therapies used within various cultures (Lindsay et al., 2010). In addition, healthcare providers may consider adding cultural practice and preference questions to routine health assessments. Improved communication about CAM use between healthcare providers and patients can lead to consideration for CAM referrals from conventional healthcare providers (Ben-Arye & Frenkel, 2008).

Self-management was the concept for this feasibility study and is found frequently in chronic illness literature. Diabetes, a chronic illness, contributes to increases in the chronic illness population. Patients with diabetes are expected to implement recommended self-

management strategies daily to promote better health outcomes and delay diabetes-associated complications.

In chronic illness, self-management is the patient's daily responsibility and includes health-promoting activities for disease management (Lorig & Holman, 2003). A patient with diabetes faces daily health challenges to maintaining wellbeing and minimizing the burden of illness. Implementing multiple daily self-management behaviors presents barriers when the individual feels overwhelmed (Chlebowy, Hood, & LaJoie, 2010).

Those living with diabetes may be required to perform blood sugar monitoring in order to maintain optimal glycemic control. There are recommended daily self-management practices such as reducing nutritional intake of refined carbohydrates and saturated fat, increasing physical activity, and reducing weight (Hoerger, Gregg, Segel, & Saaddine, 2008). Lifestyle changes may be considered to effectively implement these recommendations.

Individuals can experience a feeling of shock and additional burden when diagnosed with type 2 diabetes. They may minimize the severity of type 2 diabetes based on their healthcare provider's response. Sometimes individuals blame themselves for poor choices over the years. They may feel a lack of support or a sense of loss on what to do to manage their diabetes (Crowe et al., 2017).

Self-management for successful health promotion includes many skills: learning to problem solve, making decisions, utilizing resources, taking action, and developing partnerships between the patient and healthcare provider (Center for the Advancement of Health, 2002). Self-management education curriculum may incorporate recommended lifestyle changes. Recommended standards of diabetes self-management education from the American Diabetes Association could provide more guidance in relation to the effects of education and the

individual's health status. Despite healthcare professionals recommendations for individuals with diabetes to practice self-management Lorig & Holman (2003) found the healthcare system is not supportive of self-management education.

DPN is a complication of diabetes with multifactorial self-management concerns pertinent to access and utilization of health care. The current recommended strategies include: (1) tricyclic antidepressants, (2) serotonin and noradrenalin re-uptake inhibitors, (3) anticonvulsants, (4) local analgesics, (5) N-methyl-D-aspartate receptor antagonists, (6) aldose reductase inhibitors, (7) sodium channel blockers, and (8) non-steroidal anti-inflammatory drugs, antiarrhythmics, and opioids for DPN self-management provide minimal improvement in pain management, functionality, and quality of life (Gilron, Watson, Cahill, & Moulin, 2006; Lindsay et al., 2010). CAM may be a self-management option for individuals with DPN. There is little research on CAM therapies used for self-management in Native Hawaiians with DPN. There is a need for exploration of CAM options for those who experience little relief from conventional therapies and seek other forms of DPN management and treatment.

## **Purpose**

The objective of this feasibility study was to scrutinize the process of recruiting and interviewing Native Hawaiians and Part-Hawaiians in Hawai'i with DPN and explore reasons these individuals use CAM for self-management. There were two specific aims: (1) to describe the process of conducting a feasibility study for Native Hawaiians and Part-Hawaiians with type 2 diabetes and DPN and, (2) to describe reasons, experiences, and types of CAM used by Native Hawaiians and Part Hawaiians with type 2 diabetes and diabetic peripheral neuropathy.

## **Background: Information on Diabetes**

In the United States, there are 29.1 million people or 9.3% of the population of all ages with diagnosed or undiagnosed diabetes. These numbers are inclusive of all ages and types of diabetes. A total of 1.7 million newly diagnosed diabetes cases were reported in 2012. Pre-diabetes diagnosis accounts for 86 million Americans aged 20 years or older (CDCP, 2014). The focus of this study was type 2 diabetes in an adult, age 18 or older, Native Hawaiian population. Native Hawaiians have a higher risk of developing diabetes and diabetes complications compared to other ethnic groups in Hawai'i (King et al., 2012).

There are several types of diabetes: type 1 diabetes limits or eliminates insulin production, type 2 diabetes may be a combination of insulin resistance and insulin insufficiency, and Gestational diabetes is glucose intolerance during the third trimester of pregnancy. Type 1 diabetes occurs in five percent of diagnosed diabetic cases as compared to Type 2 diabetes present in 90-95% of diagnosed diabetic cases (CDCP, 2014). Gestational diabetes prevalence estimates are from 4.6% to 9.2% (DeSisto, Kim, & Sharma, 2014).

There are reported racial and ethnic differences for people over 20 years old who are also diagnosed with diabetes. The following adjusted percentages are 7.6% Non-Hispanic Whites, 9% Asian Americans, 12.8% Hispanics, 13.2% Non-Hispanic blacks, and 15.9% American Indians/Alaska Natives (CDCP, 2014). In the United States, diabetes prevalence and incidence trends increased from 1990 to 2008. From 2008 to 2012, diabetes prevalence and incidence trends plateaued (Geiss et al., 2014).

The term Native Hawaiian is defined as “any individual who is a descendent of the aboriginal people who, prior to 1778, occupied and exercised sovereignty in the area that now constitutes the State of Hawai'i” (U.S. Public Law 103-150, 1993, p. 1513). Native Hawaiians



have high rates of diabetes, obesity, and metabolic syndrome (Aluli, et al., 2009; Grandinetti, et al., 1998; Grandinetti et al., 2007; Grandinetti, Kaholokula, Mau, & Chow, 2010; Kaholokula, et al., 2014; Mau, Sinclair, Saito, Baumhofer, & Kaholokula, 2009). On the islands of Hawai'i, Kaua'i, and Moloka'i, prevalence of type 2 diabetes in Native Hawaiian adults are 19-24% in a population 30 years or older (Grandinetti, et al., 1998; Grandinetti, et al., 2010). The comparison of this data with the National Health and Nutrition Examination Survey (NHANES), Native Hawaiians had a fourfold increase in type 2 diabetes prevalence compared to non-Hispanic whites (Grandinetti et al., 1998).

### **Diabetes Management**

Management of diabetes is dependent on the daily lifestyle practices of those with diabetes (Adejoh, 2014). Recommended daily lifestyle practices include healthy eating patterns, regular physical exercise, taking medication as prescribed, monitoring blood glucose level, maintaining regular clinic visits, and managing stress. Balanced daily lifestyle practices are recommended for diabetes management (CDCP, 2014).

Unmanaged diabetes has been associated with heart disease, kidney failure, blindness, stroke, premature death, amputation of toes, feet, or legs and diabetic neuropathy (CDCP, 2014). These serious health complications contribute to total medical costs as well as lost work and wages estimated at \$245 billion (CDCP, 2014). The rise in medical costs doubles for those with diabetes compared to those not diagnosed with diabetes, and the risk of death is 50% higher for adults with diabetes (CDCP, 2014).

Unmanaged diabetes individuals may contribute to high rates of medical complications, high mortality rates, and preventable hospitalizations. Native Hawaiians were diagnosed at a younger age and died at a higher rate compared to other ethnic groups (Humphry, Jameson, &

Beckham,1997). There were efforts to evaluate culturally adapted community-based diabetes self-management interventions with Native Hawaiians and Pacific Islanders resulting in short-term improvement on glycemic control (Sinclair et al., 2013).

Geographically isolated, Native Hawaiians were a healthy population. With little illness, Native Hawaiians promoted hygiene, consumption of good food, and rest (Dunford, Andrews, Ayau, Honda, & Williams, 2013). A *kahuna lapa'au*, or healing priest, provided assistance to the sick and was viewed as a doctor. The forms of healing included assessing the etiology of the illness through a process inclusive of the whole family. *Kahuna lapa'au* had knowledge about many types of medicine from plants, shells, and fish. *Heiau* is a Hawaiian temple. These temples were constructed for a variety of purposes such as human sacrifices, fishing, and honoring Hawaiian Gods and healing. Special temples or *heiau* for healing were erected. Hawaiians prayed to their gods for healing. A few of the specific items of use for healing included taro, coconut, breadfruit, sweet potato, sugar cane, 'awa, and salt water to help heal wounds, manage ailments, and relieve pain (Dunford et al., 2013). In a study, modern Native Hawaiians used a healer for adolescent Native Hawaiians in Hawai'i if they identified with the Hawaiian culture supportive of health and wellness through a holistic and spiritual approach (Bell et al., 2001). Native Hawaiians in Hawai'i with a cancer diagnosis used CAM at a rate of 30% (Maskarinec, Shumay, Kakai, & Gotay, 2000). Maskarinec and colleagues (2000) in the same study found the most selected types of CAM used by Native Hawaiians with a cancer diagnosis in Hawai'i were religious healing/prayer (60%), vitamins/supplements (37.5%), and massage/body work (31%).

## **Significance of the Study**

This feasibility study is interested in seeking new knowledge about the reasons for use and types of CAM and factors that may contribute to DPN self-management in a Native Hawaiian sample population. Harrigan et al. (2006), investigated practitioner provider-delivered CAM use in Hawai'i amongst the general population. The study findings identified a number of factors for provider-delivered CAM use in the general population of Hawai'i. These factors included a higher education level, higher income, and very good or good health status. 60% of poor health status respondents used CAM, 51.4% of overweight respondents used CAM, and 52.1% of women respondents used CAM. Demographic factors such as age and race/ethnicity reflected trends in CAM use. The youngest and oldest respondents less frequently reported CAM use. Caucasians reported the highest percentage at 60% of CAM users, Filipinos reported the lowest percentage at 37.1% of CAM use, and those without health insurance reported the highest portion of CAM usage at 53.7%. Those with extreme pain that interfered with normal work were the highest percentage of people 78.3% that used alternative health care services (Harrigan et al., 2006). Hawai'i has significantly higher percentages of provider-delivered CAM use than the whole United States. This assumption is based on results of 49.9% in Hawai'i and 75% corrected for prayer use compared to 25% National Health Interview Survey (NHIS). These results suggest the need for more exploration of factors of ethnicity, potential health complications, and economic consequences of provider-delivered CAM use (Harrigan et al., 2006).

Studies conducted in Hawai'i reveal the diabetic care provided met minimum nationally recommended diabetes standards. But, the health outcomes for Native Hawaiians and Pacific Islanders remain poor. It is evident that recommended diabetic care is not adequate for Native

Hawaiians and Pacific Islanders. Hawai'i has a diabetic population that may practice CAM for treatment of DPN.

The practitioner provided-delivered CAM use in a Hawai'i study, revealed most users of CAM did not use Lomilomi, Ho'oponopono, La'au Lapa'au or other traditional Hawaiian health practices (Harrigan et al., 2006). These results may reflect a mistrust and reluctance to disclose use of Native Hawaiian Care system practices. An exploratory descriptive feasibility study could provide new knowledge of how best to study self-management with a Native Hawaiian and Part Hawaiian type 2 diabetic peripheral neuropathy population, to include identification of reasons CAM used or non-used in a Native Hawaiian DPN population.

Research is a needed to explore other self-management options such as CAM access and utilization for DPN people in Hawai'i. In addition, there needs to be special attention placed on examining self-management options like CAM usage in the Native Hawaiian population experiencing a higher prevalence of diabetes compared to other ethnic groups found in Hawai'i. This feasibility study contributed by adding new information about the reasons of self-management CAM therapies used in a Native Hawaiian DPN population on the island of O'ahu, Hawai'i.

## **Summary**

Chapter 1 presented background on diabetes peripheral neuropathy (DPN) as a complication of chronic illness type 2 diabetes. The prevalence rate of DPN was up to 50% of diabetics. The national and state statistics show a high prevalence of diabetes in ethnic subgroups and those with low levels of education. Native Hawaiians in Hawai'i have a high rate of diabetes prevalence as evident by a disproportion in the reported statistics. This researcher scrutinized the process and feasibility of this study to provide insight for future studies.

Diabetes self-management is complex to manage, and delays complications. The current literature highlights conventional treatment for DPN, a painful complication of type 2 diabetes, and provides limited or poor outcomes. CAM treatment options for DPN are presented in the literature and detailed in Appendix A. Although CAM options are presented, the studies do not discuss utilization and access reasons for those with DPN or recommendations for healthcare providers. The purpose of this feasibility study is to scrutinize the process of recruiting and interviewing the Native Hawaiian and Part-Hawaiian with type 2 diabetes complication DPN in selected Hawai'i outpatient clinics and the self-management reasons Native Hawaiians and Part-Hawaiians accessed and utilized CAM.

## CHAPTER 2. REVIEW OF THE LITERATURE

Chapter 2 is a review of the literature of self-management for Native Hawaiians with type 2 diabetes. A critical review of the literature reveals what self-management Native Hawaiian data is evident to provide high quality care and conduct future research. The concept of self-management in daily life experiences for a Native Hawaiian person with chronic illness like type 2 diabetes complication DPN is explored to attain knowledge on maintaining optimal health and quality of life. The review of the literature examines type 2 diabetes and Native Hawaiians self-management themes.

### **Self-Management**

According to Thorne, Paterson, and Russell (2003), self-management is the ability and process an individual uses in a conscious effort to gain control over their disease as opposed to being controlled by their disease. Self-management is defined by Wilkinson and Whitehead (2009) as the ability one has, together with family, community, and healthcare professionals, to manage symptoms, treatments, lifestyle changes, as well as the psychosocial, culture, and spiritual consequences of chronic diseases. These definitions are a result of a concept analysis and the reflection of the burden experienced by the individual with chronic illness.

Self-management is defined as the “ability of the individual, in conjunction with family, community, and healthcare professionals, to manage symptoms, treatments, lifestyle changes, and psychosocial, cultural, and spiritual consequences of health conditions (particularly chronic diseases)” (Richard & Shea, 2011, p. 261). Self-management is often found in the chronic disease literature. In the context of chronic disease, “chronic disease self-management is a fluid, iterative process during which patients incorporate multidimensional strategies that meet their self-identified needs to cope with chronic disease within the context of their daily living” (Miller,

Lasiter, Ellis, & Buelow, 2015, p. 158).

### **A Chronic Illness Type 2 Diabetes Self-Management**

The term diabetes self-management is an expression of abstracted characteristics associated with a specific phenomenon (Rodgers & Knalf, 2000). Nursing, education, public health, and social work literature promotes empowering the individual living with diabetes to provide self-management by creating a personalized plan supportive of the individual's culture, priorities, goals, lifestyle, and resources (Funnell & Anderson, 2004; Boren, 2007). The personalized plan is a tool to implement self-management. An individual is able to identify support needs to create a personal plan to implement and maintain self-management.

The position statement by the American Diabetes Association (ADA) standards of Medical Care in diabetes (2007) focuses on diabetes care treatment goals and identifies diagnosis, access to self-management diabetes education, physical and cognitive skills, support for people living with diabetes and a realistic diabetes treatment plan as critical. The ADA does not specify guidelines for the diabetes treatment plan. It is unclear if the plan is a collaborative effort between the healthcare provider, the individual living with type 2 diabetes and the support system. The implementation of patient partnerships with health care professionals could be clarified.

Diabetes self-management involves a partnership between the individual living with diabetes and their health care professional in order to promote a healthy lifestyle and reduce diabetes complications (Skinner et al., 2006). The relationship between an individual living with diabetes and their family members or significant other may also be the barrier for proper diabetes self-management and may lead to an incidence of diabetes complications. Chronic disease

requires lifetime management from healthcare providers, families, and patients. Diabetes is an example of a chronic disease that presents daily complex self-management decisions.

Chronic illness literature focuses on the implementation of self-management strategies, adherence to plan, and ongoing support (Cook, Larsen, Sakraida, & Pedro, 2012; Kawi, 2012; Leake, 2003; Miller et al., 2015; Rasmussen, Maindal, & Lomborg, 2012; Rothenberger, 2011; Udlis, 2011). Based on these attributes, self-management is complex and multidimensional. Although the word “self” is present, there are multiple factors not controlled by the individual. According to Udlis (2011), the social construct of self-management consists of person, family, society, and healthcare professionals. The individual’s perception is an important part of self-management concept. The mutual investment antecedent is lost when clinical outcomes are self-management success indicators based on healthcare provider’s outcomes (Udlis, 2011). If self-management outcomes are based on healthcare provider goals, then the concern for short-term implementation of self-management strategies may continue with no collaborative goal setting (Miller et al., 2015). Nursing and healthcare goals are primarily focused on improvement in self-care and symptom management (Richard & Shea, 2011). These self-management goals could have better rates of implementation if the individual was consulted to set priority goals.

### **Self-management in Native Hawaiians with Diabetes**

Native Hawaiians face some of the greatest health challenges in the State of Hawai'i (Office of Hawaiian Affairs, 1998). Diabetes contributes to the poor health status of Native Hawaiians and is one of the leading causes of death (Hawai'i State Department of Health, 2004). Other factors contributing to the high mortality rate, specifically from complications due to diabetes, are the accessibility to health care and the integration/acceptance of traditional health care beliefs and practices to support self-management.



Prior to European contact in 1778, Native Hawaiians maintained a complex social structure governed through a kapu system to sustain the health and wellness of self-sufficient communities (Casken, 2001; Dunford et al., 2013). The land belonged to all and provided life for all those who lived in Hawai'i. The Native Hawaiian social structure exemplified the concept of self-management. In a sociocultural context self-management valued environmental processes. Native Hawaiian spiritual wellness is linked to land, water, and atmosphere (Oneha, 2001).

Westerners brought new illnesses and imposed a new set of values on Native Hawaiians. The decline in Native Hawaiian health began as societal change took place. The sense of community was replaced by Western views to promote individual possessions and land ownership. The result is a most landless Native Hawaiian class with no access to the land or sense of place (Kent, 1983).

The changes brought about by Western settlers altered both the cultural environment and the values of Native Hawaiian individuals. A stable cultural environment may reduce diabetic complications and support community health. The environmental alteration may have led to contributing factors for the high incidence of diabetes. These alterations included financial, political, and cultural structure with direct impact on personal well-being. The Native Hawaiian culture promotes health through a connection with body, mind, and spirit. Diabetes wellness strives to achieve a balance between body, mind, and spirit through self-care. Native Hawaiians, though, achieve balance through a link between individual and the environment. Thus, the ADA (2007) established, recommendations for individual self-care management interventions, inferring that they may not be valued or effective with Native Hawaiians and non-white individuals living with type 2 diabetes in Hawai'i. Diabetes affects the whole person and their

community. A comprehensive and culturally competent approach to diabetes care may provide balance for individuals who value cultural practices.

A historical perspective focused on Native Hawaiian culture, diabetes, and self-management guided the review of the literature. Medicine has been a driving force in early diabetes medical discoveries and management. In the 1930's, diabetes self-management was incorporated into clinical management (Bartlett, 1986). The high incidence of indigenous populations such as Native Hawaiians with diabetes highlighted the issue of cultural competence in diabetes self-management. The term "self" may not be a priority for indigenous populations who practice interdependence.

Diabetes care may be provided by a variety of disciplines interested in the concept of self-management. There are the selected disciplines for the analysis of self-management; nursing, medicine, psychology, education, and sociology. In the literature, disciplines were selected as recognized authorities for the concept of self-management and cited by other scholars. The goal of this concept analysis was to provide a rigorous design to clarify the concept of self-management in Native Hawaiians living in Hawai'i with type 2 diabetes.

An inductive approach to collecting data consistent with the evolutionary method concept analysis was utilized in a review of the literature. Online search engines used included Cochrane Library, Cumulative Index to Nursing Allied Health Literature (CINAHL), Native Hawaiian Health Database, Pub Med MEDLINE, PsycInfo and Science Direct. Government and organizational websites such as Center for Disease Control, U.S. Census Bureau, Hawai'i State Department of Health, American Diabetes Association, and International Diabetes Federation were reviewed. An interdisciplinary data analysis approach included nursing, medicine, education, sociology, and psychology provided self-management concept information.

The literature review search strategy started with a selected timeline between 2012 and 2017 with the purpose to gather current data from the past five years. Refined keyword search terms included: self-management, type 2 diabetes, and Native Hawaiians. Twenty-nine articles resulted. However, four articles contained essential key words and met the inclusion criteria to provide knowledge on how best to conduct research with a Native Hawaiian population and type 2 diabetes self-management. Native Hawaiians with type 2 diabetes and self-management are underrepresented in the literature providing opportunity for future research.

### **Self-Regulation Factors**

The first article utilized a cross-sectional design to survey the daily dietary assessments, social support, and self-regulation factors (cognitive and behavioral) related to diet and physical activity. “Talk story” sections were employed in this survey (McEligot et al., 2010). According to McEligot et al. (2010), the condition of Native Hawaiians with type 2 diabetes may be influenced by several factors: diet, body mass index (BMI), psychosocial issues and cultural issues. There were 62 consenting participants for the original sample. The measurement outcomes were focused on socio-demographic elements, pre-existing health conditions, dietary assessments, a psychosocial questionnaire, and “talk story”. The results revealed a BMI category of obese ( $>30 \text{ Kg/m}^2$ ) for more than 50% of participants as well as low fruit and vegetable intake of one to three servings per day. Psychosocial factors influencing self-management behaviors such as diet, exercise, and preparation of healthy food with family and friends were significantly low in participants with type 2 diabetes ( $p \leq 0.05$ ). The “talk story” sections mentioned the concern about diabetes associated with weight, diet, and exercise in the Hawaiian population and barriers to implement self-regulatory factors such as regular exercise and food portions. Psychosocial concerns were individual change and community change (McEligot et al., 2010).

McEligot et al. (2010) described feasibility research strategies for work with Native Hawaiians. These strategies included meetings with community advisory board (CAB) and key organizational partnerships. Organizational partnerships established were with 'Āinahau O Kalepoi Civic Club and Pacific Islander Health Partnership (PIHP). The CAB had a pivotal role in study protocol development, questionnaire review, and recruitment. Recruitment methods were forming partnerships with Native Hawaiian groups, culturally appropriate fliers, recruitment via telephone and in person and cultural gatherings (McEligot et al., 2010).

### **Culturally Adapted Self-Management**

The second article randomized assigned participants to the Partners in Care culturally adapted self-management intervention (n=48) or wait list (delayed intervention control group) (n=34) (Sinclair et al., 2013). The Partners in Care intervention was a culturally adapted community-based diabetes self-management intervention among Native Hawaiians and Pacific Islanders. Focus groups content utilized included diabetes self-management and diabetes related complications, group-based educational format to enable social support, and a delivery method by a Native Hawaiian in a convenient community location. Several self-management content areas of type 2 diabetes participant's interest were medication and side effects, dietary intake related to blood glucose, and healthcare provider expectations related to specific examinations. Sociocultural relevant strategies included trained peer educators from the participants community, used "local" language, and integrated cultural values of family and community working together were implemented. The outcome measures included A1c (a measured percentage of glycated hemoglobin) diabetes self-management understanding, self care activities performance, and diabetes-related distress. The Partners in Care intervention decreased A1c by 1%, and improved self-management understanding, self-management performance, and glycemic

control. The conclusion was a community-based program with cultural aspects and community-based peer educators showed improvements in type 2 diabetes self-management in Native Hawaiians and Pacific Islanders.

Feasibility issues addressed by Sinclair and colleagues (2013) for the Native Hawaiians were the demands of their time related to work and family resulting in not completing participation in the study. Partners in Care, recruited participants from community-based health clinics and a Native Hawaiian community organization. Community leaders, health advocates, and researchers served Native Hawaiians and connected with the PILI 'Ohana project for Partners in Care. A concern these community entities shared, was evidence of diabetes-related complications in their communities. The role of community leaders and health advocates was to provide guidance, planning and intervention (Sinclair et al., 2013). There was evidence of community partnerships to support feasibility of Native Hawaiian research.

### **Social Support and Self-Management**

The third article, Ing et al. (2016), examined Native Hawaiian and Pacific Islander participants and the effects of a diabetes specific social support maintenance component with community-academic partnership through the PILI 'Ohana Project (POP). In a randomized controlled trial, participants (N=25) were in semi-structured support groups randomly assigned with six meetings over three months and a standard follow-up group (N=22) received six postcards over three months. The semi-structured positive support group reinforced positive changes. The outcome measures were self-management self-care behaviors and A1c control. Trained community facilitators and health professionals led semi-structured support sessions. Community facilitators provided appraisal and emotional support for participants in order to help them assemble added support from family and friends for diabetes self-management. Healthcare

professionals provided information and appraisal related to self-management activities. The baseline results for demographic and clinical measures were primarily a high school educated Native Hawaiian obese female with type 2 diabetes sample with elevated A1c. This study concluded that social support had modest improvement in type 2 diabetes self-management understanding and frequency of self care activities. However, improvements for glycemic control were not statistically significant.

