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# Adventist Affiliation and Type 2 Diabetes Pre- and Post-Complete Health Improvement Program (CHIP)

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# Walden University

College of Health Sciences

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Janie Unruh

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Walden University  
2016

Dissertation

Adventist Affiliation and Type 2 Diabetes

Pre- and Post-Complete Health Improvement Program (CHIP)

by

Janie Unruh

MA, Loma Linda University, 2007

BS, California State University, 1994

Dissertation Submitted in Partial Fulfillment

of the Requirements for the Degree of

Doctor of Philosophy

Public Health

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## Abstract

Adventists following a plant-based diet have half the prevalence and incidence of type 2 diabetes than nonvegetarian Adventists. This study used a quantitative, correlational study design to assess if there was a significant difference in type 2 diabetes prevalence rate between Adventists and non-Adventists preprogram, and if there were significant differences in biometrics between Adventists and non-Adventists with diabetes pre- and post-Complete Health Improvement Program (CHIP). This study incorporated the social ecological model for its conceptual framework and examined pre- and postprogram changes among Adventists ( $n=210$ ; 20.1%) and non-Adventists ( $n=836$ ; 79.9%) with type 2 diabetes. It used secondary data from participants in the volunteer-delivered CHIP intervention from 2006 to 2012 ( $n=7,172$ ), a whole foods, plant-based, vegan health program. Analysis showed a significant difference in the pre-CHIP diabetic state between the two groups in step one, but not after controlling for covariates in step two ( $OR=0.96$  and  $0.91$ ;  $CI=1.21$  and  $1.24$ ). A repeated measures MANOVA analysis indicated that religious affiliation (Adventist or non-Adventist) was the determining factor in improved biometric outcomes pre- and post-CHIP for TC ( $F(1) = 5.65$ ;  $p = 0.02$ ), and LDL ( $F(1) = 5.76$ ;  $p = 0.02$ ) but not for HDL ( $F(1) = 0.00$ ;  $p = 0.99$ ), TG ( $F(1) = 0.19$ ,  $p = 0.67$ ), FPG ( $F(1) = 2.71$ ,  $p = 0.10$ ), SBP ( $F(1) = 2.25$ ;  $p = 0.13$ ), DBP ( $F(1) = 1.20$ ;  $p = 0.27$ ), and BMI ( $F(1) = 1.65$ ;  $p = 0.20$ ). However, both groups improved post-CHIP in all biometrics. The implications for positive social change from this study showed that CHIP is an effective lifestyle model for improving type 2 diabetes outcomes for both Adventists and non-Adventists, a model that does not involve the use of pharmaceuticals.

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## Dedication

This research is dedicated to all my early on, past patients with diabetes who repeatedly asked a version of the question, “You really expect me to weigh and measure my food, and count carbs every meal of every day for the rest of my life? Isn’t there another way?” You encouraged me to search for another way for those who followed in your footsteps in my diabetes education classes. When I found another way, through a whole-food, plant-based, vegan diet, without carbohydrate counting or limiting caloric intake, your successors embraced it and excelled. Thank you for the challenge; it changed my life and theirs.

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## Chapter 1: Introduction to the Study

### **Introduction**

The two main types of diabetes are type 1, formerly referred to as insulin-dependent diabetes or juvenile diabetes, and type 2, formerly referred to as adult-onset diabetes. Type 1 diabetes is characterized by an absolute deficiency of insulin, and type 2 is characterized by insulin resistance and a progressive deficiency in insulin production (ADA, 2016). Type 1 diabetes accounts for 5-10% of all diabetes cases, and type 2 diabetes accounts for 90-95% (ADA, 2016). In 2009, 191,986 (0.25%) youth in the United States aged 0 to 19 years had diabetes, with 20,262 of those youth having type 2 (Pettitt et al., 2014); this number is expected to quadruple by 2050 (Imperatore et al., 2012). Prevalence is significantly higher in U.S. adults: 29.1 million (9.3%) have type 2 diabetes and 1.7 million acquire it annually (ADA, 2013). Previous research has suggested an association between improved glycemic control and biometrics after switching to a vegetarian diet (Barnard, Katcher, Jenkins, Cohen, & Turner-McGrievy, 2009; Yokoyama, Barnard, Levin, & Watanabe, 2014). This research study focused on type 2 diabetes and included all ages.

This study was specifically designed to investigate dietary and religious influences on diabetes treatment. Seventh-day Adventists (Adventists) who follow a plant-based (vegan) diet have approximately half the prevalence and incidence of diabetes compared to nonvegetarian Adventists and with lower rates of metabolic syndrome (Le & Sabate, 2014; Orlich & Fraser, 2014; Tonstad et al., 2013). Adventists are known for their healthful and similar baseline lifestyle, which is a foundational

teaching in this conservative, Protestant movement (Butler et al., 2008). This makes Adventists an ideal group for use in studying the relationships between diet and disease.

Adventists show an unusual behavioral homogeneity that makes them an ideal comparative group. Since its conception as an organization in the 1860s, this group has been taught by proscription to abstain from tobacco (98.9%), alcohol (95.4%), illicit drugs, and caffeine; this adherence significantly reduces the confounding effects of nondietary factors (Butler et al., 2008). Adventists also abstain from Biblically unclean meats such as pork and shellfish (Leviticus 11, King James Version); although a vegetarian diet is not required, it is advocated within their membership (Phillips, Kuzma, Beeson, & Lotz, 1980). A typical Adventist diet emphasizes fruits, vegetables, whole grains, legumes, and nuts, while discouraging rich desserts, spices, and highly refined foods; members are also encouraged to exercise (Butler et al., 2008; Phillips, Kuzma, Beeson, & Lotz, 1980). With this consistent foundation, Adventists then have a wide spectrum of diets from eating meat to being total vegetarian (often referred to as vegan), abstaining from all animal products including eggs, dairy, and all flesh meats. Non-Adventist research also suggests that meat consumption increases the risk of type 2 diabetes, and by switching to a vegan or vegetarian diet (includes dairy and eggs but excludes animal flesh), diabetes outcomes improve (Barnard, Levin, & Trapp, 2014; Fung, Schulze, Manson, Willett, & Hu, 2004; Pan et al., 2013).

This study examined the Adventist health message through the social ecological model (SEM; Bronfenbrenner, 1979) and how that health message has been incorporated into each level of society. It specifically used data from the Complete Health

Improvement Program (CHIP; formerly known as the Cardiac Health Improvement Project; Diehl, 1998), an Adventist-run program that has produced multiple influences at the individual, social, community, and institutional levels.

CHIP is a 30-day, professional- and volunteer-delivered, video-presented, community-setting, plant-based, whole-food, vegan, lifestyle modification program that has been adopted by the Seventh-day Adventist (Adventist) church. CHIP was designed to improve and target those with type 2 diabetes and cardiovascular disease (Rankin et al., 2012). The foundational CHIP intervention was based on a number of theoretical frameworks, but most strongly draws on the theory of planned behavior (TPB; Ajzen, 1985). As a result, it has a strong educational component to help people change attitudes, social norms, and perceived control towards leading healthier lifestyles (Morton et al., 2014a). This dissertation, however, diverged from this earlier foundation by being based on the social ecological model (SEM) described by Bronfenbrenner (1979).

The CHIP lifestyle intervention program, now referred to simply as CHIP, works with volunteers and professionals to deliver a video-based health program in a community setting (Morton, Rankin, Kent, & Dysinger, 2014a). The first 30-day CHIP lifestyle intervention was presented in 1988 and recorded in 1997, which allowed both professionals and trained CHIP volunteers to administer the program in their perspective and separate settings. At the time of this study, over 70,000 participants have gone through the program worldwide and is described in more than 25 publications (Morton et al., 2014a).

This present study drew on data and other information from 25 peer-reviewed studies on the CHIP program. Seventeen of these studies examined formally educated healthcare professionals who delivered the CHIP lifestyle intervention. Seven of these studies examined volunteers who may or may not have been medically trained. One study summarized the history of CHIP for both professionals and volunteers. This dissertation focused on the volunteer branch of the CHIP intervention. CHIP founder, Dr. Haans Diehl videotaped sixteen 2-hour presentations and made them available in 1997 to lay people (mainly Adventists) who had an interest in improving the health of people in their local communities (Rankin et al., 2012). Being a health professional was not a criterion since the program directors had only a facilitator's role, not an educator's role (Rankin et al., 2012). In these interventions, Diehl gave health education instruction via recorded video and volunteers directed group discussions, presented cooking demonstrations, and provided grocery store tours. Adventists have presented most CHIP programs.

Earlier CHIP studies have compared mean changes pre- and postprogram in terms of overall participation and between genders. However, this prior research had not determined if there was a prevalence rate difference of self-identified type 2 diabetes between Adventists and non-Adventists pre-CHIP, and if having a particular religious belief (Adventist or non-Adventist) affected biometric outcomes (total cholesterol [TC], high-density lipoproteins [HDL], low-density lipoproteins [LDL], triglycerides [TG], and fasting plasma glucose [FPG], systolic blood pressure [SBP], diastolic blood pressure [DBP], and body mass index [BMI]) in those with type 2 diabetes. This dissertation

addressed this gap in the literature by tracking biometrics via the biomarkers TC, HDL, LDL, TG, and FPG, and clinical parameters of SBP, DBP, and BMI.

Since its inception in the 1860s, the Adventist church has had a consistent, worldwide commitment and a rich history of positive social change by providing education for the prevention of disease and the relief of sickness in a variety of societal settings (Fraser, 2003). This study investigated some of the foundational elements of this social change education: giving participants the tools they needed to start and maintain a positive healthy lifestyle, and teaching the benefits of doing such. The study's implication for positive social change consists of determining whether the Adventist health message, as presented through CHIP, is an effective non-medical, whole-food, plant-based, lifestyle model in improving type 2 diabetes outcomes for Adventists and non-Adventists similarly. A planned outcome was determining whether the Adventist health message is appropriate for use as a source of inspiration, optimism, strength, and guidance in health challenges for all who choose a dietary approach to diabetes prevention and reversal without the use of pharmaceuticals, regardless of faith belief.

### **Background of the Topic**

The Adventist church has taught a progressive health reform message since its inception in the mid-1800s, including both a unique council on health and the founding of many new health-related organizations (Douglass, 1998). Adventists have published health literature showing a connection between lifestyle, diet, spirituality, and disease; they opened up their first sanitarium in 1866, the Western Health Reform Institute in Battle Creek, Michigan, later renamed Battle Creek Sanitarium (Robinson, 1943). The

Battle Creek Sanitarium applied the above unique health principles with successful patient outcomes, although the principles had not yet been validated scientifically (Robinson, 1943, p. 152). Since then, both Adventists and non-Adventists have started other similar programs that have since been scientifically validated (Fraser, 2003). Sanitariums, or live-in residential lifestyle programs such as Battle Creek Sanitarium, provide a controlled setting where participants learn to optimize their lifestyle through a whole-food, plant-based diet, exercise, and other healthful principles (Crane & Sample, 1994; McDougall et al., 2014, Slavicek et al., 2008). Examples of extant lifestyle centers include the Weimar Institute, Uchee Pines Institute & Lifestyle Wellness Center, Wildwood Lifestyle Center & Hospital, Eden Valley Institute of Wellness, Pritikin Longevity Center, and BellaVita Lifestyle Center.

In the mid-1950s, longitudinal studies by both Adventist and non-Adventist groups began to validate scientifically associations among incidence, prevalence, predisposing factors, and prognosis with lifestyle, diet, and disease. Some of these long-term studies include the following:

- the Framingham Study (Castelli et al., 1986)
- the Nurses' Health Study I and II, the Health Professional Follow-Up Study (Pan et al., 2011)
- the Adventist Health Study 1 and 2 (Rizzo, Sabate, Jaceldo-Siegl, & Fraser, 2011; Tonstad, Butler, Yan, & Fraser, 2009; Tonstad et al., 2013)
- the Adventist Mortality Study (Vang, Singh, Lee, Haddad, & Brinegar, 2008),
- the Adventist Religion & Health Study (Lee et al., 2009)

- the Adventist Health Air Pollution Study (Chen et al., 2005)

Community lifestyle programs added yet another educational dimension to teaching about lifestyle, while also teaching foundational health principles to prevent and reverse chronic disease in a stay-at-home setting. These programs are offered in a variety of settings:

- in the workplace (Levin, Ferdowsian, Hoover, Green, & Barnard, 2010)
- through local research studies (Knowler et al., 2002)
- through randomized, controlled studies (Barnard et al., 2009a)
- through private physician offices (Crowe, Ellis, Esselstyn, & Medendorp, 1995)
- at hospitals and clinics (Englert, Eiehl, Greenlaw, Willich, & Aldana, 2007)
- by faith-based groups such as CHIP (Kent et al., 2013a)

Prior research on the CHIP intervention showed that men improved more than women in all biometrics except high-density lipoprotein (HDL; Kent, Morton, Rankin, Gobble, & Diehl, 2014). In this research, HDL dropped lower in women (7.6% versus 9.1%), and those with the worse biometrics made the greatest improvements because they had the greatest amount of room to change (Kent et al., 2014). The value of monitoring HDL when assessing a change to a plant-based diet has been questioned since this and other research has observed a drop in HDL phenomenon despite overall cardiovascular risk improvement (Barnard, 1991; Esselstyn et al., 1995; Kent et al., 2013b; Morton et al., 2013; Ornish et al., 1998; Rankin et al., 2012). CHIP research has shown that the 30-day program has had the following effects:

- men reduced their body mass index (BMI) by 3.5% and women by 3.0%

- men reduced systolic blood pressure (SBP) by 5.5% and women by 5.1%
- men reduced diastolic blood pressure (DBP) by 5.9% compared to 4.8% for women
- men reduced total cholesterol (TC) by 13.2% compared to 10.1% for women
- men reduced low-density lipoproteins (LDL) by 16.3% compared to 11.5% for women
- men reduced triglycerides (TG) by 11.4% compared to 5.6% for women
- men reduced fasting plasma glucose (FPG) by 8.2% compared to 5.3% for women (Kent et al., 2014; Morton et al., 2014a)

Although CHIP is an Adventist-driven program, research has focused on outcomes comparing genders, and pre- and postbiometrics in general. However, the literature review did not identify research that compared whether coupling a certain religious belief with type 2 diabetes may differ in outcomes between Adventists and non-Adventists. Until now, it was unknown if being an Adventist or non-Adventist elicited different biometric outcomes pre- and post-CHIP in those with type 2 diabetes, and if there was a difference between the incidence rate of Adventists and non-Adventists who have self-identified themselves as having type 2 diabetes preprogram.

### **Problem Statement**

Type 2 diabetes is a national problem in the United States and globally (American Diabetes Association [ADA], 2015). Each year, approximately 1.7 million people in the United States acquire type 2 diabetes, in addition to the 29.1 million who already have the disease, which takes the life of almost 74,000 people annually, costing the national

healthcare system billions of dollars per year (ADA, 2013). Since 2002, the total U.S. economic cost of diabetes has risen from \$132 billion (ADA, 2003) to over \$245 billion in 2012 (ADA, 2013). Seventy percent of people with diabetes will die from cardiovascular disease (CVD), which includes heart disease—the number one cause of death and disability for those with diabetes (Zhao et al., 2014). The foundational treatment for diabetes and CVD is diet and lifestyle (Dinu, Abbate, Gensini, Casini, & Sofi, 2016); however, this has historically been given little attention compared to pharmaceuticals (ADA, 2015).

CVD costs in the United States are alone projected to triple from \$273 billion in 2010 to \$818 billion in 2030 (Heidenreich et al., 2011). Coronary heart disease (CHD) causes about 720,000 heart attacks each year, resulting in 380,000 deaths in the United States annually at a cost of \$108.9 billion (Murphy et al., 2013). Some of the current, well-recognized risk factors of type 2 diabetes include the following:

- being overweight (Biggs et al., 2010)
- inactivity (Hu, 2003; Jeon, Lokken, Hu, & van Dam, 2007; Plotnikoff, Costigan, Karunamuni, & Lubans, 2013)
- improper nutrition (Barnard et al., 2009; Pan et al., 2011; Tonstad et al., 2013)
- high blood pressure, cholesterol, and blood sugars (Rosner et al., 2009)
- statin medications (Mansi, Frei, Wang, & Mortensen, 2015; Macedo, Douglas, Smeeth, Forbes, & Ebrahim, 2014).

The problem addressed by this study is that the current dietary recommendations set forth by the American Diabetes Association (ADA) do not address the root cause of

type 2 diabetes, but instead manage it primarily through medications and moderate intake of all foods, regardless of their health value (ADA, 2016). A whole food, plant-based diet, without the use of animal products, improves blood sugar control better than pharmaceuticals (Knowler et al., 2002) and the standard diabetes diet (Barnard et al., 2009) without the negative side effects of pharmaceuticals (Graham et al., 2010). Moreover, some foods are more problematic, like processed carbohydrates, dairy, eggs, fat, and animal protein (Djousse, Khawaja, & Gaziano, 2016; Hu, Pan, Malik, & Sun, 2012; Lawlor, Ebrahim, Timpson, & Smith, 2005; Pan et al., 2013; Vitale et al., 2015), and others are more beneficial, like whole-plant foods and a vegan diet (Tonstad et al., 2013, Turner-McGrievy, 2008). Those with diabetes also improve FPG by replacing red meat with legumes (Hosseinpour-Niazi, Mirmiran, Hedayati, & Azizi, 2014) and by reducing red meat consumption (Pan et al., 2013). Vegetarian and vegan Seventh-day Adventists have reduced incidence (Tonstad et al., 2013) and prevalence (Tonstad et al., 2009) of diabetes and metabolic syndrome (Rizzo, Sabate, Jaceldo-Siegl, & Fraser, 2011), suggesting that dietary content has a significant effect. Additional evidence supporting this includes a drop in mortality rate (Heuch, Jacobsen, & Fraser, 2005) and ischemic heart disease the longer Adventists have been baptized members and following the recommended lifestyle (Snowdon, Phillips, & Kuzma, 1982). During a 1960s Adventist study, members baptized as children died at 71% the risk as members baptized as adults, signifying that the younger members changed their lifestyle to a vegetarian diet, the stronger their protection in dying from ischemic heart disease (Snowdon et al., 1982).

Although CHIP is an Adventist-facilitated program, a gap in the literature existed in relation to assessing if the CHIP lifestyle affected Adventists and non-Adventists differently. This current research assessed if those with a particular religious belief (Adventist) experienced different outcomes from the CHIP program when compared to those who did not hold that religious belief (non-Adventist). It was also unknown whether Adventists entered the CHIP program with a different prevalence rate of self-identified diabetes. This dissertation therefore compared eight biometric outcomes pre- and post-CHIP in Adventists and non-Adventists with type 2 diabetes, and assessed whether there was a difference in the self-identified diabetes rate between Adventists and non-Adventists pre-CHIP.

### **Purpose of the Study**

This quantitative, correlational study analyzed secondary data to assess how Adventist affiliation affected biometric outcomes. It specifically compared how having a particular religious belief (Adventist or non-Adventist) for those with type 2 diabetes affects eight biometric outcomes—TC, HDL, LDL, TG, FPG, SBP, DBP, and BMI—for pre- and post-CHIP intervention, while controlling for four covariates. It also specifically assessed if Adventists or non-Adventists entered the program with a statistically significant different rate of self-identified diabetes while controlling for five covariates. Prior research suggested that Adventists enter the CHIP program with improved baseline risk factors over non-Adventists, but non-Adventists see greater improvements because there was more room for improvement (Rankin, 2014). It was unknown how the Adventist religious belief system specifically affected CHIP biometric outcomes in those

with type 2 diabetes, although other research has revealed that religiosity can improve those outcomes (Eleuterio da Silva, Eleuterio da Silva, Marcilio, & Pierin, 2012). An examination of the research reveals limited studies comparing Adventists to non-Adventists.

### **Research Questions and Hypotheses**

The following research questions guided this study:

**Research Question 1 (RQ1):** After controlling the effects of age, gender, marital status, BMI, and parental death from diabetes before age 60, is there a statistically significant difference in self-identified type 2 diabetes prevalence rates between Adventist and non-Adventist CHIP participants preprogram between January 2006 and September 2012?

***H<sub>01</sub>*:** The self-identified diabetes prevalence rate between Adventist and non-Adventist in pre-CHIP participants is not significantly different.

***H<sub>11</sub>*:** The self-identified diabetes prevalence rate between Adventists and non-Adventists in pre-CHIP participants is significantly different.

The dependent variable tracked in answering RQ1 was self-identified diabetes. The independent variables were religiosity and testing period. Five covariates were also tracked: age, gender, marital status, BMI, and parental death from diabetes before age 60. The quantitative test used to answer this question was logistic regression.

**Research Question 2 (RQ2):** After controlling for the effects of age, gender, marital status, and parental death from diabetes before age 60, is there a statistically significant difference in the change in biometric outcomes (TC, HDL, LDL, TG, FPG,

SBP, DBP, and BMI) between Adventists and non-Adventists with self-identified diabetes pre- and post-CHIP between January 2006 and September 2012?

***H<sub>02</sub>***: There is no statistically significant difference in biometric outcomes between Adventists and non-Adventists with self-identified type 2 diabetes pre- and post-CHIP.

***H<sub>12</sub>***: There is a statistically significant difference in biometric outcomes between Adventists and non-Adventists with self-identified type 2 diabetes pre- and post-CHIP.

The dependent variables tracked in answering RQ2 were TC, HDL, LDL, TG, FPG, SBP, DBP, and BMI. The independent variables were religiosity and testing period. The covariates were age, gender, marital status, and parental death from diabetes before age 60. The quantitative test used to answer RQ2 was a multiple analysis of variance (MANOVA).

### **Conceptual Framework for This Study**

The conceptual framework for this research was based on the social ecological model (SEM) developed in the late 1970s by Urie Bronfenbrenner. SEM was initially developed to understand the factors that influenced and prevented violence in child abuse (Bronfenbrenner, 1979). The SEM is now used to explain the interconnectedness and often complex and evolving associations among society, community, interpersonal relationships, and individuals (Bronfenbrenner, 1994). In the initial model, these four associations were in a nested structure, each inside the other with the innermost position containing the individual. Moving outward, the next position was interpersonal relationships, then community, and the outermost structure was society. SEM provides a

systems way of looking at human behavior in which each level is often fluid and interactive with other levels. To make large societal changes, SEM suggests understanding the problem from each social level, then affecting each level appropriately through educational efforts. As each social level creates its own change, it affects all the other levels interchangeably.

For example, the initial SEM (Bronfenbrenner, 1979) instituted to explain abuse. The first or innermost level identified individual settings or characteristics that affect abuse, which may be, for example, in the home environment or classroom setting, and included being either the perpetrator or victim. Factors that influenced abuse included age of the child, stress level, family history of abuse, substance abuse, having a rigid belief system, and limited educational attainment (Dahlberg & Krug, 2002). In a preventative approach at the individual level, the educational outreach approach may include targeting and training for childcare staff, pediatricians, schoolteachers, and counselors.

The second layer out, next to the individual position, is interpersonal relationships, which looks at the interconnectedness between environments and relationships among those within the closest social circle (Krug, Mercy, Dahlberg, & Zwi, 2002). This level looked at family members, peers, and partners who have influence in the environment. In a preventative approach at the interpersonal relationship level, education may include mentoring and peer programs to improve problem-solving skills and parenting skills, as well as reducing seclusion.