Feasibility efforts were supported by community partners Kula No Na Po'e Hawai'i (a nonprofit serving urban Hawaiian Homesteads), Hawai'i Maoli (a nonprofit serving the Hawaiian Civic Clubs), Ke Ola Mamo (the Native Hawaiian Health Care system for Oahu), and Kōkua Kalihi Valley (a health clinic serving low-income Pacific Islanders) recruiting participants, delivered interventions, and conducted baseline assessments (Ing et al., 2016). Community researchers had a belief that social support groups promoted building relationships outside of the intervention (Ing et al., 2016). These supportive relationships may contribute to feasibility of Native Hawaiian research.

### **Distrust and Self-Management**

Distrust in Native Hawaiian communities was a significant barrier to participation in epigenetic studies, which was stated in a community-based participatory research (CBPR) approach randomized control trial interventional testing and epigenomic analyses study by Townsend et al. (2016). The purpose of the study was to describe the community-based participatory research approach and research process employed to integrate behavior and biological sciences with community health priorities. Diabetes self-management interventions for A1c, self-care activities, and diabetes distress and understanding in a sample of (N=65) were examined. Community, behavioral, and epigenomic expertise were used to understand diabetes

self-management intervention outcomes. Community-based organization Kula No Na Po'e Hawai'i had a responsibility to protect the community members they serve and was skeptical about biospecimen collection. Prior to conducting research, there were efforts made by a Native Hawaiian investigator to build relationships and community trust with open communication and accessibility to information. The Native Hawaiian researcher was invited to attend monthly PILI 'Ohana (POP) meetings with community members, principal investigators, project coordinators, and research assistants to present an overview of his epigenetic research. A mutual benefit to both the community and the science for type 2 diabetes self-management was evident. Community participant priority was met through collaborative, culturally sensitive, physically safe, comfortable, and convenient protocols such as biospecimen collection accepted by community and participants and taking place in the community. The researchers recommended ongoing open communication, committed time for relationship building, support indigenous and minority researchers to improve research and relationships in these communities, and mutual benefits to both science and the community (Townsend et al., 2016).

A self-management characteristic found in the Native Hawaiian population with type 2 diabetes is a trusting relationship with healthcare team members (Humphry et al., 1997). The provision of medical care through a community-based health care worker who can coordinate health services, is a method that reflects the social, economic and political interest of Native Hawaiians. This was found to be preferred in a multiethnic community over the traditional office-based health care system (Humphry et al., 1997). In the literature, self-management resulted in better health and wellness that improved.

Native Hawaiians living with type 2 diabetes may choose to have an active role in creating a partnership with healthcare providers in order to determine a culturally appropriate

diabetic care plan. A partnership between the individual with type 2 diabetes and the healthcare provider may improve quality of life and decrease symptoms of depression. The integration of cultural values such as a connection to the land in some form is evident in successful self-management and wellness (Oneha, 2001). Native Hawaiians value connections between political, economical, and social integration in healthcare. In summary, these connections may provide a sense of trust and diabetes self-management implementation.

Research implementation with a Native Hawaiian population was dependent on developed relationships with community gatekeepers. Potential research contributions and benefits were heard and discussed in a community meeting format. Through a concerted effort community leaders execute an evaluative system to prevent research that was not mutually beneficial or perceived as harmful to their community. These variables contribute to the feasibility of Native Hawaiian community-based participatory research.

### **Self-management Definition in Native Hawaiians**

The definition for type 2 diabetes self-management in Native Hawaiians based on the literature and was a dynamic participatory daily process during which a choice of self-determined multidimensional strategies were employed to cope with type 2 diabetes and complications of type 2 diabetes while being supported by both social relationships and collaborative partnerships. This definition recognizes the self-determining actions of the individual and importance of support.

Native Hawaiians living with type 2 diabetes may choose to collaborate and create partnerships with 'ohana (family), community, and healthcare providers. These collaborations and partnerships may help in decision-making, achieving and maintaining glycemic control, enacting a healthy diabetic lifestyle, and developing preferred cultural values. Townsend et al.



(2016) described the importance of trust in Native Hawaiian research by forming collaborative partnerships to support identified community health priorities. Diabetes-related social support groups were made up of individuals, family members, physicians, and other diabetes experts, a method preferred by the Native Hawaiian communities to reinforce culturally adapted recommended American Diabetes Association interventions and National Diabetes Education Program guidelines for a health diabetic lifestyle (Ing et al., 2016). Diabetes self-management interventions were culturally adapted for a Native Hawaiian population to assess effect on understanding of diabetes self-management, glycemic control, self-care activities, and diabetes related distress (Sinclair et al., 2013). After three months improvement of glycemic control was evident with diabetes self-management interventions in a Native Hawaiian population (Sinclair et al., 2013). Native Hawaiians with diabetes may have improved outcomes supported by socio-cultural values through 'ohana, “talk story” discussion groups, and community gatherings (McEligot et al., 2010). Through a culturally accepted method of group discussion Native Hawaiians share concern regarding diabetes (McEligot et al., 2010). Diabetes self-management outcomes and research with Native Hawaiians supports integration of culturally accepted interventions such as preliminary meetings prior to conducting research, inclusion of community, and identification of Native Hawaiian health priorities.

The concept of self-management is theoretically applicable to a variety of ethnic groups. The daily dynamic participatory process and recommended diabetic self-management activities may not be culturally accepted by individuals from ethnic groups who prefer a group approach instead of an individual-focused approach. The Western view on self-management is to promote the individual primarily without a connection to community (Kent, 1983). The concept of self-management is determined and defined by the individual. Medication adherence plays an

important role in diabetes self-management.

Native Hawaiians and Part Hawaiians represent the diversity in type 2 diabetic patients. A review of diabetes data in Asians, Native Hawaiians, and other Pacific Islanders, focused on understanding the differences in diabetes pathophysiology, suggests a need to increase Native Hawaiian clinical research. Current clinical guidelines were based on a limited Native Hawaiian representation with a possible need for different treatment guidelines (Hsu et al., 2010). Studies on diabetes treatment, prevention, and dietary guidelines are needed to support the recommended Western medicine approach in diabetes self-management.

### **Summary**

Chapter 2 presents a review of the literature of self-management utilizing the evolutionary method as a framework. The systematic review of the literature in nursing, medicine, education, psychology, and sociology was conducted. Self-management could be used for both acute and chronic conditions. There was also agreement that the person with type 2 diabetes should be the center of self-management.

Self-management attributes reveal a dynamic process. A process with multidimensional strategies implemented daily to improve health outcomes. The implication of a perceived sense of control, guided by evidence-based treatment and guidelines should be given attention in order to promote self-management.

Native Hawaiians have shown significant improvement with type 2 diabetes self-management. They have an understanding and practice self-management skills for a short duration with culturally tailored self-management programs to meet their individual and community needs. Important cultural values of families working together to support community were described to promote type 2 diabetic self-management support. However, social support

did not have a significant impact on type 2 diabetes self-management understanding and self-care behaviors. The development of relationships in the Native Hawaiian community was critical to engaging participation in research. Self-management practices in Native Hawaiians with type 2 diabetes may be known to this population, despite distrust due to previous mistreatment of scientific research performed in an effort to protect their community. There was concern that recommended diabetes-care guidelines might not be effective for the Native Hawaiian population due to limited Native Hawaiian representation in clinical research. The review of the literature revealed Native Hawaiian type 2 self-management research efforts that could be helpful for future research.

## **CHAPTER 3. METHODOLOGY**

Chapter 3 describes the specific aims, conducted feasibility study processes, and methods of analysis. There were two specific aims in this study. The first specific aim was to describe the process of conducting a feasibility study for Native Hawaiians and Part-Hawaiians with type 2 diabetes and DPN. The second specific aim was to describe reasons for CAM use, experience of CAM use, and types of CAM used by Native Hawaiians and Part-Hawaiians with type 2 diabetes and DPN self-management.

After the type 2 diabetes Native Hawaiian background review of the literature identified a problem of increased rates of diabetes in the Native Hawaiian community and the challenges individuals experience with diabetic complications such as DPN. Several research questions were formulated to reflect the knowledge gap.

1. Are Native Hawaiians and Part-Hawaiians with type 2 diabetes and DPN using CAM?
2. What are the reasons CAM are being used?
3. Do Native Hawaiians and Part-Hawaiians combine CAM therapies?
4. Are CAM therapies being used for type 2 diabetes self-management?
5. What are the characteristics of Native Hawaiian and Part-Hawaiian CAM users?

### **Feasibility Study Process**

Feasibility study is defined as “research conducted to determine whether something can or should be done and, if so how” (Morris & Rosenbloom, 2017, p. 39). The feasibility study framework was used for this study. To gain insight in the use and process of a feasibility study framework a review of current information on type 2 diabetes self-management feasibility studies was done in the Cumulative Index to Nursing and Allied Health Literature (CINAHL)

database. As a strategy, refined search words used were feasibility study, self-management, and type 2 diabetes. This search strategy resulted in 16 studies. There were 10 studies out of the 16 studies published within the past five years and reviewed.

The feasibility studies on type 2 diabetes self-management shared a similar purpose, to evaluate effectiveness, acceptability, and sustainability of self-management interventions. There was evaluation of interventions such as adapted patient centered educational intervention for type 2 diabetes self-management (Brunk, Taylor, Clark, Williams, & Cox, 2017), culturally tailored digital storytelling educational self-management intervention (Wieland et al., 2017), telephone and text-messaging diabetes self-management intervention (Wu, Sung, Chang, Atherton, Kostner, & McPhail, 2017; Haddad et al., 2014), web-based self-management intervention (Ramadas, Chan, Oldenburg, Hussien, & Quek, 2015; Nes, Eide, Krisjánsdóttir, & van Dulmen, 2013) and integrated self-management interventions (Kaltman et al., 2016). In the web-based self-management intervention for type 2 diabetes, Nes et al. (2013) recommended booster sessions for prolonged promotion of self-management. These studied self-management interventions were found to be feasible, effective and accepted by participants with type 2 diabetes.

Savage et al. (2014) feasibility study focused on the ability to retain subjects in a diabetes self-management intervention for adults experiencing homelessness. The results revealed 9 subjects recruited, 5 retained, and 2 of 3 completing the full diabetes self-management intervention (Savage et al., 2014). These finding may indicate future implementation of alternative retention strategies for subjects experiencing homelessness.

In a feasibility study with a mixed-methods design approach, Sell (2013) discovered older adults made type 2 diabetes self-management behavior changes by being accountable to

someone and having a health coach. The health coach method and accountability to someone other than a peer or family was preferred by older adults to avoid being a burden to family members or children (Sell, 2013). Another mixed-methods design feasibility study used type 2 diabetes self-management semi-structured interviews and a nurse-led or standard care (Hegney, Patterson, Eley, Mahomed, & Young, 2013). It was concluded that nurse-led care was acceptable, feasible, and sustainable (Hegney et al., 2013). These mixed-method feasibility studies provide insight for consideration to restructure the process of future research in type 2 diabetes self-management. In these feasibility studies the aim was to evaluate if the conducted could and should be done. The feasibility framework provides an opportunity to develop research processes.

The components of this feasibility study process included the setting, sample, recruitment, procedures, response rate, quality of responses, instruments, formulation and implementation of the protocol, and qualities of researcher.

### **Setting**

This feasibility study was carried out at two outpatient clinics of The Queen's Medical Center (QMC) in Honolulu, Hawai'i. The QMC is an urban medical center with a mission to provide quality health care services to improve the well-being of Native Hawaiians. The selected clinics provide diabetic care. One of the clinics provided diabetic wound care. This nurse researcher contacted and met with the manager and medical director of the clinics to assess the feasibility of conducting a study with a Native Hawaiian with type-2 diabetes. Managers and medical directors stated that the Native Hawaiian population was not a large group receiving services at these clinics, which presented a possible challenge for the nurse researcher.

This setting was selected because the nurse researcher was familiar with the general medical center and had preexisting professional relationships with clinic managers, physicians, and staff. The nurse researcher was knowledgeable of policies, procedures, and how to access basic support in this medical center. These attributes could have been a possible advantage to conduct research in this facility.

### **Sample**

Clinic patient record staff, and the clinical staff of two clinics, screened patients based on inclusion and exclusion criteria. The list of eligible patients was given to the nurse researcher. These 128 patients including Asian Americans, Pacific Islanders, and Native Hawaiians were convenience samples that met the inclusion and exclusion criteria. The inclusion and exclusion criteria included being at least age 18 years old, having been diagnosed with DPN, able to understand the English language, and able to verbalize understanding of the purpose and procedure of the study. The sample was Native Hawaiians and Part Hawaiians with DPN living on the island of O'ahu, Hawai'i receiving health care at an urban hospital-based outpatient clinic.

### **Recruitment**

The recruitment process was approved by the clinic manager, medical director, and research and institution review committee. The Queen's Medical Center Research and Institutional Review Committee identification number for this study was RA-2014-315. The University of Hawai'i at Mānoa Human Studies Program institutional review board number was CHS 22591. Recruitment process was done at two outpatient clinics. The medical director of the outpatient primary care clinic recommended to start with a list provided by clinic patient records staff based on diagnosis of type 2 DPN. A preliminary scripted phone call was made to patients with type 2 DPN in which a request to meet was made at their next scheduled clinic visit

or in person at the clinic visit. A study recruitment brochure was posted in clinics to recruit study participants.

The manager for the wound care clinic, requested that potential participants be approached in person at their clinic visit, specifically at the face-to-face clinic appointment. This was the portion of the recruitment process in which the inclusion and exclusion criteria for participation in the study was confirmed.

### **Procedures**

Both clinic managers and the medical director agreed to have clinics serve as research sites and completed the form letter of agreement that was submitted to the chairperson of the hospital institutional review committee. Physician's permission in providing service to DPN patients was required by the hospital institutional review committee and obtained by the nurse researcher prior to conducting research. An email was sent out to physicians from both clinics. Physicians confirmed support by email reply. These emails were forwarded to the researcher and the hospital institutional review committee as part of the institutional review board requirements.

The procedures were similar for both clinics: eligibility was determined at the clinic appointment, informed consent was obtained and a copy of signed forms was faxed to the Queen's Medical Center's department of research and development (see Appendix E). On the same day, the face-to-face interview with structured questionnaires of CAM and 36-Item Short Form Survey Instrument (SF-36) survey was conducted. Queen Emma Clinics and Wound Care Clinic Staff provided support by informing the nurse researcher when it would be the best time to meet with the potential participant. Data collection process occurred when: (1) the physician was done with the appointment, (2) the patient was waiting for their next appointment, or (3) the



physician was delayed and the patient was waiting. These interludes provided opportunities for the nurse researcher to confirm eligibility and start the face-to-face interviews. This method of interviewing required extensive preparation and considerable time to collaborate with patients and staff. The complexity of a multiservice primary care unit required the nurse researcher to collaborate with staff to schedule the interview before, after, or between appointments. The staff of the primary care clinic supported the nurse researcher with a private examination room for the interview process. The Queen Emma Clinic Manager communicated the importance of not disrupting the workflow involved with patient care. The nurse researcher worked closely with staff, responsible for both checking patients in and providing care to minimize disruption of the clinic workflow. In the wound care clinic, a patient appointment might take up to an hour because of wound care treatments. Patients consented to participating in the research. Participants were given a choice to either be interviewed with clinic physician and staff in the room during the interview or, for privacy, to wait until they were alone. It was only in the Wound Care Clinic that staff or a physician would be present in the private examination room for a portion of the interview.

### **Response Rate**

The nurse researcher attempted to recruit in person at the participant's clinic appointment in cases where they were not reachable by phone. The nurse researcher tried to contact potential participants who were not present for clinic visits by both home phone numbers and alternate phone numbers, which were provided by clinic staff. Response rate was calculated with the following formula, the number of participants who completed the face-to-face interview divided by the number of eligible participants who met the inclusion criteria and went through the face-to-face interview.

## **Quality of Responses**

The quality of responses was an important part of this feasibility study (Morris & Rosenbloom, 2017). The method of face-to-face interviews was referred to as the best method to collect survey data and obtain quality information (Polit & Beck, 2008). The participants might have planned to meet with the nurse researcher at their scheduled clinic visit because of the preliminary phone call and verbal confirmation by both the patient and the nurse researcher. Most of them were excited to meet, interested in hearing more about the study, and ready to participate. For those who were approached in person at the primary care clinic visit concerns about missing a scheduled transportation pick-up, and the amount of time it would take to participate were mentioned. These patients may have had multiple appointments scheduled on the same day and verbalized being tired. These reasons may potentially have compromised the quality of responses.

Patients at the wound care clinic experienced a longer appointment, which often required them to lie on an examination table for more than 30 minutes. They were interested in having someone to talk to during this visit. Participating in the study might have served as a positive distraction during their weekly clinic appointment and this may have provided quality responses. The advantages was that patients had time to answer each question, because their appointment may be scheduled for an hour compared to the Queen Emma Clinic visits, which are estimated to be 15 minutes long.

The nurse researcher stated questions from of the aforementioned surveys during the face-to-face interaction. This may be a bias because the nurse researcher may have used certain vocal tones unconsciously or individuals may have responded to the way they thought the nurse researcher wanted them to respond. For example, for CAM users the researcher asked, “What

was the advice of the healthcare professional after you discussed about CAM use?” The respondent might not have disclosed a quality response because a healthcare professional was asking this question. Another question for CAM users was, “How do you use your Western medication when you are using CAM?” Participants might choose, “no change,” because the care received from this clinic recommended that participants take Western medications. With some individuals, the nurse researcher showed them the questions and responses if they could not remember the available answer selections. The estimated completion time for both surveys was 15-30 minutes. However, for patients who did not understand the question and requested the nurse researcher to repeat or explain the question or a particular word, the interview may have lasted longer than 30 minutes and there may be biases. The percentage of participants that asked the researcher to repeat questions or clarify words was not tallied. An estimate, though, would be about 50% or more participants requested that at least one question or word to be clarified.

### **Instruments**

The selected instruments were the Hsiao-Yun Annie Chang CAM Use Survey and 36-Item Short Form Survey Instrument (SF-36). A search of the literature was performed to find an instrument to assess the CAM use in Native Hawaiians with type 2 diabetes. There were no instruments found for CAM use in a Native Hawaiian type 2 diabetic population. The demographic data was collected with the CAM Use survey. This CAM survey was selected to capture diabetic clinical data and reasons for CAM use and non-use in a type 2 diabetic population.

### **Hsiao-Yun Annie Chang CAM Use Survey**

The Hsiao-Yun Annie Chang CAM Use Survey was previously used in a diabetic outpatient clinic population in Taiwan (Chang, Wallis, & Trialongo, 2011). The CAM survey contained 133 questions with multiple responses created for use in Taiwan diabetic clinics servicing a type 2 diabetes population (Chang, et al., 2011). This instrument was selected for the focus on the reasons for CAM and previous use in a type 2 diabetic population. There was no specific CAM instrument found for Native Hawaiians. This instrument was developed for a Chinese population in Taiwan. Please see Hsiao-Yun Annie Chang CAM Use Survey in Appendix F.

### **The 36-Item Short Form Survey**

The 36-Item Short Form Survey Instrument (SF-36) was used to assess general health with a focus on eight health concepts: physical functioning, role limitations due to physical problems, social functioning, bodily pain, mental health, role limitations due to emotional problems, vitality, and general health perception (Ware, Snow, & Kosinski, 1993). These instruments were selected because the content-assessed general health with a focus on bodily pain and CAM.

The SF-36 was previously used in a study focused on Native Hawaiians with diabetes (Kaholokula et al., 2014). The SF-36 was selected to assess perceived general health and bodily pain for individuals with DPN. There were a total of 36 questions with answer selections ranging from two to six. Please see 36-Item Short Form Survey Instrument (SF-36) in Appendix G.

## **Formulation and Implementation of the Protocol**

The protocol formulated in collaboration with two outpatient clinics leadership groups was feasible. Each clinic had a different workflow, which required a different recruitment protocol. The ability to recruit potential participants was present at both sites. The Queen Emma Clinics presented more opportunities because it serviced a larger patient population compared to the Wound Care Clinic. For both sites, clinic staff and physicians were supportive of the nurse researcher by informing patients that the nurse researcher was there to discuss an opportunity to be a part of a research study or if previous arrangements were made, that the nurse researcher was there to meet with them. In the busy clinic environment, time with participants and a space to meet were made available.

## **Method of Analysis**

All of the collected data was presented in frequency and percentage. Collected data for both the CAM use and SF-36 instrument was inserted into an Excel workbook spreadsheet. The research ID codes were entered on the y-axis and the questionnaire item on the x-axis. Each item response code or text response was entered into the corresponding cell of the specific research ID.

Once all of the responses from the questionnaires were entered into the Excel workbook spreadsheet, IBM SPSS statistical software version 22.0 (henceforth referred to as SPSS) was used to analyze the data. Descriptive statistics analysis was used with special attention to frequencies and percentages in the data entered. The frequencies were helpful to the nurse researcher for identifying the total sample and subset groups within the sample. The percentages assisted with the analysis of impact in relation to the group. Frequency and percentage data output from SPSS was placed into tables for reference and review.

The initial analysis identified the sample of Native Hawaiian and Part-Hawaiian participants from the original sample of N=71. The subgroup of Native Hawaiians (n=6) and Part-Hawaiians (n=15) represented the sample for this dissertation. The method of analysis to examine collected data required the nurse researcher to think about the specific aims and potential new knowledge. Descriptive characteristics and clinical data collected from the CAM use instrument were retrieved and analyzed after the establishment of the studied Native Hawaiian and Part-Hawaiian population frequencies and percentages.

To explore Aim 2: the CAM reasons for CAM use, experience of CAM use, and CAM types used by Native Hawaiians and Part-Hawaiians with type 2 diabetes and diabetic peripheral neuropathy, the respondents were codified into 2 groups. Those reporting CAM usage were grouped as CAM users and those not using CAM were grouped as Non-CAM users. The analysis revealed one participant was a CAM user and then proceeded to stop using CAM. This participant was counted in both categories: of the CAM users and the non-CAM users. Further analysis of CAM users and non-CAM user data was done in order to examine the reasons for CAM use or non-use, experience of CAM use, and types of CAM use.

### **SF-36 Instrument**

The SF-36 assessed perceptions of general health and bodily pain. These two areas were examined for CAM use. The discovery of data in the general health and bodily pain groups guided the researcher to implement additional analysis. The researcher attempted to examine these groups with more depth and detail by comparatively analyzing the descriptive characteristics. See Figure 1 for Methodology Analysis.

The descriptive statistical analysis of a feasibility study process and CAM use by Native Hawaiian and Part-Hawaiian type 2 diabetics with diabetic peripheral neuropathy was helpful in

providing insight for the design of future studies. The limitation of the inability to generalize or make conclusions was considered. However, this contribution opens the possibility for future researchers interested in CAM use in the aforementioned populations.

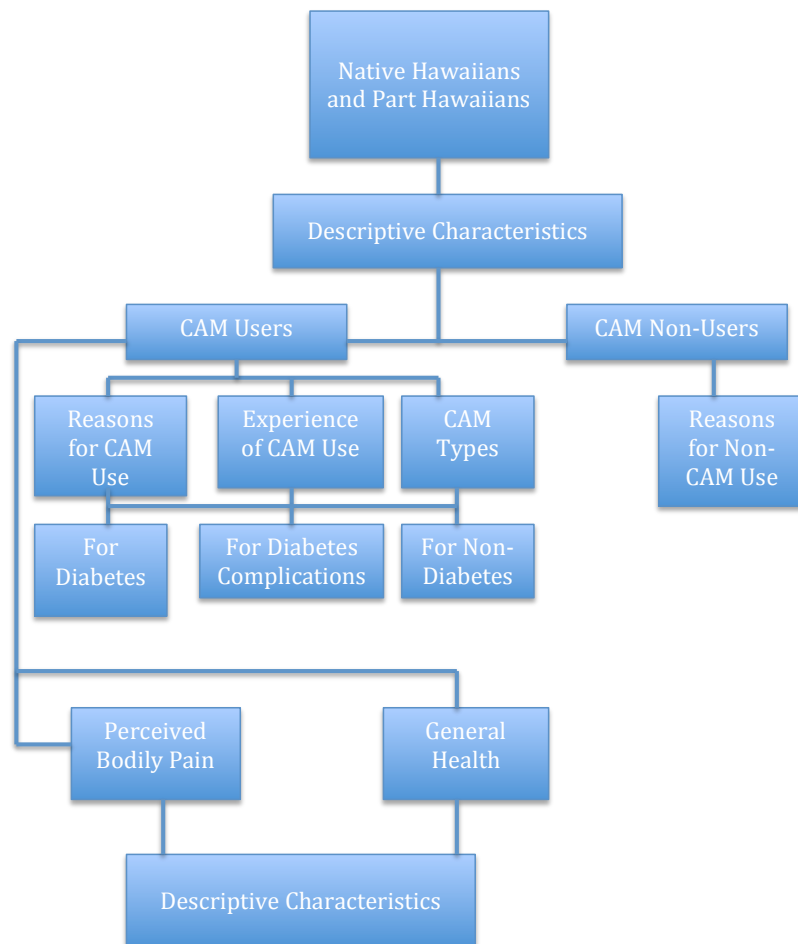


Figure 1. Methodology Analysis



## Summary

Chapter 3 provided an overview of the methodology used for this study, which included both strategies that worked and strategies that did not work. A feasibility design was recommended for this study. Chapter 3 was guided by specific aim one - to describe the process of conducting a feasibility study for Native Hawaiians with type 2 diabetes and DPN and specific aim two - to describe reasons for CAM use, experience of CAM use, and CAM types used by Native Hawaiians and Part-Hawaiians with type 2 diabetes and diabetic peripheral neuropathy.

The description provided for the conducted feasibility study included the process. Starting with a sample of Native Hawaiians and Part-Hawaiians, in a setting in urban medical center outpatient clinics, recruitment, and procedures did reveal opportunities for adjustments. The instruments selected might have presented limitations in regards to cultural appropriateness or participants being unfamiliar with questionnaire terms. It was recommended that there be development of a CAM use tool for Native Hawaiians and Part-Hawaiians. The opportunity to conduct the study with the established procedures might provide insight for future studies.

## **CHAPTER 4. FEASIBILITY STUDY RESULTS**

In Chapter 4, the results of this feasibility study are presented in the following sequence; the challenges experienced during the process of a feasibility study, descriptive characteristics of respondents, and results for reasons Native Hawaiians and Part-Hawaiians used CAM for diabetes, diabetes complications and general use. Results are summarized for the first specific aim to describe the process of conducting a feasibility study and second specific aim to describe reasons of CAM use, experience of CAM use, and CAM types used by Native Hawaiians and Part-Hawaiians with type 2 diabetes and DPN self-management.

### **Challenges in the Process of a Feasibility Study**

#### **Setting and Sample**

The urban hospital of the two selected outpatient clinics was a familiar teaching facility and supportive of research. The clinics operated on a time sensitive schedule with sometimes more than one appointment for a patient in a single day. The patient waited between appointments or had consecutive appointments that provided opportunities to participate in research.

An advantage was the support provided to the researcher from medical center's office of research and development through the Internal Review Board (IRB) process to protect research participants and review research procedures. A disadvantage of doing research in two clinics within the same urban medical center was the limited diversity of the study participants. The familiarity of the setting to the nurse researcher may serve as a bias. These disadvantages and biases may hinder the ability to generalize the findings of this study.

Of the patients available, 128 patients with diabetes neuropathy pain met inclusion criteria. Of the 128 eligible patients, 71 patients completed questionnaires. There were several

reasons that 57 potential participants were not recruited. For example, a participant did not meet inclusion criteria by appearing to have limited English capabilities or being completely non-English speaking when having met in person with researcher (n=11). Some individuals denied having diabetes peripheral neuropathy (n=7). Others were a no show, rescheduled or cancelled rescheduled or cancelled appointment (n=21). In some cases, individuals had a vacant phone number, did not have voice mail, or did not answer phone calls (n=12). Some chose not to participate because their ride came early, they said “no thanks,” “felt shy,” or “too tired” (n=6). This dissertation focused on Native Hawaiians and Part-Hawaiians only. In future dissemination efforts of this feasibility study, other ethnicities will be analyzed. As a result, the sample size decreased to N=21.

### **Recruitment**

The recruitment process presented challenges for the researcher, due to efforts to minimize disruption to the workflow of the clinic. Methods of recruitment included “phone invitation,” “posted brochures,” and “in person, face-to-face invitation.” Disadvantages of phone recruitment included participants not having a working phone, having difficulty hearing the nurse researcher’s voice over the phone, or not returning messages. This made it difficult for the nurse researcher to confirm if the patient would be interested in participating in the study or be at their next scheduled clinic visit. Study recruitment brochures were posted in the waiting areas of the outpatient clinics. There were no participants recruited through the recruitment brochure method. The advantage to the in person face-to-face approach was that it provided an opportunity for the individual to meet the nurse researcher. The face-to-face method of recruitment was advantageous with recruitment, because respondents displayed a level of

comfort and acceptance, possibly an indication of wanting to participate in the research study. See study recruitment brochure in Appendix D.

The two clinics had different operational hours. The Queen Emma Clinic provided diabetic patient care eight hours a day. The Wound Care Clinic provided diabetic patient care for four to eight hours a day. This presented limited access to potential participants. It required the nurse researcher to be flexible in time management. There was a range of one participant to nine participants recruited per day.

### **Response Rate**

A total of 128 patients were approached and 71 of them were included and completed surveys. The nurse researcher attempted to recruit participant's in person at clinic appointments if prospective participants were not reachable by phone. The nurse researcher tried to contact potential participants not present for clinic visits by calling prospective participants by both main phone numbers and alternate phone numbers, which were provided by clinic staff.

All surveys were completed after consent was obtained and inclusion criteria met. Participants met in a face-to-face meeting with the nurse researcher to complete surveys. A few questions were left blank by participants who chose not to provide an answer or did not know the answer. The original study included 71 participants who self-identified as Asian American, Pacific Islander, Native Hawaiian, Part-Hawaiian or other races. This dissertation only focused on the Native Hawaiian and Part-Hawaiian individuals (N=21). Information collected from other ethnic groups will be disseminated in the future.

### **Quality of Responses**

The quality of responses was an important part of this feasibility study (Morris & Rosenbloom, 2017). The method of face-to-face interviews was referred to as the best method to

collect survey data and obtain quality information (Polit & Beck, 2008). The participants might have planned to meet with the nurse researcher at their scheduled clinic visit because of the preliminary phone call and verbal confirmation by both the patient and the nurse researchers at a planned meeting. Most were excited to meet, interested in hearing more about the study, and ready to participate. For those who were approached in person at the primary care clinic visit concerns about missing a scheduled transportation pick-up and the amount of time it would take to participate were mentioned. These patients might have had multiple appointments scheduled on the same day and verbalized being tired. These reasons might potentially compromise the quality of responses.

Patients at the Wound Care Clinic experienced a longer appointment often requiring them to lie on an examination table for more than 30 minutes. They were interested in having someone to talk to during this visit. Participating in the study might have served as a positive distracter during their weekly clinic appointment with potentially quality responses. The advantages were that they had time to answer each question because their appointments were scheduled for an hour compared to the primary care clinic visits estimated at approximately 15 minutes duration. The participants responded positively to having the nurse researcher conducting the interview, because the once-a-week visits required them to lay on the examination table. The wound care staff liked having the nurse researcher interact with the patient, so they could do charting and wound care. The limited space and privacy was a concern for the nurse researcher in respect to obtaining quality responses. The nurse researcher collaborated with staff, what times would be best to perform data collection.

## Instruments

A disadvantage was that the Hsiao-Yun Annie Chang CAM Use Survey tool was from Taiwanese and international literature and designed to be used in Taiwanese diabetic care clinics. The length of this survey also presented a challenge for participants. Some answers used unfamiliar terms. For example, the question “Approximately, how many times have you visited DM clinics during the past year?” could be answered using the term, “fortnightly” (pronounced fôrt, nītlē ) meaning every two weeks. In some cases, this required an explanation. The sequence of questions in the clinical information session was confusing to respondents. The question “Have you been hospitalized due to diabetes condition during the last years,” was followed by the question, “How good do you feel is your health condition?” Respondents were not sure what “health condition” referred to and at times referred to their diabetic condition as their health condition when answering this question. An advantage was the assessment of clinical diabetic status, individual CAM therapies and practitioners, as well as reasons for CAM use, non-use and stopping use. The reasons for CAM use was at times, complex, and the CAM survey had three options: “for diabetes,” “for DM’s complications” and, “for non-DM specific.” Patients pondered the complexities of the questions and multiples answers before answering a question. The types of CAM presented in the survey might not represent traditional Hawaiian types of CAM. Those types were cupping, scraping, gua-sa, biofield therapy, kinesiology, reiki, tai chi, gi gong, and bioelectromagnetic-based therapies. A potential bias was the nurse researchers explanations of unfamiliar CAM therapies. The estimated time to complete the CAM survey was 20 minutes and might have taken longer if the participant did not understand the questions. Despite the lack of clarity and participant understanding of the questions presented in both

survey instruments there was a 100% completion range with potential impact on the quality of responses.

The nurse researcher stated questions from the aforementioned surveys during the face-to-face interaction. This might be a bias, because the nurse researcher might have used certain vocal tones unconsciously or individuals might have responded to the questions with the way they thought the nurse researcher wanted them to respond. For example, for CAM users the researcher asked, "What was the advice of the health care professional after you discussed about CAM use?" The respondent might not have disclosed a quality response because a health care provider was asking this question. Another question for CAM users was, "How do you use your Western medication when you are using CAM" participants might have chosen, "no change" because the care received from this clinic recommended participants to take Western medications. With some individuals the nurse researcher showed them the questions and responses if they could not remember the available answer selections. The approximate completion time to complete or of both surveys was 15-30 minutes. However, it took more than 30 minutes for patients who did not understand the question and they requested the nurse researcher to repeat or explain the question or a word contributed to an interview. The percentage of participants who asked the researcher to repeat questions or clarify words was not tallied. But, an estimate percentage would be about 50% or more participants who requested at least one question or word to be clarified.

The sequence of questions in the clinical information session was confusing to respondents. The question, "Have you been hospitalized due to diabetes condition during the last years" was followed by the question, "How good do you feel is your health condition?" Respondents were not sure what health condition the question referred to. As a result, they

referred to their diabetic condition as their health condition when answering this question. An advantage of this questionnaire was the assessment of clinical diabetic status, individual CAM therapies and practitioners, reasons for CAM use, non-use and stopping use. The reasons for CAM use at times were complex three options “for diabetes”, “for DM’s complications”, and “for non-DM specific”. Participants took time to think about this because of overlapping reasons for CAM use. The types of CAM presented in the survey might not represent types of CAM used among the Native Hawaiian or Part-Hawaiian such as cupping, scraping, gua-sa, biofield therapy, kinesiology, reiki, tai chi, gi gong, and bioelectromagnetic-based therapies. Participants would ask the nurse researcher what were those types of CAM therapies. A potential bias was the nurse researcher’s explanations of unfamiliar CAM therapies.

### **Qualities of the Nurse Researcher**

In a feasibility study, demonstration of an achievable research design provided information for future research processes, resources, management, and science development (Morris & Rosenbloom, 2017). A specific aspect to consider was the qualities of a nurse researcher as a resource. The nurse researcher, being a Native Hawaiian, PhD student, and practicing nurse, could have potential positive impact on recruitment of a Native Hawaiian DPN population. Some of these qualities were presented in the scripted introduction during recruitment and received favorable feedback. Participants asked if the nurse researcher was a Native Hawaiian nurse and were intrigued to hear, also a PhD in nursing student. To establish rapport, a respectful approach, open to hearing their story, was conveyed. Participants were friendly and willing to participate, at times sharing more than what was asked. The nurse researcher who presented herself in nursing scrub attire similar to clinic nurses as a strategy, promoted comfort and an approachable demeanor. This presentation contrasted a white coat or



professional wear that might not be familiar or create resistance. The qualities of the nurse researcher might have worked for this Native Hawaiian and Part-Hawaiian population.

### **Descriptive Characteristics of Native Hawaiian Participants**

A total of 21 participants ranged from 41 to 77 years old with a mean of 57.76 and standard deviation of 10.425. The sample size N=21 represents the Native Hawaiian and Part-Hawaiian ethnic group. The majority of participants were younger than age 70 (86%). Of the participants, 86% with an education level of high school or above. Out of the participants, 86% were single, widowed, or separated/divorced. There were 14% who reported being married or living with a partner. Of the respondents, 86% reported living with others. 95% of the respondents reported having health insurance.

Clinical information provided showed that 43% had diabetes for more than ten years. Of all participants, 57% were receiving insulin treatment. In addition to that, 29% were treated with insulin and oral treatment for diabetes. Diabetes education was attended by 62% of respondents. Detailed characteristics of participants are displayed in Table 1.

**Table 1**  
*Descriptive Characters of the Participants N=21*

<b>Descriptive Characters of the Participants-continued</b>		
<b>Total Household Monthly Income</b>		
	Under \$1200	n=12 (57%)
	\$1200-2400	n=5 (24%)
	\$2401-3600	n=2 (10%)
	\$3601-4800	n=1 (5%)
	More than \$4800	n=1 (5%)
<b>Health Insurance</b>		
	No	n=1 (5%)
	Yes	n=20 (95%)
<b>Clinical Information</b>		
<b>How long have you had diabetes?</b>		

	1 -10 years	n=12 (57%)
	>10-20 years	n=4 (19%)
	>20-30 years	n=2 (10%)
	>30-40 years	n=2 (10%)
	>40 years	n=1 (4%)
<b>Do you have any one in your family and relative who has diabetes?</b>		
	No	n=1 (5%)
	Parents/Grandparents	n=16 (76%)
	Brothers or sisters	n=14 (67%)
	Relatives	n=11 (52%)
	Sons or daughters	n=3 (14%)
	Other	
<b>Have you been hospitalized due to diabetes condition during last years?</b>		
	No	n=15 (71%)
	Yes	n=6 (28%)
	If yes, how many times?	
	1 time	n=4 (66%)
	3 times	n=1 (33%)
	4 times	n=1 (33%)
<b>How good do you feel is your health condition?</b>		
	Very poor and poor	n=6 (29%)
	Good and Very good	n=15 (71%)
<b>What current treatment for DM has been prescribed or suggested by your physician? (Choose all that apply)</b>		
	<b>Diet + Exercise</b>	n=13 (62%)
	<b>Oral Agent</b>	n=14 (67%)
	<b>Tablets/per day</b>	
	1 tablet/per day	n=4 (30%)
	2 tablets/per day	n=7 (50%)
	3 tablets/per day	n=1 (7%)
	5 tablets/per day	n=1 (7%)
	6 tablets/per day	n=1 (7%)
	<b>Insulin Injection</b>	n=12 (57%)
	Units/per day	
	5 units/per day	n=1 (8%)
	17 units/per day	n=1 (8%)
	18 units/per day	n=1 (8%)
	20 units/per day	n=2 (17%)
	50 units/per day	n=1 (8%)
	55 units/per day	n=1 (8%)
	69 units/per day	n=1 (8%)
	70 units/per day	n=1 (8%)
	125 units/per day	n=1 (8%)
	155 units/per day	n=1 (8%)
	200 units/per day	n=1 (8%)

	<b>Oral agent and Insulin injection</b>	n=6 (29%)
<b>Have you ever attended a diabetes education program?</b>		
	No	n=8 (38%)
	Yes	n=13 (62%)
What kind of education?	One to one education	n=9 (69%)
	Lecture Education	n=8 (61%)
	Self-education	n=0
	Other: Brochures	n=1 (7%)
<b>Note: Participants could select more than one response.</b>		

### Reasons and Types of CAM Use

The reasons and types of CAM used by Native Hawaiians and Part-Hawaiians with DPN are listed in Table 2 in past 12 months, for diabetes, for diabetes mellitus complications, and for non-diabetes mellitus. DPN is a type of diabetic complication. The listed CAM types (ie. cupping, scraping/gu-sa, biofield therapy, bioelectromagnetic-based therapies, and homeotherapy) on the survey might not be familiar to the Native Hawaiian or Part-Hawaiian respondent and resulted in low percentages for CAM use. The four highest CAM therapies used for diabetes complications by 16 participants out of N=21 were diet modification (31%), manipulative based therapy (19%), supernatural healing (19%), and Western herbal medicine (19%). The least used CAM therapies were Chinese herbal medicines (13%), nutritional supplements (13%), acupuncture (6%), folk therapies (6%), biofield therapy (6%), aromatherapy (6%), and mind-body therapy (12%). The CAM practitioners used for diabetic mellitus complications were traditional Chinese medicine practitioner (12%), herbalist (6%), religious/psychic healer (6%), and naturopath practitioner (6%). CAM therapies and practitioners not used for diabetic complications were cupping, scraping (Gu-sa), bioelectromagnetic-based therapies (electrotherapy, polarity, magnetic therapy), homeopathy, chiropractor, and other CAM therapies reported like carving, talk therapy, and physical therapy.

The highest used CAM therapies in the SF-36 group with self-rated “health as excellent, very good, and good” (38%), were nutritional supplements (multivitamins, fish oil, glucosamine, chromium) (50%), and Western herbal medicine (25%). The least used types of CAM were diet modification (13%), manipulative based therapy (chiropractic, osteopathic, kneading (Tui-an)) (13%), supernatural healing (absorption frighten, God healing, divination, name change) (13%), mind-body therapy (meditation, yoga, hypnosis) (13%), and other CAM therapies like talk therapy (13%). Surprisingly, nutritional supplements were used by (50%) of CAM users with perceived excellent, very good, or good health.

Highest used CAM therapies in the SF-36 group with “none to mild pain” (n=9) were nutritional supplements (44%), diet modification (22%), supernatural healing (22%), Western herbal medicine (22%), and other CAM therapies (22%). CAM therapies least used were manipulative-based therapy (11%), mind-body therapy (11%), and religious healer (11%). Other CAM therapies reported by this group included talk therapy and carving hobby therapy. There was high use of nutritional supplements (44%). The results for CAM use with SF-36 subgroups were presented in Table 2.

**Table 2**  
***Complementary and Alternative Medicine (CAM) Use and Type 2 Diabetes***

<b>CAM Users (N=16)</b>		
<b>Nutritional Supplements (Multivitamins, fish oil, glucosamine, chromium)</b>		
	Past 12 months	n=5 (31%)
Why did you use?		
	For Diabetes	n=3 (19%)
	For Diabetes Mellitus Complications	n=2 (13%)
	For Non-Diabetes Mellitus	n=5 (31%)

<b>Diet Modification (Organic food, special food design, body cleansing diet, macrobiotic diet)</b>		
	Past 12 months	n=6 (38%)
Why did you use?		
	For Diabetes	n=6 (38%)
	For Diabetes Mellitus Complications	n=5 (31%)
	For Non-Diabetes Mellitus	n=1 (6%)
<b>Chinese herbal medicines (Ginseng and Limzig)</b>		
	Past 12 months	n=2 (13%)
Why did you use?		
	For Diabetes	n=2 (13%)
	For Diabetes Mellitus Complications	n=2 (13%)
	For Non-Diabetes Mellitus	n=1 (6%)
<b>Acupuncture (Acupressure)</b>		
	Past 12 months	n=0
Why did you use?		
	For Diabetes	n=1 (6%)
	For Diabetes Mellitus Complications	n=1 (6%)
	For Non-Diabetes Mellitus	n=3 (19%)
<b>Cupping, Scraping (Gu-sa)</b>		
	Past 12 months	n=0
Why did you use?		
	For Diabetes	n=0
	For Diabetes Mellitus Complications	n=0
	For Non-Diabetes Mellitus	n=1 (6%)

<b>Manipulative based therapy (chiropractic, osteopathic, kneading (Tui-am)</b>		
	Past 12 months	n=4 (25%)
Why did you use?		
	For Diabetes	n=3 (19%)
	For Diabetes Mellitus Complications	n=3 (19%)
	For Non-Diabetes Mellitus	n=6 (38%)
<b>Folk Therapies (Knife therapy, water therapy, fire therapy)</b>		
	Past 12 months	n=2 (13%)
Why did you use?		
	For Diabetes	n=3 (19%)
	For Diabetes Mellitus Complications	n=1 (6%)
	For Non-Diabetes Mellitus	n=1 (6%)
<b>Biofield Therapy</b>		
	Past 12 months	n=1 (6%)
Why did you use?		
	For Diabetes	n=1 (6%)
	For Diabetes Mellitus Complications	n=1 (6%)
	For Non-Diabetes Mellitus	n=1 (6%)
<b>Supernatural healing (Absorption frighten, God healing, divination, change name)</b>		
	Past 12 months	n=4 (25%)
Why did you use?		
	For Diabetes	n=3 (19%)
	For Diabetes Mellitus Complications	n=3 (19%)
	For Non-Diabetes Mellitus	n=4 (25%)

<b>Bioelectromagnetic-based therapies (Electrotherapy, Polarity, Magnetic Therapy)</b>		
	Past 12 months	n=1 (6%)
Why did you use?		
	For Diabetes	n=0
	For Diabetes Mellitus Complications	n=0
	For Non-Diabetes Mellitus	n=2 (13%)
<b>Western herbal medicine (bilberry, bitter melon, opuntia, fenugreek seed, and aloe)</b>		
	Past 12 months	n=3 (19%)
Why did you use?		
	For Diabetes	n=3 (19%)
	For Diabetes Mellitus Complications	n=3 (19%)
	For Non-Diabetes Mellitus	n=3 (19%)
<b>Aromatherapy (essential oil)</b>		
	Past 12 months	n=2 (13%)
Why did you use?		
	For Diabetes	n=1 (6%)
	For Diabetes Mellitus Complications	n=1 (6%)
	For Non-Diabetes Mellitus	n=2 (13%)
<b>Mind-Body Therapy (Meditation, yoga, hypnosis)</b>		
	Past 12 months	n=3 (19%)
Why did you use?		
	For Diabetes	n=2 (13%)
	For Diabetes Mellitus Complications	n=2 (13%)

	For Non-Diabetes Mellitus	n=3 (19%)
<b>Homeopathy</b>		
	Past 12 months	n=0
Why did you use?		
	For Diabetes	n=0
	For Diabetes Mellitus Complications	n=0
	For Non-Diabetes Mellitus	n=0
<b>Complementary and Alternative Medicine Practitioners</b>		
<b>Traditional Chinese medicine practitioner</b>		
	Past 12 months	n=2 (13%)
Why did you use?		
	For Diabetes	n=2 (13%)
	For Diabetes Mellitus Complications	n=2 (13%)
	For Non-Diabetes Mellitus	n=2 (13%)
<b>Chiropractor</b>		
	Past 12 months	n=0
Why did you use?		
	For Diabetes	n=0
	For Diabetes Mellitus Complications	n=0
	For Non-Diabetes Mellitus	n=4 (25%)
<b>Herbalist</b>		
	Past 12 months	n=1 (6%)
Why did you use?		
	For Diabetes	n=1 (6%)



	For Diabetes Mellitus Complications	n=1 (6%)
	For Non-Diabetes Mellitus	n=1 (6%)
<b>Religious healer/ Psychic healer</b>		
	Past 12 months	n=1 (6%)
Why did you use?		
	For Diabetes	n=1 (6%)
	For Diabetes Mellitus Complications	n=1 (6%)
	For Non-Diabetes Mellitus	n=2 (13%)
<b>Naturopath Practitioner</b>		
	Past 12 months	n=1 (6%)
Why did you use?		
	For Diabetes	n=1 (6%)
	For Diabetes Mellitus Complications	n=1 (6%)
	For Non-Diabetes Mellitus	n=1 (6%)
<b>Any other CAM therapies</b>		
<b>Carving (Hobby Therapy) “Keeps my sanity.”</b>		
	Past 12 months	n=0
Why did you use?		
	For Diabetes	n=0
	For Diabetes Mellitus Complications	n=0
	For Non-Diabetes Mellitus	n=1 (6%)
<b>Talk Therapy</b>		
	Past 12 months	n=0

Why did you use?		
	For Diabetes	n=0
	For Diabetes Mellitus Complications	n=0
	For Non-Diabetes Mellitus	n=1 (6%)
<b>Physical Therapy</b>		
	Past 12 months	n=1 (6%)
Why did you use?		
	For Diabetes	n=0
	For Diabetes Mellitus Complications	n=0
	For Non-Diabetes Mellitus	n=1 (6%)
<b>NOTE: Complementary and Alternative Medicine (CAM) and Type 2 Diabetes Participants (N=21) were asked have you ever used a specific CAM therapy in these questions. The numbers here indicate a participant may have answered with multiple answers.</b>		

## Perception of Health

### SF-36 Items for Short Form Survey Instrument

The disadvantage of this tool was the variable number of responses to each question from a two-point to a six-point scale. Participants had trouble remembering the six available responses. The nurse researcher, who sat next to the patients, read the question and then showed them the question. The questions, “Did you feel full of pep,” “Have you felt so down in the dumps that nothing could cheer you up,” and, “Have you felt downhearted and blue,” were difficult for some participants to understand. Specifically the words “pep”, “dumps”, and “blue” were not familiar. The nurse researcher explained the words “pep,” as energy, “dumps,” as a low point, and, “blue”, as sad.