The third level takes a broader view yet by looking at the outward community settings, such as schools, neighborhoods, workplaces, and other places where social

relationships occur and abuses happen. In a preventative approach, the strategies targeted changing the climate of these places, including after-school programs, recreation center activities, and family fun nights (Bronfenbrenner, 1979). Focusing on community settings fosters safer neighborhoods, schools, and communities.

The outermost or fourth level looks at the society at large, creating a broader influence that inhibited abuse through cultural and social norms (Krug et al., 2002). Societal strategies included targeting social media, health and education policies, social and economic policies, and social norm campaigns. Focusing on the societal level changes the way the public thinks, and when facing a particular situation, society would ideally take a more positive approach. Each of the four influential levels of society work together to create change, individuals learn new norms in every social level.

Since the time of the original model, Bronfenbrenner (Bronfenbrenner, 1994) and others (Attorney General's Sexual Assault Task Force, 2006; Golden, McLeroy, Green, Earp, & Lieberman, 2015) have continued to modify, update, and revise the SEM. It now includes institutions as a fifth social influence, and nestles it in between community and societal as its new fourth layer, with societal being bumped out to the fifth level. Realizing that institutional processes also play a role in social influence and behavior change—such as anti-bullying programs, strict anti-abuse laws, zero tolerance policies, group home rules and staff training, media education, and guidelines for reporting abuse—this additional social layer was also added. The SEM attempts to explain human behavior as it relates to the interrelationships among each social influence and recurring patterns. The SEM has also been expanded to a wide variety of health promotion settings,

which views the person and the differing social environments as interlinking influences (Raingruber, 2014, p. 64).

Given the complexity of a comprehensive, multilevel, health promotion intervention, it is essential to consider the individual, relational, community, institutional, and societal impacts that influence and sway health outcomes. Targeting one specific social level about health would not be as effective as simultaneously concentrating on multiple health factors considering healthy and unhealthy lifestyle principles come from each social level in reciprocal influences (Raingruber, 2014, p. 64). The SEM assumes people are more likely to succeed when multiple supportive social environments are activated, cumulative, and combined, which all influence, shape, and support one other. The dissemination of the Adventist health message has taken similar shape, reaching every sector of society, with CHIP intersecting three of those levels. See Figure 1.

At its inception in the 1860's, the Adventist church's foundation was built upon the biblical mandates of Matthew 28:19-20 and Revelation 14:6-12 to go into all the world to proclaim the gospel. Adventists believe that the gospel message includes the responsibility to care for their body, which has guided much of their outreach (1 Corinthians 3:16; 2 Corinthians 6:16; 3 John 2; Romans 12:1-2; Seventh-day Adventist World Church, 2016). The church has embraced its signature health message following the example of Jesus to relieve suffering (Matthew 15:29-31), believing there is a connection between healthful living, a clear mind, a healthy body, and true worship (White, 1909, ST, para. 7-9).

With its unique vision of promoting health in all sectors of society, the Adventist health message has naturally fit into the SEM model. CHIP takes shape within the community setting but also influences the relationship-building and individual environments in society. CHIP is one educational piece within the entire Adventist Health Message. At an individual level, health reform is encouraged by the church (General Conference of Seventh-day Adventists, 2010, p. 91; White, 1948, 9T, p. 158) through personal Bible study, reading healthful living books penned by Ellen G. White, and in keeping up to date with current day research that still fits into the Adventist health principles foundation. It is from these sources that knowledge, skills, attitudes, and CHIP principles are learned and encouraged. In that inner social sphere, each CHIP participant makes the necessary healthful changes they learned throughout the program to improve their TC, HDL, LDL, TG, FPG, BMI, SBP, and DBP. In order to investigate the intersection of religion and health, this dissertation also included the covariates of age, gender, marital status, BMI, and parental death from diabetes before age 60, since each one has been shown to be a factor in diabetes development.

In the second outer social sphere, relationship building, or social networking, friends, family, and church groups model the Adventist health message and CHIP's healthful teachings to one another, where people learn new social norms through the local church via health sermons, bulletin inserts often termed health nuggets, and small support groups such as CHIP (General Conference of Seventh-day Adventists, 2010, p. 26-27, 139-140). In the third social sphere, community influence, the Adventist church offers community health lectures and classes such as CHIP, Pathway to Health, independent

ministry health outreach, plant-based, vegan cooking classes, and stop-smoking, depression, and stress-control programs (General Conference of Seventh-day Adventists, 2010, p. 91; White, 1948, 9T, p. 112).

The fourth and more broad social sphere, institutional influences, includes the Adventist Development & Relief Agency (ADRA) for disaster relief and health dissemination, publishing agencies, and Adventist Book Centers where a host of literature may be purchased (General Conference of Seventh-day Adventists). The fifth and most outer social sphere contains the societal influences the Adventist church uses as its broadest form of health education and outreach, and includes worldwide Adventist television and satellite with their health programs, the Blue Zone, the Adventist health studies as published research, and the worldwide Adventist health care system (White, 1938, p. 75).

Within the multifaceted social ecological model, the Adventist health message touches each level of the social sphere from personal to relational, community, institutional, and societal, with CHIP influencing many levels. Each social sphere is influenced by the next, and the environment is continually being shaped depending on whom each one meets and learns from (Raingruber, 2014, p. 65). One does not have to be a member of the Adventist church to be influenced by one or more of the many levels of the church's health message. The majority of the CHIP participants are non-members, and the church's health message permeates every level of society.

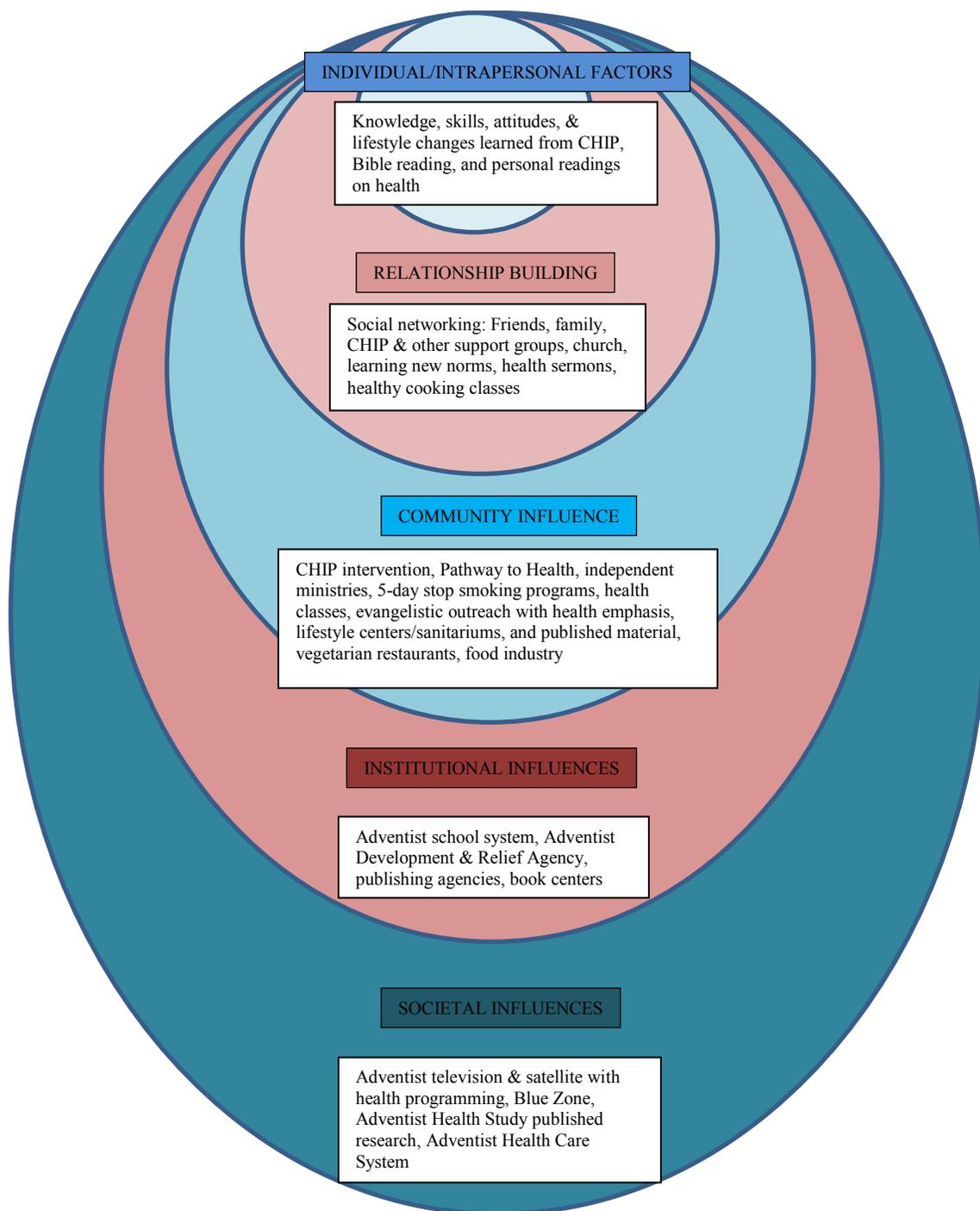


Figure 1. *Societal influences of the Adventist health message depicted through the social ecological model.*

### **Nature of the Study**

The nature of this study was a quantitative, correlation research design, which used secondary data excluding identification markers, having received permission from CHIP researchers to share their data for the purpose of this dissertation. Data was collected from 241 programs from 163 sites, between January 2006 and September 2012, involving 7,172 individuals. Volunteer directors underwent a 2-day training seminar to receive training manuals, program content, and instruction on how to deliver the sixteen 2-hour group sessions. Program content included its philosophy and methods and how to lead cooking classes, grocery store tours, group discussions, and exercise classes, and the prerecorded video education. Video instruction included education on a plant-based diet, exercise, behavioral change, self-worth, modern medicine's strengths and weaknesses, smoking, cholesterol, fiber, lifestyle and health, and epidemiology and risk factors of CVD, type 2 diabetes, atherosclerosis, hypertension, obesity, and dyslipidemia.

Pre- and post-CHIP measurements included blood samples for TC, HDL, LDL, TG, and FPG, and height and weight for BMI, and blood pressure (BP), and were the variables for this study. The dependent variable in RQ1 were self-identified diabetes, and the independent variables were religiosity and testing period. The covariates were age, gender, marital status, BMI, and parental death from diabetes before age 60. The dependent variables in RQ2 were TC, HDL, LDL, TG, FPG, SBP, DBP, and BMI, with religiosity and testing period as independent variables. The covariates were age, gender, marital status, and parental death from diabetes before age 60. Diet, race, income, and exercise information were not captured and are therefore not available. Only participants

who attended 13 of 16 sessions and completed a self-reported medical, lifestyle pre-questionnaire and pre- and postassessments were defined as graduated and included in this study.

A quantitative correlational research design was chosen for this research since it provided valuable data for looking at relationships between variables, with the intent to generalize findings from a sample to a population (Creswell, 2009), testing the impact of the interventional CHIP program on a specified group of people. The variables were measured using the statistical analysis of MANOVA and regression analysis. The final report was controlled for confounders, protected against biases, and reproducible and generalizable to the population. Traditionally, quantitative designs provide reliability, objectivity, as well as internal and external validity (Trochim & Donnelly, 2008).

### **Operational Definitions**

*Body mass index (BMI):* A measurement of body fat in relation to weight and height. BMI is calculated by dividing weight in kilograms by height in meters squared. BMI is a screening tool to categorize weight from underweight, normal weight, overweight, to categories of obesity (Garrow & Webster, 1984). CHIP used the World Health Organization (WHO) BMI categories, measured as  $\text{kg/m}^2$  (Alberti & Zimmet, 1998). A normal BMI is 18.5 to 24.9  $\text{kg/m}^2$ .

*Complete Health Improvement Program (CHIP):* A 30-day intensive, community-based, plant-based, video-delivered, comprehensive health education, and lifestyle program (Diehl, 1998).

*Diastolic blood pressure (DBP):* The bottom number of the two numbers recorded when the blood pressure is taken. It is the relaxation phase of the heart after pressure has been placed against the wall of the blood vessel, and blood fills the heart again. CHIP used the NCEP Treatment Panel III classification system to categorize DBP, measured in mmHg (NCEP, 2002). A normal diastolic pressure is <80 mmHg.

*Fasting plasma glucose (FPG):* A measurement of blood sugar without caloric intake for at least eight hours. CHIP used the Treatment Panel III classification system to categorize FPG, measured in mg/dL (NCEP, 2002). A normal FPG for this study is considered <110 mg/dl.

*Graduate:* In the context of this study, a CHIP participant who attended 13 of 16 CHIP sessions, completed a self-reported medical and lifestyle prequestionnaire, and completed pre- and postassessment questionnaire (Kent et al., 2014).

*High-density lipoproteins (HDL):* A carrier of cholesterol through the blood stream, typically thought of as good cholesterol. CHIP used the National Cholesterol Education Program (NCEP) Treatment Panel III classification system to categorize HDL, LDL, and TG, measured in mg/dL (NCEP, 2002). A normal HDL is 40-60 mg/dl.

*Low-density lipoproteins (LDL):* A carrier of cholesterol through the bloodstream, typically thought of as bad cholesterol. CHIP used the NCEP Treatment Panel III classification system to categorize HDL, LDL, and TG, measured in mg/dL (NCEP, 2002). A normal LDL is <100 mg/dl.

*Plant-based diet:* A diet based upon fruits, vegetables, whole grains, legumes, and nuts, without the use of animal products. Referred to as the Optimal Diet in CHIP (Englert et al., 2004). Often also called a vegan or total vegetarian diet.

*Professionally-delivered:* In the context of this study, a term to describe a delivery of the CHIP program in a workplace or clinical setting by formally trained and educated health professionals (Morton et al., 2014a).

*Self-selected:* CHIP participants choosing to participate in the health education program and paid for this service (Diehl, 1998).

*Seventh-day Adventist (Adventist):* A member of a conservative, Protestant, worldwide, and growing body of about 18 million members with a worldwide focus on health and health outreach (Seventh-day Adventist World Church (SDAWCH), 2015a).

*Systolic blood pressure (SBP):* The top number of the two numbers recorded when the blood pressure is taken. It is the pressure phase exerted on the blood vessel walls as the heart constricts, pushing blood out of the heart into the body. CHIP used the NCEP Treatment Panel III classification system to categorize SBP, measured as mmHg (NCEP, 2002). A normal SBP is <120 mmHg.

*Total cholesterol (TC):* A blood test result showing the sum total of circulating LDL, HDL, and very low-density lipoprotein (VLDL). CHIP used the Framingham Risk Classification for stratifying TC, measured in mg/dL (Wilson et al., 1998). A normal TC is <160 mg/dl.

*Triglycerides (TG):* A form of fat in blood. CHIP used the NCEP Treatment Panel III classification system to categorize TG, measured in mg/dL (NCEP, 2002). A normal TG is <150 mg/dl.

*Type 2 diabetes:* A metabolic disorder with glucose inefficiency coupled with overproduction (Sacks et al., 2011). A diagnosis of diabetes requires a FPG of >125 mg/dL on two separate occasions (ADA, 2016)

*Volunteer-delivered:* In the context of this study, a term to describe delivery of the CHIP program by facilitators mainly sourced from the Adventist church who wanted to positively affect their community. Facilitators participating in volunteer-delivered services required no special formal education, they instead attended a 2-day training seminar to develop facilitator skills and receive certification (Kent et al., 2014).

### **Assumptions**

A plant-based diet is typically lower in calories, fat, trans fats, cholesterol, and the glycemic index, as well as being higher in fiber and nutrient density than the typical American diet (Barnard et al., 2009b; Levin et al., 2010) and the diet set forth by the American Diabetes Association (ADA; Barnard et al., 2009a). My assumption was that as individuals with diabetes from both faith groups switch from the standard American diet (SAD) to a plant-based diet, both would see improvements in their biometric outcomes, but it was unknown as to whether one group would outperform the other due to their faith group. Those on a vegan diet develop diabetes at a rate of 0.54%, which is significantly lower than the 2.12% rate for those on nonvegetarian diets (Tonstad et al., 2013).

Similarly, the prevalence of diabetes incrementally reduces as the diet changes from meat-based (7.6%) to vegan (2.9%) (Tonstad et al., 2009).

A second assumption was that those who self-identified “have you ever been told by a doctor you have diabetes” were referring to type 2 diabetes. This was a reasonable assumption because 90-95% of those with diabetes have type 2 (ADA, 2016). When a clarification of the word “diabetes” is not given, the assumption is normally that it refers to type 2. In addition, it is assumed type 2 since CHIP targets individuals with type 2, not another. If CHIP participants had asked for clarification as to which type of diabetes was meant on the pre-assessment questionnaire, they would have been told type 2. Lastly, those with type 1 or 1.5 diabetes are often not attracted to lifestyle programs since those types of diabetes are less associated with lifestyle and considered a progressive, lifetime condition (ADA, 2016).

It is also assumed that all who stated they had diabetes, actually had it and that those who did not mark it, did not have the disease. It is possible that some people who had diabetes did not know it, and therefore did not mark the box. Others may have simply not marked the box though they had diabetes. Lastly, it is assumed that all the biometrics were input into the CHIP database correctly by each location director, and that the database supplied was correct.

Many extant studies demonstrate that there are improvements in the symptoms of type 2 diabetes when switching to a plant-based diet that excludes all animal products. Many studies compare Adventists to other Adventists with different eating patterns, but there are an insufficient number of studies comparing Adventists to non-Adventists with

diabetes and their effects of switching to a plant-based CHIP diet while implementing CHIP. A gap in the literature existed when it comes to assessing if a particular religious belief system has an influence on biometric outcomes on those with diabetes.

### **Scope and Delimitations of the Study**

This study design included data from 7,172 self-selected participants who had participated in 241 CHIP programs given at 163 sites from Canada and the United States between January 2006 and September 2012. Participants were taught and prescribed a whole-food, plant-based diet and other healthful lifestyle principles as the intervention to improve chronic disease biometric outcomes. Programs were facilitated mainly by Seventh-day Adventist volunteers after having attended a two-day instruction workshop and given all required materials to facilitate the program. The foundational treatment for type 2 diabetes is diet and lifestyle (ADA, 2016), but literature gives little attention to diet and lifestyle in comparison, and more attention is paid to pharmaceuticals, despite their greater negative potential side effects over dietary changes (Graham et al., 2010; Kannan et al., 2016; Lincoff, Wolski, Nicholls, & Nissen, 2007; Solomon & Winkelmayr, 2007). CHIP addresses the root cause of diabetes through improving the diet and lifestyle, which also reduces the risk of metabolic syndrome (Rankin, 2013; Rankin et al., 2012; Morton et al., 2014b).

The only requirements for participants of the volunteer-delivered study was the ability to pay \$200-\$250 for the course, attend at least 13 of 16 sessions, complete a self-reported medical questionnaire and a baseline and postintervention lifestyle questionnaire, and have biometrics assessed, which included giving a blood sample; all

ages were included. Participants were encouraged to join the post-CHIP support group for further education, reinforcement, and support, but this was not a requirement.

The CHIP intervention is based on a number of theoretical frameworks, which included the health belief model (HBM), the social cognitive theory (SCT), and the transtheoretical model (TM). However, its foundational support comes from the theory of planned behavior (TPB; Morton et al., 2014a), a model based upon changing attitudes of healthy living, fostering social norms, and increasing self-efficacy (Ajzen, 2011). Because of these strong educational components having been incorporated into the CHIP intervention, health literacy, accountability, and perceived control improve post-CHIP biometrics (Aldana et al., 2005). These frameworks are not investigated further in this present study.

### **Limitations**

Limitations are an intrinsic part of all research, which may affect the validity, and is therefore necessary to reflect on and recognize and eliminate them in future research; several limitations are outlined here.

1) CHIP does not have a control group in which to compare outcomes. However, the Rockford CHIP has published research using randomized clinical control trials with results for the professional programs showing similar outcomes as the volunteer branch (Aldana et al., 2005a; Aldana et al., 2005b; Merrill, Taylor, & Aldana, 2008).

2) Participants attending CHIP were self-selected and therefore may be more motivated, ready, and willing to make the necessary changes to a plant-based diet. In the transtheoretical model of behavior change, participants may have moved from the

precontemplation and contemplation stages and were in the preparation phase, where they were already taking the steps to make changes (Bartholomew, Parcel, Kok, & Gottlieb, 2006, p. 110-113).

3) Participants were self-identified when asked on the lifestyle evaluation, “have you ever been told by a doctor you have diabetes”; verification was not requested. It is possible that those with gestational diabetes, type 1 or 1.5 may have been included, but there is no way to know. Considering that 90-95% of people who have diabetes, have type 2 (ADA, 2016), the number of other types of diabetes would have been very negligible. Had others been included, it would have only diluted the final results.

4) A diet diary and exercise log was not obtained from participants, so it was unknown as to how much change or adherence there was to the diet and exercise, and the effects those changes had on the biometrics. However, considering the positive outcomes and assuming that all participants did not fully adapt the diet, less adherence would have diluted the outcomes, and had there been more compliance, it would have strengthened the outcomes.

5) An accurate medication diary was not obtained from participants throughout the CHIP intervention, though participants informed facilitators that they had either reduced or removed their medications by doctors order (Rankin et al., 2012). Again, had this data been gathered, the net cause would have created a diluted effect.

6) Data was input into the CHIP online databank by the local facilitators, and it is unknown if errors occurred during data entry. However, with 241 CHIP programs given

at 163 sites throughout North America, it is unlikely, considering all the CHIP programs, whether volunteer- or professional-facilitated programs, had similar outcomes.

Because this was a secondary study, further limitations and biases were minimal, since the trial planning and trial implementation had already occurred. Bias can occur during the planning phase of research, data collection, analysis, and publication (Pannucci & Wilkins, 2010). Biased language (Rudestam & Newton, 2007) has been eliminated. Known and available confounders were controlled for.

### **Significance of the Study**

The results of this research made an original contribution to the literature by assessing how a particular religious belief affected biometric outcomes in CHIP participants with type 2 diabetes. The results of this study answered if the established CHIP lifestyle education program was equally beneficial for Adventists and non-Adventists alike for those with diabetes. Adventists are known for their healthful, baseline lifestyles and reduction in diabetes over their non-Adventist counterparts (Alexander, Lockwood, Harris, & Melby, 1999; Fonnebo, 1992). By giving all participants the tools they need to start and maintain a positive healthy lifestyle and teaching its benefits, the positive social change from this study showed that the Adventist health message, as presented through CHIP, is an effective non-medical, whole-food, plant-based, lifestyle model in improving type 2 diabetes outcomes for all people, regardless of their Adventist status. The Adventist health message is a source of inspiration, optimism, strength, and guidance for many people with diabetes who desire

to control, prevent, or reverse this disease through a non-medical, nonpharmaceutical lifestyle approach.

### **Summary**

Chapter 1 introduced the health challenges and the financial impact of type 2 diabetes in the United States and its association with a nonvegetarian diet. A diet consisting of whole plant foods reduce the risk of diabetes while animal products increase the risk, and as the diet moves more towards vegan, the lower the risk of diabetes (Tonstad et al., 2013). As a plant-based program, the CHIP community program given by Adventists has the potential of influencing large numbers of people, and when incorporated, reduces risk factors for chronic disease (Rankin et al., 2012).