The assessment of general health status in patients with DPN was obtained through the Short Form (36) Health Survey. The majority of respondents rated their general health as fair and poor (62%). In general, compared to one year ago, 66% respondents rated their health now as “much better”, or “somewhat better” than one year ago. All 21 Native Hawaiian and Part-Hawaiian respondents stated that they were limited either, “a lot” or, “a little” with vigorous activities such as running, lifting heavy objects, or participating in strenuous sports. Climbing one flight of stairs, walking more than a mile, and walking several blocks were limited a lot, or a little, (67%) and (57%) respectively. As far as moderate activities, bending/kneeling, stooping or walking one block, 52% of respondents were limited either a lot or a little. The majority, 95% did not have limitations with bathing or dressing self.

More than 50% of respondents did not have problems with work, regular daily activity, or social activities as a result of their physical health or emotional problems in the past four weeks. However, there were 57% of respondents with moderate, severe, and very severe bodily pain during the past four weeks. Despite the high reports of pain 71% respondents reported pain referring to it with either, “not at all” or “a little bit” and during normal work as, “not at all”, or, “a little bit”.

During the past four weeks, more than 75% of respondents felt very nervous, down in the dumps, that nothing could cheer them up, downhearted, or blue. They felt as least one of these attributes either some of the time, a little of the time, or none of the time. Of the respondents, 70% felt calm and peaceful, worn out, or happy all of the time or most of the time, or a good bit of the time. The responses were similar for the question, “Did you feel full of pep?” with a percentage that was from all of the time, most of the time, and a good bit of the time at 52%. For 47% of the participants, the answer was for some of the time, a little of the time or none of

the time. Less than half of respondents reported having a lot of energy (42%), and felt tired (47%), some of the time, all of the time, most of the time, or a good bit of the time. The response of mostly false, and definitely false, were selected by more than (60%) of respondents for statements, “I seem to get sick a little easier than other people,” “I am as healthy as anybody I know,” and, “I expect my health to get worse.” For the statement, “My health is excellent”, 47% of respondents selected, “don’t know.” In Table 3, detailed information on the results from the SF-36 short form survey was presented.

**Table 3**  
*SF36 Items for Short Form Survey Instrument N=21*

<b>In general, would you say your health is:</b>	
Excellent, Very good, Good	n=8 (38%)
Fair and Poor	n=13 (62%)
<b>Compared to one year ago, how would you rate your health in general now?</b>	
Much better and Somewhat better now than one year ago	n=14 (66%)
About the same	n=5 (24%)
Somewhat worse and much worse now than one year ago	n=2 (9%)
<b>Does your health now limit you in these activities If so, how much?</b>	
Vigorous activities, such as running, lifting heavy objects, participating in strenuous sports	
Yes, Limited a lot and limited a little n=21 (100%)	No, not limited at all
Moderate activities, such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	
Yes, Limited a lot and limited a little n=11 (52%)	No, not limited at all n=10 (47%)
Lifting or carrying groceries	
Yes, Limited a lot and limited a little n=8 (38%)	No, not limited at all n=13 (62%)
Climbing one flight of stairs	
Yes, Limited a lot and limited a little n=14 (67%)	No, not limited at all n=7 (33%)
Bending, kneeling, or stooping	
Yes, Limited a lot and limited a little n=11 (52.4%)	No, not limited at all n=10 (47%)
Walking more than a mile	
Yes, Limited a lot and limited a little n=14 (67%)	No, not limited at all n=7 (33%)

Walking several blocks		
Yes, Limited a lot and limited a little n=12 (57%)	No, not limited at all n=9 (42%)	
Walking one block		
Yes, Limited a lot and limited a little n=11 (52%)	No, not limited at all n=10 (47%)	
Bathing or dressing yourself		
Yes, Limited a lot and limited a little n=1 (5%)	No, not limited at all n=20 (95%)	
<b>During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of your physical health?</b>		
Cut down the amount of time you spent on work or other activities		
	Yes	n=9 (42%)
	No	n=12 (57%)
Accomplished less than you would like		
	Yes	n=10 (47%)
	No	n=11 (52%)
Were limited in the kind of work or other activities		
	Yes	n=10 (47%)
	No	n=11 (52%)
Had difficulty performing the work or other activities (for example, it took extra effort)		
	Yes	n=10 (47%)
	No	n=11 (52%)
<b>During the past 4 weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?</b>		
Cut down the amount of time you spent on work or other activities		
	Yes	n=7 (33%)
	No	n=14 (66%)
Accomplish less than you would like		
	Yes	n=8 (38%)
	No	n=13 (61%)
Didn't do work or other activities as carefully as usual		
	Yes	n=5 (23%)
	No	n=16 (76%)
<b>During the past 4 weeks, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?</b>		
	Not at all and Slightly	n=15 (72%)
	Moderately, quite a bit, and extremely	n=6 (28%)
<b>How much bodily pain have you had during the past 4 weeks?</b>		
	None, Very Mild, and Mild	n=9 (43%)
	Moderate, Severe, and Very Severe	n=12 (57%)

<b>During the past 4 weeks, how much did pain interfere with your normal work (including both work outside the home and housework)?</b>		
	Not at all and A little bit	n=15 (71%)
	Moderately, quite a bit, and extremely	n=6 (28%)
<b>How much of the time during the past 4 weeks...</b>		
Did you feel full of pep?		
	All of the time, most of the time, and a good bit of the time	n=11 (52%)
	Some of the time, a little of the time, and none of the time	n=10 (47%)
Have you been a very nervous person?		
	All of the time, most of the time, and a good bit of the time	n=0
	Some of the time, a little of the time, and none of the time	n=21 (100%)
Have you felt so down in the dumps that nothing could cheer you up?		
	All of the time, most of the time, and a good bit of the time	n=2 (9%)
	Some of the time, a little of the time, and none of the time	n=19 (90%)
Have you felt calm and peaceful?		
	All of the time, most of the time, and a good bit of the time	n=16 (71%)
	Some of the time, a little of the time, and none of the time	n=5 (23%)
Did you have a lot of energy?		
	All of the time, most of the time, and a good bit of the time	n=9 (42%)
	Some of the time, a little of the time, none of the time	n=12 (57%)
Have you felt downhearted and blue?		
	All of the time, most of the time, and a good bit of the time	n=5 (23.8%)

	Some of the time, a little of the time, and none of the time	n=16 (76%)
Did you feel worn out?		
	All of the time, most of the time, and a good bit of the time	n=10 (47%)
	Some of the time, a little of the time, and none of the time	n=11 (52%)
Have you been a happy person?		
	All of the time, most of the time, and a good bit of the time	n=15 (71%)
	Some of the time, a little of the time, and none of the time	n=6 (28%)
Did you feel tired?		
	All of the time, most of the time, and a good bit of the time	n=10 (47%)
	Some of the time, a little of the time, and none of the time	n=11 (52%)
<b>During the past 4 weeks, how much of the time has your physical health or emotional problems interfered with your social activities (like visiting with friends, relatives etc.)?</b>		
	All of the time, most of the time, and some of the time	n=6 (28%)
	A little of the time and none of the time	n=15 (72%)
<b>I seem to get sick a little easier than other people</b>		
	Definitely true and mostly true	n=4 (19%)
	Don't Know	n=1 (4%)
	Mostly False and definitely false	n=16 (76%)
<b>I am as healthy as anybody I know</b>		
	Definitely true and mostly true	n=5 (24%)
	Don't Know	n=2 (9%)
	Mostly false and definitely false	n=14 (67%)
<b>I expect my health to get worse</b>		

	Definitely true and mostly true	n=7 (33%)
	Don't Know	n=1 (4%)
	Mostly false and definitely false	n=13 (61%)
<b>My health is excellent</b>		
	Definitely true and mostly true	n=5 (23%)
	Don't Know	n=10 (47%)
	Mostly false and definitely false	n=6 (28%)

### **Reasons for Not Using or Stopped Using CAM**

Of the 21 participants, six did not use CAM (n=5, 24%) or stopped using CAM (n=1, 5%). The respondent that stopped using CAM was also accounted for as a CAM user. Thus, there is an overlap in CAM use and CAM non-use. The CAM survey instrument asked about respondents experience with CAM use, reasons for not using CAM, or stopping use of CAM. The CAM survey instrument recognized the respondent that stopped CAM use as a CAM user and CAM non-user. Reasons for not using CAM or stopping the use of CAM included “never heard of them,” “do not think they really work,” “do not know where to purchase CAM (not available in my area),” “have heard of stories that CAM is not good for you,” “worried about negative side-effects,” and “felt they are too expensive.” A “no” response was selected by (66%) of respondents who also selected, “my health care professionals are opposed to my use of CAM,” “do not want to mix up anything with your Western medicine,” “feel they are harmful,” and, “are dissatisfied with them.” Reasons such as “have heard of stories that CAM is not good for you,” “worried about negative side-effects,” and “feel they are too expensive,” were 50% yes, and 50% no. See Table 4 for detailed results for not using CAM or stopping use of CAM.



**Table 4**  
***Reasons for Not Using CAM or stopping Use of CAM***

<b>Reasons for not using CAM or stopping use of CAM</b>		
<b>Why you never use CAM or why you stop using CAM to help you control your diabetes? N=6</b>		
<b>No CAM use</b>		n=5 (24% of 21 participants)
<b>Stopped CAM use</b>		n=1 (5%)
<b>You did not use CAMs because you</b>		
Never heard of them	No	n=2 (33%)
	Yes	n=4 (66%)
Do not know where to purchase CAM (Not available in my area)	No	n=2 (33%)
	Yes	n=4 (66%)
My health care professionals are opposed to my use of complementary and alternative medicine	No	n=4 (66%)
	Yes	n=2 (33%)
Do not want to mix up anything with your Western medicine	No	n=4 (66%)
	Yes	n=2(33%)
Do not think that they really work	No	n=2 (33%)
	Yes	n=4 (66%)
Have heard of stories that CAM is not good for you	No	n=3 (50%)
	Yes	n=3 (50%)
Worried about negative side-effects	No	n=3 (50%)
	Yes	n=3 (50%)
Feel they are harmful	No	n=4 (66%)
	Yes	n=2 (33%)
Feel they are too expensive	No	n=3 (50%)
	Yes	n=3 (50%)
Dissatisfied with them	No	n=4 (66%)
	Yes	n=2 (33%)
Other:		n=0

## **Experience of CAM Use**

Out of 21 respondents, a total of 16 (76%) participants reported being CAM users. One respondent was a CAM user and then stopped using CAM. The two most important reasons for CAM use were “recommended by their health care professionals” (44%), and “other reasons,” (38%), providing an opportunity to share their personal response such as, “Be at peace with one’s self”, “Alternative for stress relief Convenient”, “Pain in back and neck”, “Pain relief, not from diabetes”, “Relieve pain”, and, “Parents and Chinese medication” was reported by of respondents. The five least selected reasons for CAM use were “CAM was consistent with their culture” (19%), “People around you believe in CAM treatment” (13%), “Believe in CAM for the treatment of diabetes” (13%), “Dissatisfaction with Western medicine” (6%), and, “believe CAMs are safer than Western medicine (fewer side-effects)” (6%).

Of the participants, 25% or more reported obtaining CAM use information from friends (38%), a physician (31%), partner or family (25%) or a nurse (25%). The lowest responses for obtaining information regarding CAM use were the media, newspapers, magazines (13%), CAM practitioners (6%), or medical book or research journal (6%). No respondents selected a pharmacist (0%) for obtaining information about CAM use.

The proportion of respondents who had knowledge of the ingredients in their herbal medicine was equal to those who had no idea. Of the respondents, 25% knew the ingredients of their herbal medicine and 25% the ingredients were completely unknown to them. Other choices were, “unknown, but it was from CAM practitioner,” “unknown but it shown on the can,” and “other”; none of these were not selected.

The majority of CAM users (69%) reported that the type of CAM they should use was their decision. The least selected reasons chosen by respondents were that family decided what type of CAM to use (13%), or that a physician recommended prior to back surgery for (6%). No respondents selected “your friend’s decision”, or “your CAM practitioner decision.”

More than half of respondents reported no change in Western medication when using CAM (81%). Minority (6%) reduced the dose of Western medicines when using CAM. While CAM was used, Western medicine was not used either separately, at different times, or stopped. The cost of CAM was assessed, and 88% of respondents paid under \$500 per month.

Out of the respondents, 38% reported health care professionals encouraged them to use CAM after discussing CAM use. A smaller 6% reported health care professionals discouraged them from using CAM. Responses of why respondents might not discuss CAM use with their health care professional included, “I think that the health care professionals do not have adequate knowledge of CAM therapies” (50%), “I think it is safe, thus no need to discuss” (38%), “I never think of it,” “Health care professional did not ask it,” and “I think that there was not sufficient time to discuss” for (19%), as well as, “I think that health care professionals would discourage CAM use” for 19%. One respondent (6%) chose, “other” as selection for CAM use not discussed with their health care professional because, “Hard to accept Western model. Cut! Cut! Cut! Not a solution to me. Cultural medicine starts with prayer.” Other comments respondents added were, “Educate doctors on other types of alternative medicine,” “Care providers need to have aloha,” and “The wound care clinic staff are the best!” See Table 5 for the experience of CAM use.

**Table 5**  
**Experience of CAM Use**

<b>Experience of CAM Use</b>		
<b>Experienced CAM use (includes participant with previous CAM use and stopped CAM use)</b>	N=16 (76%)	
<b>What is the most important reason that made you start to use CAM? Note: respondents selected multiple responses.</b>		
Dissatisfaction with Western medicine	n=1 (6%)	
Believe CAMs are safer than Western medicine (fewer side-effects)	n=1 (6%)	
People around you believe in CAM treatment	n=2 (13%)	
CAM is consistent with my culture	n=3 (19%)	
Believe in CAM for the treatment of diabetes	n=2 (13%)	
Recommended by health care professionals	n=7 (44%)	
Other: "Be at peace with ones self." "Alternative for stress relief. Convenient." "Pain in back and neck." "Pain relief, not from diabetes." "Relieve pain." "Parents and Chinese medication." (The selection of other most important reasons reported by participants)	n=6 (38%)	
<b>NOTE:</b> Two participants choose more than one answer from the selection. One participant selected five selections and one participant selected two selections. For the choice other there were six participants.		
<b>From where did you get the information regarding CAM use? N=16</b>		
Partner & Family	No	n=9 (56%)
	Yes	n=4 (25%)
Participants did not answer		n=3 (19%)
Friends	No	n=8 (50%)
	Yes	n=6 (38%)
Participants did not answer		n=2 (13%)
Physician	No	n=8 (50%)
	Yes	n=5 (31%)
Participants did not answer		n=3 (19%)
Pharmacist	No	n=13 (81%)
	Yes	n=0
Participants did not answer		n=3 (19%)
Nurse	No	n=9 (56%)
	Yes	n=4 (25%)
Participants did not answer		n=3 (19%)
Media, Newspaper, Magazine	No	n=11 (69%)
	Yes	n=2 (13%)
Participants did not answer		n=3 (19%)

Medical book or research journal	No	n= 12 (75%)
	Yes	n=1 (6%)
Participants did not answer		n=3 (19%)
CAM Practitioners	No	n=12 (75%)
	Yes	n=1 (6%)
Participants did not answer		n=3 (19%)
<b>Do you know the ingredients of your herbal medicine when you used it?</b>		
Know it.		n=4 (25%)
Completely unknown		n=4 (25%)
Unknown, but it was from CAM practitioner		n=0
Unknown, but it shown on the can		n=0
Other:		n=0
Eight participants did not answer this question		n=8 (50%)
<b>Who mostly decides what type of CAM that you should use? It is:</b>		
Your decision		n=11 (69%)
Your family's decision		n=2 (13%)
Your friend's decision		n=0
Your CAM practitioner decision		n=0
Other: "Physician recommended prior to back surgery."		n=1 (6%)
Two participants did not answer this question		n=2 (13%)
<b>How do you use your Western medication when you are using CAM?</b>		
No Change		n=13 (81%)
Use separately and use at different times		
Reduce the dose of Western medicines		n=1 (6%)
Stopped Western medicines		
Participants did not answer		n=2 (13%)
<b>Approximately, how much money have you paid for CAM (in general per month)?</b>		
\$ under 500		n=14 (88%)
\$ 501-1000		n=0
\$1001-1500		n=0
\$1501-2000		n=0
More than \$		n=0
Participants did not answer		n=2 (13%)
<b>What was the advice of the health care professional after you discussed about CAM use?</b>		
Encourages you to take it		n=6 (38%)
Discourages you from taking it		n=1 (6%)
Feels it's entirely up to me; has no strong feelings about it		n=0
Warns you of possible side-effects regarding CAM use		n=0
Warns you that some may interfere with your regular treatment		n=0
Other:		n=0
Participants did not answer		n=9 (56%)
<b>Reasons you may not discuss CAM use with your health care professional</b>		
I never think of it	No	n=4 (25%)

	Yes	n=3 (19%)
Participants did not answer		n=9 (56%)
Health care professionals did not ask it	No	n=4 (25%)
	Yes	n=3 (19%)
Participants did not answer		n=9 (56%)
I think that there was not sufficient time to discuss	No	n=4 (25%)
	Yes	n=3 (19%)
Participants did not answer		n=9 (56%)
I think it is safe, thus no need to discuss	No	n=1 (6%)
	Yes	n=6 (38%)
Participants did not answer		n=9 (56%)
I think that the health care professionals would discourage CAM use	No	n=4 (25%)
	Yes	n=3 (14%)
Participants did not answer		n=9 (56%)
I think that the health care professionals do not have adequate knowledge of CAM therapies	No	n=5 (31%)
	Yes	n=8 (50%)
Participants did not answer		n=3 (19%)
Others: “Hard to accept Western model. Cut! Cut! Cut! Not a solution to me. Cultural medicine starts with prayer.”		n=1 (6%)
<b>Do you have any comments you would like to add?</b>		
Educate doctors on other types of alternative medicine.		
Care providers need to have aloha. The wound care clinic staff are the best!		

Percentages of respondents who reported health as excellent, very good or good health were 38%, and fair or poor health, 62%. CAM use by a Native Hawaiian DPN group who reported in excellent, very good, or good health was 88% (n=8), while others (n=13) who reported fair or poor health were (see Table 6). The duration of diabetes was similar for both groups ranging from 1-41 years. The high CAM users (88%) were from the self-reported excellent, very good, or good health group. The excellent, very good, or good health group was younger than 67 years old, religious (87%), high school educated (88%), single with a monthly household income of more than & \$1200 (88%), not employed females (63%) and had health insurance and lives with others (100%). They had religious/spiritual beliefs (100%), and lived

with others (100%). Participants who reported “fair or poor” health were the low CAM users. The characteristics of this “fair or poor” health group were younger than 78 years old, religious (62%), most with a high school education (69%), single (38%), male (62%) with a total household income more than \$1200 (62%). Percentages of religious/spiritual beliefs and lived with others of these participants were 62% and 77% respectively. Please see Table 6 for results from SF36 perceived general health, CAM use, and descriptive characteristics.

**Table 6**  
***SF36 Perceived General Health, CAM Use, and Descriptive Characteristics***

<b>In general, would you say your health is:</b>				
Excellent, Very good, or Good	n=8 (38%) of 21 respondents	CAM Use	n=7 (88%)	
Fair or Poor	n=13 (62%) of 21 respondents	CAM Use	n=9 (69%)	
<b>General Health is Excellent, Very good, or Good n=8 (38%)</b>			<b>CAM User n=7 (88%)</b>	
Diabetes Duration	1-41 years	n=8	n=7	1-41 years
Age	41-66 years	n=8	n=7	41-74 years old
Gender	Male	n= 3 (38%)	n=2 (29%)	
	Female	n=5 (63%)	n=5 (71%)	
Education	Middle School	n=1 (12%)	n=1 (14%)	
	High School	n=7 (88%)	n=6 (86%)	
	Bachelors Degree	n=0	n=0	
	Graduate School	n=0	n=0	
Marital Status	Married	n=1 (13%)	n=1 (14%)	
	Single	n=5 (62%)	n=4 (57%)	
	Widowed	n=1 (13%)	n=1 (14%)	

	Separated	n=1 (13%)	n=1 (14%)	
Employment	Full-time	n= 1(13%)	n=2 (29%)	
	Part-time	n=1 (13%)	n=1 (14%)	
	Retired	n=2 (25%)	n=1 (14%)	
	Not Working	n=3 (38%)	n=3 (42%)	
Religious/Spiritual Beliefs	No	n= 1 (13%)	n=0	
	Yes	n=7 (88%)	n=7 (100%)	
Lives with others	No	n=0	n=0	
	Yes	n=8 (100%)	n=7 (100%)	
Total Household Monthly Income	<\$1200	n=1 (13%)	n=4 (57%)	
	\$1200-2400	n=5 (63%)	n=2 (28%)	
	\$2401-3600	n=2 (25%)	n=1 (14%)	
	\$3601-4800	n=0	n=0	
	More than \$4800	n=0	n=0	
Health Insurance	No	n=0	n=0	
	Yes	n=8 (100%)	n=7 (100%)	
<b>General Health is Fair or Poor n=13 (61%)</b>			<b>CAM User n=9 (69%)</b>	
Diabetes Duration	1.5-40 years	n=13	n=9	5-40 years
Age	48-77 years	n=13	n=9	52-77 years old
Gender	Male	n=8 (62%)	n=5 (56%)	
	Female	n=4 (30%)	n=4 (44%)	
Education	Middle School	n=2 (15%)	n=1 (11%)	



	High School	n=9 (69%)	n=6 (67%)
	Bachelors Degree	n=1 (8%)	n=1 (11%)
	Graduate School	n=1 (8%)	n=1 (11%)
Marital Status	Married	n=2 (15%)	n=1 (11%)
	Single	n=5 (38%)	n=3 (33%)
	Widowed	n=3 (23%)	n=2 (22%)
	Separated	n=3 (23%)	n=3 (33%)
Employment	Full-time	n=2 (15%)	n=1 (11%)
	Part-time	n=0	n=0
	Retired	n=5 (38%)	n=3 (33%)
	Homemaker (working at home)	n=1 (8%)	n=1 (11%)
	Other: Self Employed and Disabled.	n=2 (15%)	n=2 (22%)
	Not Working	n= 3 (23%)	n=2 (22%)
Religious/Spiritual Beliefs	No	n=5 (38%)	n=3 (33%)
	Yes	n=8 (62%)	n=6 (67%)
Lives with others	No	n= 3 (23%)	n=2 (15%)
	Yes	n= 10 (76%)	n=7 (78%)
Total Household Monthly Income	<\$1200	n=5 (38%)	n= 2 (22%)
	\$1200-2400	n=8 (62%)	n=6 (67%)
	\$2401-3600	n=0	n=0

	\$3601-4800	n=0	n=1 (11%)
	more than \$4800	n=0	n=0
Health Insurance	No	n=1 (8%)	n=1 (11%)
	Yes	n=12 (92%)	n=8 (88%)
<b>Note: Total respondents (N=21), CAM Users (n=16), Non-CAM Users n=5 + n=1 Stopped using CAM (n=6). The stopped using CAM respondent was counted as a CAM user and CAM non-user.</b>			

Participants who reported, “none to mild bodily pain” represented 43% of the Native Hawaiians and Part-Hawaiians N=21 while others reported a “moderate to severe bodily pain” rating represented 57%. CAM use for those with “none to mild bodily pain”, was 89%, and 67% for those with “moderate to very severe pain” (see Table 7). Descriptive characteristics of the group, “none to mild pain”, included diabetes duration of 1-41 years, a wide age range of 41-77 years, male gender (56%), female gender (44%), and most respondents not employed (66%). The education level was at a high school level for 89% of participants. The “none to mild bodily pain” CAM user (n=8) (89%) group who were: single, widowed, or separated, had religious beliefs, reported “living with others” and had “a total household income of less than \$1200 per month”, also reported “having health insurance”.

The participants reporting “moderate to very severe bodily pain group” used less CAM (67%), were younger by five years, and experienced one year less in diabetes duration when compared to the group reported “none to mild body pain.” Gender in the “moderate to severe bodily pain group” was predominantly male (58%), with a high school or higher education (83%), and reported higher total household monthly income equal to greater than \$1200 (41%). The majority of participants were not employed (66%), but had health insurance (92%). The “moderate to very severe pain” group reported less religious and spiritual beliefs (58%), and

reported a higher percentage of living with others (92%). Please refer to Table 7 for results on SF36 bodily pain and descriptive characteristics.

**Table 7**  
***SF36 Bodily Pain and Descriptive Characteristics***

<b>How much bodily pain have you had during the past 4 weeks? N=21</b>			
		<b>None to Mild Pain</b>	<b>Moderate to Very Severe Pain</b>
Participants		n=9 (43%)	n=12 (57%)
CAM Use		n=8 (89%)	n=8 (67%)
Diabetes Duration		1-41 years	1.5 -40 years
Age		41-77 years	50-72 years
Gender	Male	n=5 (56%)	n=7 (58%)
	Female	n=4 (44%)	n=5 (41%)
Education	Middle School	n=1 (11%)	n=2 (16%)
	High School	n=8 (89%)	n=8 (67%)
	Bachelor Degree		n=1 (8%)
	Graduate School		n=1 (8%)
Marital Status	Married	n=1 (11%)	n=2 (16%)
	Single	n=5 (56%)	n=5 (41%)
	Widowed	n=2 (22%)	n=2 (16%)
	Separated	n=1 (11%)	n=3 (25%)
Employment	Full-time	n=2 (22%)	n=2 (16%)
	Part-time	n=1 (11%)	n=1 (8%)
	Retired	n=2 (22%)	n=5 (41%)

	Homemaker (working at home)		n=1 (11%)
	Not Working	n=4 (44%)	n=2 (16%)
	Other: (self-employed and disabled)		n=2 (16%)
Religious Beliefs	No	n=1 (11%)	n=5 (42%)
	Yes	n=8 (88%)	n=7 (58%)
Lives with others	No	n=2 (22%)	n=1 (8%)
	Yes	n=7 (78%)	n=11 (92%)
Total Household Monthly Income	<\$1200	n=5 (56%)	n=7 (58%)
	\$1200-2400	n=3 (33%)	n=2 (17%)
	\$2401-3600	n=1 (11%)	n=1 (8%)
	\$3601-4800		n=1 (8%)
	>\$4800		n=1 (8%)
Health Insurance	No		n=1 (8%)
	Yes	n=9 (100%)	n=11(92%)

## Summary

The study results identified 21 participants completing the two standardized tools. The participants consisted of a self-identified Native Hawaiian and Part-Hawaiian sample. The recruitment processes used to seek participation by Native Hawaiian and Part-Hawaiian individuals showed that interpersonal connections between the researcher and the stakeholders of the research site, as well as the connection between the research and the study populations, were the key elements in successfully carrying out the feasibility study. The recruitment process also

showed that providing services to the community prior to presenting the research intent was the foundation for developing necessary connections.

The results for the first specific aim, revealed the challenges experienced while conducting a feasibility study for Native Hawaiians and Part-Hawaiians with type 2 diabetes and DPN such as respondents availability, clinic schedules, and healthcare provider preferences. The second specific aim results described reasons for CAM use, experience of CAM use, and CAM types used by Native Hawaiians and Part-Hawaiians with type 2 diabetes and DPN self-management. Descriptive statistical analysis frequency results reveal the characteristics of CAM users and non-CAM users related to perceived bodily pain and health.

## CHAPTER 5. DISCUSSION

Knowledge of CAM use amongst Native Hawaiian peoples in the literature was limited. Lack of CAM use knowledge identified a need for further exploration in Native Hawaiian peoples. There was an opportunity to explore CAM use and potentially gain new knowledge.

The objective of this feasibility study was to scrutinize the process of recruiting and interviewing Native Hawaiians in Hawai'i with DPN and explore reasons these individuals use CAM for self-management. Studies such as this may provide valuable culturally appropriate knowledge of the usage of CAM by Native Hawaiians with type 2 diabetes. This feasibility study was presented based on two specific aims: (1) to describe the process of conducting a feasibility study for Native Hawaiians with type 2 diabetes and DPN and, (2) to describe reasons, experiences, and types of CAM used by Native Hawaiians with type 2 diabetes and diabetic peripheral neuropathy.

### **Specific Aim 1**

Specific aim 1 was to describe the process of conducting a feasibility study for Native Hawaiians with type 2 diabetes and DPN. Interpersonal connections were the key elements that initiated the process of this feasibility study. The Native Hawaiian perceived “fictive kin” (hoahānau) as family (Ka'opua, 2008). The concept of “fictive kin” was the social network of individuals with informal relationships (Jordan-Marsh & Harden, 2005).

The setting and sample of this feasibility study selected, showed the importance of established community partnerships and the nurse researcher's service before the research intent. In this feasibility study setting, urban hospital outpatient clinics prior relationships was formed by the nurse researcher's employment at the medical center and was familiar to staff. The nurse researcher has had experience with this sample caring for Native Hawaiian patients in the

selected urban hospital. In a Hawaiian Homestead type 2 diabetic study, described partnerships between academic and community-based organizations formed over a decade (Townsend et al., 2016). These relationships might be preceded by distrust by the Native Hawaiian community.

The feasibility study revealed the need for culturally appropriate tools to measure CAM use in Native Hawaiians. The literature indicated there were no instruments found for CAM use in Native Hawaiians and Part Hawaiians. The selected CAM survey and SF-36 survey possessed limitations in culturally appropriate, unfamiliar terms, and confusing question sequence, possibly affecting the quality of response. To minimize the limitations of selected instruments, the nurse researcher sat with each respondent to provide assistance with reading questions, clarifying questions, and provided a culturally accepted face-to-face semi-structured interview approach. The CAM use survey should not be used for future research with Native Hawaiian population. A culturally appropriate tool providing CAM types previously used and reasons familiar to Native Hawaiians is recommended for future research.

The procedures and processes of this feasibility study were found to be acceptable to the Native Hawaiian and Part-Hawaiian community. The procedures were developed to support the sample based on recommendations from the healthcare providers from the outpatient clinics. In contrast, direct involvement of community members at the initial phases of research development can identify practical challenges and was recommended for research with indigenous historically disadvantaged populations (Sharp & Foster, 2002). Other studies describe successful culturally tailored community-based participatory research in the Native Hawaiians with type 2 diabetes was documented in the literature (Kaholokula et al., 2014; Sinclair et al., 2013; Townsend et al., 2016).

There may be a sense of trust between the individual and their health care professional to support CAM use. Trust inhibits the Native Hawaiian's participation in research and required time devoted to build relationships (Townsend et al., 2016). The nurse researcher established rapport through respectful communication to build trust with patients. Prior to clinic appointments, the nurse researcher communicated with participants by telephone or in person and established trust with staff through dialogue about the feasibility protocol. The qualities of the nurse researcher such as being a Native Hawaiian may have contributed to the ability to recruit participants and conduct research with a Native Hawaiian population. In comparison to another study, Burkett and Morris (2015) recommended nurse researchers to practice the process of gradual immersion to develop trusting relationships to ensure truth in results.

Factors inclusive of recruitment, response rate, organizational support and patient population for this feasibility study are important to consider for a larger study in the future. In this feasibility study an IRB approval and an individualized recruitment process was needed for each clinic. The physicians and directors of the clinics requested specific approaches in addition to IRB recommendations. Accessibility to potential diabetic peripheral neuropathy patients at one of the clinics required the clinic director authorizing a DPN list to the nurse researcher (provided by a clinic records staff member). The complexities of working within the organizational research department, clinic leadership, staff and patients should be considered and described in the future methodological designs. Previously established professional relationships supported the recruitment research efforts. The individual patients were difficult to reach by phone. It is discovered during this feasibility study, in-person interaction to recruit study participants did positively impact the response rate. Other recruitment options such as email, phone, or mailed survey methods maybe less effective with this population. Minimization of



disruption to clinic appointment time gained clinic administration and staff support. The researcher was required to adjust time and approach based on the priority of the clinic schedule. For all factors mentioned there were challenges but the overall response by patients and staff were positive.

Recommendations for future research would be to have focus groups or “talk story”, a potentially useful method to develop a culturally tailored questionnaire of CAM use in this population. The “talk story” strategy was used during the recruitment phase to establish rapport and trust. The “talk story” strategy was used during the recruitment phase to establish rapport and trust. In a self-management study to recruit Asian Pacific Islanders in Hawai'i with type 2 diabetes, a “talk story” approach was implemented (Wong et al., 2015). A familiar form of communication for childhood experienced in the Hawaiian Islands “talk story” was reflective of “*malama* or caring” a Hawaiian value (Wong, et al., 2015).

### **Specific Aim 2**

The Specific Aim 2, the results describe reasons for CAM used by Native Hawaiians with type 2 diabetes and diabetic peripheral neuropathy by performing a face-to-face interview to collect data. This feasibility study revealed CAM use for participants with diabetic neuropathy pain. Types of CAM use were nutritional supplements, diet modification, Chinese herbal medicine, acupuncture, cupping/scrapping, manipulative-based therapy, folk therapies, biofield therapy (kinesiology, reiki, tai chi, Gi gong), supernatural healing, and bioelectromagnetic-based therapies. Western herbal medicine, aromatherapy, mind-body therapy, homeopathy, seeing a traditional Chinese medicine practitioner, seeing an herbalist, seeing a religious healer/psychic healer, or seeing a naturopath practitioner were also reportedly used.

Comparatively, CAM use for those participants with a perception of “excellent, very good, or good health” and CAM use for, “fair or poor health” respondents did not use CAM. Consistent with another study, Harrigan et al. (2006) reported CAM use higher for respondents with a higher health rating. However, CAM use was higher in lower income and educated respondents compared to Harrigan et al. (2006) study on provider CAM use. The reason for this inverse relationship between high CAM use and low income and education was unclear.

A discrepancy was revealed in respondents perceived health rating. In the CAM survey diabetes clinical information assessment data section, respondents were asked the question “How good do you feel is your health condition?” Respondents felt their health condition was, “good and, very good”. In the SF-36 survey, respondents were asked the question “In general, would you say your health is: excellent, very good, good, fair or poor”. Most respondents rated their health was “excellent, very good, and good”. CAM survey confusing questions posed clarification from respondents for the CAM survey’s question terms “health condition”. Although, the question does not refer to diabetes most respondents rated their diabetes condition. It may have been the question placement in the diabetes clinical assessment survey sequence of questions that contributed to a rating respondent diabetes condition. People diagnosed with type 2 diabetes are often diagnosed with other health issues such as obesity, cardiovascular disease, and kidney disease. These other potential diagnosis may contribute to the lower perceived general health rating for people with type 2 diabetes.

For this feasibility study, Native Hawaiian participants were higher CAM users than CAM use reported in the general United States Population (NCCAM, 2014). Respondents who reported, “none to mild bodily pain” used CAM at a higher rate. To compare the groups, low

CAM users had, “moderate to very severe pain”. These findings could not determine if CAM use had an effect on bodily pain but, reveal bodily pain characteristics of CAM users.

Health beliefs and attitudes contribute to CAM use in a type 2 diabetic population (Chang, Wallis, & Tiralongo, 2012). Additional characteristics of a type 2 diabetes CAM user suffered more diabetes-related symptom distress, engaged in self-care behaviors, with positive attitudes towards CAM and had higher social support (Chang et al., 2012). The health beliefs and attitudes in the Native Hawaiian and Part Hawaiian with type 2 diabetes population, could be assessed to describe CAM use.

The diet modification and supernatural healing were the leading CAM types used by Native Hawaiians and Part Hawaiians with type 2 diabetes and DPN. Individuals with type 2 diabetes were aware of recommended diet modifications to manage hyperglycemia or hypoglycemia. These recommendations came from by healthcare professionals and participants claimed to use it in this feasibility study. Hsu and colleagues (2012) reviewed the literature and found dietary guidelines for Americans, in 2010, applicable to Native Hawaiian when cultural adaptations are made. Food was a cultural factor and should be considered in the management of hyperglycemia, hypertension and hyperlipidemia.

In a CAM utilization study, spiritual and religious individuals are identified as more likely to utilize CAM therapies that involve prayer, meditation, and spiritual healing (Ellison, Bradshaw, & Roberts, 2012). Most Native Hawaiian respondents had religious/spiritual beliefs and implemented and used supernatural healing as a CAM therapy for diabetic complication self-management. Manipulative body therapies, biologically based therapies, and mind-body therapies are found as commonly used CAM therapies (Rhee & Harris, 2017). Individuals with chronic diseases are more likely to use CAM (Tindle, Davis, Phillips, & Eisenberg, 2005).

Native Hawaiians and Part Hawaiians with type 2 diabetes and diabetic peripheral neuropathy responded CAM use was recommended by their health care professional. Respondents started to use CAM after discussion with health care professionals on CAM use. CAM was encouraged and recommended by health care professionals. Native Hawaiians reported the type of CAM they choose to use was their decision and, “CAM was consistent with their culture”. CAM was used without change to Western medicine. Native Hawaiians reported CAM use was their decision with encouragement to use CAM from their health care professionals, and maintained current Western medicine while using CAM.

Perceptions and attitudes of physicians to CAM use were perceived as not-evidence based treatments (Al-Omari, Al-Qudimat, Hmaidan, & Zaru, 2013). Physicians would like to learn more about CAM with the lack of scientific studies on CAM and the widely accepted CAM use in patient’s culture (2013). Nurses have a positive attitude towards CAM use, report CAM offered in their facilities, and used CAM for self-care (Jong, Lunqvist, & Jong, 2015). Based on findings in the literature health care professionals have varied perceptions and attitudes of CAM.

In the literature, there were studies on the prevalence of CAM use and descriptors of those who use CAM for specific reasons (Fox, Coughlan, Butler, & Kelleher, 2010; Harris, Cooper, Relton, & Thomas, 2012; Tindle et. al, 2005). Studies that inquired about the most important reason an individual started to use CAM are limited. A qualitative study provided a decision-making process approach to reasons for CAM use in a type 2 diabetic sample population (Chang, Wallis, Tiralongo, & Wang, 2012). There were four categories that emerged from the data; recognizing the need for using CAM, assessing the potential CAM prior to use, matching CAM use to personal philosophy, and ongoing evaluation of CAM (Chang et al.,

2012). It supports further research into relationships between CAM therapies used with a larger sample and it was noted that pain was not the only reason for CAM use.

### **Feasibility of Conducting a Larger Study**

The feasibility study revealed two instruments used which may not be appropriate to gain knowledge of CAM use in Native Hawaiians. These instruments might not be the best fit for a Native Hawaiian and Part Hawaiian population. Thus, would not be recommended in future studies with a Native Hawaiian or Part Hawaiian study population.

### **Implications for Research, Practice, Education, and Policy**

The feasibility study indicated the importance of a culturally appropriate instrument of CAM use. The “talk story” strategy for collecting data was used in studies with Native Hawaiians and described as culturally acceptable (McEligot, et al., 2010). In future research, the acceptable “talk story” research data collection strategy should be considered with a Native Hawaiian population. Native Hawaiians preferred to select “other” as a response for research questions (when available) to provide their response in their own words.

Based on the findings of this feasibility study CAM was used primarily as a supplement to conventional medicine for DPN self-management. Vinik, Emir, Cheung, and Whalen (2013) found conventional treatment for individuals with chronic pain from DPN experienced improvement in quality of life related to pain relief, function, and sleep disturbance. These symptoms were difficult to manage despite pharmacological therapeutic modalities for diabetic neuropathic pain. Thus, the result that CAM serves this population as a supplement to conventional medicine highlights the complexities and limitations of conventional treatment. The result of this feasibility study may reflect the need for CAM use.

## **Practice**

Health care professionals' assessment of CAM use on health self-management is important because a high number of adults with chronic disease use CAM (Ben-Arye & Frenkel, 2008). The use of CAM could affect prescribed treatments and cause adverse effects. In this feasibility study, health professionals recommended the use of CAM. There was specific focus on diet modification reported for a diabetic population. Ben-Arye and colleagues (2008) developed a useful tool, in the primary care setting, to consider when referring individuals for CAM. To support future research with Native Hawaiians, a research instrument should be developed for CAM use. Instrument development could assist CAM use assessment by health care professionals. This may improve safe self-management efforts for individuals seeking to supplement conventional therapy. Practitioners could initiate assessment for CAM use and become educated on the types of CAM their patients use to coordinate health promotion and prevention (Hawk, Ndetan, & Evans, 2012).

## **Education**

Educational programs for health care professionals have the opportunity to expand their curriculum to include a course on CAM. CAM use is present in a variety of patient populations. It is important for health care professionals to understand the risk of harm to patients if CAM is incompatible with conventional treatment. The first step is educating health care professionals in the area of CAM therapies, and encouraging open communication about CAM use with patients for their safety. CAM use could serve in health prevention and wellness education.

## **Policy**

Policy development to investigate the safety of CAM could be considered. The availability for a variety of CAM was present. There was concern for the safety of the general

public accessing CAM and conventional therapies. Healthcare professionals could be an active voice in needed policies to promote safe CAM therapies and regulate potentially unsafe use of CAM. A collaborative effort between researchers, practitioners, educators, and policy developers are critical in a new emerging prominence of CAM use.

### **Limitations**

There are several limitations of this feasibility study. There was a bias with a convenience sample type, and inclusive of Native Hawaiians and Part-Hawaiians. The study exposed barriers for recruitment. For example, patients did not have a phone or did not come to their clinic visit. Additionally, the self-reporting structure of the interview could have been a bias. The recruitment process method was started prior to clinic appointment for one group and was challenging when clinic patients did not show up for scheduled appointments. Individuals in this setting had limited access to receiving telephone calls. Some individuals were shy, did not have the time or were tired and not able to participate. Other variables that could have impacted feasibility of research in these settings are the concerns related to having multiple appointments scheduled on the day, limiting time to participate in research or transportation pick-up times. Participants were often accompanied by a family member and did not drive to their appointment, creating a sense of dependence on others, limiting time to participate and could have affected the quality of responses.

The in-person meeting was supportive of survey completion for most participants. The setting was two outpatient clinics, possibly limiting presented data because the survey is not representative of other settings. Limited results may be improved with a larger sample. These findings may not be generalized to all people with DPN.

## **Conclusion**

In conclusion, this feasibility study provided challenges in implementation, descriptive findings for demographic characteristics of a Native Hawaiian and Part Hawaiian with type 2 diabetes and DPN population in Hawai'i that differed by education, and income level (when compared to other CAM studies). The key finding of this feasibility study was a process with healthcare professionals initiating assessment of CAM use in a Native Hawaiian and Part-Hawaiian with type 2 diabetes and DPN population in Hawai'i. The research procedure should include culturally tailored instruments and data collection methods such as, "talk story" in the future. The standardized tools contained structured questions used in this feasibility were not culturally appropriate. However, the open-ended questions allowed participants to verbalize what types of CAM they used. Some participants have not had a healthcare provider ask about their CAM practices and appreciated the opportunity to discuss what CAM practices were helpful to their health self-management. CAM therapies were used for general use and diabetic use. The population studied used a variety of CAM types and independently decided to use CAM based on healthcare provider recommendations. CAM use was present and health care providers should devote time to learning more about types of CAM used, reasons for CAM used, and implications for CAM users to adjust, research, practice, educate and change policy.



## APPENDICES

## APPENDIX A

### **CAM treatment for DPN Studies**

Studies selected met the following inclusion criteria: (1) research that implemented a form of alternative therapy intervention for diabetic peripheral neuropathy pain management in adults; (2) written in English; and (3) conducted within the last 10 years. Exclusion criteria eliminated non-English text, published more than 10 years ago, and non-research based studies.

A literature search was conducted via the PUBMED MED-LINE, CINAHL, and COCHRANE databases from 2002-2012. The search option selected was Boolean/phrase with selected limitations such as full text, English language, research article, and peer reviewed. To maximize search “MM” exact major subject heading and “MH” exact subject heading were used with selected search terms. The search terms were (MM “Diabetic Neuropathies+”), (MM “Pain”), (MM “Diabetes Mellitus+”) or (MM “Diabetes Patients”), (MM “Peripheral Nervous System Diseases+”) and (MM “Alternative Therapies”). The plus sign next to a subject heading means there are narrower subjects within the general subject search.

The search resulted in 150 citations from the disciplines of medicine, nursing, and psychology. After the review of the citations, there were 11 articles that met the inclusion criteria. Articles were reviewed to ensure a sufficient sample. Each database was searched on several different occasions before the 11 articles were selected. The papers selected for the sample were read and key data was entered into a matrix method according to Garrard (2007). See Appendix B for a summary of CAM treatment studies for DPNP. The data consisted of author, publication year, purpose, alternative therapy studied, sample size, research study design, and instrument. The designs of the studies were: pretest-posttest experimental design (N=5), randomized control trials (N=2), placebo-controlled single blinded randomized study (N=1),

randomized double blind (N=1), experimental (N=1) and randomized double-blind crossover (N=1). All studies were conducted on adult participants. The geographic location varied from four studies conducted in the United States, one in the Republic of Slovenia, one in the United Kingdom, one in China, two in Germany and two in Italy. Two of the studies incorporated examination of other neuropathy types.

### **CAM treatment themes identified for DPN**

Alternative therapies and complementary and alternative medicine (CAM) studied to reduce diabetic peripheral neuropathy pain (DPNP) in adults were *mind-body medicine, natural products and other CAM therapies*. There were no studies in CAM group manipulative and body-based practices (National Center for Complementary and Alternative Medicine, 2012). Acupuncture (3 studies) and meditation (2 study) represent the mind and body medicine for studies to reduce DPNP. There were studies on the effect of natural products (4 studies), Neuragen PN, NGX-4010, topical capsaicin cream and acetyl-L-carnitine on DPNP. Natural products were researched to determine efficacy on DPNP relief. Neuragen PN (Li, 2010), categorized as a natural product, is a mixture of six homeopathic substances and five plant based oils. The NGX-4010 is an 8% capsaicin patch and is the active ingredient of capsicum peppers (Forst et al., 2002). Acetyl-L-carnitine (DeGrandis & Minardi, 2002) is a natural dietary supplement, which assists with increased glucose and phospholipid metabolism. Other CAM and alternative therapies studied to reduce DPNP were transcutaneous electrical neuropathy stimulation (TENS) (two studies) and frequency-modulated electromagnetic neural stimulation (FREMS) (one study). One study reported participants maintain a diary to document use of pain medication with alternative therapies (Ahn, Bennani, Freeman, Hamdy, & Kaptchuck, 2007).

### **Mind-Body Medicine**

## ***Acupuncture***

Acupuncture is a meridian-based therapy with a focus to insert needles at precise body points to achieve a select therapeutic action (Tong et al., 2010). It is one of the oldest forms of alternative medicine used in Traditional Chinese Medicine (TCM) over the past 2500 years (Tong et al., 2010). There is evidence of DPNP reduction in several acupuncture studies.

Acupuncture was studied as an adjunct therapy to conventional diabetes therapy (diet treatment, hypoglycemic agents, insulin and hypotensive agents) to relieve DPNP (Tong, Guo, & Han, 2010). Traditional acupuncture had significant improvement in motor and sensory nerve function measures, improvement in lower extremity numbness, spontaneous pain, temperature perception and rigidity in upper extremities (Tong et al., 2010). In all three studies, acupuncture was statistically significant in reducing DPNP (Ahn et al., 2007, Green & McClellon, 2006, & Tong et al. 2010). Acupuncture in the traditional form was more effective on DPNP relief than other types of acupuncture such as sham (Tong et al., 2010) and Japanese Kiiko-Matsumoto acupuncture (Ahn et al., 2007).

## ***Meditation***

There are different types of meditation such as transcendental meditation (TM) a repetition method focuses on a word, phrase, or sound and zazen mindful meditation is practiced formally while in a sitting position (Teixeira, 2010). Mindfulness meditation is an Eastern cultural practice traced to Buddhism. In Western culture, there is the non-secular form of mindfulness meditation to end suffering through self-transcendence and enlightenment. It is used in clinical practice and research to promote clinical relaxation and overall health. A pilot study was conducted to examine the efficacy of a mindful meditation on quality of life (QOL), pain relief, and sleep quality in adults with chronic DPN (Teixeira, 2010). The effect of mindful

meditation was not statistically significant for QOL, neuropathic pain relief, and sleep quality. Despite the lack of statistical significance, a positive relationship was identified between pain severity and sleep quality. Thus, participants with increased pain severity experienced decreased sleep quality (Teixeria, 2010).

### ***Natural Products***

Complementary medicine natural product category includes herbal medicines or botanicals, vitamins, minerals, and other natural products (NCCAM, 2012). *Neuragen PN*, a blend of homeopathic substances and essential oils (Li, 2010), *NGX-4010*, 8% capsaicin patch (Webster, Peppin, Murphy, Tobias, & Vanhove, 2012), topical capsaicin cream (Forst et al., 2002) and *Acetyl-L-carnitine*, a natural biochemical (DeGrandis & Minardi, 2002) are four natural products studied to promote DPN pain relief. *Neuragen PN* (Li et al., 2010), *NGX-4010* (Webster et al., 2012), and topical capsaicin cream (Forst et al., 2002) studies were conducted in the United States and *Acetyl-L-carnitine* (DeGrandis et al., 2002) conducted in Italy.