This research incorporated the social ecological model (Bronfenbrenner, 1979) to explain the influence, interconnectedness, fluidity, and complex associations that occur among and between the social groups: individual, interpersonal relationships, the community, organizations, and the society at large. This study assessed if there was a statistically significant difference in the change in biometric outcomes (TC, HDL, LDL, TG, FPG, SBP, DBP, and BMI) between Adventists and non-Adventists with self-identified diabetes pre- and post-CHIP between January 2006 and September 2012. It also assessed if there was a statistically different self-identified diabetes prevalence rate in Adventists and non-Adventists preprogram. The nature of this study was a quantitative secondary data analysis collected from 241 program sites between 2006 and 2012 involving 7,172 graduates. The knowledge gap and potential contribution has been addressed. Per CHIP research, the Adventist health message has been an effective

nonmedical, whole-food, plant-based, lifestyle model in improving type 2 diabetes and other chronic diseases.

## Chapter 2: Literature Review

### **Introduction**

Type 2 diabetes and its precursor, prediabetes, have substantial implications for general and individual overall health and life expectancies, U.S. federal and state health care costs, household budgets, and employer costs. By 2020, an estimated 52% of the United States adult population will have either prediabetes or diabetes, up from 40% in 2010 (United Health Center for Health Reform & Modernization, 2010). At the time of this study, diabetes was the seventh leading cause of death in the United States (CDC, 2013a).

Type 2 diabetes has significant financial and medical costs. Persons with diabetes on average spend 2.3 times more money on healthcare and have 2.9 times more doctor visits than their counterparts who do not have diabetes (Dall et al., 2010). Persons with diabetes also require more hospital admissions, home health visits, emergency room services, prescription drugs, medical supply needs, and use of nursing homes (Dall et al., 2008). Over 81% of people with diabetes take some kind of diabetes medication (CDC, 2013b). They also lose between 3.3 and 18.7 years of life, while incurring higher lifetime health care costs, from \$8,946 to \$159,380 more, depending on age at diagnosis, ethnicity, and gender (Leung, Pollack, Colditz, & Chang, 2015).

Many studies have shown lifestyle approaches to be cost-effective (Eriksson et al., 2010; Jacobs-van der Bruggen et al., 2009) while reducing medication use (Englert, Diehl, Greenlaw, & Aldana, 2012). Several lifestyle programs exist that address preventing and controlling diabetes, including the Complete Health Improvement

Program (CHIP; Diehl, 1998), the focus of this study. CHIP is a multifactorial lifestyle educational program focused on diet, exercise, and stress reduction for the purpose of improving health outcomes for chronic diseases including diabetes, coronary artery disease (CAD), and hypertension (Diehl, 1998; Rankin et al., 2012). CHIP was initially based on the theory of planned behavior, and as a result included a strong educational component designed to improve health attitudes, promote healthy social norms through support groups, and improve perceived control through self-efficacy (Kent et al., 2014).

### **Literature Search Strategy**

The literature search for this dissertation was a comprehensive search using Walden University's online library system to identify articles, using the following databases: Academic Search Complete, PubMed, and CINAHL & MEDLINE Simultaneous Search. Search terms included key words with no limit in years and found anywhere in the text, title, or abstract of the article. The journal articles were peer-reviewed and reviewed in either full text or abstract format. The following keyword searches yielded highly variable results: Complete Health Improvement Program (8), Coronary Health Improvement Project (46), Adventist (3,929), type 2 diabetes and vegan diet (235), vegetarian diet (909), type 2 diabetes and lifestyle medicine (82), Hans Diehl (86), D. Ornish (120), Pritikin (10), and lifestyle intervention and diabetes (5,614). Other articles were found using the snowball effect, and through informal conversations with researchers to locate articles that were in-press but had not yet been published. The article selection excluded research on institutionalized subjects and women with gestational diabetes, while including research on both U.S. and international participants.

### **Conceptual Framework**

This study used the Social Ecological Model (SEM) framework to evaluate the effect of the Adventist health message as taught through the CHIP intervention. The SEM was designed to promote health by focusing on the social accumulated effects of five social influence levels (Raingruber, 2014): interpersonal relationships, intrapersonal relationships, community, institution, and societal influences, all of which have a combined and cumulative effect on an individual. People succeed by having a supportive social environment at every level; the model assumes that each social environment influences human behavior accumulatively.

SEM has been used in a variety of public health settings, with the most notable ones being Mothers Against Drunk Driving (MADD) and Students Against Driving Drunk (SADD; DeJong et al., 1998). Over a period of 25 years, MADD changed an entire country's perception about drunk driving by targeting individuals and peer-related relationships, forming community chapters, pressuring lawmakers to pass tough criminal laws, and using media to reinforce their message (DeJong et al., 1998). Intervening on behalf of a drunken person and choosing a designated driver have both become socially acceptable messages (DeJong et al., 1998). The SEM has also been used to assess drinking patterns in a variety of settings, from home to bars, pubs, restaurants, and friend's or relative's home, as well as appraising the impulse to drink more (Gruenewald, Remer, & LaScala, 2014).

Schwartz, Tuchman, Hobbie, and Ginsberg (2011) broadened the traditional SEM, building a model for guiding chronically ill adolescents and young adults to

transition easier into adult health care. The new model incorporates pre-existing constructs, such as health care access, sociodemographics, medical status and risk, and IQ, as well as modifiable subjective variables, such as knowledge, goals, beliefs and expectations, skills and efficacy, relationships, and psychosocial functioning of all stakeholders involved (the patient, providers, and parents). This inclusion of additional stakeholders was intended to facilitate other clinicians and investigators building evidence-based evaluation tools to help make an optimal transition for chronically ill young adults.

The SEM has also been used for several other contexts. Dunn, Kalich, Henning, and Fedrizzi (2015) used focus groups based on the five social levels of the SEM to understand the multifaceted barriers and contributing factors for breastfeeding in low-income women. Barriers at each social level were then turned into educational opportunities to support breastfeeding, which ranged from teaching new mothers and family the importance of breastfeeding, to placing a baby-friendly hospital initiative, to implementing new workplace policies. Baral, Logie, Grosso, Wirtz, and Beyrer (2013) used the five social levels of the SEM to characterize the multilevel risks of HIV infection, turning each risk level into an evidence-based behavioral and structural intervention. As is characteristic of the SEM, each social level was found to be fluid and interactive with each other social level.

## Literature Review

### Type 2 Diabetes

Diabetes is a chronic, progressive disease characterized by high blood sugars caused by either a lack of insulin or inefficient use of the insulin by the body (ADA, 2016). The most common form of diabetes is type 2, which traditionally occurred in older people but now has been found to occur in younger people of any age (ADA, 2016). Approximately 29.1 million people in the United States already have type 2 diabetes; approximately 1.7 million people in the United States acquire the disease annually (ADA, 2013). Type 2 diabetes kills almost 74,000 people annually in the United States and costs the U.S. national healthcare system billions of dollars per year (ADA, 2013).

Since 2002, the annual total economic cost of diabetes in the United States has risen from \$132 billion (ADA, 2003) to over \$245 billion in 2012 (ADA, 2013). Seventy percent of people with diabetes will die from cardiovascular disease (CVD), which includes heart disease, their number one cause of death and disability (Zhao et al., 2014). CVD costs are projected to triple from \$273 billion in 2010 to \$818 billion in 2030 (Heidenreich et al., 2011). Coronary heart disease (CHD) takes the life of 380,000 people annually at a cost of \$108.9 billion, causing about 720,000 heart attacks each year (Murphy, Xu, & Kochanek, 2013).

Some of the current, well-recognized risk factors of type 2 diabetes include the following:

- being overweight (Biggs et al., 2010)

- inactivity (Hu, 2003; Jeon, Lokken, Hu, & van Dam, 2007; Plotnikoff, Costigan, Karunamuni, & Lubans, 2013)
- improper nutrition (Barnard et al., 2009a; Pan et al., 2011; Tonstad et al., 2013)
- high blood pressure, cholesterol, and blood sugars (ADA, 2016)

Complications of diabetes include cardiovascular disease, albuminuria, hypertension, dyslipidemia, poor healing, retinopathy, neuropathy, erectile dysfunction, peripheral artery disease, and foot complications (ADA, 2016). Major risk factors for type 2 diabetes includes ethnicity, being 45 years old and older, having a BMI of 25 kg/m<sup>2</sup> or greater, and being on certain medications (ADA, 2016). Diabetes and its complications are both considered insidious and progressive by Western medicine standards (ADA, 2016), and treatments include limited lifestyle education, oral medications, and insulin (ADA, 2016). However, on a plant-based, whole-food diet without the use of animal products, and exercise, this disease can be reversed and prevented (Le & Sabate, 2014).

The precursor to diabetes is the metabolic syndrome, a cluster of symptoms related to an increased risk of CVD, microvascular complications, and stroke (ADA, 2016). CVD is accompanied by hypertension and dyslipidemia, and it is the major morbidity and mortality event contributing to the high costs of diabetes treatment (ADA, 2013). Metabolic syndrome is characterized as having three of five risk factors according to the “harmonized definition” as set forth in 2009 by a joint effort among the International Diabetes Federation Task Force on Epidemiology and Prevention; the

National Heart, Lung, and Blood Institute; the American Heart Association; the World Heart Federation; the International Atherosclerosis Society; and the International Association for the study of Obesity (Alberti et al., 2009). These interrelated risk factors include central obesity, hypertension, raised TG, low HDL, and dysglycemia. These factors occur together routinely and are present in most people with type 2 diabetes.

The harmonized definition for the criteria diagnosing metabolic syndrome includes the following:

- 1) Elevated waist circumference that is population and country specific
- 2)  $TG \geq 150$  mg/dL (1.7 mmol/L)
- 3) HDL  $< 40$  mg/dL (1.0 mmol/L) for males and  $< 50$  mg/dL (1.3 mmol/L) for females
- 4) SBP  $\geq 130$  and/or DBP  $\geq 85$  mmHg
- 5) FPG  $\geq 100$  mg/dL

In order to categorize these and all data variables, CHIP used the conventional risk factor categories set up by the NCEP Adult Treatment Panel III classification system (Panel, NCEPNE, 2002) except for TC, for which it used the Framingham risk classification (Wilson et al., 1998). The Framingham risk classification allowed for five categories of classification, and a more detailed analysis, instead of three categories that the NCEP used (Rankin et al., 2012). Classifications for each biometric for this current research are categorized as listed:

TC (mg/dL):  $< 160$ ; 160-199; 200-239; 240-280;  $> 280$

HDL (mg/dL):  $< 40$ ; 40-60;  $\geq 60$

LDL (mg/dL): <100; 100-129; 130-159; 160-190; >190

TG (mg/dL): <100; 100-199; 200-500; >500

FPG (mg/dL): <110; 110-125; >125

SBP (mm Hg): <120; 120-139; 140-160; >160

DBP (mm Hg): <80; 80-89; 90-100; >100

BMI (kg/m<sup>2</sup>): <18.5; 18.5-24.9; 25-30; >30

### **Early Health History**

Health reformers point out that a healthy, active lifestyle and a plant-based diet have been around for millennia; these are not new concepts or fads in disease prevention, as many believe (Sabate, Ratzin-Turner, & Brown, 2001). Plant-based diets and timeless lifestyle principles have been intuitively taught and prescribed since the time of Hippocrates, and later studied for their effectiveness; they continue to be researched today (Schwarz & Greenleaf, 2000). Hippocrates (460 BC-370 BC) was a Greek physician known as the “father of modern medicine,” and his timeless Hippocratic Oath articulates the medical ethos of “do no harm.” Historically, this has been an oath taken by physicians (Copland, trans. 1825; Karagiannis, 2014). In addition, Hippocrates is known for his proverb, “let food be thy medicine and thy medicine be thy food.” He understood and taught the connection between disease and lifestyle, the causation of illness, and ageless principles of health as written throughout the Hippocratic corpus (Karagiannis, 2014). Another well-known, early health reformer was Sylvester Graham, a Presbyterian minister, best known for his creation of coarse graham bread and the graham cracker, all originally made without additives and chemicals, and minimally processed (Graham,

1835, 1837). He also emphasized vegetarianism, the elimination of tea and coffee, and abstinence in order to properly nourish the body for disease prevention (Wendell, 1835).

Comprehensive health reform contemporaries to Graham were William Alcott, who founded The American Vegetarian Society (Robinson, 1965), and Joseph Bates, a seaman and early pioneer of the Seventh-day Adventist movement in 1839. He organized a temperance society and advocated for discarding coffee, tea, meat, butter, cheese, pies, and rich cakes in order to preserve health and prevent disease. John Harvey Kellogg, another early Adventist health reformer most notably known for his Kellogg's breakfast cereal, advocated for coffee and tea substitutes, vegetarian health reform (Robinson, 1965), and tobacco cessation (Kellogg, 2002). He also helped start holistic Battle Creek Sanitarium where he became the chief physician in 1876 under the encouragement of Ellen G. White, another early Adventist pioneer who progressively began to understand the connection between mind, body, health, diet, and worship (Robinson, 1965).

Beginning in 1863, White became the most outspoken Adventist health reformer, advocating for not only a vegetarian diet and abstinence in coffee, tea, alcohol, and tobacco, but advanced the health reform cause by encouraging a plain, wholesome 2-meals per day diet that eliminated swine flesh. White also advocated dress reform, exercise, cleanliness of self and surroundings, trust in God, fresh air, proper nightly and weekly rest, moderate sunshine, and water as treatment modalities over medications (Robinson, 1965; Schwarz & Greenleaf, 2000). White, who claimed her knowledge came from God, went on to become the most translated American author in history, influencing

millions worldwide on a variety of important topics, all with only a third-grade education (White, 2000). Her work is discussed in further detail later.

Since the startup of Battle Creek Sanitarium, other non-Adventist current-day health reformers validate these health principles, such as Nathan Pritikin, founder of the Pritikin Longevity Research Institute in 1976, and John A. McDougall, founder of McDougall's Health & Medical Center in 2002, have incorporated into their own practice health principles similar to the ones espoused by Ellen White. Pritikin, an engineer and inventor, was found to have heart disease at 40 years old but reversed it through a very low-fat, high-fiber, low-cholesterol, mainly plant-based diet and exercise, and then marketed it to others through his own program (Morton et al., 2014a). An autopsy upon Pritikin's death 27 years later showed no signs of heart disease (Hubbard, Inkeles, & Barnard, 1985). While working at Pritikin's residential center, and seeing cost as a limitation for attendees, Hans Diehl became inspired to start the CHIP program, the program of focus for this current research. This Adventist-facilitated program cost less, and participants did not have to leave home, making it well accepted and attended (Morton et al., 2014b).

Over 100 research articles have been published on the Pritikin diet. Pritikin's research revealed that the diet led to a 37% reduction in meeting metabolic syndrome criteria, a 3% BMI reduction, a 12-15% reduction in FPG and LDL respectively, a 15% reduction in TC, a 36% reduction in TG, and a 3% reduction in HDL after a 12-15 day residential stay (Sullivan & Klein, 2006). The limitations in this study were that it was retrospective and not randomized with controls, the patients were highly motivated, and

longer-term results needed follow up. After a 26-day program, FPG dropped from 178 to 134, 77% discontinued oral hypoglycemic agents, 72% discontinued insulin, and one was placed on insulin. After a two and three year follow up FPG remained similar, but 40% restarted oral agents and 22% restarted insulin, with the calories from fat being the difference in adding back the medication (Barnard, Massey, Cherny, O'Brien, & Pritikin, 1983).

Just as Pritikin sought to treat his own CVD through diet, so did John McDougall, MD. Through his diet, he successfully reversed the effects of a massive stroke he experienced, which had left him paralyzed on the left side for 2 weeks (McDougall, 2001). Between 2002 and 2011, 1,615 patients attended McDougall's residential program, and after seven days in the program there was a reduction in CVD risk from 7.5% to 5.5% (McDougall et al., 2014). Participants also showed significant health improvements in FPG, blood pressure, and lipid levels; 19%, 14% and 20% of participants reduced their SBP, DBP, and TC to normal, respectively. McDougall also published the first study, though small, on improving prognosis for breast cancer through a plant-based diet, which reduced cholesterol by 16%, prolactin by 38%, estrogen by 37%, and estradiol by 45% (McDougall, 1984).

Neal Barnard, a psychiatrist and founder of Physicians Committee for Responsible Medicine, has written approximately 17 books to date and routinely authors research articles linking health and nutrition (Barnard et al., 2014a; Barnard, Levin, & Trapp, 2014b; Bunner, Agarwal, Gonzales, Valente, & Barnard, 2014). When comparing a vegan, plant-based diet to the diet recommended by the ADA for 74-weeks (Barnard et

al., 2009a) and 22-weeks (Turner-McGrievy et al., 2008), Barnard and his colleagues found that both diets were well accepted and adhered to, but the vegan diet led to a greater improvement in macronutrients intake, glycohemoglobin A1c (HgbA1c) and plasma lipids, while reducing the need for more medications (Barnard et al., 2009a).

A 22-week worksite study with 109 employees with either diabetes or who were overweight found that that a vegan diet improved all health-protective nutrients and reduced TC and saturated and total fat, though LDL and TC differences were not statistically significant (Levin et al., 2010). Those on the vegan diet lost significantly more weight and reduced their BMI (Levin et al., 2010), and those in the intervention group experienced greater improvements in mental health, diet satisfaction, and physical health (Katcher, Ferdowsian, Hoover, Cohen, & Barnard, 2010).

### **Lifestyle Medicine**

Lifestyle medicine is an evidence-based, clinical discipline focusing on the prevention, management, and treatment of disease through lifestyle changes such as diet, exercise, stress management, tobacco discontinuance, rest, alcohol reduction, and a variety of other nonmedical modalities (American College of Lifestyle Medicine, n.d.; American College of Preventive Medicine, n.d.). A healthy lifestyle is the first line of defense for many chronic diseases (Fraser, 2009), and while a call for uniformity in this practice has been attempted to help physicians feel more confident (Lianov & Johnson, 2010), many believe they are still ill equipped to counsel on such topics (Dacey, Arnstein, Kennedy, Wolfe, & Phillips, 2013; Lianov & Johnson, 2010). “Lifestyle should

be the foundation of our healthcare system” but is not covered by insurance, so is not included in most physician practices (Hyman, Ornish, & Roizen, 2009, p. 12).

The American College of Lifestyle Medicine (2012) described CHIP (Rankin et al., 2012) as “yielding some of the most impressive recorded clinical changes ever in the literature. The results were achieved by volunteers, making this a most cost effective model for combating chronic disease.” Several other historical studies and pioneers highlight the effectiveness of lifestyle medicine.

### **Lifestyle Programs**

Since the mid-1950s, longitudinal studies have begun to reveal associations between incidence, prevalence, predisposing factors, and prognosis between lifestyle and diet in type 2 diabetes; these long-term studies include the following:

- the Framingham Study (Castelli et al., 1986)
- the Nurses’ Health Study I and II (Belanger, Hennekens, Rosner, &, Speizer, 1978; Pan et al., 2011)
- Health Professional Follow-Up Study (Pan et al., 2011)
- the Adventist Health Study 1 and 2 (Rizzo, Sabate, Jaceldo-Siegl, & Fraser, 2011; Tonstad et al., 2009; Tonstad et al., 2013)
- Adventist Mortality Study (Vang, Singh, Lee, Haddad, & Brinegar, 2008)

In addition, live-in, residential lifestyle programs provide a controlled setting where participants learn to optimize their diet (McDougall et al., 2014, Slavicek et al., 2008). However, the live-in approach is expensive for some, and participants must leave

home and work to attend the program, only to return home to what is often minimal psychosocial support.

An alternative to live-in, residential lifestyle programs are those that teach lifestyle principles in a classroom setting, instructing patients how to manipulate diet and lifestyle factors to reduce the risk or the prevalence of chronic diseases like diabetes or methods of controlling or reversing them. Examples of research using vegan, plant-based interventional programs include the following:

- workplace research (Levin et al., 2010)
- randomized, controlled studies (Barnard et al., 2009a)
- the Diabetes Prevention Program's clinical trials comparing diet to pharmaceuticals (Knowler et al., 2002)
- private physician offices (Crowe, Ellis, Esselstyn, & Medendorp, 1995; Esselstyn, 1999)

Many studies have shown the benefit of lifestyle approaches to be cost-effective and offer good value for the money (Bertram, Lim, & Barendregt, 2010; Eriksson et al., 2010; Jacobs-van der Bruggen et al., 2009).

### **Clinical Health Programs**

In addition to the residential lifestyle centers, current private practice practitioners such as surgeon, Caldwell Esselstyn, and Dean Ornish, also got involved in health reform teaching a plant-based diet without the use of animals. Results from research on 22 of Esselstyn's patients with severe CAD revealed that after 10 years, CVD had been arrested with no new myocardial infarctions for the 11 who remained on the interventional, plant-

based, low-fat diet (Crowe et al., 1995). Of the other 11 patients, six dropped out but remained on the diet without further cardiac events, the remaining five dropouts who returned to their original diet suffered a total of 10 cardiac events. Another study (Esselstyn & Golubic, 2014b) presented three case histories of patients with advanced heart disease progression who had been treated with the normal standard of care of multiple surgeries and medications, yielding unsatisfactory results. After switching to a whole-food, plant-based diet and removing animal products, each markedly and promptly improved. Another group of 177 patients reported similar results (Esselstyn, Gendy, Doyle, Golubic, & Roizen, 2014).

Ornish published over 40 research articles on his plant-based comprehensive lifestyle program (Ornish, n.d.). He published the first randomized clinical trial to evaluate the progression of atherosclerosis without drugs, instead prescribing a plant-based diet and lifestyle (Ornish et al., 1983; Ornish et al., 1990; Ornish et al., 1998). Compared to the control group, after 24 days, for the group that adhered to the diet, the frequency of angina episodes intervention was reduced by 91% and cholesterol by 21% (Ornish et al., 1983). Sixty-one percent of participants reported no chest pain after 3 years of continuing to be on the program at an average cost difference between \$18,119 for the intervention group and \$47,647 for the control group (Ornish & Multicenter Lifestyle Demonstration Project Research Group, 1998).

In a study of 24 sites with 2,974 men and women, the Ornish program evaluated participants at baseline, after 24 weeks, and 12 months to evaluate longer-term results (Silberman et al., 2010). Of the 78.1% (n=2,322) who remained enrolled in that program

after one year, significant improvements in both subjective and CVD risk factors were seen in glycohemoglobin A1c (HgbA1c), BMI, LDL, TC, SBP, DBP, and TG; HDL remained unchanged. Due to the success of these comprehensive lifestyle programs, as of September 2010, Medicare reimbursed for both the outpatient Ornish program and the residential Pritikin program (Harvard Health Letter, 2010).