### ***Neuragen PN***

*Neuragen PN* (Li, 2010) application resulted in a significant reduction in peripheral neuropathy pain. The McGill Pain Questionnaire and Visual Analog Scale (VAS) was presented on a personal digital assistant (PDA) with the Purdue Momentary Assessment Tool (PMAT, Bangstate, Inc.) to assess participant's pain reduction (Li, 2010). Participants reported significant pain reduction (93.3%) within 30 minutes of *Neuragen PN* topical application and up to eight hours post treatment. There were 18 diabetic participants and 94% reported pain reduction within 30 minutes of treatment as compared to 11% in the placebo group (2010). According to researchers, *Neuragen PN* is recommended as a safe and effective alternative to conventional treatment for temporary peripheral neuropathy pain relief.

### ***NGX-4010 8% Capsaicin Patch***

*NGX-4010*, 8% capsaicin patch (Webster et al., 2012) and *capsaicin cream* (Forst, et al., 2002) were topical interventions studied for DPNP relief. The *NGX-4010* was applied after one of three topical anesthetics to assist in patch tolerability and participants used additional pharmacological analgesics (Webster et al., 2012). The average pain score reported on the Numeric Pain Rating Score was 5.4-5.9 with a zero score represents no pain and a 10 score is the worst possible pain. There was an overall decrease in pain by 30% in all groups with a pain relief up to 12 weeks after a single application (Webster et al., 2012). The capsaicin (0.05%) cream study (Forst et al., 2002) treated one foot and left the other participant's foot untreated. A total symptom score was obtained from four ten point scales to assess pain, dysesthesia, hypesthesia, and muscle weakness at baseline, four weeks and eight weeks. There was a decrease in the total symptom score with improvement specific to hypesthesia and warmth perception threshold. Evidence of adverse reaction to sensory nerve fiber function or neurovascular control was not present during the eighth week treatment period. Overall, the investigators concluded there is a beneficial effect of topical capsaicin cream treatment for symptomatic diabetic neuropathy (Forst et al., 2002).

*Acetyl-L-carnitine*, a natural biochemical (DeGrandis et al., 2002) was administered in an intramuscular form for 10 days and an oral form for 355 days to determine the efficacy and tolerability for the treatment of diabetic neuropathy. There was statistical significance with patient reported nerve conduction velocity ( $p < 0.01$ ) and visual analogue scale ( $p < 0.0$ ) significantly decreased after 12 months of treatment. There was good tolerability of Acetyl-L-carnitine and minimal adverse reactions but, primarily related to gastrointestinal. Electrophysiological parameters were significantly improved and serve as reliable markers for

diabetic neuropathy progression (DeGrandis et al., 2002). Acetyl-L-carnitine is a safe and tolerable option for DPNP relief.

### **Other CAM and Alternative Therapies**

In other CAM and alternative therapies group, there were two studies found in the literature that utilize *Transcutaneous Electrical Neuropathy Stimulation* (TENS) (Moharic & Burger, 2010) (Grossrau et al., 2011) and one study evaluated *Frequency-modulated Electromagnetic Neural Stimulation* (FREMS) (Bosi et al., 2005). There was no other CAM and alternative therapies found in the literature to represent Eastern and Western movement-based therapies, traditional healers, energy fields, or whole medical systems.

#### ***Transcutaneous Electrical Neuropathy (TENS).***

Other CAM and alternative therapies found in the literature included two forms of electrical and electromagnetic stimulation. TENS affect on painful diabetic neuropathy had a significant effect on sensory thresholds by increased cold pain and decreased heat pain from baseline in a non-stimulated thenar or base of the thumb (Moharic et al., 2010). There was no change in the lower extremities where the TENS was applied (Moharic et al., 2010). However, the second study had no statistical significance with micro-TENS application to lower extremities (Grossrau et al., 2011). In the placebo group 25% responded to therapy compared to 23% responded in the treatment group. There may have been decreased efficacy because of the micro level of current administered compared to conventional TENS that use electrical stimulation measured in milliamps (Grossrau et al., 2011). Both studies view TENS as a safe alternative method to neuropathy pain relief.

#### ***Frequency-modulated Electromagnetic Neural Stimulation (FREMS)***

*Frequency-modulated Electromagnetic Neural Stimulation* (FREMS) is different from

TENS with sequences of modulated electrical stimuli change automatically in pulse frequency, duration, and voltage amplitude (Bosi et al., 2005). Bosi and colleagues studied the efficacy of FREMS as a novel treatment for painful diabetic neuropathy (2005). In a sample of 31 participants with the group divided to form a FREMS group and a placebo group of 15 and 16 participants there was statistical significance in the FREMS group. Daytime pain ( $p=0.0025$ ) and night-time pain ( $p=0.0107$ ) VAS score was significantly decreased in the FREMS group. There was statistical significance with an increase in sensory tactile perception with monofilament assessment ( $p=0.0077$ ) and decreased foot vibration perception threshold ( $p=0.001$ ). At the four-month follow-up, all parameters were tested and resulted in statistically significant outcomes. It was concluded that FREMS is a safe and effective therapy for diabetic peripheral neuropathy pain (Bosi et al., 2005).

Review of the types of CAM treatments for DPNP and implications for use in the Native Hawaiian population was summarized (see appendix C). These researched treatments have little significance on management of DPN. Acupuncture from the CAM mind-body modality provided significant improvement in motor and sensory nerve function measures, improvement in lower extremity numbness, spontaneous pain, temperature perception and rigidity in upper extremities (Tong et al., 2010). Utilization of these researched CAM DPNP treatments may be difficult to access because of cost and availability. Cultural acceptance may not support utilization of particular CAM treatments. But with support, knowledge, and understanding from healthcare providers a collaborative treatment plan for DPNP to include conventional and complementary and alternative medicine could be accessed and utilized.

### **Analysis of Cochrane Database CAM DPN Studies**

There is limited research about the reasons people use CAM (Chang, Wallis, &



Tiralongo, 2010). The Cochrane Database reviewed the effects of vitamin B for treating generalized peripheral neuropathy, the beneficial and harmful effects of acupuncture therapy for symptomatic diabetic neuropathy, and Chinese herbal medicine for people with diabetic peripheral neuropathy (Ang et al., 2008; Chen, Zhang, Xinxue, Yang, & Liu, 2013; Zhao, Zhang, & Zhao, 2006). Based on the Cochrane Database reviews there is a gap in knowledge and an opportunity to conduct studies on reasons people use CAM for DPN. The CAM DPNP studies are limited to providing information on types of CAM to manage DPNP. The studies do not provide information if these CAM treatments are selected and used by DPNP patients. The evaluations of CAM treatments do not provide recommendations for use on patients outside of the research study.

## CAM Treatment Studies for Diabetic Peripheral Neuropathy Pain

Authors, Year	Purpose	Subjects		Data	Relevant Results
		# of Subjects & Characteristics	Design	Source or Instrument	
<i>Mind-Body Medicine</i>					
<i>Acupuncture</i>					
Ahn, Bennani, Freeman, Hamdy, & Kaptchuck (2007)	To assess the feasibility of studying two acupuncture styles, Traditional Chinese Medicine (TCM) and Japanese Kiiko-Matsumoto style acupuncture. To obtain preliminary data for the clinical and mechanistic effects of acupuncture on diabetic neuropathy.	n=7	Randomized Control Trial	Weekly acupuncture treatments over a period of 10 weeks. An 11 point Likert Scale daily pain severity score was recorded 4 times a day. A diary was used to record pain, sleep interference due to nocturnal pain, glucose control, use of pain medication, Profile of Mood States scores, the pain rating index portion of SF-MPQ, SF36 Quality of Life Questionnaire, and blood tests (CBC, Crt, and HgbA1C).	<ul style="list-style-type: none"> <li>• Pain scores were lower for the Japanese Acupuncture group initially.</li> <li>• Sensation improved for the TCM group.</li> <li>• The Pain Rating Index of the SF-MPQ noted a decrease in pain for both groups.</li> <li>• For both groups there were no changes in mood or blood test results.</li> <li>• This study was unable to determine the clinical and mechanistic effects for physiological response to diabetic peripheral neuropathy pain.</li> </ul>
Green & McClennon (2006)	To determine the effectiveness of acupuncture on peripheral diabetic neuropathy.	n=88	Pre-test posttest Experimental design	1 hour initial appointment includes health and pain assessment. Completion of short form McGill questionnaire in week 1 and week 6. Each participant received 6 acupuncture sessions once a week for 6 weeks.	<ul style="list-style-type: none"> <li>• Results were analyzed using the student t-tests.</li> <li>• Pre acupuncture scores were 20.1 and post acupuncture scores were 10.7.</li> <li>• There were 67 participants with reduced pain.</li> <li>• Monthly 'top up' acupuncture continued for 29 participants.</li> <li>• At the end of the acupuncture course 10 participants reduced or stopped peripheral diabetic neuropathy medication.</li> <li>• There 12 participants who reported no pain reduction.</li> </ul>
Tong, Guo, & Han (2010)	To investigate the effects of acupuncture on diabetic peripheral neuropathy.	n=63 Diabetic Peripheral Neuropathy patients between age 35-52.	Pre-test Posttest Experimental Design	42 cases treated with acupuncture. 21 cases exposed to sham acupuncture. The difference between acupuncture and sham acupuncture was needle manipulation. A 2:1 ratio used to determine randomization for groups. All patients participated	<ul style="list-style-type: none"> <li>• No statistical significance in glycemic control.</li> <li>• Statistical significance present in nerve function.</li> <li>• In the acupuncture group, three of the six measures in</li> <li>• motor nerves demonstrated significant improvement</li> <li>• (<math>p &lt; 0.05</math>) over the 15-day treatment period.</li> <li>• There were no significant improvement in the sham acupuncture group.</li> </ul>

				<p>in one session per day lasting 30 minutes for 15 days. The method to measure nerve function was electromyography and the vibration perception <i>threshold</i> was measured on the medial malleolus in the lower extremities using a hand-held biothesiometer. A standardized questionnaire was used to assess subjective data.</p>	<p>The two measures of sensory function, forearm and distal sensory nerve conduction velocity were improved in the acupuncture group.</p> <ul style="list-style-type: none"> <li>- The vibration perception threshold was significantly different between the groups.</li> <li>• Subjective symptoms over time. <ul style="list-style-type: none"> <li>- In the acupuncture group, participants reported improvement on numbness of lower extremities, spontaneous pain in lower extremities, rigidity in upper extremities, and alteration in temperature perception in lower extremities.</li> </ul> </li> </ul>
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**Meditation**

Teixeira (2010)	<p>To evaluate the effect of mindfulness meditation on QOL among adults with diabetes living with symptomatic (pain, numbness, and/or reduced feeling in 1 or more extremity) DPN. Also, to highlight the cost effectiveness of mindful meditation and low risk.</p> <p>Hypotheses *Mindfulness meditation will have a positive effect on QOL in adults with PDPN as measured by scales from the Neuropathy-Specific Quality of Life Tool (NeuroQOL). *There will be</p>	<p>n = 20 n = 10 Group A was given meditation instructions and satisfaction log. This group used a meditation CD 5 days a week. n = 10 Group B placebo control group received nutrition class and maintained a 4 week diet log. A convenience sample of type 2 diabetic adults living with chronic PDPN. The DPN symptoms pain and/or numbness experienced for ≥ 6 months for a male or female 50-92 years of age.</p>	<p>Pretest-Posttest Experimental Design</p>	<p>Baseline and week 4 data were collected with the Demographic Form, Neuropathic Pain Scale (NPS), NeuroQol, and the Pittsburgh Sleep Quality Index (PSQI).</p>	<ul style="list-style-type: none"> <li>• Hypothesis 1 – No significant difference between the groups. The adjusted mean score for the pain QOL was 4 points less compared to the control group.</li> </ul> <p>Comparison on Means Using NeuroQol</p> <p>Constructs</p> <table border="1"> <thead> <tr> <th>N</th> <th>Unadjusted Mean (SD)</th> <th>Adjusted Mean (SD)</th> </tr> </thead> <tbody> <tr> <td>Overall QOL Group B (Placebo)10 Group A (Intervention)10</td> <td>2.90 (0.88) 3.50 (0.53)</td> <td>3.02 (0.63) 3.39 (0.63)</td> </tr> <tr> <td>Symptom-related QOL Group B (Placebo) 10 Group A (Intervention)10</td> <td>2.40 (1.47) 2.20 (1.40)</td> <td>2.44 (0.74) 2.16 (0.74)</td> </tr> <tr> <td>Pain QOL Group B (Placebo) 10 Group A (Intervention)10</td> <td>24.70 (20.89) 22.30 (11.91)</td> <td>25.38 (11.42) 21.62 (11.42)</td> </tr> <tr> <td>Emotion QOL Group B (Placebo) 10 Group A (Intervention) 10</td> <td>13.40 (12.12) 13.50 (7.49)</td> <td>13.65 (8.92) 13.25 (8.92)</td> </tr> <tr> <td>Sensory/ motor QOL Group B (Placebo)10 Group A (Intervention)10</td> <td>19.4 (12.87) 18.2 (9.89)</td> <td>18.10 (7.17) 19.51 (7.17)</td> </tr> </tbody> </table> <ul style="list-style-type: none"> <li>• Hypothesis 2 – No statistical significance between the groups for post-intervention pain intensity.</li> </ul> <p>Comparison of Pain Scores From Neuropathic</p>	N	Unadjusted Mean (SD)	Adjusted Mean (SD)	Overall QOL Group B (Placebo)10 Group A (Intervention)10	2.90 (0.88) 3.50 (0.53)	3.02 (0.63) 3.39 (0.63)	Symptom-related QOL Group B (Placebo) 10 Group A (Intervention)10	2.40 (1.47) 2.20 (1.40)	2.44 (0.74) 2.16 (0.74)	Pain QOL Group B (Placebo) 10 Group A (Intervention)10	24.70 (20.89) 22.30 (11.91)	25.38 (11.42) 21.62 (11.42)	Emotion QOL Group B (Placebo) 10 Group A (Intervention) 10	13.40 (12.12) 13.50 (7.49)	13.65 (8.92) 13.25 (8.92)	Sensory/ motor QOL Group B (Placebo)10 Group A (Intervention)10	19.4 (12.87) 18.2 (9.89)	18.10 (7.17) 19.51 (7.17)
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	a decrease in DPN pain severity with the use of mindfulness meditation. *There will be an inverse relationship between DPN pain severity and sleep quality.				Pain Scale		
					N	Unadjusted Mean (SD)	Adjusted Mean (SD)
					Pain intensity Group B (Placebo) 10 Group A (Intervention) 10	2.89 (1.96) 4.80 (3.12)	3.09 (0.63) 4.62 (0.63)
					Pain Unpleasantness Group B (Placebo) 10 Group A (Intervention) 10	2.40 (1.47) 2.20 (1.40)	2.44 (0.74) 2.16 (0.74)
<ul style="list-style-type: none"> <li>Hypothesis 3 – No statistical significant improvement noted for pain severity between groups. However, there was a positive relationship between pain severity and sleep quality.</li> </ul>							
			N=16	PSQI	Mean (SD)		
			Pain-NeurQol	0.531	23.5 (16.6)		
			PSQI		6.9 (4.8)		

*Natural Products*

*Neuragen PN*

Li (2010)	To investigate the effect of Neuragen PN (a mixture of six homeopathic substances and five plant based oils) on neuropathic pain reduction.	n=60 Individuals with peripheral neuropathy. n=18 Diabetic induced peripheral neuropathy.	Pre-test posttest Experimental design	n=30 treatment (Neuragen PN) n=30 placebo McGill Pain Questionnaire and Visual Analogue Scale (VAS). These assessment tools were administered at specific time points (2,3,4,5,6,7,8,& 9 hr) using a PDA software system. Each participant received two sessions.	<ul style="list-style-type: none"> <li>There was significant pain reduction reported using the VAS between the treatment group and placebo group.</li> <li>Within 30 minutes of receiving treatment the Neuragen PN 60 (93.3%) participants reported pain reduction and in the placebo group, 21 (35%) reported pain reduction.</li> <li>Out of the 18 diabetic participants 94% in the Neuragen PN reported pain reduction within 30 minutes compared to 11% in placebo group.</li> <li>There was 50% maximum pain relief reported in the Neuragen PN group compared to 3% in the placebo group.</li> <li>Pain relief was statistically significant up to 8 hrs.</li> </ul>
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NGX-4010 8% Capsaicin Patch					
Forst, Pohlmann, Kunt, Goitom, Schulz, Lobig, Engelbach, Beyer, & Pfutzner (2002)	To investigate the impact of topical capsaicin cream application on small nerve fiber function and neurovascular control.	n=13 n=10 completed the study, 2 participants discontinued due to adverse events and 1 was eliminated due to inadherence to study protocol.	Pre-test Post-test experimental design.	<p>* Capsaicin applied to one foot and the participant's other foot was left untreated.</p> <p>* Total "symptom score" based on sum of four 10 point scales to assess pain, dysesthesia (abnormal sensation), hypesthesia (reduced sensation), and muscle weakness were assessed at baseline, week 4, &amp; week 8.</p> <p>* Peripheral large nerve assessment was done at the metatarsophalangeal joint of the great toe with vibration perception threshold at the measurement with biothesiometry (Vibra Tester 100, PHYWE, Gottingen, Germany).</p> <p>* Small nerve fiber function was measured by the determination of cold, heat, and pain perception threshold at the dorsum of the foot with a marstock stimulator (path-Tester, PHYE, Gottingen, Germany).</p> <p>* Blood sample obtained to measure substance P levels.</p> <p>* A laser Doppler fluxometry (LDF, MBF 3D, Moor Instruments, Devon, UK) was used to measure microvascular blood flow response to heat stimulus and acetylcholine.</p> <p>* Venous blood sample measured HbA1c.</p>	<ul style="list-style-type: none"> <li>• No change in blood sugar control as evidence by HgbA1c.</li> <li>• Total symptom score was decreased in the capsaicin-treated foot. The specific symptom improvement was for hypesthesia.</li> <li>• No adverse affects on tested sensory nerve fiber functions.</li> <li>• Blood flow response to heat stimulus revealed no significant change but in capsaicin-treated feet there was a slight decline in acetylcholine.</li> <li>• Serum P levels (a neuropeptide and functions as a neurotransmitter with peripheral pain sensation) increased significantly in the 4 week for the local capsaicin treatment and decreased in the following weeks.</li> </ul>
Webster, Peppin, Murphy, Tobias, & Vanhove (2012)	To assess safety, tolerability, and preliminary efficacy of NGX-4010, a capsaicin 8% patch, after one of three topical anesthetics.	n= 117 post-herpetic neuralgia, HIV-associated distal sensory polyneuropathy or painful diabetic neuropathy.	Randomized Control Trial	<p>* Randomized to receive pre-treatment from one of three topical anesthetic and receive a 60 or 90 minute NGX-4010 patch treatment for 12 weeks.</p> <p>* Numeric Pain Rating Scores (NPRS) for "pain now" and "average pain for the past 24hours" recorded at 9pm in a diary at baseline and from 2 to 12 weeks.</p> <p>* Patient Global Impression of Change (PGIC) and investigator-rated Clinical Global Impression of Change (CGIC) were assessed at weeks 2, 6, &amp;</p>	<ul style="list-style-type: none"> <li>• Majority of patients were white, male with PDN.</li> <li>• Average pain scores were 5.4 to 5.9 on the average Numeric Pain Rating Scale (NPRS). A 0 score signifies no pain and a 10 score signifies the worst possible pain on the NPRS.</li> <li>• At baseline, more than half of patients were receiving concurrent neuropathy treatment.</li> <li>• At least one adverse effect from pretreatment was reported by 50-59% of participants in all three</li> </ul>

				12.	<p>groups.</p> <ul style="list-style-type: none"> <li>• The “pain now” NPRS score on the day of treatment decreased after pretreatment and slightly increased after patch application.</li> <li>• Dermal irritation was minimal with a maximum dermal assessment score of 2 out of 7.</li> <li>• A 27.2%-34.3% patient reported pain reduction between weeks 2 to 12.</li> <li>• A 45%-50% of patients responded to treatment based on a <math>\geq 30\%</math> mean decrease in pain from baseline.</li> <li>• No significance in type of topical analgesic pretreatment or patch application time of 60 minutes or 90 minutes.</li> <li>• At week 12, the PGIC analysis revealed 58%-71% patients reported improvement as slightly, much, or very much and 35%-42% reported much or very much improved. Similar findings present in the CGIC.</li> </ul>
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*Acetyl-L-Carnitine*

DeGrandis & Minardi (2002)	To assess the efficacy and tolerability of acetyl-L-carnitine (Levacecarnine; LAC) versus placebo in treatment of diabetic neuropathy.	n=20 multicenter n=333 patients	Randomized, double blind, placebo controlled, parallel-group study	<p>* LAC or placebo IM 1000mg/day dose for 10 days and daily 2000mg oral dose for 355 days.</p> <p>* Nerve conduction velocity (NCV) and amplitude in sensory (ulnar, sural, and median) and motor (median, ulnar and peroneal)</p> <p>* Visual analogue scale (VAS)</p>	<ul style="list-style-type: none"> <li>• Statistical significance reported in patients treated with LAC for mean NVC and amplitude compared to placebo (p &lt;0.01).</li> <li>• The mean VAS significantly decreased after 12 months of treatment by 39% from baseline in LAC treated patients (p&lt;0.0) as compared to a decrease of 8% in placebo patients.</li> </ul>
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Other CAM and Alternative Therapies

*Transcutaneous Electrical Neuropathy Stimulation (TENS)*

Moharic & Burger (2010)	To determine whether TENS improves small fiber function diminished because of painful diabetic neuropathy.	n = 46 Painful Diabetic Neuropathy (PDN) 6 months or longer reports of neuropathic symptoms affecting primarily the lower limbs.	Experimental design	Michigan Neuropathy Screening Instrument (MNSI), Marstock method for thermal and pain threshold assessment, Thermal stimulator (TSA 2001 Thermal Sensory Analyser, Medoc Ltd, Ramat Yishai, Israel), VSA 3000 Vibratory Sensory Analyser (Medoc Ltd., Ramat Yishai, Israel), von Frey's hair (Aesthesiometer, Somedic, Sweden).	<ul style="list-style-type: none"> <li>Statistically significant.</li> <li>Thenar Cold Pain P = 0.0001 Heat Pain P = 0.0001</li> <li>TENS significantly influenced the sensory threshold with the increase of cold pain from baseline and heat pain decreased from baseline at thenar.</li> <li>TENS application to lower extremities for three hours daily for three weeks.</li> <li>Improved heat pain and cold pain thresholds in non-stimulated areas up to a month after treatment.</li> </ul>
Grossrau, Wahner, Kuschke, Konrad, Reichmann, Wiedemann, Sabatowski. (2011)	To assess the effect of micro-TENS in reducing neuropathic pain in patients with PDN.	n = 41 n = 22 Verum group n = 19 Placebo group European Diabetics with PDN	Placebo-controlled, single blinded randomized study	Standardized questionnaires (Pain Disability Index [PDI], neuropathic pain score [NPS], Center for Epidemiologic Studies Depression Scale [CES-D]) assessed pain intensity, pain disability, as well as quality of life.	<ul style="list-style-type: none"> <li>No statistical significance.</li> <li>6 out of 21 (23%) in the treatment group responded to therapy.</li> <li>10 out of 19 (25%) in the placebo group responded to therapy.</li> <li>Number of pain attacks, patients' general condition, and patients' depression score do not respond to micro - TENS.</li> <li>Before treatment and after 4 week treatment. Pain attacks/day P = &gt;0.07 Patients' general condition P = &gt;0.5 Patients' depression score P = &gt;0.3</li> </ul>
<i>Frequency-modulated Neural Stimulation (FREMS)</i>					
Bosi, Conti, Vermigli, Cazzetta, Peretti, Cordoni, Galimberti, & Scionti (2005)	To evaluate the efficacy of frequency-modulated electromagnetic neural stimulation (FREMS) as a novel treatment for painful diabetic neuropathy.	n=31 Painful diabetic neuropathy patients.	Randomized double-blind crossover study	Sequence 1 n=15 Sequence 2 n= 16 (FREMS group & Placebo group) Daytime/Night-time pain measured by 0-100 VAS, tactile sensation measured by Semmes-Wienstein monofilament test, foot vibration perception threshold measured with biothesiometer (Bio-Medical Instrument Company, Newbury, OH, USA), and motor nerve conduction velocity (MNCV) and sensory nerve conduction velocity (SNCV) measured by Micromed System 98 (Myoquick, Treviso, Italy) in Milan, and in Perugia Medlelec Premier	<ul style="list-style-type: none"> <li>FREMS significantly reduced daytime (p=0.0025) and night-time (p=0.0107) VAS pain score (all p&lt;0.02).</li> <li>FREMS significantly increased sensory tactile perception with monofilament assessment (p=0.0077), MNCV (p=0.0019) and decreased foot vibration perception threshold (p=0.0001).</li> <li>No significant changes in placebo group.</li> <li>Baseline data was not significantly different between groups.</li> <li>At the 4 month follow-up results were statistically significant in all parameters</li> </ul>

				Plus (TECA, NY, USA) was used.	(daytime pain score $p < 0.01$ , night-time pain score $p < 0.01$ , vibration perception threshold $p < 0.05$ , sensory perception assessed by monofilament $p < 0.001$ , MNCV $p < 0.05$ modified by FREMS during treatment and overall quality of life.
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## APPENDIX B

### Types of CAM (NCCAM, 2012)

CAM Group	Samples of CAM Types
Natural Products	Herbal medicine, vitamins, minerals, and probiotics.
Mind-Body Medicine	Meditation, yoga, acupuncture, deep-breathing exercising, guided imagery, hypnotherapy, progressive relaxation, qi gong, and tai chi.
Manipulative and Body-Based Practices	Spinal manipulation (chiropractic/osteopathic) and massage therapy.
Other CAM Practices	Eastern and Western Movement-based therapies (Feldenrais method, Alexander technique, pilates, rolfing structural integration, and trager pshychophysical integration), traditional healers (Native American healer/medicine man), energy fields (magnet therapy, light therapy, qi gong, Reiki, and healing touch), and whole medical systems (Ayurvedic medicine and traditional Chinese medicine).

National Center for Complementary and Alternative Medicine. What is Complementary and Alternative Medicine? 2012. Available from: <http://nccam.nih.gov/health/whatiscam> accessed July 27, 2014.

## APPENDIX C

### CAM DPNP Treatment Implications for Native Hawaiians

Theme	Implications for Native Hawaiians with DPNP
Mind-Body Medicine	Native Hawaiians practice <i>lomi</i> (massage) a form of mind-body medicine to achieve healing.
Acupuncture	Native Hawaiians may consider this useful to achieve a select therapeutic action such as pain reduction. As a method of Eastern medicine, the insertion of needles may be more acceptable.
Meditation	It is inexpensive and can be done as an individual or with others. Native Hawaiians may consider outdoor venues to meditate to support connection between mind, body, and spirit.
Natural Products	Native Hawaiians obtain natural products from the <i>'āina</i> (land) or <i>kahakai</i> (seashore) for sustenance and health maintenance.
Neuragen PN	The cost of the natural product is not mentioned and therefore could present a concern. Native Hawaiians are consumers

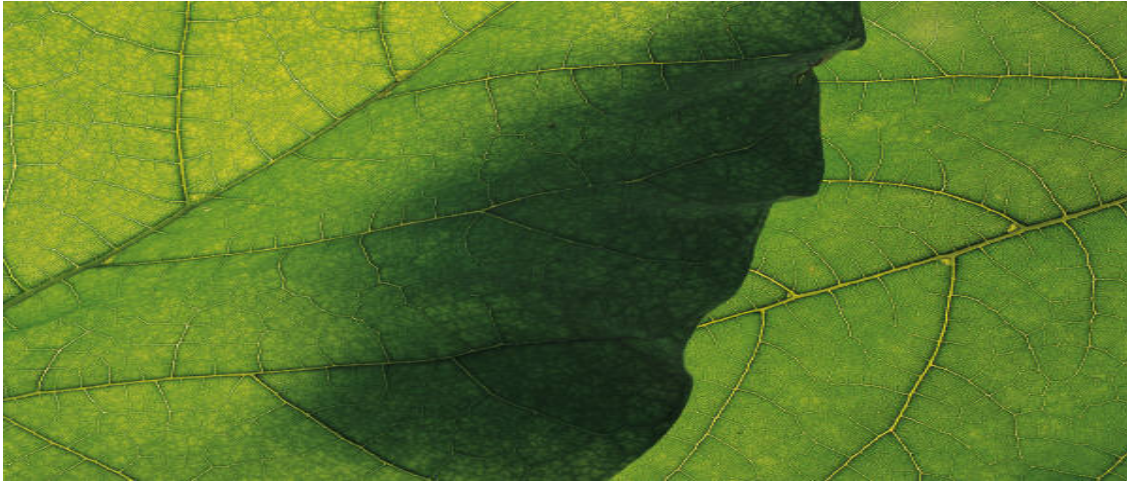
	of affordable natural products.
NGX-4010 8% Capsaicin Patch	The reports of burning sensation side effects may not be tolerable for Native Hawaiians. But, the beneficial pain reduction may outweigh the initial side effect.
Acetyl-L-Carnitine	Native Hawaiians may not prefer this method of intramuscular injections and oral doses of Acetyl-L-Carnitine. It is a natural biochemical and administered in a traditional pharmacological manner.
<b>Other CAM and Alternative Therapies</b>	Native Hawaiians may prefer holistic CAM treatments such as religious healing/prayer, vitamins/supplements, and massage/bodywork.
Transcutaneous Electrical Neuropathy (TENS)	The administration of electrical current for pain relief may not be the preferred CAM therapy for Native Hawaiians. Electricity is a Western form of therapy that may disrupt the balance between body, mind, and spirit.
Frequency-modulated Electromagnetic Neural Stimulation (FREMS)	Although this is different from TENS with sequences of modulated electrical stimuli

	<p>alterations, Native Hawaiians may not connect with these forms of CAM therapy. There is a question to cost and accessibility to FREMS treatment not presented in the literature.</p>
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## APPENDIX D

### Recruitment Brochure

## Complementary and Alternative Medicine Study



*Do you have diabetes peripheral neuropathy? You may be eligible to be a part of this study. It is voluntary, confidential, and you may withdraw at anytime from the study. There is a one time 15-30 minute meeting with a researcher.*

*Purpose: To determine how many people use Complementary and Alternative Medicine (CAM) and different types of CAM for diabetes peripheral neuropathy.*

Principle Investigator: Mahealani Suapaia, MS, RN,

If you have questions contact Queen's Medical Center, Office of Research and Development, The Queen's Medical Center 1301 Punchbowl Street, Honolulu, HI 96813, 808-691-4106 office, 808-691-7897 fax

## APPENDIX E

THE QUEEN'S MEDICAL CENTER  
HONOLULU, HAWAII

### INFORMED CONSENT TO TAKE PART IN A CLINICAL RESEARCH STUDY

Title of Study: Exploration of Complementary and Alternative Medicine Use for Management of Diabetic Peripheral Neuropathy: A Multivariate Approach

Principal Investigator: Mahealani Suapaia, MS, RN

*Address* 2528 McCarthy Mall, Webster Hall, Honolulu, Hawaii 96822

*Phone* 808-236-5829

Sub-investigator(s): Dr. Chen-Yen Wang

Sponsor: N/A.

#### INFORMED CONSENT

You are being asked to take part in this research study *because you have diabetes peripheral neuropathy*. This is a research study that will *explore the types of Complementary and Alternative Medicine used by those with diabetes peripheral neuropathy*.

Before you decide whether or not to take part in this study, you must understand the purpose, how it may help, any risks, and what you have to do. This process is called informed consent. The researcher(s) will talk with you about the study and the informed consent form. The consent also gives you information about what health information will be collected as part of the research study and how that information will be used or disclosed. Once you understand the study, and if you agree to take part, you will be asked to sign this consent form. If you sign this form you are agreeing to take part in this study and to allow the use and disclosure of your medical records and health information collected in connection with your part in this study. You will be given a **signed** copy to keep. If you do not sign this consent form, you may continue to receive care, but not as part of this study.”

Before you learn about the study, it is important that you know the following:

- Taking part in this study is of your own free will.
- You may decide not to take part in the study or stop being in the study at any time without it making any difference to your care now or in the future, or to any benefits that you are allowed.

- If the study changes in any way which could make a difference to your taking part, you will be told about the changes and may be asked to sign a new consent form.

## PURPOSE OF THE STUDY

This research study is being done to:

- 1) *Describe types of Complementary Alternative Medicine (CAM) used to manage Diabetes Peripheral Neuropathy.*

## PROCEDURES

### *Screening*

If you decide to take part in this study, you will be asked to sign this consent form.

1. You will be asked to complete three questionnaires. One of questionnaires will be a short interview. A researcher will be available to assist you with the questionnaires.

## RISKS

1. There may be a risk of psychological stress by taking part in this study.

## BENEFITS

Taking part in this study may help you feel better but no guarantee can be made and it is possible that no good response will happen. Knowledge gained from this study may help other people in the future.

## OTHER TREATMENT

You may choose to not take part in this study without it making a difference in the care that you get now or in the future.

## CONFIDENTIALITY

**Federal Privacy Regulations provide safeguards for privacy, security, and authorized access to health information.** The confidentiality of all study-related records will be kept according to all applicable laws. Information gained during this study and information known about you will be confidential (private) to the extent permitted by state and federal law. The results of this research may be presented at meetings or in publications; however, your identity will not be disclosed.

## USE AND DISCLOSURE (RELEASE) OF YOUR HEALTH INFORMATION

By signing this form you are authorizing the collection, use and release of your personal health information in medical records and diagnostic imaging and any health information gathered about you as part of this study. Your information will only be used/disclosed as described in this consent form and as permitted by state and federal laws. Your personal health information is health information about you that could be used to identify you. This information may include information about AIDS or HIV infection, treatment for alcohol and/or drug abuse, or mental health or psychiatric services.

The purposes of releasing your protected health information are to collect the data needed to complete the research, to properly monitor (watch) how the study is done, and to answer research questions related to this study.

There is no expiration date to this authorization.

Who may receive, use or release information:

Your medical records and any health information related to this study may be used or released in connection with this research study to the following:

- *Mahealani Suapaia and Dr. Chen-Yen Wang* and his/her research staff for the purposes of conducting this research study.
- The Research and Institutional Review Committee of QMC and staff members of the Research Regulatory Office for purposes of overseeing the research study and making sure that your ethical rights are being protected.
- Providers and other healthcare staff of QMC involved in your care.

Who may receive the information by the above groups:

The individuals or groups named above may release your medical records, this consent form and the information about you created by this study to:

- The sponsor of this study and their designees (*N/A*)
- Federal, state and local agencies having oversight over this research, such as The Office for Human Research Protections in the U.S. Department of Health and Human Services, Food and Drug Administration, the National Institutes of Health,
- Representatives of outside groups hired by QMC Research Department for audits to make sure studies are done as required.
- *Dr. James Davis, Biostatistician, University of Hawaii School of Medicine*
- *University of Hawai'i at Manoa*

There is a possibility that your information may be released again by the sponsor of the study or governmental agencies described above and no longer covered by federal privacy rules.

Right to Withdraw or Stop Taking Part in the Study

You may refuse to sign this authorization. If you refuse to sign the authorization, you will not be able to take part in this study. If you choose not to be in the study, or choose to withdraw from the study, or if you refuse to sign the authorization, it will not make a difference in your usual treatment, or your payment, and it will not change your eligibility for any health plan or health plan benefits that you are allowed.



If you decide to end your taking part in the study or you are removed from the study by the researcher (study doctor), you may revoke (take away) your authorization. In order to take away this authorization, you must send a letter/notice to the researcher in charge of this study. Send the written notice to the researcher to the address listed on the original consent form.

If you take away your authorization, your part in the study will end and the study staff will stop collecting medical information from you and about you. The researchers and sponsor will continue to use information that has already been collected, but no new information about you will be collected unless the information is about an adverse event (a bad side effect) related to the study or to keep the scientific integrity of the study. If an adverse event happens, we may need to review your entire medical record.

#### Access to Your Information

As is usually the case, you may see the information in your medical record; however, the records and information related only to the study are kept separately will not be available to you until the study is finished. If you wish to review your study records after the completion of the study, you should request this from the principle investigator.

#### *For Certificate of Confidentiality,*

This research study is covered under a Certificate of Confidentiality given by the Department of Health and Human Services. The Certificate protects the researchers (study doctors, and staff) from being forced to release any research information (data) in which you are identified, even under court order or subpoena, for criminal (related to a crime), administrative, or legislative proceedings. The information can be released if you or your guardian requests it in writing. This protection is not absolute. It does not, for example, apply to any state requirements to report certain communicable diseases, or to release information in cases of medical necessity. The researcher(s) must report cases of suspected child or elder abuse to the appropriate authorities.

#### COSTS

1. There is no cost to the participant.
2. Participant volunteers to take part in the study.

Any procedure or test related only to this research study and not normally be done will be explained to you, and is explained in this consent form. All costs for doctors fees, medication (including drugs to treat any side effects), laboratory tests, x-rays or scans, and hospital costs will be charged to you as if you were not part of this study. The sponsor of this study and the study doctor do not have any funding (money) to pay for any of these costs. Your insurance company may not pay for some (or all) of these tests and procedures because this is a research study. If your medical insurance does not cover any of these costs, you will be responsible for

payment. Because these costs can be very high, you should talk about the kind of insurance coverage you have with your doctor and insurance company before you decide to take part in this study. You can have financial counseling to go over your insurance coverage and get an estimate of your share of the cost.

### TREATMENT AND COMPENSATION FOR INJURY

If you are injured as a result of being in this study, you will get immediate medical care and treatment. No money will be given to patient to cover these expenses. Your medical costs will be paid by you or through medical insurance and/or other forms of medical coverage. Please contact PI Mahealani Suapaia in case of research related injury.

If you have an injury or illness (get sick) as a result of being in this study, immediate emergency medical care and treatment that may be needed will be available at the usual charge. The sponsor of the study and the study doctor do not have any funding (money) to pay for treating the injury or illness. Your insurance company may not pay for some (or all) of the treatment of the injury or illness as a result of being in this study. If your medical insurance does not pay for these medical costs, you alone will be responsible for payment. There is no way of knowing what the costs will be. You should talk about the kind of insurance coverage you have with your doctor and insurance company before you decide to take part in this study. You can have financial counseling to go over your insurance coverage.

If you are injured or become sick directly from taking part in this study, *you* will pay for the reasonable costs of medical treatment for your injuries. You must be sure to:

- 1) Talk with study doctor or the study nurse of the injury right away, and
- 2) Carefully follow all study directions.

If your illness or injury did not result from the study treatment(s) or study procedures, the study researchers will not pay for your treatment. Your insurance company may not pay for some (or all) of the treatment of the injury or illness. If your medical insurance does not pay for these medical treatments, you alone will be responsible for payment.

The Queen's Medical Center and the study researchers have not set aside any other kind of compensation (payment) for lost wages or other damages or losses resulting from any injury that you may get from taking part in this study.

### REMOVAL FROM THE STUDY

You take part in this study of your own free will. You may be taken off the study without your consent for any of the following reasons:

- Unable to follow researchers instructions.

### WHO TO CONTACT

If you feel that you have been injured as a result of taking part in this study, *Mahealani Suapaia* principle investigator, 808-236-5829.

If you have any questions about your treatment, your rights as a volunteer or any other matter relating to this study, you may call *Mahealani Suapaia* at 808-236-5829 and talk about any questions that you might have.

If you cannot get satisfactory answers to your questions or you have comments or complaints about your treatment in this study, you may contact:

Research & Institutional Review Committee  
The Queen's Medical Center  
1301 Punchbowl Street  
Honolulu, HI 96813  
Phone: (808) 691-4512

**AGREEMENT TO TAKE PART AND CERTIFICATION and AUTHORIZATION OF PROTECTED HEALTH INFORMATION -**

I, or my legally authorize representative (the legal person who cares for me) have read and understand the description of this study such as the purpose and nature of this study, its expected length, the procedures to be done, reasonably known risks and discomforts, benefits to expect, other treatments I may have, release of my medical records, payment and medical treatment for injury, and removal without my consent for this research study.

I am taking part in this study of my own free will. I may withdraw (stop taking part) and/or withdraw my authorization for use and release of protected health information at any time after signing this consent form without it making a difference to my care now or in the future or any loss of benefits that I am allowed. My consent does not take away my legal rights in case of carelessness or negligence of anyone connected with this study. My signature means that I have read the information above or that it has been read to me, my questions have been satisfactorily answered, and at any time I have other questions, I can contact the researcher listed on the first page.

**Specially Protected Health Information**

I agree to the release of the following information should it be contained in my medical records: Acquired Immune Deficiency Syndrome (AIDS or HIV), alcohol and/or drug abuse treatment, or behavioral or mental health services.

cc: **Signed copy** of consent/authorization form to patient

\_\_\_\_\_  
Subject's Name (Print)                      Subject's Signature                      Date/ Time

\_\_\_\_\_  
Witness' Name (Print)                      Witness' Signature                      Date/ Time  
(Witnessing Signature Only)                      \*\*\*\*\*

I have explained this research to the above subject. In my judgment the subject is voluntarily and knowingly giving informed consent and has the legal capacity to give informed consent to take part in this research study.

\_\_\_\_\_  
Investigator's Name (Print)                      Investigator's Signature                      Date/ Time  
(Individual obtaining Subject's consent)

(Investigator: fax a copy of this signed page to Research Regulatory Office at 691-7897 within 24 hours of signing.)

*[Please leave 2 inches at the bottom of this page blank. This is reserved for the RIRC stamping.]*

**CONSENT TO TAKE PART and AUTHORIZATION OF PROTECTED HEALTH INFORMATION - IF SUBJECT IS UNABLE TO CONSENT:**

As a legally authorized representative of the subject, my signature indicates that I have read this form, or it has been read to me, I have had the study explained to me, I have had answers to my questions, and I am satisfied with the information that I have been given. I am giving consent for the subject listed below to take part in this study and authorize the use and release of their protected health information. I can withdraw (stop taking part) and or take away the authorization for the use and release of protected health information at any time after signing this for without it making a difference to the subject's care now or in the future or any loss of benefits that I am allowed. My consent does not take away legal rights in care of carelessness or negligence of anyone connected with this study. I will be given a signed copy of this consent form.

Specially Protected Health Information

I agree to the release of the following information if it is in the subject's medical records: Acquired Immune Deficiency Syndrome (AIDS or HIV), alcohol and/or drug abuse treatment, or behavioral or mental health services.

\_\_\_\_\_ is not able to consent  
Name of the Subject (print)

\_\_\_\_\_  
Name of Legal Representative (print)  
Representative

\_\_\_\_\_  
Signature of Legal Representative

\_\_\_\_\_  
Description of legal authority to act on behalf of subject

\_\_\_\_\_  
Date/ Time

\_\_\_\_\_  
Witness' Name (Print)  
(Witnessing signature only)

\_\_\_\_\_  
Witness' Signature

\_\_\_\_\_  
Date/ Time

\*\*\*\*\*

Based on my clinical judgment, this subject is not able or is incompetent to independently consent to participate in this research study.

\_\_\_\_\_  
Investigator's Name (Print)

\_\_\_\_\_  
Investigator's Signature

\_\_\_\_\_  
Date/ Time

(Individual obtaining the Legally Authorized Representative's consent)

(Investigator: Fax a copy of this signed page to Research Regulatory Office at 691-7897 within 24 hours of signing.)

*[Please leave 2 inches at the bottom of this page blank. This is reserved for the RIRC stamping.]*

## **Addendum to Consent Form**

### **Authorization to Use and Release Personal Health Information (PHI) for**

Researchers/Investigators/Study Doctor: *Mahealani Suapaia, MS, RN and Dr. Chen-Yen Wang*

Study Title: Exploration of Complementary and Alternative Medicine Use for Management of Diabetic Peripheral Neuropathy: A Multivariate Approach

The federal government has created a new privacy rule called the Health Insurance Portability and Accountability Act of 1996 (HIPAA). It gives you the right to decide who can use and release your personal health information (also called “protected health information” or PHI). This form, called an “Authorization”, explains your rights and how your health information will be used and released for this study.

#### Description and purpose of information to be released:

By signing this form, you will be allowing or “authorizing” the use and release of your personal health information in medical records and diagnostic imaging and any health information gathered about you at as part of this study. Your personal health information is health information about you that could be used to identify you. This information may include information about AIDS or HIV infection, venereal disease, treatment for alcohol and/or drug abuse, or mental health or psychiatric services.

The purposes of releasing your protected health information are to collect the data needed to complete the research, to properly monitor (watch) how the study is done, and to answer research questions related to this study.

#### Who may receive, use or release information:

Your medical records and any health information related to this study may be used or released in connection with this research study to the following:

- *Mahealani Suapaia, MS, RN and Dr. Chen-Yen Wang* and his/her research staff for the purposes of conducting this research study.
- The Research and Institutional Review Committee of QMC and staff members of the Research Regulatory Office for purposes of overseeing the research study and making sure that your ethical rights are being protected.
- Providers and other healthcare staff of QMC involved in your care.

#### Who may receive the information by the above groups:

The individuals or groups named above may release your medical records, this consent form and the information about you created by this study to:

- The sponsor of this study and their designees (*N/A*)
- Federal, state and local agencies having oversight over this research, such as The Office for Human Research Protections in the U.S. Department of Health and Human Services, Food and Drug Administration, the National Institutes of Health,

- *Dr. James Davis, University of Hawaii at Manoa John A. Burns School of Medicine Biostatistician.*

There is a possibility that your information may be released again by the sponsor of the study or governmental agencies described above and no longer covered by federal privacy rules.

You will not be identified by name in any published reports, or scientific publications, or meetings.

#### Right to Withdraw or Stop Taking Part in the Study

You may refuse to sign this authorization. If you refuse to sign the authorization, you will not be able to take part in this study. If you choose not to be in the study or if you refuse to sign the authorization, it will not make a difference in your usual treatment, or your payment, and it will not change your eligibility for any health plan or health plan benefits that you are allowed.

If you decide to end your taking part in the study or you are removed from the study by the researcher (study doctor), you may revoke (take away) your authorization. In order to take away this authorization, you must send a letter/notice to the researcher in charge of this study. Send the written notice to the researcher to the address listed on the original consent form.

If you take away your authorization, your part in the study will end and the study staff will stop collecting medical information from you and about you. The researchers and sponsor will continue to use information that has already been collected, but no new information about you will be collected unless the information is about an adverse event (a bad side effect) related to the study or to keep the scientific integrity of the study. If an adverse event happens, we may need to review your entire medical record.

#### Access to Your Information

You may not be allowed to see or get copies of certain information in your medical records collected as part of this research study while the research is going on. Once the research is completed, you will be able to access or get copies of the information.

There is no expiration date to this authorization.

You will get a signed copy of this consent form to keep.

\_\_\_\_\_  
Subject's Name (Print)                      Subject's Signature                      Date/ Time

**If subject unable to sign:**

\_\_\_\_\_  
Representative's Name (Print)      Representative's Signature      Date/ Time  
*If signed by a personal representative of the subject, a description of the representative's legal authority to act on behalf of the subject must be stated below:*

\_\_\_\_\_

\_\_\_\_\_  
Witness' Name (Print)                      Witness' Signature                      Date/ Time  
\*\*\*\*\*

I have explained this authorization to the above subject. In my judgment the subject is voluntarily and knowingly giving authorization and has the legal capacity to give authorization to take part in this research study.

\_\_\_\_\_  
Investigator's Name (Print)              Investigator's Signature              Date/ Time  
(Individual obtaining Subject's consent)

\_\_\_\_\_  
Translator's Name (if appropriate)      Translator's Signature              Date/ Time  
(Print)



## APPENDIX F

### Hsiao-Yun Annie Chang CAM Use Survey Instrument Interview schedule

Thank you for participating in this research. This research is to understand your experience of diabetes and your usage of complementary and alternative medicine (CAM). There is no right or wrong answer. The information that you provide is very valuable which will become a reference for when we care for patients with diabetes. Any information obtained will be kept strictly confidential and your name will not be associated with it. I'll expect the interview to take about 20 minutes to complete. Have you got any question you would like to ask before I start this interview survey?

Now I'd like to begin by asking you some general questions about your diabetes.