### **Long-Term Studies in Lifestyle**

Epidemiological studies, with a focus on disease prevention, partnership, disease risk factor identification, disease surveillance, and disease cause and effect, are the cornerstones and guides of public health decisions and evidence-based practice (Blumenthal, & Yancey, 2004). Some of the first epidemiological studies were the infamous Tuskegee Syphilis Study (1932-1972; Roy, 1995) and the Framingham Heart Study (1948-present; Mahmood, Levy, Vasan, & Wang, 2014). In 1954, the Adventists began a progressive series of longitudinal, cohort studies:

- Adventist Mortality Study (AMS; 1958-1966)
- Adventist Health Study-1 (AHS-1; 1974-1988)
- AHS-2 (2002-present), and their sub-studies
- Adventist Health Air Pollution Study (1976-present)
- Adventist Religion and Health Study (2006-present; Loma Linda University School of Public Health, 2015a)

Other well-known non-Adventist, key epidemiological studies include the China-Cornell-Oxford Project I and II (the China Study I [1983-1984] and II [1989-1990]), and the Nurses' Health Study I and II (1976 and 1989).

The Framingham Study followed 5,209 adults from Framingham, Massachusetts to understand cardiovascular disease. The study was inspired by health concerns after President Franklin Roosevelt (1882-1945) died from CVD (Mahmood et al., 2014). Out of this research came the Framingham risk scores, a 10-year prediction of cardiovascular risk development, which shifted the focus of CVD from treatment to prevention (Rodondi et al., 2012). With over 1,000 published medical articles, this study clearly shows an association between diet, lifestyle, and disease (Millen & Quatromoni, 2001; Millen et al., 2005; Millen et al., 2006; Posner et al., 1995; Wolongevicz et al., 2010).

The China Study surveyed 6,500 people in 130 rural villages in China, examining the correlation between animal products and chronic disease such as diabetes, coronary artery disease (CAD), and certain cancers (Campbell, Parpia, & Chen, 1998). Campbell found that the greater the proportion of plant foods in the diet, the fewer chronic diseases, and that there was no point at which further reduction of animal products did not help. Rural China participants on average consumed a diet low in animal products and high in plant foods, which consisted of half the fat and three times the fiber than what Americans consume; 90% of their protein came from plants. Americans on average have a diet that is 30-45% fat; American men have a 16.7-fold increase in mortality rate over their Chinese counterparts, and American women have a 5.6-fold increase (Campbell & Chen, 1999).

The Nurses' Health Studies (NHS) has yielded over 1,400 studies (National Health Sciences, n.d.) following 121,700 female nurses in NSH-1 and 116,671 female nurses in NSH-2 since 1976 and 1989, respectively (Pan et al., 2011). The NHS indicates

a clear correlation between meat consumption, other dietary factors and type 2 diabetes (de Munter, Hu, Spiegelman, Franz, & van Dam, 2007; Devore et al., 2009; Fung, Schulze, Manson, Willett, & Hu, 2004; Fung, McCullough, van Dam, & Hu, 2007; Jiang et al., 2002; Pan et al., 2011; Schulze et al., 2004; Schulze et al., 2005; Sun et al., 2010; Wedick et al., 2012).

### **Adventist Health Movement History**

A worldwide, growing body of about 18 million members, the Seventh-day Adventist church is a conservative Protestant movement that believes the Christian experience is meant to pervade the whole life, emulating the gospel ministry and health ministry of Jesus (Seventh-day Adventist World Church, 2015a). Though they officially established themselves as a church in 1863, they have been meeting and growing since the 1840s (Seventh-day Adventist World Church [SDAWCH], 2015b). Since its inception, their movement has been based on health outreach, with now well over 75,000 churches, 21 vegetarian-focused food industries, 175 hospitals and sanitariums, 136 nursing homes and retirement centers, 269 clinics and dispensaries, 34 orphanages and children's homes, and 10 airplane and medical launches, located in 216 of the 238 countries around the world (SDAWC, 2015b).

Founded by the Adventist church in 1956, their largest health and humanitarian outreach program is the Adventist Development and Relief Agency (ADRA), a leading nongovernmental organization (NGO) stationed throughout 125 countries (ADRA, n.d.). ADRA provides health promotion, humanitarian relief, food distribution, and disaster relief in times of disaster and for long-term development for those in poverty and distress.

The focus of their worldwide work is to promote health, provide food and water, protect the vulnerable, support families, help establish livelihoods, and respond to emergencies. Their second largest faith-based health outreach program is the Adventist Health System (AHS), operating 8,100 licensed beds within 45 hospitals in 10 U.S. states, seeing more than 4.5 million patients per year (Adventist Health System, n.d.). The church also operates urgent care centers, hospice care, home health care, and skilled nursing facilities.

In line with keeping their health vision, one of the Adventist's 28 fundamental beliefs includes believing that the key to wellness lies in temperance and health reform, as well as keeping the body free from alcohol, tobacco, mind-altering substances, and other harmful chemicals (Ministerial Association, General Conference of Seventh-day Adventists, 2005). The Adventist health message also includes promoting clean, healthy lives through the intake of fresh air, pure water, moderate sunlight, daily exercise, one day weekly and nightly rest, trust in God, moderation of all things healthful, and a diet abstaining from meat but including legumes, nuts, grains, fruits, vegetables, and a source of B-12 (Seventh-day Adventist World Church, 2015c).

The Adventist's message of health started as early as 1848 when Ellen G. White (1827-1915) spoke out about the harmful effects of coffee, tea, and tobacco (White, 1870). Progressively through her years, she presented new dietary and non-dietary health principles, as the denomination was able to accept more changes (Douglass, 1998, *Emergence of a Health Message*). Compilations of her decades-long messages of healthful living, reside under several titles but most notably, in *Counsels on Diet and Foods* (White, 1938). Other more-current healthy-living titles include *Counsels on Health*

(1923), *Ministry of Healing* (1905), *Temperance* (1949), and *Medical Ministry* (1932), some of them compiled after her death, with some original titles and full books adopting more modern titles.

White began to understand the relation of physical health to spirituality in 1863, and continued educating the church until the time of her death in 1915 (Douglass, 1998, *Reviewing A Century of Health Reform Principles*). Though many of these health principles are taught in modern days as a matter of fact and integrally related, in her day her views collectively were extreme (Douglass, 1998). The CHIP intervention and White's principles share a similar healthful foundation. With only a third grade education, who claimed her message came from God, White's health message (White, 1938) included the following:

- Obeying the natural laws of health will prevent many illnesses
- Turning towards a healthy diet will help reverse diseases; improper eating is a cause of disease
- Tobacco, coffee, tea, alcohol, and wine are slow poisons
- Freely eat of fresh fruits and vegetables
- Eat nuts in moderation. Some nuts are more healthful than others such as almonds are more healthful than peanuts.
- Drinking plenty of pure fresh water will help maintain health and cure many illnesses
- The flesh of swine is never to be eaten
- Outdoor exercise is healthful for mind and body

- Overworking breaks down the body
- Overeating is intemperate
- Temperance and moderation in all things healthful
- Many people die prematurely solely from eating animal flesh foods and should not be eaten
- Caring for the body is a spiritual commitment to God
- Fasting provides curative powers
- A time will soon come when eating dairy, cream, eggs, and butter will be unhealthful due to the increase disease of animals
- Cleanliness of the home and body is important
- Do not drink beverages including water with meals
- Eat more raw foods and fewer cooked foods
- Eating between meals is injurious to the stomach and digestive system
- Eating two meals per day is better than three but if a third meal is taken in the day, it should be easily digestible and light, and should be taken several hours before bedtime. Adequate time between meals are necessary for proper digestion.
- Rich cakes, pies, and puddings are injurious, as is the combination of sugar and milk
- Those who are used to a meat-based diet will not at first relish a more simple diet; adjustment takes time.

- Pickles, vinegar, spices, baking soda, baking powder, lard, cheese, grease, and too much salt are harmful

### **Adventist-Related Research**

Adventists have been involved in health education since its inception in the 1840s, educating both its members and the public (Robinson, 1965; Schwarz & Greenleaf, 2000). In 1954, Adventists entered the field of epidemiological research, and since then have published hundreds of peer-reviewed research articles (Hardinge & Stare, 1954a; Hardinge & Stare, 1954b). Adventists have participated in five large, longitudinal studies all based out of Loma Linda, California: AMS (1958-1966), AHS-1 (1974-1988), Adventist Health Air Pollution Study (1976-present), AHS-2 (2002-present), and Adventist Religion and Health Study (2006-present), all focusing on the different aspects of relationship between diet, lifestyle, and disease (Lee et al., 2009; Loma Linda University School of Public Health, 2015b). Adventists have proven that they are quite willing to participate in health research studies.

Adventists are an ideal group to study since by proscription for over 160 years, nearly all abstain from smoking (98.9%) and alcohol (95.4%), thereby reducing the confounding effects of these nondietetic factors (Butler et al., 2008). Adventists also abstain from biblically unclean meats such as fish without fins and scales, pork, and shellfish (Leviticus 11) and are encouraged to abstain from caffeinated beverages, tea, rich desserts, highly refined foods, and spices. Moreover, Adventists advocate exercise and a vegetarian diet high in fruits, vegetables, nuts, and grains—though a vegetarian diet is not required (Phillips et al., 1980). A wide array of diets are practiced among this

group; the percentages may slightly vary from study to study, but generally the earlier studies reported Adventists were 4.2% total vegetarian or vegan, 31.6% lacto-ovo vegetarian, 11.4% pesco-vegetarian, 6.1% semi-vegetarian (having meat fewer than one time per week), and 46.8% not vegetarian (Butler et al., 2008). Partly as a result of diet and exercise, the earlier the age of baptism into the church, the lower the relative rate (RR) of death (Snowdon et al., 1982); for those baptized as children as compared to adults, the RR of ischemic heart disease death was 0.71, with reduced mortality rates for men but not women (Heuch et al., 2005).

The AMS was the first major Adventist research study raising awareness to the link between diet and health, enrolling 22,940 Californians (Phillips, Lemon, Beeson, & Kuzma, 1978) with a 5- and 25-year follow up. Compared to the American Cancer Society (ACS), a group being researched at the same time as the AMS with similar education and incomes, Phillips et al. (1980) reported a lower mortality ratio in Adventists for all-cause cancers (males 0.60, females 0.76), all-cause deaths (males 0.66, females 0.88), coronary heart disease (males 0.66, females 0.98), and most cancers. However, despite the improved outcomes for diabetes, most cancers (breast, ovaries, colon, ovaries, rectum, and prostate), and vascular diseases, male Adventists had a higher ratio in stomach cancer (1.41) and women had an equal ratio in lymphoma and leukemia (1.00), as well as higher nonspecific circulatory conditions (1.01) than the ACS group.

Comparing cancer risk of California Adventists with that of the general California population, many results were even better in outcomes for diabetes, vascular disease, and cancers than those from the ACS studies (Phillips, 1980). This new knowledge in the

AMS brought up further questions regarding what specifically was it about the Adventist lifestyle that allowed them to live longer, which led into AHS-1 (Beeson, Mills, Phillips, Andress, & Fraser, 1989).

AHS-1 was designed to discover which aspects of the Adventist lifestyle provided the disease protection found in the AMS (Beeson et al., 1989). Baseline data for the AHS-1 included 34,198 non-Hispanic Adventist California Caucasians, where 55.2% were ovo-lactovegetarian or vegan, 6% ate meat daily [Snowdon, 1988], and 50% were converts not born into the church; researchers were able to follow up with 98.8% of the participants over 12 years (Beeson et al., 1989). A meta-analysis of five prospective studies, which included the AHS-1 and AMS, revealed that vegetarians had lower rates of death from heart disease (0.76 average) and mortality from any cause (0.95). Further, the vegetarians had lower cholesterol and BMI, less tobacco and alcohol use, and exercised more than nonvegetarians (Key et al., 1998). Eating nuts at least four times per week also reduced the risk of CHD by 37% (Kelly & Sabate, 2006). Overall, the survival advantage of California Adventists comparing vegetarians to nonvegetarians was 3.6 years of additional life in one study (Singh, Sabate, & Fraser, 2003) and 7.28 years longer in men and 4.42 years for women in another study (Fraser & Shavlik, 2001). Longevity in Adventists has been known since 1969, when Lemon and Kuzma (1969) reported a 6.2-year greater life expectancy in California Adventist men and 3.7 years for California Adventist women than the life expectancy of the general U. S. population.

In 1977, researchers expanded the AHS-1 and began investigating the long-term effects of air pollution on health outcomes such as CHD, all-cause mortality, and newly

diagnosed cancers, as well as the symptoms of emphysema, bronchitis, and asthma. The majority of Adventists do not smoke (98.2%), which reduces distortion when doing this kind of study (Beeson et al., 1989).

The AHS-2 recruited over 96,000 Adventists from the United States and Canada, making it the largest prospective study of its kind (Butler et al., 2008), and includes the largest study on African Americans (Herring, Butler, Hall, Montgomery, & Fraser, 2010). They sought to answer a number of questions: Is heredity or lifestyle more important? Does faith influence health outcomes? Which foods prevent diseases such as Alzheimer's, cancer, diabetes, arthritis, and heart disease? Which foods improve quality of life? In addition, why do African Americans have disproportionate numbers of heart disease and cancers? In the AHS-1 group (Butler et al., 2008), 8% are vegan compared to 2% of the general population (Gallup, 2012), 28% are lacto-ovo-vegetarian compared to 5% of the general population (Gallup, 2012), 16% are either pescovegetarian or semivegetarian, and 48% are nonvegetarian.

Compared to nonvegetarians, the AHS-2, AHS-1, and AMS combined found vegans had 5 points lower BMI, 75% less risk of hypertension, between 47% and 78% lower risk of diabetes, 14% less risk of all-cancer, but had a 73% increase risk of urinary tract cancer, 42% lower risk in CVD mortality, and 55% lower risk for ischemic heart disease (IHD; Le & Sabate, 2014). Le & Sabate (2014) also found that the dietary habits of Adventists contain more fiber than the average intake, and those that do eat meat, consume less than the average intake. Diet reduces the risk of many health disparities but

does not account for all. In addition to diet, socialization and religion have also been predictors of longevity—hence, the Adventist Religion and Health Study.

The Adventist Religion and Health Study is a subset of the AHS-2 group consisting of 11,000 United States and Canadian Adventists, which set out to determine which aspects of religion effected health outcomes (Lee et al., 2009). So far, this study has shown that those who have higher intake of fresh fruits, vegetables, olive oil, beans, and nuts have improved moods and food choices, while desserts, soda, fast food, sweets, and red meat were associated with a negative mood and additional negative food choices (Ford, Jaceldo-Siegl, Lee, Youngbert, & Tonstad, 2013). Other preliminary results show that those who experience poverty are more religious, but abused individuals are less religious. Further, religious engagement may improve health outcomes for adults when they experienced abuse early in life (Morton, Lee, Haviland, & Fraser, 2012).

Some of the limitations of the Adventist Health Studies are as follows:

1. Little dietary data on fruit and vegetable intake were collected in AMS, and information was not gathered on meat substitutes that many Adventists use, such as beans, nuts, and prepackaged vegetarian protein (Snowdon, 1988).
2. Information on social or church activities were not collected, despite these having been shown to reduce mortality and could have created confounding on a vegetarian diet and disease outcomes (Snowdon, 1988).
3. Four to seven percent of data items on the questionnaire were not answered, including sensitive and nonsensitive items (Beeson et al., 1989).

4. The questionnaire took on average between 1.25-3.5 hours to complete, and had a low rate of males (34.9%) and Hispanics (0%). The questionnaire was not offered in Spanish (Butler et al., 2008).
5. Since only Adventists are represented, the findings are less generalizable to other non-Adventist vegetarians.
6. The baseline for the vegetarian and vegan diet were the Adventist meat-eaters, who in general eat less meat than the general population (Le & Sabate, 2014). This reporting may result in smaller observed effects.

The strengths of the Adventist Health Studies include the following:

1. Many studies have greater than 90% participant follow up; other researchers are glad to get 50% on these kinds of studies.
2. Adventists have low alcohol and tobacco use, which reduces confounding and increases statistical power.
3. There is church support at all levels: members are willing to participate in research and administration encourages members to participate.
4. AHS-2 has an in-depth food questionnaire.
5. AHS-2 includes broad geographical locations.
6. AHS-2 includes a large number of Blacks.
7. AHS-2 includes a comprehensive calibration study measuring error and validity (Butler et al., 2008).

8. The focus of these studies represent vegetarian Adventists, and the study uses consistent operational definitions of differing dietary patterns (Le & Sabate, 2014).

### **Complete Health Improvement Program (CHIP) History**

In addition to the denominational-wide prospective Adventist Health Studies, many members have also started independent health ministries, such as residential and community health programs; CHIP is one such program. Hans Diehl founded the Complete Health Improvement Program in 1986 after working with Nathan Pritikin, the founder of the Pritikin Longevity Center, a residential, live-in lifestyle center (Morton et al., 2014a). As participants progressed through this lifestyle program, Diehl found significant improvements of their chronic diseases within only a few weeks. The Pritikin Program guidelines consisted of a very low fat, low sodium, high fiber, plant-based diet, except for one 3.5 ounce serving of fish or chicken once per week, 45-60 minutes of daily exercise, and no alcohol, tobacco, or caffeine (Roberts, Nosratola, & Barnard, 2002). The diet allowed for 10% fat, 25 mg of cholesterol, 10%-15% mainly plant protein, and 75%-80% complex carbohydrates (Pritikin, 1984). Sixty-seven subjects (52 men and 15 women; mean age, 60±10 years) on the Pritikin three-week residential program showed a 31% reduction of metabolic syndrome by implementing the very low fat, high fiber, low sodium diet (Sullivan & Klein, 2006). Eleven men (21%) showed a 41.3% reduction in LDL, a 46.2% reduction in fasting insulin, a 13.6% drop in SBP, a 9.8% reduction in DBP, a 41.3% reduction in TG, and a 14.8% drop in HDL (Roberts, Nosratola, & Barnard, 2002).

Seeing the limitations to this artificial but powerfully-principled residential health setting, Diehl set out to create his own program teaching similar health principles, except offering it in a 30-day community setting. His program cost less by negating the necessity of having to leave work or travel distances, it provided community support, and allowed participants to grow and adapt in their own home environment as they learned through the program (Morton et al., 2014a). Diehl presented his first 4-week, 16-session CHIP program in 1988 in Creston, British Columbia, Canada to an audience of 400. For the next several years, he traveled in and out of the United States teaching CHIP.

The primary goal of the program was to reduce the symptoms associated with heart disease and diabetes, such as high lipids, blood pressure, and blood sugars through a whole-food, plant-based, vegan diet (Diehl, 1998). The secondary goal was to reduce weight, reduce the need for pharmaceuticals, eliminate tobacco, improve stress, and increase exercise (Diehl, 1998). The CHIP diet, called the Optimal Diet, and lifestyle consists of 30 minutes of daily exercise (Morton et al., 2014b), 15% fat, 10%-15% plant protein, 65%-70% complex carbohydrates, fewer than 50 mg cholesterol, fewer than 10 teaspoons sugar, low salt, at least 40 grams fiber, and 8-10 glasses of water (Englert, Diehl, Greenlaw, Willich, & Aldana, 2007). Participants were encouraged to stop smoking and attend monthly alumni meetings. CHIP was driven by the theory of planned behavior (TBH; Ajzen, 1985), which included a strong educational component, targeting attitudes, social norms, and perceived volitional control.

In 1997, sponsored by the Lifestyle Medicine Institute, the International Nutrition Research Foundation, Borgess Health Alliance, and the Center for Science in the Public

Interest, Diehl videoed the program for a live audience in Kalamazoo, Michigan and presented the first research of that group in 1998 (Diehl, 1998). This program was packaged into a curriculum for both professionally educated health professionals and nonhealth trained volunteers who attended a 2-day CHIP training session (Rankin et al., 2012). The Kalamazoo program graduated 288 self-selected, paying participants.

Being a health professional was not a criterion for volunteers since the directors had only a facilitator's role, not an educator's role. Health education was presented by Diehl via video, and the volunteers then directed group discussions, gave cooking demonstrations, and provided grocery store tours. The volunteer channel has been largely adopted by the Seventh-day Adventist church (Morton et al., 2014a). In 2000, Roger Greenlaw initiated the professional CHIP channel with the Rockford cohort program, enrolling 1,517 paying, self-selected participants between 2000 and 2002 (Englert et al., 2007) with a goal of enrolling 5,000 participants over seven years, giving the program every six months (Englert et al., 2004). CHIP continues to be an intensive educational program given in 40 hours over four to five weeks, four evenings per week plus two Sundays.

### **CHIP-Related Research**

CHIP has now educated over 70,000 participants worldwide by professionals and volunteers and has been written up in more than 25 publications (Morton et al., 2014a). This present study made use of 22 peer-reviewed research studies on the CHIP program. Seventeen CHIP studies examined healthcare professionals delivering the CHIP lifestyle

intervention, seven examined volunteers, and one summarized the history of CHIP for both volunteers and professionals, and all are discussed next.

**First-recorded CHIP: Kalamazoo, Michigan.** In 1997, Diehl delivered and video recorded CHIP before 400 people in Kalamazoo, Michigan and published the first CHIP results in the *American Journal of Cardiology* (Diehl, 1998). Two hundred and eighty-eight graduated of the 304 enrollees (Diehl, 1988). Consistent with later CHIP research, those with the greatest needs improved the most (Diehl, 1998; Englert et al., 2004; Morton et al., 2014a; Rankin et al., 2012). Men who had cholesterol levels above 279 mg/dL reduced their cholesterol by 33%, 34% saw a reduction in LDLs with levels greater than 189 mg/dL, 39% saw a reduction of TG if between 400 and 599 mg/dL, but a lowering of HDL if their total-to-HDL cholesterol ratios were above 6.0 mg/dL (Diehl, 1998). Morbidly obese men (150% ideal body weight or higher) lost 13.7 pounds, the most of any weight category after the four-week program. FPG also improved over the program length. Thirty percent of those with diabetes cut their insulin by as much as 30%, which increased confounding, due to the reduction of diabetes and other medications for hypertension and hyperlipidemia. The above results may actually be more profound since most participants reduced or eliminated medications.

Though men improved more than women overall, women improved as well (Diehl, 1998). Women lost on average 5.2 pounds, glucose dropped by 6.7%, TC dropped by 21.6 %, and similar to men, dropped also in the good HDL cholesterol by 6.6 %, which has subsequently been written up in Kent et al. (2013b).

**Rockford CHIP: Professional-channel.** The first publication from the

professional Rockford CHIP cohort appeared in 2004 (Englert et al., 2004). Fifteen peer-reviewed articles highlighted results from Rockford, all given by health professionals in either a community (Englert, Diehl, & Greenlaw, 2012) or workplace setting (Aldana, Greenlaw, Diehl, Englert, & Jackson, 2002). Another professionally delivered CHIP intervention program out of Vanderbilt University (Shurney et al., 2012) published an article tracking healthcare expenditures of employee participants for 26 weeks.

The Rockford CHIP (Englert et al., 2004; Englert et al., 2007) found similar results in all biometrics as Kalamazoo, and additionally found reduced depression and improved sleep and stress through nutrient improvement (Merrill, Taylor, & Aldana, 2008). However, serum C-reactive protein (CRP) did not significantly improve over baseline despite improvements in weight, BMI, saturated fat, and body fat percentage (Merrill et al., 2008). The researchers suggested that was possibly due to the small sample size in an otherwise generally healthy population. In addition, as with the Kalamazoo population, men in the Rockford population improved more over women, though both improved, and those with the highest risk factors had the greatest improvements, this included those with high blood sugar levels (Englert, Diehl, Greenlaw, & Aldana, 2012). Of the 237 participants who had diabetes, 154 were on diabetes medications, and 83 were unaware of their diabetes status. Forty-two percent of participants on insulin, and 44% on oral antidiabetics were advised by their doctor to reduce their dosage. Thirty-five percent reduced their glucose below 125 mg/dl and 10% reduced it to below 100 mg/dl in 30 days.

**CHIP volunteer-channel.** In addition to the CHIP intervention being delivered

through a professional channel, it has also been largely adopted by the Seventh-day Adventist church through a volunteer channel delivered by trained nonmedical people in their local community (Morton et al., 2014a). Volunteers attended a 2-day training workshop and learned about the video-presentations and their role as facilitators (Rankin et al., 2012). To date, five peer-reviewed articles (Kent et al., 2013b; Kent et al., 2014; Morton et al., 2014a; Morton et al., 2014b; Rankin et al., 2012) on the North American volunteer programs have resulted from a dissertation by Rankin (2013), and since then, groups from Australasia (New Zealand and Australia; Kent et al., 2013a; Morton et al., 2013); and Appalachia, Ohio in the United States (Drozek et al., 2014) have also been reported on. Morton et al. (2014b) gives a comprehensive picture of the CHIP history, evaluation, outcomes, and comparisons of previous professional and volunteer programs and Morton et al., (2014b) reported specifically on Canadian outcomes.

Of the seven volunteer-delivered research articles published in peer-reviewed journals, one focused on the HDL implications in the metabolic syndrome and the potential lack of its usefulness (Kent et al., 2013b); one focused on gender differences on chronic risk factors (Kent et al., 2014); one examined aggregated outcomes of Canadian's pre- and postdisease risk factors—BMI, SBP, DBP, FPG, and blood lipid profile (Morton et al., 2014b); one looked at the pre- and postdisease risk factors of the North American CHIP cohort (Rankin et al., 2012); and one presented the CHIP history, evaluation, and outcomes summarizing the risk factors in both the volunteer and professional delivered programs (Morton et al., 2014a). The dissertation focused on reducing risk factors associated with metabolic syndrome (Rankin, 2013).

Similar to the North American disease risk factor results, rural Appalachia, Ohio (Drozek et al., 2014) and Australasia (Morton et al., 2013) were also assessed for risk factors immediately following the CHIP program. A subset of the Australasia cohort (Kent et al., 2013a) was assessed for long-term effectiveness. Comparable to the professionally-delivered, prerecorded CHIP intervention, the volunteer-delivered, prerecorded CHIP intervention garnered similar results: those with the highest chronic disease risk factors made the greatest improvements (Rankin et al., 2012), HDL dropped despite improved outcomes in other risk factors (Kent et al., 2013a), and men improved more than women, though both genders improved overall (Kent et al., 2014).

Both the professionally-delivered (PD) and volunteer-facilitated (VF) programs assessed pre- and postbiometric changes in TC, HDL, LDL, TRI, BMI, SBP and DBP, and FPG (Morton et al., 2014a). In aggregated data, the mean age for the VF (n=7085) was 2.7 years older, at 56.8 years, than the professionally-delivered (PD; n=4678), both had more females than males, BMI was reduced by 3.5% (PD) and 3.3% (VF), SBP drop was equal at 5.0%, DBP dropped 5.2% (PD) and 5.1% (VF), TC dropped 11.3% (PD) and 11.4% (VF), HDL dropped 9.1% (PD) and 13.4% (VF), LDL dropped 12.5% (PD) and 8.6% (VF), TG dropped 7.3% (PD) and 8.1% (VF), and FPG dropped 5.5% (PD) and 6.1% (VF).

In comparison, considering the outcomes of the volunteer-delivered program, it may present itself as a cost-effective adjunct to professional health care (Shurney et al., 2012). Shurney et al. (2012) reported significant savings in medical costs in CHIP participants with diabetes from the previous year's quarter and after the CHIP program

the following year's quarter. Medical costs were reduced by 45.5% and 40.3% in quarter one and two compared to an increase in medical costs of 5.4% and 21.2% in the same two quarters for non-CHIP participants with diabetes. Prescription costs also declined by 14.7% and 13.8% in quarter one and two for CHIP participants, but rose by 11.5% and 7.6% for non-CHIP participants. The average number of office visits was significantly reduced, as was the number of prescriptions filled. Other comprehensive lifestyle modification programs have seen similar results such as the Diabetes Prevention Program (DPP), which has shown prevention or delay in diabetes incidences for 10 years for lifestyle (34% reduction) versus metformin (18% reduction; Knowler et al., 2009), but without the pharmaceutical side effects (Hung et al., 2015; Kalantar-Zadeh & Rhee, 2015).

Several factors may explain the significant biometric risk reduction as observed in the CHIP intervention. Participants were self-selected and may have been more motivated and ready for change, as shown by a low attrition rate (3%), the necessity to pay for the program (Morton et al., 2014b), and a short 4-week intervention (Morton et al., 2014a). Limitations in the CHIP intervention included a lack of control group, and compliancy was not evaluated. A confounding factor was that many participants either discontinued or reduced their medication use, potentially diminishing the observed effectiveness in biometrics (Rankin et al., 2012). Despite the limitations, CHIP's strength is the sample size, and the strong and focused educational element, which concentrates on comprehensive lifestyle choices of improving diet, exercise, and sleep, stress reduction, emotional health and self-worth, overcoming obstacles, and maintenance (Kent et al.,

2014). CHIP addresses the root causes of diabetes, which is diet and lifestyle.

Although most volunteer-facilitated CHIP programs are presented by Adventists, and a body of evidence exists comparing mean changes in the pre- and postprogram disease risk factors and between genders, a literature gap exists when it comes to understanding how having a specific faith belief may affect biometric outcomes within the CHIP program for those with type 2 diabetes. It is also unknown if Adventists enter the CHIP program with a different rate of diabetes compared to non-Adventists.

### **CHIP Video-Presentation**

The volunteer- and professionally-delivered CHIP program consisted of sixteen 2-hour group sessions, which included a 1-hour recorded health lecture by the founder, Diehl, live demonstration cooking classes, a grocery store tour, group discussions, and exercise classes (Englert et al., 2004; Rankin et al., 2012). Video content instructions included the following:

- plant-based nutrition
- exercise
- behavioral change
- self-worth
- accomplishments and limitations of modern medicine
- smoking
- cholesterol
- dietary fiber
- lifestyle and health

- CVD
- diabetes
- atherosclerosis
- hypertension
- obesity
- dyslipidemia (Englert et al., 2004; Rankin et al., 2012)

Video-facilitated education has been used successfully in a variety of health education programs. Maltinsky, Hall, Grant, Simpson, and MacRury (2013) evaluated a work-based pilot video conferencing program targeting diabetes education for rural healthcare professionals with limited training options. Video conferencing promoted equal learning as in-person, but had less spontaneous interaction with the instructor. A different qualitative, motivational, video-based program (Essien et al., 2011) assessed the cost-effectiveness, stability, and feasibility in HIV prevention for women in Southwestern Nigeria (n=346) where resources were limited. The results indicated that both the interventional motivational video and the control didactic video equally increased HIV knowledge, but the motivational video significantly improved condom use and reduced the number of sexual partners and alcohol use before sex at the six-month follow up over the didactic video. The limitation in this study is that all behavioral outcomes were self-reported, and subjects were from a convenience sample. However, there was random assignment, and retention rate was high.

In another study, a tuberculosis (TB) video-education program shown to immigrants and refugees in an English as a Second Language (ESL) classroom entering

the United States (n=159) increased TB knowledge, with participants increasing test scores from 56% to 82% correct. Ninety-four percent of those using ESL stated the video instruction format was appropriate for learning, and self-efficacy increased from 77% to 90% (Wieland et al., 2013). Overall, knowledge increased significantly in all learning sections by viewing video-recorded educational sessions. These studies and others highlight the effectiveness of using a prerecorded educational video as a learning medium (Canter, Rao, Patrick, Alpan, & Altman, 2015).

### **Volunteer-Delivered Lifestyle Programs**

Volunteer-facilitated, community-based, lifestyle programs have the potential to impact larger numbers of people while reducing costs significantly (Baron et al., 2008; Knowler et al., 2009; Siabani, Driscoll, Davidson, & Leeder, 2014; Shurney et al., 2012). The purpose of this dissertation was to analyze the volunteer-facilitated aspect of the CHIP intervention, though medical professionals also present the intervention program and have been studied separately. The CHIP intervention has mainly been adopted by volunteers from the Seventh-day Adventist church wishing to affect positive change in their community (Morton et al., 2014a). Extant literature reveals the most common volunteer setting is related to a health-orientation setting, with the volunteer possessing a protestant or Catholic religious affiliation, and who engages in prayer with altruistic values (Moore, Warta, & Erichsen, 2014).

In other research, health indicators for chronic heart failure (Siabani et al., 2014), CVD risk factors (Rankin et al., 2012), and an at-home exercise program (Castro, Pruitt, Buman, & King, 2011; Etkin, Prohaska, Harris, Latham, & Jette, 2006) also improved

following educational programs presented by trained volunteers. More encouraging, some research shows that trained volunteers may be more effective than paid professionals (Castro et al., 2011), and equally as effective (Morton et al., 2014b). Whether the trained volunteer is a peer or an undergraduate college student and younger, participants significantly improve their health outcomes under their guidance (Dorgo, King, & Brickey, 2009). Research shows that both participants and volunteers benefit in perception, enjoyment, motivation, role modeling, and retention whether receiving or presenting the program (Dorgo et al., 2009).

### **Summary and Conclusion**

Diabetes is having a substantial impact on society in health and life expectancy and in health care costs for individuals, employers, and state and federal budgets. A plethora of dated and contemporary evidence exists in the literature showing the effectiveness of a comprehensive lifestyle, plant-based, vegan program in the reduction of chronic diseases such as diabetes and CVD; the cure and reversal is in the cause. Adventists have been successfully sharing a progressive and unique health message with the world in a multitude of settings since the 1840s, which reverses and reduces the risk of disease. Studies also show that lifestyle approaches are more cost-effective than a pharmaceutical, Western type of approach while reducing medication usage. Research reveals that Adventists and non-Adventists who follow this counsel and adhere to a plant-based diet have lower incidences of diabetes and CVD. Adventist programs such as CHIP focus on diet, exercise, and stress reduction and have the potential to impact large numbers of people while reducing costs significantly due to targeting the root cause of

disease. Despite a lack of control group and selection bias, with its large sample size, the CHIP modification intervention has shown to be an effective 30-day, community-based, video-presented, plant-based, lifestyle program delivered by both volunteers and professionals. The CHIP research has been consistent showing that participants with the greatest needs improved the most, and men improved more than women did though all improved. However, despite the volunteer program being presented and adopted mainly by the Adventist church, there was a research gap when assessing program effectiveness between Adventists and non-Adventists with diabetes.

## Chapter 3: Research Method

### Introduction

The purposes of this study were to determine the relationship between religiosity and preprogram diabetic rate, and to compare if having a particular religious belief (Adventist or non-Adventist) significantly affected biometric outcomes for those with type 2 diabetes pre- and post-CHIP. This quantitative, correlational, secondary data, research design study examined the rate difference between religiosity and self-identified preprogram diabetic state, and assessed how religiosity affected postbiometrics. The Walden University Institutional Review Board (IRB) approved this research with approval number 11-09-15-0065108.

The following research questions guided this study:

**Research Question 1 (RQ1):** After controlling the effects of age, gender, marital status, BMI, and parental death from diabetes before age 60, is there a statistically significant difference in self-identified type 2 diabetes prevalence rates between Adventist and non-Adventist CHIP participants preprogram between January 2006 and September 2012?

**H<sub>0</sub>1:** The self-identified diabetes prevalence rate between Adventist and non-Adventist in pre-CHIP participants is not significantly different.

**H<sub>1</sub>1:** The self-identified diabetes prevalence rate between Adventist and non-Adventist in pre-CHIP participants is significantly different.

The quantitative test used to answer RQ1 was logistic regression.

**Research Question 2 (RQ2):** After controlling for the effects of age, gender, marital status, and parental death from diabetes before age 60, is there a statistically significant difference in the change in biometric outcomes (TC, HDL, LDL, TG, FPG, SBP, DBP, and BMI) between Adventists and non-Adventists with self-identified diabetes pre- and post-CHIP between January 2006 and September 2012?

***H<sub>02</sub>*:** There is no statistically significant difference in biometric outcomes between Adventists and non-Adventists with self-identified type 2 diabetes pre- and post-CHIP.

***H<sub>12</sub>*:** There is a statistically significant difference in biometric outcomes between Adventists and non-Adventists with self-identified type 2 diabetes pre- and post-CHIP.

The quantitative test used to answer RQ2 was a MANOVA.

### **Research Design and Rationale**

This study utilized a quantitative methodology with a correlational design using a secondary data set from CHIP. This quantitative approach was selected in order to understand statistically how lifestyle factors relate to disease outcomes and having a specific faith belief. Correlational research was conducted because this design looks at relationships among variables (Leedy and Omrod, 2010). There were no time or resource constraints in this study; the overall objective was to determine the relationships between the variables of religiosity, preprogram diabetic state, and biometric outcomes.

In RQ1, the independent variables were religiosity and pre- and post-CHIP measurement testing periods. The dependent variable was self-identified diabetes, having been told by a doctor they have diabetes, and the covariates were age, gender, marital

status, BMI, and parental death from diabetes before age 60. In answering RQ1, an experimental design using logistic regression was employed to quantify the difference in diabetes rate between Adventists and non-Adventists.

The independent variables for RQ2 were religiosity and testing period. The dependent variables were the biomarker outcomes attained through blood sample testing for TC, HDL, LDL, TG, and FPG and the clinical parameters of SBP, DBP, height and weight measurements for BMI, and the covariates were age, gender, marital status, and parental death of diabetes before age 60. In answering RQ2, MANOVA, a correlational research design was used to quantify the biometric changes from pre- to post-CHIP in Adventists and non-Adventists with type 2 diabetes.

## **Methodology**

### **Population**

The total population of 7,172 included community members from 241 programs located at 163 venues throughout Canada and United States between January 2006 and September 2012. The population consisted of those who self-identified themselves as Adventist or non-Adventist, self-identified themselves on the health-screening questionnaire as having been told by a doctor they had diabetes, and graduated from the CHIP program. The CHIP participants underwent a total of 32 hours of instruction over a 30-day period that included the following:

- a one-hour video-instruction health lecture by Hans Diehl
- cooking classes
- grocery store tours

- group discussions
- exercise instruction (Rankin et al., 2012)
- instruction on intelligent self-care through more self-awareness of what their

body needed and how it felt.

The one-hour video-instruction included education on the following:

- a plant-based diet
- exercise
- behavioral change
- self-worth
- modern medicine's strengths and weaknesses
- smoking
- cholesterol
- fiber
- lifestyle and health
- the epidemiology and risk factors of CVD, diabetes, atherosclerosis,

hypertension, obesity, and dyslipidemia (Rankin et al., 2012).

Participants were also encouraged to move towards a whole-food, plant-based, vegan diet emphasizing fresh fruits and vegetables, whole grains, legumes, and nuts without emphasis on caloric restriction. Specific dietary and lifestyle recommendations included the following:

- <15% of calories from fat
- <10 teaspoons of added sugar

- <5,000 mg salt (2,000 mg sodium)
- <50 mg cholesterol
- consuming 2-2.5 liters or eight 10-ounce glasses of water daily
- 30 minutes of daily aerobic exercise
- stress reduction strategies
- encouragement to join the CHIP monthly alumni support group (Rankin et al., 2012).

Participants were also encouraged to maintain contact with their physician throughout the program, since experience has shown many participants need to have their medications reduced due to these lifestyle changes. Prior to CHIP, all filled out a preprogram baseline health questionnaire, and again post-CHIP. Included were questions about demographics, medication use, medical and family history, use of tobacco, alcohol, and caffeine, religiosity, and behaviors of activity, rest, and diet. Trained phlebotomists also drew blood for TC, HDL, LDL, TG, and FPG. Each participant was weighed and measured for height to calculate BMI and had their blood pressure taken.

There were no restrictions on participant demographics of age, gender, marital status, BMI, or parental death of diabetes prior to age 60, and were controlled for. To be included, participants had to have graduated from a CHIP program, defined as having attended at least 13 of 16 sessions, completed a self-reported medical and lifestyle prequestionnaire, and completed both the pre- and postprogram assessment.

### **Sampling and Sampling Procedure**

The required sample size for this study was calculated to determine the number of samples necessary for a statistically significant result. The sample size was calculated considering three factors: (a) effect size, (b) level of significance, and (c) power of the study. Cohen's (1988) effect size accounts for the strength of the relationship between variables. The level of significance or alpha level was used to assess the null hypothesis, providing it was true, for the probability of its rejection. The power of the study was determined by the probability of being able to reject a false null hypothesis. A Cohen medium effect size of 0.25, a power of 0.80, and a level of significance of 0.05 were used in this study. A power of 0.80 is in alignment with Gravetter and Wallnau's (2013) statement, which is normal for quantitative research. Use of the medium effect size was intended to prevent excessiveness in terms of either leniency or strictness, simultaneously. A significance level of 0.05 was used because this is typical for quantitative studies.

A G\*Power sample calculator was used to compute the required sample size for this study, as suggested by Faul, Erdfelder, Lang, and Buchner (2009). A two-tailed or nondirectional hypothesis test was conducted, employing the statistical test of repeated measures MANOVA with two groups (Adventists with diabetes and non-Adventists with diabetes) and two numbers of measurements (pre- and postprogram). A medium effect size in the sample size computation involved in the repeated measures MANOVA, and the value of the medium effect size for an ANCOVA test is 0.25. A medium effect size was chosen so that the G\*power computation can neither have a very small or large

sample size. The important factors under consideration were to be able to achieve an 80% power in the statistical analysis, which meets the minimum size for a quantitative analysis, and to have a level of significance of 0.05.

The minimum sample size for this study computed by the G\*Power sample size calculator was 66 (see Appendix A). A minimum of 66 individuals had to be included so that the power of the statistical analysis reached 80%, which would allow the null hypothesis to be rejected. To account for the minimum 66-sample requirement, the participants were divided among the two sample groups of Adventists with diabetes (n=210) and non-Adventists with diabetes (n=836), for a total of 1,046 data sets.

Data were obtained from the CHIP database, a secondary source. A purposeful sampling strategy was chosen because study participants had to match inclusion criteria in order to be eligible for participation in the study. The inclusion criteria were as follows: self-identified as Adventist or non-Adventist; self-identified as having diabetes; having graduated from CHIP, and filled out the proper questionnaires. All ages in the original samples were included.

### **Procedures for Recruitments, Participation, and Data Collection: Using Archival Data**

The data required for RQ1 included the dependent variable of diabetes state; the independent variables of self-reported religiosity affiliation and testing period; and the covariates of age, gender, marital status, BMI, and parental death from diabetes before age 60. The data required for RQ2 included the dependent variables of TC, HDL, LDL, TG, FPG, SBP, DBP, and height and weight calculated for BMI; religious affiliation and

testing period as the independent variables; and the covariates of age, gender, marital status, and parental death of diabetes prior to age 60. BMI was a covariate for RQ1 and an outcome variable for RQ2. The variable information was obtained through secondary data collection from the CHIP database between January 2006 and September 2012. Secondary data were obtained from the CHIP database and its analysis used as an investigative tool for answering new questions (Andrews, Higgins, Andrews, & Lalor, 2012).

To achieve access, a written request for permission to utilize CHIP information was submitted to the Lifestyle Medicine Institute with a description of how it was to be used. This email consisted of the permission letter, an explanation of the purpose of the study, and how the data were to be used in the study. In return, the CHIP organization will receive an overall summary report at the study's conclusion.

The CHIP database resides in Wahroonga, Australia. In the course of my contacts with CHIP researchers, they had given permission and encouragement to analyze the CHIP data for this study. See data use agreement in appendix C. The data from the CHIP database represented 7,172 unidentifiable, self-selected subjects from 241 volunteer-delivered CHIP programs conducted at 163 locations throughout Canada and the United States between January 2006 and September 2012. The CHIP database consisted of age, gender, marital status, TC, HDL, LDL, TG, SBP, DBP, FPG, BMI, and self-identified diseases and religious affiliation.

The deidentified data set was provided in an Excel spreadsheet format that needed to be uploaded to statistical assessment software, SPSS v23.0. In order to maintain

anonymity codes were assigned in place of participants' names. Data preparation was conducted in an Excel sheet to prepare for data analysis. The columns displayed the study variables as an enumerated list, while the rows listed the response data of the different samples.

### **Instrumentation and Operationalization of Constructs**

The data gathered through the CHIP database were representative of the total sample of Adventists and non-Adventists who had diabetes since it included all participants who participated under the volunteer-branch of CHIP between January 2006 and September 2012. The data gathered from the data source were analyzed using SPSS v23.0 software in preparation for the data analysis. There were no issues with the validity and reliability of the data, as they were derived from both secondary and preexisting sources. No testing or survey assessments were used with the targeted samples. It was expected that the data of the samples in the CHIP database were complete. The coding and operationalization of the study variables are presented in Table 1 below.

Table 1

*Operationalization and Coding of Study Variables*

Variable Name	Variable Type	Operationalization	Coding/Values
Self-identified preprogram diabetic state	Dependent variable	Categorical	1 = Previous history 2 = No previous history
High-density lipoproteins	Dependent variable	Continuous	Actual number of HDL
Low-density lipoproteins	Dependent variable	Continuous	Actual number of LDL
Triglycerides	Dependent variable	Continuous	Actual number of TG
Total cholesterol	Dependent variable	Continuous	Actual number of TC
Fasting plasma glucose	Dependent variable	Continuous	Actual number of FPG
Systolic blood pressure	Dependent variable	Continuous	Actual number of systolic blood pressure or the top number of the blood pressure chart
Diastolic blood pressure	Dependent variable	Continuous	Actual number of diastolic blood pressure or the bottom number of the blood pressure chart
Body mass index	Dependent variable	Continuous	Actual number of body mass index computed by dividing the weight in kilograms (kg) with the height in centimeters (cm) squared at baseline
Religiosity self-identified affiliation as a Seventh-day Adventist	Independent variable	Categorical	1/True = Seventh-day Adventist 2/False = non-Adventist
Testing period	Independent variable	Categorical	0 = Pretest 1 = Posttest
Age	Covariates	Continuous	Actual number of age at baseline date of birth
Gender	Covariates	Categorical	1 = Male 2 = Female
Marital status	Covariate	Categorical	1 = Single, divorced, or widowed 2 = Married
Parental death from type 2 diabetes before age 60	Covariate	Categorical	1 = With family history 2 = No family history

### **Data Analysis Plan**

Data were analyzed using SPSS version 23.0. Normality testing was conducted on the data of the study variables of the population to ensure that the assumptions required for a parametric statistical test were fulfilled. The analysis was conducted by examining the skewness and kurtosis statistics, as well as the normality plots in the histograms. Normal distribution of data were a required assumption of parametric statistical analysis such as the MANOVA analysis. In addition, a line graph was created from the data of each study variable to account for the possible presence of anomalous figures or noticeable outliers within the data prior to conducting the statistical analysis. These outliers were removed from the data set.