#### A. Clinical information

<b>1</b>	<b>How long have you had diabetes?</b>	_____ months or _____ yrs	
<b>2.</b>	<b>Do you have any one in your family and relative who has diabetes?</b>	<input type="checkbox"/> <sub>0</sub> No <input type="checkbox"/> <sub>1</sub> Parents/Grandparents <input type="checkbox"/> <sub>2</sub> Brothers or sisters <input type="checkbox"/> <sub>3</sub> Relatives <input type="checkbox"/> <sub>4</sub> Sons or daughters <input type="checkbox"/> <sub>5</sub> Other_____	
<b>3.</b>	<b>Approximately, how many times have you visited DM clinics during the past year?</b>	<input type="checkbox"/> <sub>0</sub> At least fortnightly <input type="checkbox"/> <sub>1</sub> At least monthly <input type="checkbox"/> <sub>2</sub> At least 3 month <input type="checkbox"/> <sub>3</sub> At least yearly <input type="checkbox"/> <sub>4</sub> Other_____	
<b>4.</b>	<b>Have you been hospitalised due to diabetes condition during the last years?</b>	<input type="checkbox"/> <sub>0</sub> No <input type="checkbox"/> Yes→ How many times? _____(used as data)	
<b>5.</b>	<b>How good do you feel is your health condition?</b>	<input type="checkbox"/> <sub>0</sub> Very poor <input type="checkbox"/> <sub>1</sub> Poor <input type="checkbox"/> <sub>2</sub> Good <input type="checkbox"/> <sub>3</sub> Very good	
<b>6.</b>	<b>What current treatment for DM has been prescribed or suggested by your physician?</b>	<input type="checkbox"/> <sub>6.1</sub> Diet +Exercise	<b>How many...?</b>
<input type="checkbox"/> <sub>6.2</sub> Oral agent		<input type="checkbox"/> <sub>6.21</sub> _____tablets/per day	
<input type="checkbox"/> <sub>6.3</sub> Insulin injection		<input type="checkbox"/> <sub>6.31</sub> _____ units/ per day	

		<input type="checkbox"/> <sub>6.4</sub> Other: _____
<b>5.</b>	<b>Have you ever attended a diabetes education program?</b> Yes→ What kind of education?	<input type="checkbox"/> <sub>0</sub> No <input type="checkbox"/> Yes→ <input type="checkbox"/> <sub>1</sub> One to one education <input type="checkbox"/> <sub>2</sub> Lecture education <input type="checkbox"/> <sub>3</sub> Self-education <input type="checkbox"/> <sub>4</sub> Other _____

Now I am going to run through a list of medicines and therapies. I would like you to tell me whether you have ever used these medicines and therapies before you were diagnosed with Type 2 diabetes, or after you were diagnosed with Type 2 diabetes, and during the past 12 months? *(Please tick the box if participants have been used)*

#### D. CAM checklist

Have you ever used	Before diabetes	After diagnosis	12Ms	Why did you use? (28.3-41.3)
<b>28</b> • <b>Nutritional supplements</b> (multivitamins, fish oil, glucosamine, chromium)	28	28.1	28.2	<input type="checkbox"/> <sub>0</sub> For diabetes <input type="checkbox"/> <sub>1</sub> For DM's complications <input type="checkbox"/> <sub>2</sub> For non-DM specific
<b>29</b> • <b>Diet modification</b> (organic food, special food design, body cleansing diet, macrobiotic diet)	29	29.1	29.2	<input type="checkbox"/> <sub>0</sub> For diabetes <input type="checkbox"/> <sub>1</sub> For DM's complications <input type="checkbox"/> <sub>2</sub> For non-DM specific
<b>30</b> • <b>Chinese herbal medicines</b> (Ginseng, Limzig )	30	30.1	30.2	<input type="checkbox"/> <sub>0</sub> For diabetes <input type="checkbox"/> <sub>1</sub> For DM's complications <input type="checkbox"/> <sub>2</sub> For non-DM specific
<b>31</b> • <b>Acupuncture</b> (acupressure)	31	31.1	31.2	<input type="checkbox"/> <sub>0</sub> For diabetes <input type="checkbox"/> <sub>1</sub> For DM's complications <input type="checkbox"/> <sub>2</sub> For non-DM specific
<b>32</b> • <b>Cupping, Scraping</b> (Gua-sa)	32	32.1	32.2	<input type="checkbox"/> <sub>0</sub> For diabetes <input type="checkbox"/> <sub>1</sub> For DM's complications <input type="checkbox"/> <sub>2</sub> For non-DM specific
<b>33</b> • <b>Manipulative based therapy</b> (chiropractic, osteopathic, kneading (Tui-an))	33	33.1	33.2	<input type="checkbox"/> <sub>0</sub> For diabetes <input type="checkbox"/> <sub>1</sub> For DM's complications <input type="checkbox"/> <sub>2</sub> For non-DM specific
<b>34</b> • <b>Folk therapies</b> (Knife therapy, water therapy, fire therapy)	34	34.1	34.2	<input type="checkbox"/> <sub>0</sub> For diabetes <input type="checkbox"/> <sub>1</sub> For DM's complications <input type="checkbox"/> <sub>2</sub> For non-DM specific
<b>35</b> • <b>Biofield therapy</b> (Kinesiology, Reiki, Tai chi, Gi gong)	35	35.1	35.2	<input type="checkbox"/> <sub>0</sub> For diabetes <input type="checkbox"/> <sub>1</sub> For DM's complications <input type="checkbox"/> <sub>2</sub> For non-DM specific

Have you ever used		Before diabetes	After diagnosis	12Ms	Why did you use? (28.3-41.3)
36	<b>Supernatural healing</b> (Absorption frighten, God healing, divination, change name)	36	36.1	36.2	<input type="checkbox"/> <sub>0</sub> For diabetes <input type="checkbox"/> <sub>1</sub> For DM's complications <input type="checkbox"/> <sub>2</sub> For non-DM specific
37	<b>Bioelectromagnetic-based therapies</b> (Electrotherapy, Polarity, Magnetic therapy)	37	37.1	37.2	<input type="checkbox"/> <sub>0</sub> For diabetes <input type="checkbox"/> <sub>1</sub> For DM's complications <input type="checkbox"/> <sub>2</sub> For non-DM specific
38	<b>Western herbal medicine</b> (bilberry, bitter melon, opuntia, fenugreek seed, and aloe)	38	38.1	38.2	<input type="checkbox"/> <sub>0</sub> For diabetes <input type="checkbox"/> <sub>1</sub> For DM's complications <input type="checkbox"/> <sub>2</sub> For non-DM specific
39	<b>Aromatherapy</b> (essential oil)	39	39.1	39.2	<input type="checkbox"/> <sub>0</sub> For diabetes <input type="checkbox"/> <sub>1</sub> For DM's complications <input type="checkbox"/> <sub>2</sub> For non-DM specific
40	<b>Mind-body therapy</b> (Meditation, yoga, hypnosis)	40	40.1	40.2	<input type="checkbox"/> <sub>0</sub> For diabetes <input type="checkbox"/> <sub>1</sub> For DM's complications <input type="checkbox"/> <sub>2</sub> For non-DM specific
41	<b>Homeopathy</b> (homeopathic medicine)	41	41.1	41.2	<input type="checkbox"/> <sub>0</sub> For diabetes <input type="checkbox"/> <sub>1</sub> For DM's complications <input type="checkbox"/> <sub>2</sub> For non-DM specific

Now I am going to run through a list of variety of CAM practitioners. I would like you to tell me whether you have ever consulted any of those practitioners before you were diagnosed with Type 2 diabetes, or after you were diagnosed with Type 2 diabetes, and during the past 12 months? *(Please tick the box if participants have been used)*

#### E. A checklist of CAM practitioners

Have you ever seen a		Before diabetes	After diabetes	12Ms	Why? (42.3-46.3)
42	<b>Traditional Chinese medicine practitioner</b>	42	42.1	42.2	<input type="checkbox"/> <sub>0</sub> For diabetes <input type="checkbox"/> <sub>1</sub> For DM's complications <input type="checkbox"/> <sub>2</sub> For non-DM specific
43	<b>Chiropractor</b>	43	43.1	43.2	<input type="checkbox"/> <sub>0</sub> For diabetes <input type="checkbox"/> <sub>1</sub> For DM's complications <input type="checkbox"/> <sub>2</sub> For non-DM specific
44	<b>Herbalist</b>	44	44.1	44.2	<input type="checkbox"/> <sub>0</sub> For diabetes <input type="checkbox"/> <sub>1</sub> For DM's complications <input type="checkbox"/> <sub>2</sub> For non-DM specific
45	<b>Religious healer</b>	45	45.1	45.2	<input type="checkbox"/> <sub>0</sub> For diabetes <input type="checkbox"/> <sub>1</sub> For DM's complications

Have you ever seen a		Before diabetes	After diabetes	12Ms	Why? (42.3-46.3)
	/Psychic healer				<input type="checkbox"/> <sub>2</sub> For non-DM specific
46	Naturopath practitioner	46	46.1	46.2	<input type="checkbox"/> <sub>0</sub> For diabetes <input type="checkbox"/> <sub>1</sub> For DM's complications <input type="checkbox"/> <sub>2</sub> For non-DM specific

Except for the therapies just mentioned, have you used any others, please feel free to let me know. It is very important to me to have all the information. For example, urine therapy, colon irrigation. *(Please fill the therapy in the next page)*

Have you ever seen		Before diabetes	After diabetes	12Ms	Why you used it?
					<input type="checkbox"/> <sub>1</sub> For diabetes <input type="checkbox"/> <sub>2</sub> For DM's complications <input type="checkbox"/> <sub>3</sub> For non-DM specific
					<input type="checkbox"/> <sub>1</sub> For diabetes <input type="checkbox"/> <sub>2</sub> For DM's complications <input type="checkbox"/> <sub>3</sub> For non-DM specific
					<input type="checkbox"/> <sub>1</sub> For diabetes <input type="checkbox"/> <sub>2</sub> For DM's complications <input type="checkbox"/> <sub>3</sub> For non-DM specific
					<input type="checkbox"/> <sub>1</sub> For diabetes <input type="checkbox"/> <sub>2</sub> For DM's complications <input type="checkbox"/> <sub>3</sub> For non-DM specific
					<input type="checkbox"/> <sub>1</sub> For diabetes <input type="checkbox"/> <sub>2</sub> For DM's complications <input type="checkbox"/> <sub>3</sub> For non-DM specific

Now I'd like to know why you never use CAM or why you stop using CAM to help you control of your diabetes. The answer is either yes or no.

#### F. The reasons for not using CAM or stopping the use of CAM

You did not use CAMs because you		
47.	Never heard of them	<sub>0</sub> No <sub>1</sub> Yes
48.	Do not know where to purchase CAM (Not available in my area)	<sub>0</sub> No <sub>1</sub> Yes
49.	My health care professionals are opposed to my use of complementary and alternative medicine	<sub>0</sub> No <sub>1</sub> Yes
50.	Do not want to mix up anything with your Western medicine	<sub>0</sub> No <sub>1</sub> Yes
51.	Do not think that they really work	<sub>0</sub> No <sub>1</sub> Yes

<b>52.</b>	<b>Have heard of stories that CAM is not good for you</b>	<b>0No</b>	<b>1Yes</b>
<b>53.</b>	<b>Worried about negative side-effects</b>	<b>0No</b>	<b>1Yes</b>
<b>55.</b>	<b>Feel they are harmful</b>	<b>0No</b>	<b>1Yes</b>
<b>56.</b>	<b>Feel they are too expensive</b>	<b>0No</b>	<b>1Yes</b>
<b>57</b>	<b>Dissatisfied with them</b>	<b>0No</b>	<b>1Yes</b>

**Other:** \_\_\_\_\_

If patient never use CAMs, please go to page 7 and question 78.

Next I'd like to understand your experience of CAM use. The questions are an important part of the study, so please answer as accurately as you can.

**H. CAM survey**

58.	<b>What is the most important reason that made you start to use CAM?</b>	<input type="checkbox"/> <sub>1.1</sub> Dissatisfaction with Western medicine <input type="checkbox"/> <sub>1.2</sub> Believe CAMs are safer than Western medicine(fewer side-effects) <input type="checkbox"/> <sub>1.3</sub> People around you believe in CAM treatment <input type="checkbox"/> <sub>1.4</sub> CAM is consistent with my culture <input type="checkbox"/> <sub>1.5</sub> Believe in CAM for the treatment of diabetes <input type="checkbox"/> <sub>1.6</sub> Recommended by health care professionals <input type="checkbox"/> <sub>1.7</sub> Other: _____					
<b>From where did you get the information regarding CAM use? (Please tick the box )</b>							
59.	<b>Partner&amp; Family</b>	0No	1Yes	60.	<b>Friends</b>	0N o	1Yes
61.	<b>Physician</b>	0No	1Yes	62.	<b>Pharmacist</b>	0N o	1Yes
63.	<b>Nurse</b>	0No	1Yes	64.	<b>Media, Newspaper, Magazine</b>	0N o	1Yes
65.	<b>Medical book or research journal</b>	0No	1Yes	66.	<b>CAM Practitioners</b>	0N o	1Yes
Others:							
67	<b>Do you know the ingredients of your herbal medicine when you used it?</b>	<input type="checkbox"/> <sub>0</sub> Know it. <input type="checkbox"/> <sub>1</sub> Completely unknown <input type="checkbox"/> <sub>2</sub> Unknown, but it was from CAM practitioner <input type="checkbox"/> <sub>3</sub> Unknown, but it shown on the can <input type="checkbox"/> <sub>4</sub> Other: _____					
68	<b>Who mostly decides what type of CAM that you should use? It is :</b>	<input type="checkbox"/> <sub>0</sub> Your decision <input type="checkbox"/> <sub>1</sub> Your family's decision <input type="checkbox"/> <sub>2</sub> Your friend's decision <input type="checkbox"/> <sub>3</sub> Your CAM practitioner decision <input type="checkbox"/> <sub>4</sub> Other: _____					
70.	<b>How do you use your Western medication when you are using CAM?</b>	<input type="checkbox"/> <sub>0</sub> No change <input type="checkbox"/> <sub>1</sub> Use separately and use at different times <input type="checkbox"/> <sub>2</sub> Reduce the dose of Western medicines <input type="checkbox"/> <sub>3</sub> Stopped Western medicines					

		<input type="checkbox"/> <sub>4</sub> Others
<b>69.</b>	<b>Approximately, how much money have you paid for CAM (in general per month)?</b>	<input type="checkbox"/> <sub>0</sub> \$ under 500 <input type="checkbox"/> <sub>1</sub> \$501-1000 <input type="checkbox"/> <sub>2</sub> \$1001-1500 <input type="checkbox"/> <sub>3</sub> \$1501-2000 <input type="checkbox"/> <sub>4</sub> More than \$ _____
<b>71.</b>	<b>Have you told your doctor or nurse about your use of CAM?</b>	<input type="checkbox"/> <sub>0</sub> Yes → Go to Q 71 <input type="checkbox"/> <sub>1</sub> No → Go to Q 72 <input type="checkbox"/> <sub>2</sub> Did not use Western medicine at that time.
<b>72.</b>	<b>What was the advice of the health care professional after you discussed about CAM use?</b>	<input type="checkbox"/> <sub>0</sub> Encourages you to take it <input type="checkbox"/> <sub>1</sub> Discourages you from taking it <input type="checkbox"/> <sub>2</sub> Feels it's entirely up to me; has no strong feeling about it <input type="checkbox"/> <sub>3</sub> Warns you of possible side-effects regarding CAM use <input type="checkbox"/> <sub>4</sub> Warns you that some may interfere with your regular treatment <input type="checkbox"/> <sub>5</sub> Other : _____
<b>The following statements give possible reasons for the fact that you may not discuss CAM use with your health care professionals. The answer is either yes or no.</b>		
<b>73.</b>	<b>I never think of it</b>	<input type="checkbox"/> <sub>0</sub> No <input type="checkbox"/> <sub>1</sub> Yes
<b>74.</b>	<b>Health care professionals did not ask it</b>	<input type="checkbox"/> <sub>0</sub> No <input type="checkbox"/> <sub>1</sub> Yes
<b>75.</b>	<b>I think that there was not sufficient time to discuss</b>	<input type="checkbox"/> <sub>0</sub> No <input type="checkbox"/> <sub>1</sub> Yes
<b>76.</b>	<b>I think it is safe, thus there is no need to discuss</b>	<input type="checkbox"/> <sub>0</sub> No <input type="checkbox"/> <sub>1</sub> Yes
<b>77.</b>	<b>I think that the health care professionals would discourage CAM use</b>	<input type="checkbox"/> <sub>0</sub> No <input type="checkbox"/> <sub>1</sub> Yes
<b>78</b>	<b>I think that the health care professionals do not have adequate knowledge of CAM therapies</b>	<input type="checkbox"/> <sub>0</sub> No <input type="checkbox"/> <sub>1</sub> Yes
	<b>Others:</b> _____	

We are almost finished with the interview. In the final part, I'd like to ask you some general questions about yourself.

**P. Demographic variable**

<b>124</b>	<b>Sex</b>	<input type="checkbox"/> <sub>0</sub> Male <input type="checkbox"/> <sub>1</sub> Female
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125.	<b>How old are you?</b>	_____yrs.
126.	<b>What is your highest level of education?</b>	<input type="checkbox"/> <sub>0</sub> No schooling <input type="checkbox"/> <sub>1</sub> Elementary school <input type="checkbox"/> <sub>2</sub> Middle school <input type="checkbox"/> <sub>3</sub> High school <input type="checkbox"/> <sub>4</sub> Bachelor degree <input type="checkbox"/> <sub>5</sub> Graduate school
127.	<b>What is your martial status?</b>	<input type="checkbox"/> <sub>0</sub> Married (Living with a partner) <input type="checkbox"/> <sub>1</sub> Single (never married) <input type="checkbox"/> <sub>2</sub> Widowed <input type="checkbox"/> <sub>3</sub> Separated (Divorced)
128.	<b>What statement best describes your employment status?</b>	<input type="checkbox"/> <sub>0</sub> Full-time <input type="checkbox"/> <sub>1</sub> Part-time <input type="checkbox"/> <sub>2</sub> Homemaker (working at home) <input type="checkbox"/> <sub>3</sub> Retired <input type="checkbox"/> <sub>4</sub> Not working <input type="checkbox"/> <sub>5</sub> Other_____
129.	<b>Do you have religious/spiritual beliefs?</b>	<input type="checkbox"/> <sub>0</sub> No <input type="checkbox"/> <sub>1</sub> Yes
130.	<b>What is your race?</b>	<input type="checkbox"/> <sub>0</sub> Native Hawaiian <input type="checkbox"/> <sub>1</sub> Part-Hawaiian <input type="checkbox"/> <sub>2</sub> Other Pacific Islander <input type="checkbox"/> <sub>3</sub> Asian <input type="checkbox"/> <sub>4</sub> Other_____
131.	<b>Do you live with others?</b>	<input type="checkbox"/> <sub>0</sub> No <input type="checkbox"/> <sub>1</sub> Yes
132.	<b>How much is your total household income monthly?</b>	<input type="checkbox"/> <sub>0</sub> \$ under 1200 <input type="checkbox"/> <sub>1</sub> \$1200-2400 <input type="checkbox"/> <sub>2</sub> \$2401-3600 <input type="checkbox"/> <sub>3</sub> \$3601-4800 <input type="checkbox"/> <sub>4</sub> more than \$4800
133.	<b>Do you have health insurance?</b>	<input type="checkbox"/> <sub>0</sub> No <input type="checkbox"/> <sub>1</sub> Yes



This completes our interview. Thank you for taking the time to answer these questions. Do you have any comments you would like to add?

Thank you for taking the time to complete this questionnaire. Your opinion is highly valued.

Chang, H.-Y.A., Wallis, M., & Tiralongo, (2011). Use of complementary and alternative medicine among people with type-2 diabetes in Taiwan: A cross-sectional survey. *Evidence Based Complementary and Alternative Medicine*, Article ID 983792.

APPENDIX G

**36-Item Short Form Survey Instrument**

Circle one number for questions below:

1. In general, would you say your health is:	
Excellent	1
Very good	2
Good	3
Fair	4
Poor	5

2. <b>Compared to one year ago,</b> how would you rate your health in general <b>now?</b>	
Much better now than one year ago	1
Somewhat better now than one year ago	2
About the same	3
Somewhat worse now than one year ago	4
Much worse now than one year ago	5

The following items are about activities you might do during a typical day. Does **your health now limit you** in these activities? If so, how much?

(Circle One Number on Each Line)

	Yes, Limited a Lot	Yes, Limited a Little	No, Not limited at All
3. <b>Vigorous activities</b> , such as running, lifting heavy objects, participating in strenuous sports	[1]	[2]	[3]
4. <b>Moderate activities</b> , such as moving a table, pushing a vacuum cleaner, bowling, or playing golf	[1]	[2]	[3]
5. Lifting or carrying groceries	[1]	[2]	[3]
6. Climbing <b>several</b> flights of stairs	[1]	[2]	[3]
7. Climbing <b>one</b> flight of stairs	[1]	[2]	[3]
8. Bending, kneeling, or stooping	[1]	[2]	[3]
9. Walking <b>more than a mile</b>	[1]	[2]	[3]
10. Walking <b>several blocks</b>	[1]	[2]	[3]
11. Walking <b>one block</b>	[1]	[2]	[3]
12. Bathing or dressing yourself	[1]	[2]	[3]

During the **past 4 weeks**, have you had any of the following problems with your work or other regular daily activities **as a result of your physical health**?

**(Circle One Number on Each Line)**

	Yes	No
13. Cut down the amount of time you spent on work or other activities	1	2
14. <b>Accomplished less</b> than you would like	1	2
15. Were limited in the <b>kind</b> of work or other activities	1	2
16. Had <b>difficulty</b> performing the work or other activities (for example, it took extra effort)	1	2

During the **past 4 weeks**, have you had any of the following problems with your work or other regular daily activities **as a result of any emotional problems** (such as feeling depressed or anxious)?

**(Circle One Number on Each Line)**

	Yes	No
17. Cut down the <b>amount of time</b> you spent on work or other activities	1	2
18. <b>Accomplished less</b> than you would like	1	2
19. Didn't do work or other activities as <b>carefully</b> as usual	1	2

20. During the **past 4 weeks**, to what extent has your physical health or emotional problems interfered with your normal social activities with family, friends, neighbors, or groups?

**(Circle One Number)**

Not at all 1

Slightly 2

Moderately 3

Quite a bit 4

Extremely 5

21. How much **bodily** pain have you had during the **past 4 weeks**?

**(Circle One Number)**

None 1 Very mild 2 Mild 3 Moderate 4 Severe 5 Very severe 6

22. During the **past 4 weeks**, how much did **pain** interfere with your normal work (including both work outside the home and housework)?

**(Circle One Number)**

Not at all 1 A little bit 2 Moderately 3 Quite a bit 4 Extremely 5

These questions are about how you feel and how things have been with you **during the past 4 weeks**. For each question, please give the one answer that comes closest to the way you have been feeling.

How much of the time during the **past 4 weeks** . . . **(Circle One Number on Each Line)**

	All of the Time	Most of the Time	A Good Bit of the Time	Some of the Time	A Little of the Time	None of the Time
23. Did you feel full of pep?	1	2	3	4	5	6
24. Have you been a very nervous person?	1	2	3	4	5	6

25. Have you felt so down in the dumps that nothing could cheer you up?	1	2	3	4	5	6
26. Have you felt calm and peaceful?	1	2	3	4	5	6
27. Did you have a lot of energy?	1	2	3	4	5	6
28. Have you felt downhearted and blue?	1	2	3	4	5	6
29. Did you feel worn out?	1	2	3	4	5	6
30. Have you been a happy person?	1	2	3	4	5	6
31. Did you feel tired?	1	2	3	4	5	6

32. During the **past 4 weeks**, how much of the time has your **physical health or emotional problems** interfered with your social activities (like visiting with friends, relatives, etc.)?

**(Circle One Number)**

All of the time 1

Most of the time 2

Some of the time 3

A little of the time 4

None of the time 5

How TRUE or FALSE is each of the following statements for you.

**(Circle One Number on Each Line)**

	Definitely True	Mostly True	Don't Know	Mostly False	Definitely False
33. I seem to get sick a little easier than other people	1	2	3	4	5
34. I am as healthy as anybody I know	1	2	3	4	5
35. I expect my health to get worse	1	2	3	4	5
36. My health is excellent	1	2	3	4	5

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SAMPLE: Letter of Agreement with other Departments

Chairman  
Research and Institution Review Committee  
The Queen's Medical Center  
1301 Punchbowl Street  
Honolulu, Hawaii 96813

Re: Research study entitled:  
Exploration of Complementary and Alternative Medicine  
Use for Management of Diabetic Peripheral Neuropathy: A  
Multivariate Approach

Dear Chairman:

This letter is to verify that I have discussed the above research project with each applicable department (e.g. Pharmacy, Diagnostic Laboratory Services, Imaging, etc.) at The Queen's Medical Center.

Janet Onsgaard authorized representative from REC Department at The Queen's Medical Center, agrees that we can perform this study as outlined in the research protocol and Form 3 of the Research Application.

Janet Onsgaard MD  
Signature of OMC department representative

10/14/14  
Date

Michael Siegel  
Signature of Principal Investigator

10/14/14  
Date

*Dr Onsgaard recommends PI calling  
DINP before they come in to REC  
and ask to meet with them after  
REC appointment.*

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