Descriptive and inferential statistics were used to analyze the data gathered and presented in Chapter 4. Descriptive statistics describe the demographics and other information of the samples and study variables obtained from the CHIP database. Frequencies and percentages describe categorical data, such as the dependent variable of biometric outcomes, the independent variables of religiosity and testing period, and the covariates of gender, marital status, and parental death from diabetes prior to age 60. Central tendency measures of mean and standard deviation summarizes the continuous variability of the dependent variables, which included the biometric measurements of TC, HDL, LDL, TG, and FPG; height and weight measured for BMI, SBP, and DBP; and the covariate of age. Percentages of those who met the criteria of each biometric variable pre- and post-CHIP were added to provide information on the percentage of those who met or fell within the normal range for these biometrics pre- and postprogram.

The research questions, hypotheses, and discussion on specific analysis follows.

**Research Question 1 (RQ1):** After controlling the effects of age, gender, marital status, BMI, and parental death from diabetes before age 60, is there a statistically significant difference in self-identified type 2 diabetes prevalence rates between Adventist and non-Adventist CHIP participants preprogram between January 2006 and September 2012?

***H<sub>0</sub>1:*** The self-identified diabetes prevalence rate between Adventist and non-Adventist in pre-CHIP participants is not significantly different.

***H<sub>1</sub>1:*** The self-identified diabetes prevalence rate between Adventist and non-Adventist in pre-CHIP participants is significantly different.

The dependent variable tracked in answering RQ1 was self-identified diabetes. The independent variables were religiosity and testing period. The five covariates were: age, gender, marital status, BMI, and parental death from diabetes before age 60. The quantitative test used to answer this question was logistic regression.

To answer RQ1, I conducted a logistic regression analysis to investigate whether there was a significant difference in the self-identified preprogram diabetes rate between Adventists and non-Adventists, while controlling the effects of the covariates of age, gender, marital status, BMI, and parental death from diabetes before age 60. RQ1 dealt solely with the preprogram data and involved comparing Adventists and non-Adventists. Logistic regression determined whether religious affiliation predicted the dichotomous dependent variable of whether a subject had preprogram diabetes. Using logistic regression was justifiable because the dependent variable was a categorical dichotomous

variable, the independent variables were categorical dichotomous, while the covariates are continuous variables either measured as intervals or ratios. The value of a continuous variable is not limited to a certain range, but rather continuous within a certain interval. A level of significance of 0.05 was used in the hypothesis testing.

**Research Question 2 (RQ2):** After controlling for the effects of age, gender, marital status, and parental death from diabetes before age 60, is there a statistically significant difference in the change in biometric outcomes (TC, HDL, LDL, TG, FPG, SBP, DBP, and BMI) between Adventists and non-Adventists with self-identified diabetes pre- and post-CHIP between January 2006 and September 2012?

***H<sub>0</sub>2:*** There is no statistically significant difference in biometric outcomes between Adventists and non-Adventists with self-identified type 2 diabetes pre- and post-CHIP.

***H<sub>1</sub>2:*** There is a statistically significant difference in biometric outcomes between Adventists and non-Adventists with self-identified type 2 diabetes pre- and post-CHIP.

The dependent variables tracked in answering RQ2 were TC, HDL, LDL, TG, FPG, SBP, DBP, and BMI. The independent variables were religiosity and testing period. The covariates were age, gender, marital status, and parental death from diabetes before age 60. The quantitative test used to answer RQ2 was MANOVA.

To answer RQ2, I conducted a repeated measures MANOVA. This test was performed to determine whether the dependent variables of the biometric outcomes were significantly different across the independent variables of religiosity with diabetes and the repeated measure of the testing period while controlling the effects of the covariates.

A repeated measures MANOVA was used because the independent variables were categorically measured and had more than two identified groups. This approach was also used because there were multiple dependent variables determining the effects of the covariates (Babbie, 2012). The repeated measures MANOVA determined whether there were differences between independent groups on more than one dependent variable while also examining the difference between the preintervention and postintervention measurements of the participants.

The independent variables in the repeated measures MANOVA were religiosity with diabetes while the repeated measure was the testing period. The dependent variables included the biometric measurements of TC, HDL, LDL, TG, FPG, SBP, DBP, and BMI, as well as the covariates of age, gender, marital status, and parental death from diabetes prior to age 60. The repeated measures MANOVA determined whether the religiosity with diabetes and testing period significantly accounted for variations in the biometric outcomes, while controlling for the influences of age, gender, marital status, and parental death from diabetes prior to age 60. The analysis of multiple independent variables, dependent variables, and covariates was included in one repeated measures MANOVA analysis in order to compare the effects of various independent variables on the dependent variables. In addition, the repeated measure as represented by the variable testing period on the dependent variables was also investigated to determine whether the effects of religiosity with diabetes on dependent variables were significantly different in the pretest and posttest period.

The effect examination for the repeated measure of the testing period determined whether the CHIP intervention had an effect on the biometrics. A significance level of 0.05 was used in the analyses. There was a significant difference or relationship if the  $p$ -value was less than or equal to the level of the significance value. In instances wherein the repeated measures MANOVA determined significant relationships between independent and dependent variables, a post hoc Tukey's test of multiple comparisons was conducted to further identify the relationships.

### **Threats to Validity**

This study had very few threats to validity; the data obtained from this known database has been extensively used in previous research involving chronic disease risk factors (Kent et al., 2013b; Kent et al. 2014; Morton et al., 2014a; Morton et al., 2014b; Rankin et al., 2012). One of the threats to the external validity of the study was nonresponse bias because it could affect generalizing to other populations, wherein the data set of samples is not complete because some of the information from the study variables was missing. The threat caused a slight decrease in the sample size. As a result, this study involved a reasonable number of samples computed from the power analysis. It was ensured that all of the data for each of the study variables collected from the CHIP database were complete. The number of samples collected was greater than the minimum of 66 data sets required to set a certain allowance.

### **Ethical Procedures**

This study was reviewed and approved by members of the Walden's Institutional Review Board (IRB) with approval number 11-09-15-0065108. Because secondary data

were used in this study and the data were preexisting and previously gathered, it was not necessary to use informed consent forms, nor were there ethical concerns. However, permission to use and access the CHIP database was obtained prior to its use in the study.

It was important to ensure the confidentiality and anonymity of the individual data considered in the study and no identifiable information was obtained or used in this study. All of the data sets from the samples obtained from the database was coded to ensure that each individual's responses remained unidentifiable; all data came to me deidentified.

All data gathered in this study will be kept in a username and password-protected computer, which will only be accessed by me. Data obtained from the database will be stored for a minimum of five years per Walden's procedure. Any data stored on a hard drive will be electronically deleted after five years. I had no conflicts of interest related to this study, and no incentives were used in this study.

### **Summary**

Chapter 3 included a discussion of the research design, population, sampling and sampling procedures, instrumentation and operationalization of constructs, data collection procedures and recruitment of participants, data analysis plan, threats to validity, and ethical procedures. This study involved a quantitative research design with the objective of determining relationships between religiosity and preprogram diabetic state and religiosity with diabetic disease state and biometric outcomes. Secondary data were used from the CHIP database to obtain information on the pre- and post-CHIP measurements of the independent variables of religiosity with diabetes, and testing period, the dependent

variables, and the covariates. Data analysis in SPSS version 23.0 included descriptive statistics, logistic regression, and MANOVA, which addressed the research questions of the study.

## Chapter 4: Results

### Introduction

The purpose of this quantitative correlational study was to determine the relationship between religious affiliation and preprogram diabetic state, and comparing religiosity and biometric outcomes in those with type 2 diabetes pre- and post-CHIP. This study utilized a secondary data set from CHIP to investigate if there was a significant difference in the self-identified preprogram diabetic state between Adventists and non-Adventists, and examined how a particular religious affiliation (Adventist or non-Adventist) in those with type 2 diabetes affected eight biometric outcomes pre- and post-CHIP intervention. The study data were analyzed using logistic regression analysis and a repeated measures MANOVA to address the two primary research questions. The following research questions and hypotheses guided the analysis for this study:

**Research Question 1 (RQ1):** After controlling the effects of age, gender, marital status, BMI, and parental death from diabetes before age 60, is there a statistically significant difference in self-identified type 2 diabetes prevalence rates between Adventist and non-Adventist CHIP participants preprogram between January 2006 and September 2012?

***H<sub>0</sub>1:*** The self-identified diabetes prevalence rate between Adventist and non-Adventist in pre-CHIP participants is not significantly different.

***H<sub>1</sub>1:*** The self-identified diabetes prevalence rate between Adventist and non-Adventist in pre-CHIP participants is significantly different.

**Research Question 2 (RQ2):** After controlling for the effects of age, gender, marital status, and parental death from diabetes before age 60, is there a statistically significant difference in the change in biometric outcomes (TC, HDL, LDL, TG, FPG, SBP, DBP, and BMI) between Adventists and non-Adventists with self-identified diabetes pre- and post-CHIP between January 2006 and September 2012?

**H<sub>02</sub>:** There is no statistically significant difference in biometric outcomes between Adventists and non-Adventists with self-identified type 2 diabetes pre- and post-CHIP.

**H<sub>12</sub>:** There is a statistically significant difference in biometric outcomes between Adventists and non-Adventists with self-identified type 2 diabetes pre- and post-CHIP.

In overview, this chapter addresses the research questions and the statistical analysis results by section. First, the demographic information is provided for the CHIP samples; second, the descriptive statistics of study variables are provided; third, the statistical tests are discussed for RQ1 and RQ2; fourth, the logistic regression analysis and repeated measures MANOVA are presented for each biometric pre- and postprogram.

### **Data Collection**

The population of respondents consisted of 7,172 self-selected Adventists and non-Adventists that attended the CHIP program between January 2006 and September 2012. There were no discrepancies in data collected to the plan presented in chapter 3. The frequency and percentage summaries of the participants' demographic variables of self-identified diabetes, religiosity, gender, marital status, and parental death from

diabetes prior to age 60 are summarized in Table 2. Of the total 7,172 CHIP participants, 14.6% (1,036) self-identified themselves as having been told by a physician they had diabetes; 21.2% (1,523) self-identified Adventist affiliation; 78.8% (5,649) self-identified as non-Adventist. There were more married participants (64.3%; 4,614) than single, divorced, or widowed (22.5%; 1,612), and 66.6% (4,774) were women. Two hundred and thirty-three (3.2%) participants reported a history of parental death from type 2 diabetes before age 60. Descriptive statistics of mean and standard deviation were used to summarize the data regarding age (Table 3). The average age of the population was 57.38 years ( $SD = 13.01$ ), ranging from 9 to 103, with 86 participants under 18 years old. Two hundred and ten (210) Adventists self-identified as having diabetes preprogram, compared to 836 non-Adventists (see Table 4). No participants under 18 years old were reported as having diabetes.

Table 2

*Frequency and Percentage Summaries of Demographic Information (N = 7,172)*

Category	<i>n</i>	%
<b>Self-identified preprogram diabetic state</b>		
No previous history with diabetes	6,126	85.4
Previous history with diabetes	1,036	14.5
Missing	10	0.1
<b>Religiosity self-identified affiliation as a Seventh-day Adventist</b>		
Non-Adventist	5,649	78.8
Adventist	1,523	21.2
<b>Gender</b>		
Male	2,394	33.4
Female	4,774	66.6
Missing	4	<0.1
<b>Marital Status</b>		
Single, divorced, widowed	1,612	22.5
Married	4,614	64.3
Missing	946	13.2
<b>Parental death from type 2 diabetes before age 60</b>		
With family history	233	3.2
No family history	4,399	61.3
Missing	2,540	35.4

Table 3

*Descriptive Statistics Summaries of Age (N = 7,172)*

<i>N</i>	Minimum	Maximum	<i>M</i>	<i>SD</i>
7164	9	103	57.38	13.01

Table 4

*Cross Tabulation of Religiosity and Self-Identified Preprogram Diabetic State (N = 6,126)*

Religious affiliation		Self-identified preprogram diabetic state				Total	
		No		Yes		<i>n</i>	%
		<i>n</i>	%	<i>n</i>	%		
Religiosity self-identified affiliation as Seventh-day Adventist	Non-Adventist	4,783	78.1	836	79.9	5,619	78.3
	Adventist	1,343	21.9	210	20.1	1,553	21.7
Total		6,126	100.0	1,046	100.0	7,172	100.0

## Results

### Descriptive Statistics of Study Variables

Table 5 summarizes the descriptive statistics of the study variables. Descriptive statistics of means and standard deviation were used to summarize the data of the continuous-measured study variables, which were the dependent variables of the biometric outcomes (TC, HDL, LDL, TG, FPG, SBP, DBP, and BMI). The statistics included the summaries of the responses in the self-reported medical and lifestyle prequestionnaire and the pre- and postassessment questionnaire.

The comparison of the pre- and postprogram assessment showed that all biometrics of the population mean change were lower after completing CHIP. The largest improvements were seen in those who resided in the highest risk category except LDL. From pre- to postclass, the largest mean change reductions were seen in the TG outcomes from 639.61 to 629.11 (-10.50 mg/dl), FPG from 165.86 to 156.66 (-6.12 mg/dl), TC from 309.46 to 305.46 (-4.01 mg/dl), DBP from 110.66 to 107.53 (-3.13 mmHg), and SBP from 173.80 to 172.45 (-1.35 mmHg). The majority of participants (36.82 preclass

mean and 36.42 postclass mean) were in the  $\geq 30$  BMI category both preprogram (n=3534/49.3%) and postprogram (n=2860/39.9%). The largest mean change in LDL were those within the normal range and dropped their mean change by -3.39 mg/dl (79.37 to 75.98). From pre- to postclass, 14.8% more participants met the normal criteria for TC, an additional 12.3% met the normal criteria for LDL, 5.0% more met the criteria for a normal FPG, 9.6% more met the normal criteria for a normal SBP, 11.4% more met the normal criteria for DBP, an additional 2.9% met the normal BMI criteria, 7.7% less participants met the criteria for a normal HDL, and 0.4 less participants met the normal criteria for a normal TG.

Table 5

*Descriptive Statistics Scores of Pre- and Postprogram Biometric Outcomes Categorized by Disease Risk Factor (n=7,172)*

Risk Factor	Preprogram n (%)	Postprogram n (%)	Preprogram (Mean $\pm$ SD)	Postprogram (Mean $\pm$ SD)	Mean change (95% confidence interval) (%)
<b>Total cholesterol, mg/dl</b>					
<160	1550 (21.6)	2611 (36.4)	139.42 $\pm$ 16.00	135.96 $\pm$ 17.17	-3.46 (5.57, 7.68) (-2.48)
160-199	2689 (37.5)	2585 (38.9)	180.06 $\pm$ 11.25	178.33 $\pm$ 11.31	-1.72 (15.62, 17.29) (-0.96)
200-239	1976 (27.6)	1148 (17.3)	217.20 $\pm$ 11.25	215.37 $\pm$ 10.91	-1.83 (26.07, 28.29) (-0.84)
240-280	721(10.1)	256 (3.39)	255.07 $\pm$ 10.91	254.47 $\pm$ 10.83	-0.60 (37.50, 42.05) (-0.24)
>280	182 (2.5)	42 (0.6)	309.46 $\pm$ 34.81	305.46 $\pm$ 21.40	-4.01 (53.23, 68.14) (-1.30)
<b>High-density lipoproteins, mg/dl</b>					
<40	3397 (47.4)	4073 (56.8)	37.99 $\pm$ 6.88	37.12 $\pm$ 6.99	-0.87 (1.52, 1.91) (-2.28)
40-60	2252 (31.4)	1699 (23.7)	50.76 $\pm$ 5.52	50.72 $\pm$ 5.60	-0.04 (4.08, 4.66) (-0.07)
>60	1465 (20.4)	867 (12.1)	71.21 $\pm$ 11.82	69.48 $\pm$ 10.41	-1.73 (8.86, 9.94) (-2.43)
<b>Low-density lipoproteins, mg/dl</b>					
<100	2392 (33.4)	3275 (45.7)	79.37 $\pm$ 15.48	75.98 $\pm$ 16.46	-3.39 (4.01, 5.52) (-4.28)
100-129	2299 (32.1)	2118 (29.5)	114.17 $\pm$ 8.60	113.24 $\pm$ 8.40	-0.93 (12.21, 13.84) (-0.82)
130-159	1520 (21.2)	895 (12.5)	142.48 $\pm$ 8.50	141.87 $\pm$ 8.51	-0.61 (21.30, 23.55) (-0.43)
160-190	576 (8.0)	222 (3.1)	171.14 $\pm$ 8.1	171.02 $\pm$ 8.06	-0.12 (29.21, 33.32) (-0.07)
>190	213 (3.0)	59 (0.8)	209.61 $\pm$ 21.04	209.10 $\pm$ 23.43	-0.52 (41.84, 50.80) (-0.25)
<b>Triglycerides, mg/dl</b>					
<150	4629 (64.5)	4597 (64.1)	94.67 $\pm$ 29.95	94.54 $\pm$ 29.37	-0.13 (-5.84, -3.80) (-0.14)
150-199	1184 (16.5)	1075 (15.0)	171.56 $\pm$ 13.81	171.47 $\pm$ 14.22	-0.09 (11.08, 17.10) (-0.05)
200-500	1233 (17.2)	950 (13.2)	269.99 $\pm$ 62.76	265.23 $\pm$ 60.51	-4.76 (46.67, 55.55) (-1.76)
>500	60 (0.8)	15 (0.2)	639.61 $\pm$ 118.10	629.11 $\pm$ 85.70	-10.50 (237.83, 340.28) (-1.64)
<b>Fasting plasma glucose, mg/dl</b>					
<110	4534 (63.2)	4891 (68.2)	87.61 $\pm$ 7.90	86.61 $\pm$ 7.94	-1.00 (0.56, 1.13) (-1.14)
110-125	1708 (23.8)	1270 (17.7)	108.40 $\pm$ 6.91	108.06 $\pm$ 6.93	-0.33 (7.13, 8.31) (-0.31)
>125	835 (11.6)	464 (6.5)	165.86 $\pm$ 44.23	156.66 $\pm$ 32.79	-6.12 (29.16, 34.29) (-5.54)
<b>Systolic blood pressure, mmHg</b>					
<120	1563 (21.8)	2251 (31.4)	110.16 $\pm$ 7.29	109.60 $\pm$ 7.52	-0.56 (-2.71, -1.51) (-0.51)
120-139	3047 (42.5)	2959 (41.3)	128.73 $\pm$ 5.85	127.97 $\pm$ 5.75	-0.76 (4.44, 5.32) (-0.59)
140-160	1831 (25.5)	1121 (15.6)	147.94 $\pm$ 6.43	147.01 $\pm$ 6.23	-0.93 (12.88, 14.20) (-0.63)
>160	564 (7.9)	193 (2.7)	173.80 $\pm$ 12.06	172.45 $\pm$ 9.70	-1.35 (23.58, 26.93) (-0.78)

(Continued)

Table 5

*Descriptive Statistics Scores of Pre- and Postprogram Biometric Outcomes Categorized by Disease Risk Factor (n=7,172)*

Risk Factor	Preprogram n (%)	Postprogram n (%)	Preprogram (Mean $\pm$ SD)	Postprogram (Mean $\pm$ SD)	Mean change (95% confidence interval) (%)
<b>Diastolic blood pressure, mmHg</b>					
<80	3285 (45.8)	4101 (57.2)	70.49 $\pm$ 6.41	69.79 $\pm$ 6.76	-0.70 (-0.74, -0.08) (-0.99)
80-89	2366 (33.0)	1872 (26.1)	83.22 $\pm$ 2.93	82.81 $\pm$ 2.81	-0.41 (5.64, 6.33) (-0.49)
90-100	1171 (16.3)	501 (7.0)	93.69 $\pm$ 3.56	93.12 $\pm$ 3.36	-0.57 (10.20, 11.22) (-0.61)
>100	180 (2.5)	49 (0.7)	110.66 $\pm$ 14.72	107.53 $\pm$ 7.84	-3.13 (18.41, 24.42) (-2.83)
<b>Body mass index, Kg/m<sup>2</sup></b>					
<18.5	51 (0.7)	46 (0.6)	17.54 $\pm$ 0.90	17.65 $\pm$ 0.75	0.11 (-0.01, 0.33) (0.62)
18.5-24.9	1347 (18.8)	1555 (21.7)	22.68 $\pm$ 1.63	22.66 $\pm$ 1.64	-0.02 (0.43, 0.53) (-0.10)
25-29.9	2109 (29.4)	2049 (28.6)	27.48 $\pm$ 1.41	27.47 $\pm$ 1.43	-0.01 (0.84, 0.90) (-0.05)
$\geq$ 30	3534 (49.3)	2860 (39.9)	36.82 $\pm$ 6.19	36.42 $\pm$ 5.96	-0.40 (1.26, 1.33) (-1.07)

### Normality Testing

Prior to conducting the statistical analysis, statistical assumptions for normality of the study variables on the population were tested to ensure that the data followed normal distribution. Normality testing was only conducted on the study variables that were continuously measured. These included the dependent variables of the biometrics (TC, HDL, LDL, TG, FPG, SBP, DBP, and BMI) and age. The histograms for normality testing on the population are presented in Appendix B.

Each study variable histogram distribution formed a bell-shaped curve pattern, representing a normal distribution. Although the bell-shaped pattern formed in each of the graphs was not a perfect representation, this is considered acceptable. Each biometric variable and age exhibited a normal distribution; thus, the normality assumption for all

the study variables was not violated.

### **Logistic Regression Results for Research Question One (RQ1)**

The following research question guided this analysis:

**RQ1:** After controlling the effects of age, gender, marital status, BMI, and parental death from diabetes before age 60, is there a statistically significant difference in self-identified type 2 diabetes prevalence rates between Adventist and non-Adventist CHIP participants preprogram between January 2006 and September 2012?

**H<sub>0</sub>1:** The self-identified diabetes prevalence rate between Adventist and non-Adventist in pre-CHIP participants is not significantly different.

**H<sub>1</sub>1:** The self-identified diabetes prevalence rate between Adventist and non-Adventist in pre-CHIP participants is significantly different.

The dependent variable tracked in answering RQ1 was self-identified diabetes. The independent variables were religiosity and testing period. Five covariates were also tracked: age, gender, marital status, BMI, and parental death from diabetes before age 60. The quantitative test used to answer this question was logistic regression.

A logistic regression analysis was performed to investigate whether there was a significant difference in the self-identified preprogram diabetic state between Adventists and non-Adventists, while controlling for the covariate effects of age, gender, marital status, BMI, and parental death from diabetes before age 60. The dependent variable of self-identified diabetic state was a dichotomously measured variable with the binary codes of 0 (no previous history with diabetes) and 1 (previous history with diabetes). RQ1 aimed to compare Adventists and non-Adventists in self-identified prevalence rate

of diabetes pre-CHIP program. A level of significance of 0.05 was used in the analysis. The self-identified diabetes state between Adventists and non-Adventists would be significantly related if the  $p$ -value of the effect of religion were less than or equal to the level of significance value of 0.05.

The logistic regression model generated was a two-step approach. The first step determined the effects of the covariates of age, gender, body mass index, marital status, and parental death from type 2 diabetes before age 60, on the self-identified diabetes state. The second step determined the effects of the independent variables of religiosity and testing period on the diabetes state, while controlling for the effects of the covariates of age, gender, marital status, BMI, and parental death from diabetes before age 60. The covariates and the independent variables were treated as categorical variables in the logistic regression model. Table 6 summarizes the logistic regression results with confidence intervals and odds ratios

For step 1, the results showed that all of the covariates of age (Wald (1) = 191.55,  $p < 0.001$ ), gender (Wald (1) = 19.28,  $p < 0.001$ ), BMI (Wald (1) = 494.16,  $p < 0.001$ ), marital status (Wald (1) = 16.34,  $p < 0.001$ ), and parental death from diabetes before age 60 (Wald (1) = 165.30,  $p < 0.001$ ) have significant effects on the dependent variable of self-selected diabetic state. This suggested that there is a significant difference in the preprogram diabetic state of the sample when there are differences in these covariates.

For step 2, the results showed that the independent variables of religiosity (Wald (1) = 0.30,  $p = 0.58$ ) and testing period (Wald (1) = 2.08,  $p = 0.15$ ) did not have a significant effect on the self-identified preprogram diabetic state, after controlling for the

covariates. Therefore, the self-identified diabetes state between Adventists and non-Adventists pre-CHIP was not significantly different. The results of the logistic regression failed to reject the null hypothesis for RQ1. The odds ratio of religiosity was 0.96 and the odds ratio of testing period was 0.91. The effects of religiosity and testing period were insignificant. The odds or probability of having preprogram diabetic state cannot be dependent based on religiosity and testing period.

Table 6

*Logistic Regression Results of Effects of Diabetes State (n = 7,172)*

Step	Variable	B	SE	Wald	df	Sig.	Exp (B) /Odd Ratio	95% C.I. for EXP(B)	
								Lower	Upper
Step 1	Age	0.04	0.00	191.55	1	0.00*	1.04	1.03	1.05
	Gender (1)	0.29	0.07	19.28	1	0.00*	1.34	0.66	0.85
	Body mass index	0.09	0.00	494.16	1	0.00*	1.10	1.09	1.11
	Marital status (1)	0.29	0.07	16.34	1	0.00*	1.33	0.66	0.87
	Parental death from type 2 diabetes before age 60 (1)	1.45	0.11	165.30	1	0.00*	4.27	0.19	0.29
	Constant	-7.07	0.24	838.37	1	0.00*	0.00		
Step 2	Religiosity self- selected affiliation as a Seventh-day Adventist (1)	-0.04	0.08	0.30	1	0.58	0.96	0.90	1.21
	Testing period (1)	-0.09	0.06	2.08	1	0.15	0.91	0.97	1.24
	Constant	-7.03	0.25	818.75	1	0.00*	0.00		

*Notes.* Variable(s) entered on Step 1: Age, Gender, Body Mass Index (BMI), Marital Status, Parental death from type 2 diabetes before age 60. Independent Variable(s) entered on Step 2: Religiosity self-identified affiliation as a Seventh-day Adventist, Testing period. Dependent Variable: Diabetes State. \*Significant at level of significance of  $\leq 0.05$

**Repeated Measures MANOVA Results for Research Question Two (RQ2)**

The following research question guided this analysis:

**RQ2:** After controlling for the effects of age, gender, marital status, and parental death from diabetes before age 60, is there a statistically significant difference in the change in biometric outcomes (TC, HDL, LDL, TG, FPG, SBP, DBP, and BMI) between

Adventists and non-Adventists with self-identified diabetes pre- and post-CHIP between January 2006 and September 2012?

***H<sub>0</sub>2:*** There is no statistically significant difference in biometric outcomes between Adventists and non-Adventists with self-identified type 2 diabetes pre- and post-CHIP.

***H<sub>1</sub>2:*** There is a statistically significant difference in biometric outcomes between Adventists and non-Adventists with self-identified type 2 diabetes pre- and post-CHIP.

The dependent variables tracked in answering RQ2 were TC, HDL, LDL, TG, FPG, SBP, DBP, and BMI. The independent variables were religiosity and testing period. The covariates were age, gender, marital status, and parental death from diabetes before age 60. The quantitative test used to answer RQ2 was MANOVA.

Table 7 summarized the descriptive statistics of all the biometric outcomes segregated between the Adventists with diabetes and non-Adventists with diabetes.

The highest percentage of Adventists and non-Adventist entered and exited CHIP with a normal HDL, LDL, TG, FPG, and DBP. Adventists achieved a greater mean change reduction in TC (-5.37 vs. -4.28), SBP (-2.59 vs. -1.42), DBP (-1.25 vs. -0.79), and BMI (-0.42 vs. -0.26) than non-Adventists postclass. Non-Adventists achieved the greatest mean change reduction postclass in the highest risk category of HDL (-1.70 vs. -0.48), LDL (-1.91 vs 7.87), TG (-68.34 vs. 11.0), and FPG (-12.74 vs. 6.12) over Adventists. Adventists achieved the greatest mean change reduction postclass in the highest risk category of TC (0.15 vs 3.27), SBP (-1.86 vs. -1.42), DBP (-1.25 vs. 1.95), and BMI (-0.42 vs. -0.26). However, in every highest risk category both groups reduced

the percentage of participants from pre- to postclass, and both groups increased the percentage of participants in the normal category in LDL, TG, TC, FPG, SBP, DBP, and BMI.

Table 8 presents the results of the repeated measures MANOVA. This determined the main effect of whether the repeated measures statistics of the dependent variables of the biometric outcomes in the pretest and posttest were significantly different due to religious affiliation. It also determined whether the repeated measures and the between-subject factor of religiosity have a two-way influence to each of the eight dependent variables. A repeated measures MANOVA was conducted to determine whether the dependent variables of the biometric outcomes were significantly different across the independent variables, while controlling for the effects of the covariates. The repeated measures MANOVA was performed to determine whether religiosity with diabetes and testing period significantly accounted for variations in the biometric outcome measurements. A level of significance of 0.05 was used in the MANOVA. Significant differences in biometric outcomes were observed if the  $p$ -value of the  $F$  statistics of the MANOVA was less than or equal to the level of significance set at 0.05. The within-subject factor was the repeated measures scores or the testing periods (pretest and posttest), and the between-subject factor was religiosity (Adventist or non-Adventist).

The interaction effects of the within-subject factor of the testing periods and the between-subject factor of religiosity had significant effects on the biometric outcomes of TC ( $F(1) = 5.65; p = 0.02$ ) and LDL ( $F(1) = 5.76; p = 0.02$ ). The interaction effects of the within-subject factor of the testing periods and the between-subject factor of religiosity

did not have any significant effects on the biometric outcomes of HDL ( $F(1) = 0.00$ ;  $p = 0.99$ ), TG ( $F(1) = 0.19$ ,  $p = 0.67$ ), FPG ( $F(1) = 2.71$ ,  $p = 0.10$ ), SBP ( $F(1) = 2.25$ ;  $p = 0.13$ ), DBP ( $F(1) = 1.20$ ;  $p = 0.27$ ), and BMI ( $F(1) = 1.65$ ;  $p = 0.20$ ). Only the biometric outcomes of TC and LDL between the Adventists with diabetes and non-Adventists with diabetes after they underwent the CHIP intervention were significantly different from the pretest to the posttest, and was due to religious affiliation. The hypothesis, “There is a significant difference in biometric outcomes between Adventists and non-Adventists with self-identified type 2 diabetes pre- and post-CHIP,” was supported by the results of the analysis, and therefore the null hypothesis for RQ2 was rejected. Although both groups improved in all the other biometrics pre- to post-CHIP, these improvements were not due to religious affiliation.

**Table 7**  
*Descriptive Statistics Scores of Pre- and Postprogram Biometric Outcomes Between Adventists (n=210) and Non-Adventists With Diabetes Categorized by Risk Factor Classification (n=836)*

Risk Factor	Adventists with diabetes					Non-Adventists with diabetes				
	Baseline n (%)	30 d, n (%)	Baseline (Mean ± SD)	30 d, (Mean ± SD)	Mean change (95% confidence interval) (%)	Baseline n (%)	30 d, n (%)	Baseline (Mean ± SD)	30 d, (Mean ± SD)	Mean change (95% confidence interval) (%)
<b>High-density lipoproteins, mg/dl</b>										
<40	52 (24.9)	77 (36.8)	33.44 ± 5.06	32.65 ± 5.13	-0.78 (1.09, 3.51) (2.34)	237 (28.3)	323 (38.6)	32.67 ± 4.85	32.60 ± 5.05	-0.07 (-0.14, -0.06) (0.21)
40-60	100 (47.8)	99 (47.7)	49.51 ± 5.64	48.70 ± 6.28	-0.81 (2.60, 4.84) (1.64)	412 (49.3)	391 (46.8)	49.15 ± 5.78	48.22 ± 5.80	-0.93 (2.99, 4.21) (1.89)
>60	57 (27.3)	33 (15.8)	73.31 ± 17.15	72.83 ± 14.09	-0.48 (5.11, 11.36) (0.65)	187 (22.4)	122 (14.6)	73.40 ± 11.81	71.70 ± 11.02	-1.70 (7.21, 9.93) (2.32)
<b>Low-density lipoproteins, mg/dl</b>										
<100	77 (36.8)	131 (62.7)	79.91 ± 15.47	78.34 ± 15.08	-1.58 (5.03, 11.65) (1.97)	336 (40.2)	463 (55.4)	78.92 ± 16.79	74.23 ± 16.74	-4.69 (-0.22, -0.11) (5.94)
100-129	57(27.3)	47 (22.5)	113.74 ± 9.37	114.89 ± 8.07	1.15 (15.13, 20.93) (-1.01)	265 (31.7)	248 (29.7)	114.25 ± 8.63	112.04 ± 8.20	-2.21 (0.32, 0.48) (1.93)
130-159	45 (21.5)	20 (9.6)	142.18 ± 8.96	143.50 ± 9.46	1.32 (17.82, 29.95) (-0.93)	164 (19.6)	99 (11.8)	142.22 ± 8.30	142.70 ± 9.15	0.48 (0.78, 1.01) (-0.34)
160-190	22 (10.5)	8 (3.8)	171.44 ± 8.60	169.50 ± 8.68	-1.94 (15.11, 40.83) (1.13)	55 (6.6)	21 (2.5)	171.69 ± 8.23	171.09 ± 7.91	-0.60 (1.02, 1.52) (0.35)
>190	8 (3.8)	3 (1.4)	220.46 ± 29.85	228.33 ± 18.82	7.87 (15.32, 67.61) (-3.57)	16 (1.9)	5 (0.6)	204.11 ± 11.53	202.20 ± 12.72	-1.91 (27.08, 51.45) (0.94)
<b>Triglycerides, mg/dl</b>										
<150	127 (60.8)	147 (70.3)	89.84 ± 32.14	94.87 ± 30.64	5.03 (-12.68, -1.83) (-5.59)	531 (63.5)	592 (70.8)	93.62 ± 29.73	95.64 ± 29.84	2.02 (-9.68, -3.99) (-2.16)
150-199	35 (16.7)	34 (16.3)	168.81 ± 11.39	172.01 ± 14.27	3.20 (3.67, 32.50) (-1.90)	159 (19.0)	127 (15.2)	171.34 ± 14.05	169.70 ± 14.03	-1.64 (11.04, 24.73) (0.96)
200-500	45 (21.5)	27 (12.9)	259.82 ± 57.01	277.30 ± 56.68	17.47 (22.67, 70.68) (-6.73)	140 (16.7)	114 (13.6)	274.29 ± 68.97	262.93 ± 65.03	-11.36 (35.54, 64.56) (4.14)
>500	2 (1)	1 (0.5)	639.00 ± 59.40	650.00 (.)	11.00 (-2452.77, 2756.77) (-1.72)	6 (0.7)	3 (0.4)	669.67 ± 60.87	601.33 ± 47.26	-68.34 (118.79, 502.21) (10.21)

(continued)

**Table 7**  
*Descriptive Statistics Scores of Pre- and Postprogram Biometric Outcomes Between Adventists (n=210) and Non-Adventists With Diabetes Categorized by Risk Factor Classification (n=836)*

Risk Factor	Adventists with diabetes					Non-Adventists with diabetes				
	Baseline n (%)	30 d, n (%)	Baseline (Mean ± SD)	30 d, (Mean ± SD)	Mean change (95% confidence interval) (%)	Baseline n (%)	30 d, n (%)	Baseline (Mean ± SD)	30 d, (Mean ± SD)	Mean change (95% confidence interval) (%)
<b>Total cholesterol, mg/dl</b>										
<160	44 (21.1)	90 (43.1)	137.14 ± 17.97	135.94 ± 17.78	-1.20 (2.31, 13.35) (0.87)	201 (24)	367 (43.9)	138.49 ± 16.90	134.21 ± 17.82	-4.28 (0.89, 7.58) (3.09)
160-199	65 (31.1)	77 (36.8)	179.10 ± 11.12	178.08 ± 11.82	-1.02 (15.64, 25.52) (0.57)	325 (38.9)	297 (35.5)	180.49 ± 11.53	177.30 ± 11.07	-3.19 (15.11, 20.01) (1.77)
200-239	67 (32.1)	28 (13.4)	218.00 ± 11.31	215.69 ± 11.21	-2.31 (23.95, 34.85) (1.06)	224 (26.8)	143 (17.1)	217.13 ± 11.11	215.41 ± 10.84	-1.72 (24.08, 30.67) (0.79)
240-280	23 (11)	10 (4.8)	257.47 ± 9.29	252.10 ± 10.27	-5.37 (26.81, 62.52) (2.09)	69 (8.3)	26 (3.1)	254.55 ± 10.92	253.70 ± 10.47	-0.85 (30.09, 41.92) (0.33)
>280	10 (4.8)	4 (1.9)	307.60 ± 30.29	307.75 ± 28.63	0.15 (25.19, 80.61) (-0.05)	17 (2.0)	3 (0.4)	297.40 ± 14.16	300.67 ± 10.41	3.27 (28.81, 80.88) (-1.10)
<b>Fasting plasma glucose, mg/dl</b>										
<110	166 (79.4)	178 (85.2)	91.52 ± 8.30	89.05 ± 9.08	-2.46 (0.63, 3.50) (2.69)	663 (79.3)	731 (87.4)	91.65 ± 9.19	90.20 ± 9.13	-1.45 (22.95, 39.54) (1.58)
110-125	166 (8.1)	17 (8.1)	115.53 ± 4.17	115.82 ± 4.11	0.29 (3.79, 15.83) (-0.25)	78 (9.3)	40 (4.8)	116.59 ± 4.49	115.79 ± 4.68	-0.80 (3.26, 12.02) (0.69)
>125	166 (12.4)	14 (6.7)	175.81 ± 72.66	181.93 ± 65.54	6.12 (11.94, 45.40) (-3.48)	95 (11.4)	65 (7.8)	170.99 ± 47.60	158.25 ± 33.24	-12.74 (22.95, 39.54) (7.45)
<b>Systolic blood pressure, mmHg</b>										
<120	50 (23.9)	93 (44.5)	111.51 ± 6.74	108.92 ± 7.88	-2.59 (-0.40, -0.12) (2.32)	207 (24.8)	349 (41.7)	110.60 ± 7.79	109.76 ± 7.59	-0.84 (-0.39, -0.25) (0.76)
120-139	83 (39.7)	83 (39.7)	129.41 ± 5.86	128.08 ± 6.06	-1.33 (0.22, 0.50) (1.03)	350 (41.9)	339 (40.6)	129.04 ± 5.95	128.43 ± 5.90	-0.61 (0.24, 0.38) (0.47)
140-160	55 (26.3)	26 (12.4)	146.71 ± 5.63	147.73 ± 6.21	1.02 (0.76, 1.20) (-0.70)	205 (24.5)	125 (15)	148.22 ± 6.22	147.37 ± 6.33	-0.85 (14.27, 18.47) (0.57)
>160	21 (10)	7 (3.3)	173.43 ± 7.85	171.57 ± 12.25	-1.86 (0.94, 1.82) (1.07)	74 (8.9)	23 (2.8)	174.68 ± 12.41	173.26 ± 7.88	-1.42 (1.05, 1.47) (0.81)

(continued)

**Table 7**  
*Descriptive Statistics Scores of Pre- and Postprogram Biometric Outcomes Between Adventists (n=210) and Non-Adventists With Diabetes Categorized by Risk Factor Classification (n=836)*

Risk Factor	Adventists with diabetes					Non-Adventists with diabetes				
	Baseline n (%)	30 d, n (%)	Baseline (Mean ± SD)	30 d, (Mean ± SD)	Mean change (95% confidence interval) (%)	Baseline n (%)	30 d, n (%)	Baseline (Mean ± SD)	30 d, (Mean ± SD)	Mean change (95% confidence interval) (%)
<b>Diastolic blood pressure, mmHg</b>										
<80	117 (56)	145 (69.4)	69.07 ± 7.04	70.15 ± 6.44	1.08 (-3.77, -0.13) (-1.56)	430 (51.4)	572 (68.4)	70.11 ± 6.70	70.17 ± 6.46	0.06 (-0.21, -0.13) (-0.09)
80-89	57 (27.3)	52 (24.9)	83.37 ± 2.87	83.38 ± 2.97	0.01 (3.38, 7.32) (-0.01)	270 (32.3)	202 (24.2)	83.36 ± 2.76	82.94 ± 2.73	-0.42 (0.46, 0.61) (0.50)
90-100	31 (14.8)	11 (5.3)	93.48 ± 3.19	92.36 ± 3.20	-1.12 (8.77, 15.44) (1.20)	114 (13.6)	60 (7.2)	93.87 ± 3.34	93.08 ± 3.24	-0.79 (0.92, 1.22) (0.84)
>100	4 (1.9)	1 (0.5)	104.25 ± 2.87	103.00 (.)	-1.25 (-4.93, 41.43) (1.20)	22 (2.6)	2 (0.2)	107.55 ± 7.04	109.50 ± 2.12	1.95 (1.52, 2.29) (-1.81)
<b>Body mass index, Kg/m<sup>2</sup></b>										
<18.5	5 (2.4)	25 (12)	17.20 ± 1.73	17.15 ± 1.43	-0.05 (0.22, 0.44) (0.27)	9 (1.1)	57 (6.8)	17.88 ± 0.12	17.77 ± 0.90	-0.11 (-0.06, 0.04) (0.62)
18.5-24.9	38 (18.2)	44 (21.1)	22.48 ± 1.85	22.45 ± 1.86	-0.04 (-0.04, 0.20) (0.17)	154 (18.4)	194 (23.2)	22.69 ± 1.46	22.59 ± 1.54	-0.10 (-0.05, 0.05) (0.44)
25-29.9	67 (32.1)	64 (30.6)	27.90 ± 1.70	27.84 ± 1.74	-0.06 (0.22, 0.44) (0.21)	284 (34.0)	275 (32.9)	27.83 ± 1.72	27.87 ± 1.77	0.04 (0.22, 0.35) (-0.14)
≥30	99 (47.7)	76 (36.4)	37.31 ± 6.87	36.88 ± 7.32	-0.42 (0.25, 0.62) (1.13)	389 (46.5)	310 (37.1)	37.82 ± 5.94	37.56 ± 5.56	-0.26 (0.27, 0.43) (0.69)

Table 8

*Results of Tests of Within-Subjects and Between-Subjects Effects (n = 560)*

Source	Measure	Testing Period	Type III Sum of Squares	df	MS	F	Sig.
Testing Period	TC	Linear	275.82	1	275.82	0.83	0.36
	HDL	Linear	54.10	1	54.10	2.14	0.14
	LDL	Linear	463.85	1	463.85	1.71	0.19
	TG	Linear	1072.83	1	1072.83	0.66	0.42
	FPG	Linear	27.45	1	27.45	0.18	0.68
	SBP	Linear	73.01	1	73.01	0.59	0.44
	DBP	Linear	0.20	1	0.20	0.00	0.95
	BMI	Linear	2.14	1	2.14	2.79	0.10
Testing Period * Religiosity self-identified affiliation as Seventh-day Adventist	TC	Linear	1880.04	1	1880.04	5.65	0.02*
	HDL	Linear	0.00	1	0.00	0.00	0.99
	LDL	Linear	1558.66	1	1558.66	5.76	0.02*
	TG	Linear	300.80	1	300.80	0.19	0.67
	FPG	Linear	421.89	1	421.89	2.71	0.10
	SBP	Linear	280.07	1	280.07	2.25	0.13
	DBP	Linear	59.37	1	59.37	1.20	0.27
	BMI	Linear	1.27	1	1.27	1.65	0.20
Error (Testing Period)	TC	Linear	186128.99	559	332.97		
	HDL	Linear	14115.78	559	25.25		
	LDL	Linear	151283.83	559	270.63		
	TG	Linear	905897.16	559	1620.57		
	FPG	Linear	86955.29	559	155.56		
	SBP	Linear	69443.99	559	124.23		
	DBP	Linear	27634.27	559	49.44		
	BMI	Linear	428.58	559	0.77		

## Summary

This study aimed to compare religious affiliation and how each affected biometric outcomes pre- and post-CHIP intervention in those with type 2 diabetes, and to assess if Adventists or non-Adventists entered CHIP with different prevalent rates of diabetes. The specific data analyses conducted include descriptive statistics, logistic regression analysis, repeated measures MANOVA, and frequency and percentages.

The results of the logistic regression analysis showed that religious affiliation and testing period did not have a significant effect on the self-identified preprogram diabetes rate once step two was completed. The results of the logistic regression failed to reject the null hypothesis for RQ1. The results of the repeated measures MANOVA showed that the interaction effects of the within-subject factor of the testing periods and the between-subject factor of religiosity had significant effects on the biometric outcomes of TC and LDL. The null hypothesis for RQ2 was rejected; there was a significant difference in biometric outcomes for TC and LDL between Adventists and non-Adventists with self-identified type 2 diabetes pre- and post-CHIP, which were due to Adventist affiliation. Pre- and post-CHIP Adventists had a higher TC and LDL than non-Adventists. When compared to non-Adventists, having an Adventist affiliation revealed little difference pre- and post-CHIP in both the percentage of members who fell within the highest risk factor range and those who fell within the normal range, and in some parameters scored worse.

## Chapter 5: Discussion, Conclusions, and Recommendations

### Introduction

The current standard U.S. dietary recommendations to prevent and reverse diabetes do not address the root cause of diabetes; instead, diabetes is commonly managed in the United States through medications and moderation of all foods, regardless of their health value (ADA, 2016). A whole-food, plant-based, vegan diet addresses the root cause of diabetes and can reverse and prevent this disease (Yokoyama et al., 2014). A diet higher in animal protein increases the risk of diabetes while a diet higher in vegetable protein reduces the risk (Malik, Li, Tobias, Pan & Hu, 2016; Vigiouliouk et al., 2015), with no threshold when further reduction of animal products does not help (Campbell, Parpia, & Chen, 1998). This study addressed a gap in the literature by assessing if having a particular religious affiliation had an influence on biometric outcomes pre- and post-CHIP, a plant-based, vegan intervention program. The purposes of this study were to determine the relationship between religiosity and preprogram diabetes state, and to determine if there was a statistically significant difference in the biometric changes between Adventists and non-Adventists with diabetes pre- and post-CHIP in those with type 2 diabetes.

The logistic regression analysis in RQ1 failed to reject the null hypothesis. The IV of religiosity and testing period did not have a significant effect on the self-identified diabetes state between Adventists and non-Adventists, after controlling for the covariates. The reported diabetes rates—78.8% of non-Adventists and 21.2% of Adventists—was not significant because of the influence of the covariates, and the null hypothesis was not

rejected. In RQ2, the repeated MANOVA analysis showed that biometric outcomes between Adventists with diabetes and non-Adventists with diabetes were significantly different due to religious affiliation in LDL and TC pre- and post-CHIP and therefore rejected the null hypothesis. Both groups improved in the percentage of participants who moved into the normal category for all biometrics. Both groups reduced the percentage of participants who were in the highest risk category.

### **Interpretation of the Findings**

Previous CHIP research has presented pre- and postbiometrics in general and in gender differences (Kent et al., 2014; Morton et al., 2014a) but not in religious differences. During the latter part of finishing this dissertation, Kent et al. (2015), published new research that assessed biometric changes among religious affiliation (Adventist and non-Adventist) pre- and post-CHIP. They reported that Adventists and non-Adventists achieved similar biometric improvements post-CHIP though non-Adventists improved in more areas, and those who were in the greatest risk categories improved the most, similar to previous CHIP findings (Kent et al., 2015). Though my current research additionally targeted those with type 2 diabetes in addition to Adventist affiliation, Kent et al. (2015), found similar outcomes; this shows that regardless of participant's Adventist or diabetes status, they can see improvements at the post-CHIP intervention stage.

This study also showed that the self-identified diabetes state between Adventist and non-Adventist in pre-CHIP participants was not found to be significantly different, which was similar to the more recent publication on religiosity by Kent (2015). This was

not surprising considering CHIP targets those with diabetes and other chronic diseases and Adventists may be drawn to an Adventist health program. This group of Adventists would not be representative of the entire denomination.

The present study showed that having a particular religious belief, either Adventist or non-Adventist with diabetes, did elicit significant improvement differences in LDL and TC pre- and post-CHIP and was due to religious affiliation. The other biometrics improved also, but was due to factors other than religion, and may be due to lifestyle factors not currently captured in the CHIP questionnaires, such as gender, income, readiness to learn, and changes in medication, diet, and exercise. Adventists with diabetes had a higher mean in the normal category preprogram for FPG and DBP.

Non-Adventists had a higher mean in the normal disease risk category preprogram for HDL, LDL, TG, TC, SBP, and BMI. Postclass Adventists had a higher mean in the normal category for HDL, LDL, SBP, and DBP. Non-Adventists had a higher mean in the normal category for TG, TC, FPG, and BMI. Adventists had a higher percentage of participants in the highest category preclass in HDL, LDL, TG, TC, FPG, SBP, and BMI. Non-Adventists had a higher percentage of participants in the highest preclass in DBP. Postclass Adventists had a higher percentage of participants in the highest category in HDL, LDL, TG, TC, SBP, and DBP, where non-Adventists were higher in BMI and FPG. Adventists made a greater mean change reduction in the highest disease risk category in SBP, DBP, and BMI, and non-Adventists in HDL, LDL, TG, and FPG. In the highest category, Adventists increased their postclass mean change LDL by 7.87, TG by 11.00, TC by 0.15, and FPG by 6.12. In the highest category, non-Adventists

increased their postclass mean change TC by 3.27 and DBP by 1.95. Both groups increased the percentage of participants who entered into a lower HDL category.

The literature review presented evidence showing the effectiveness of a comprehensive plant-based, lifestyle program in the reduction of chronic disease such as diabetes and cardiovascular disease, and has the potential to impact large numbers of people while reducing health costs significantly (Shurney et al., 2012). Despite the lack of a control group and selection bias, this study, with its large sample size, indicated that the volunteer-delivered CHIP modification intervention program is an effective 30-day, community-based, video-presented, plant-based, lifestyle program (Morton et al., 2014a).

The literature review pointed out that trained volunteers have improved health indicators for chronic disease such heart failure (Siabani et al., 2014), CVD risk factors (Rankin et al., 2012), and at-home exercise programs (Castro, Pruitt, Buman, & King, 2011; Etkin, Prohaska, Harris, Latham, & Jette, 2006). The only apparent adverse outcome in CHIP was the increase of participants who reduced their HDL, which has also been seen throughout other CHIP research and other plant-based, vegan health programs. Although its implications are disputed, a reduction is not considered a detriment when switching to a plant-based diet (Barnard, 1991; Esselstyn et al., 1995; Kent et al., 2013b; Kent et al., 2015; Morton et al., 2013; Ornish et al., 1998; Rankin et al., 2012), or when accompanied by a normal LDL (Bartlett et al., 2016).

The social ecological model (Bronfenbrenner, 1979) depicts how the Adventist health message has influenced the five social levels of society: individual, intrapersonal, community, institutional, and societal, and how CHIP intersected with three: individual,

intrapersonal, and community. The five social levels have a greater effect on an individual's health outcomes when combined and accumulated (Raingruber, 2014, p. 64). Targeting one specific social level about health would not be as effective as simultaneously concentrating on multiple health factors considering healthy and unhealthy lifestyle principles come from each social level in reciprocal influences (Raingruber, 2014, p. 64) and may be indicative of research outcomes in this study.

This research supports positive social change by showing that CHIP is a valuable contributor and model program for improving chronic health indicators for all people, regardless of Adventist affiliation. This study contributed original knowledge to the existing CHIP literature by extending the population's characteristics to add a specific disease process, comparing a specific faith affiliation, and adding covariates. The variables and population characteristics of the present study were not unlike previous CHIP studies, thus it contributed additional empirical evidence to the field.

### **Limitations of the Study**

Several limitations of this study were present. First, there was a lack of a control group, which limits the generalization of the results of this study. However, Rockford CHIP, the professional division of CHIP, has published research using randomized clinical control trials, with results showing similar positive outcomes as the volunteer division (Aldana et al., 2005a; Aldana et al., 2005b; Merrill, Taylor, & Aldana, 2008).

Second, diet, exercise, and medication diaries were not obtained from CHIP participants, so it was unknown as to how much change there was to these variables, and the effects those changes had on the biometric outcomes. However, participants informed

facilitators that they had either reduced or removed their medications by doctor's order and made other lifestyle changes (Rankin et al., 2012). Had this data been factored into the results, it would have only produced a diluted effect considering diet, exercise and medications have direct effects on the biometrics used in this study. Factoring out these variables would only strengthen the results. Other variables not captured but may have contributed to the outcome of this study include race, social and church support, income, and readiness to learn; thus, the influence of these variables in this study were also not possible to measure.

Third, participants were self-identified in diabetes state, Adventist affiliation, and class participation. Participants were asked on the Lifestyle Questionnaire, "Have you ever been told by a doctor you have diabetes?" Therefore, they were self-identified, and their diabetes state or type was not verified. It is possible that those with gestational diabetes, type 1, or 1.5 (as opposed to type 2 diabetes that the present study focused on) may have been included in the self-identification. Considering that 90-95% of people with diabetes have type 2 (ADA, 2016), the number of other types of diabetes likely would have been very negligible. There were also 86 children in the population group, but none were listed as having diabetes.

It is also possible that participants may have not accurately checked their Adventist status. Membership verification was not clarified, nor was the option to mark Adventist or non-Adventist defined. Some participants who marked their Adventist affiliation may have had loose associations with the church and others may have been frequent visitor but not members, others may have simply missed the question.

Participants were also self-selected to participate in the CHIP program, and may have been more motivated, ready, and willing to make the necessary changes to a plant-based diet (Bartholomew et al., 2006, p. 110-113).

Lastly, original CHIP data were input into the CHIP online databank by the local facilitators and a cleaned up data set shared for this research; it is unknown if errors occurred during data entry at any point. Considering other CHIP outcomes are all similar, this again suggests that such errors, if they existed, had a negligible effect. Further limitations and biases would have been minimal, since this research used secondary data, and the trial planning and trial implementation had already occurred.

### **Recommendations**

CHIP is an effective 30-day lifestyle modification program in reducing chronic disease risk factors in both Adventists and non-Adventists with diabetes. However, Adventist affiliation influenced participants significantly pre- and post-CHIP. Further research recommendations include:

- additional studies comparing Adventists and non-Adventists in other disease processes
- investigating further the reduction of HDL in those switching to a plant-based diet and incorporating those things into the program which are known to have a positive effect on HDL such as omega-3, DHA, and ALA supplementation
- using a control group with the volunteer leg for broader generalizations
- capturing diet, race, income, medication usage changes, and exercise

- validating diabetes state per ADA standards by a glycohemoglobin A1c or two FPG tests (ADA, 2016)
- comparing those who self-identify themselves as having diabetes on the health questionnaire and the single FPG obtained preprogram
- incorporating an additional teaching session which focuses on trust in God as part of the Adventist health message and compare outcomes with a control group
- questioning how long the Adventists have been a baptized member to compare outcome differences among themselves

### **Implications for Practice**

Since the mid-1800s, the Adventist health message has been a source of inspiration, optimism, strength, and guidance for those facing a variety of health challenges without the use of medications. This message, as presented through CHIP, advocates a nonmedical, lifestyle approach to improve disease outcomes for people regardless of faith affiliation. The foundational causes, as well as treatment for managing and reversing type 2 diabetes, are diet and lifestyle, but these factors are often given little attention over Western medicine's dietary approach and its costly, often ineffective, pharmaceutical approaches, which are often prescribed despite their side effects (Graham et al., 2010; Kannan et al., 2016; Lincoff, Wolski, Nicholls, & Nissen, 2007; Solomon & Winkelmayr, 2007). CHIP is a desired program for those who want a natural approach to diabetes prevention and reversal without the use of pharmaceuticals. The positive social impact is that CHIP has demonstrated that regardless of having a specific faith

(Kent et al., 2015), those with type 2 diabetes may also attend CHIP, apply the principles to their own lives, and expect to see similar improvements.

Considering the strong educational component of CHIP, as well as its solid, scientifically researched foundation, and the fact that the program does not demand adherence to an Adventist ideology (and provides limited spiritual teaching in general because it targets a more secular community), introducing this program in places that care for those with chronic disease may be beneficial. Incorporating CHIP into hospitals, long-term care facilities, prisons, and other large and small institutions, workplaces, and the home setting may be effective in reducing both morbidity and mortality due to chronic disease, as well as realizing a substantial cost benefit (Leung et al., 2015). Considering that religion plays a role in health and healing (McKenzie, Modeste, Marshak, & Wilson, 2015; Snowdon et al., 1982), and trusting in God is an Adventist health principle, it is reasonable to investigate whether a more focused spiritual approach affect health outcomes. Additional research using a control group with trusting in God as an additional teaching module may prove beneficial.

### **Conclusion**

This chapter contained the analysis interpretation of comparing Adventists and non-Adventists with diabetes pre- and post-CHIP intervention, a volunteer-facilitated, plant-based, community health program to improve chronic disease risk factor outcomes. The diabetes rate was also discussed between the two groups. MANOVA, logistic regression, frequencies, and percentages were used to analyze and describe the data.

Over the past many decades, much research has been published and dedicated to assessing a plant-based, vegan diet as an intervention to reverse and prevent type 2 diabetes. Counsel on this lifestyle has been given since the time of Hippocrates and progressively throughout the Adventist movement for the past almost 160 years. A whole-foods, vegan diet is a viable prescription for individuals with diabetes willing to follow such a plan especially if they desire a pharmaceutical-free approach. The results of this study add empirical data to the existing literature, which shows the need for a paradigm shift in treating diabetes. A positive social change begins at any of the five levels of society and can have a spreading and pervasive influence as seen with the spread of the Adventist health message going worldwide and depicted through the SEM.

This study has shown that both Adventists and non-Adventists with diabetes benefit from applying CHIP's nutrient-dense, whole-food, plant-based dietary principles, but more so for non-Adventists in LDL and TC. Overall, both groups improved in all areas. A diet high in plant foods without the additional use of animal products, coupled with other practical and timeless lifestyle principles, is an effective means to improve biometric outcomes for those with type 2 diabetes. Programs such as CHIP are needed at a time when chronic disease is at an all-time high, and will be necessary to expand this and other similar programs if there is to be a reduction in chronic disease rates, not only in North America but also worldwide.

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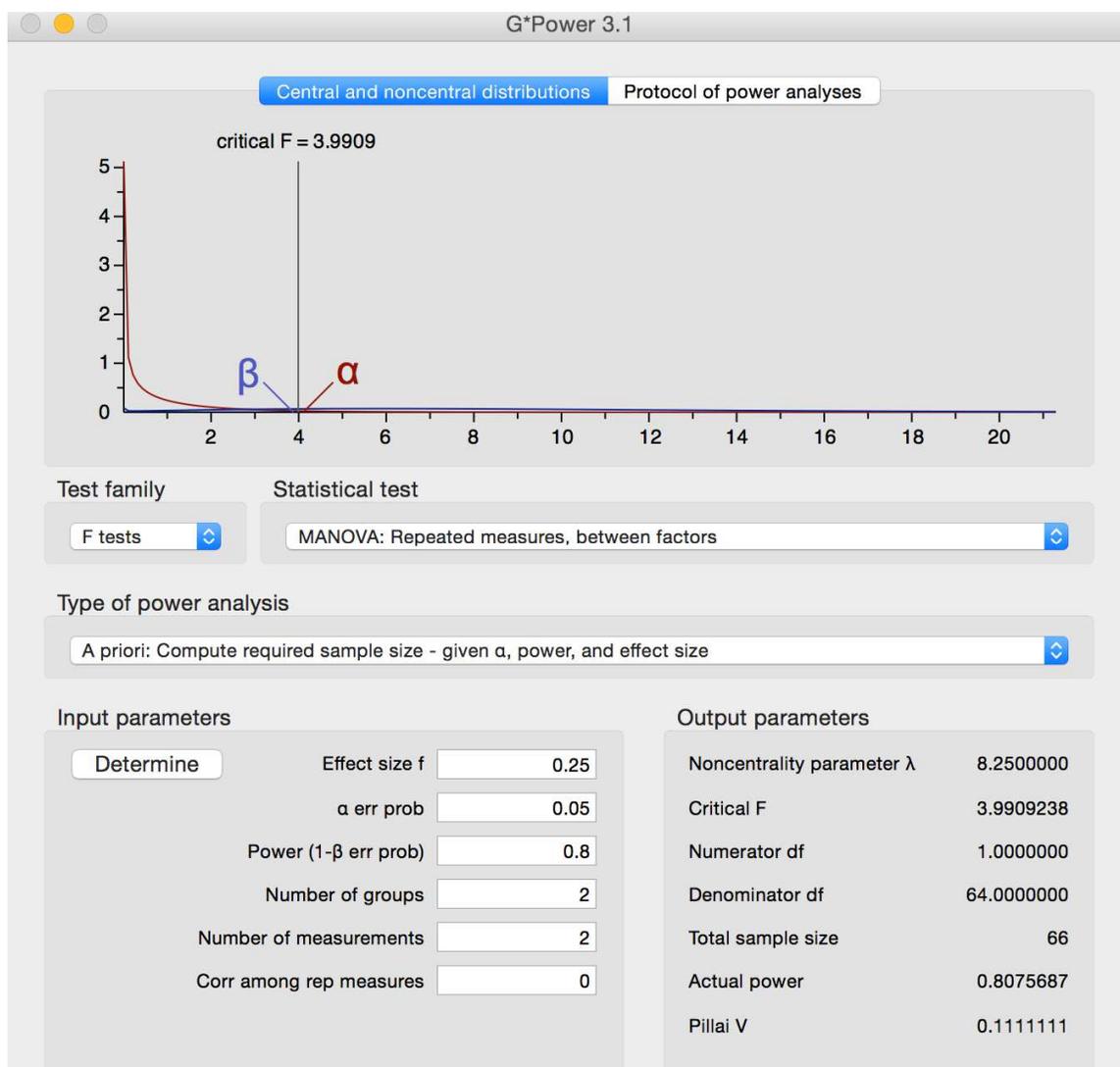
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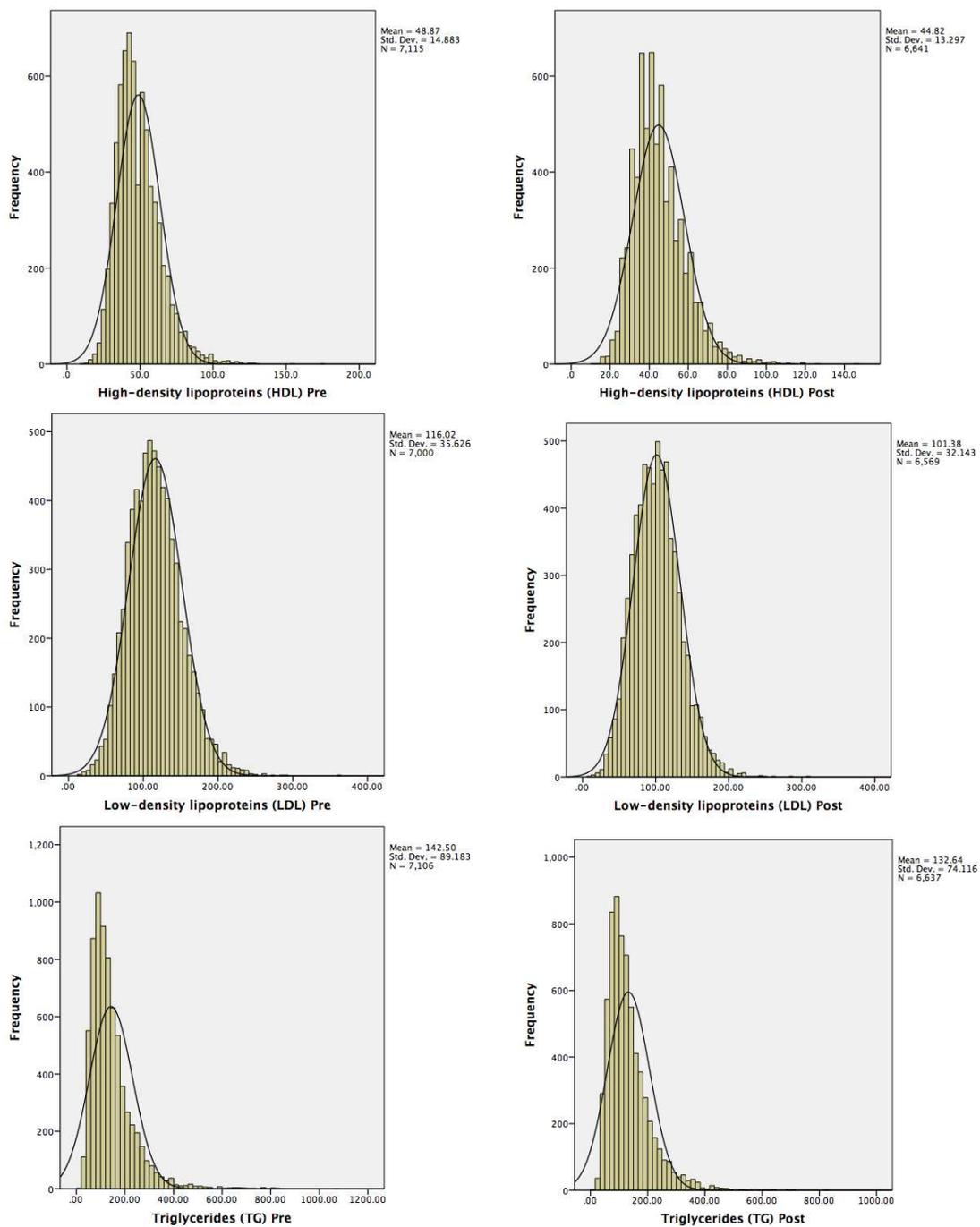
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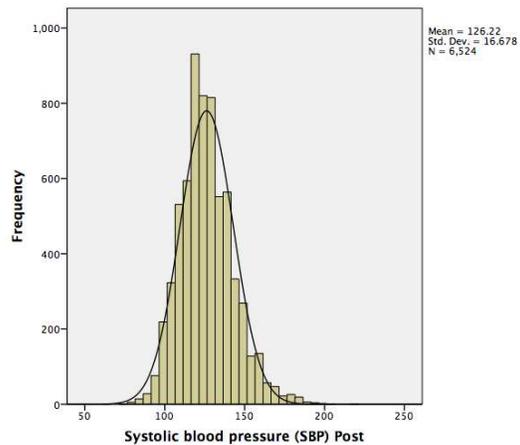
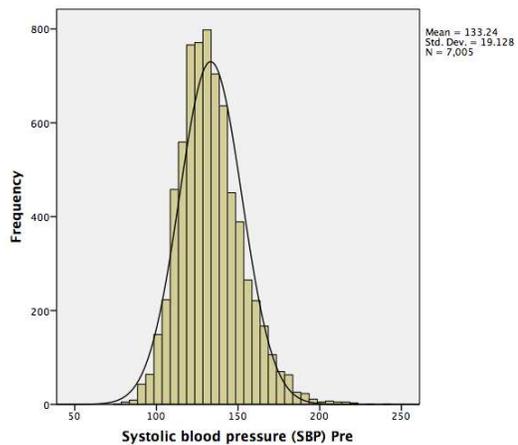
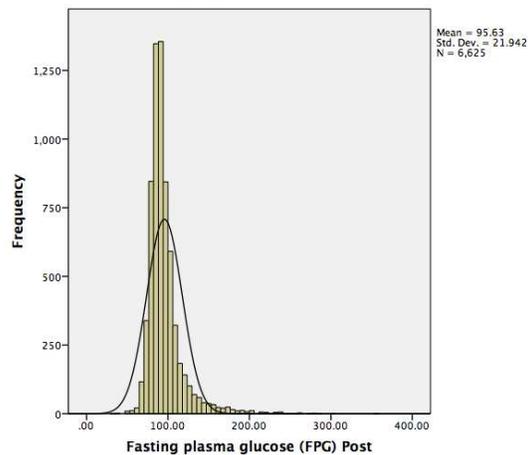
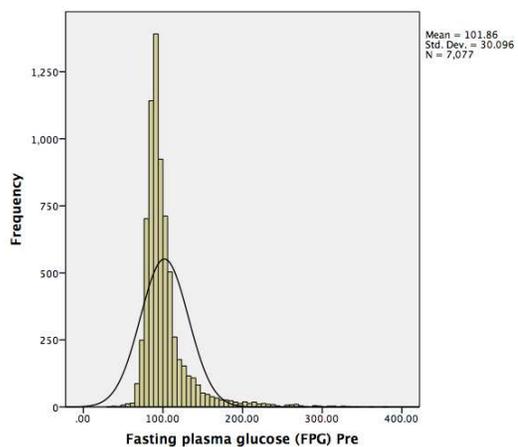
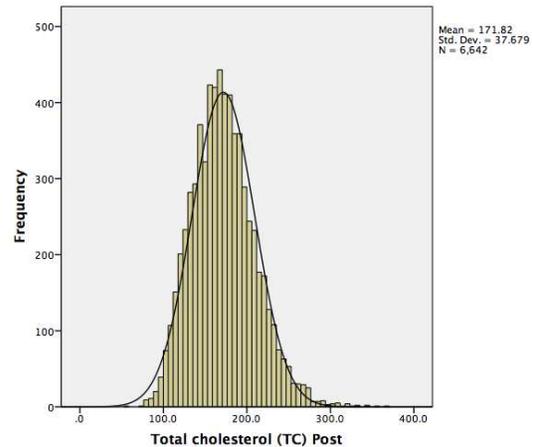
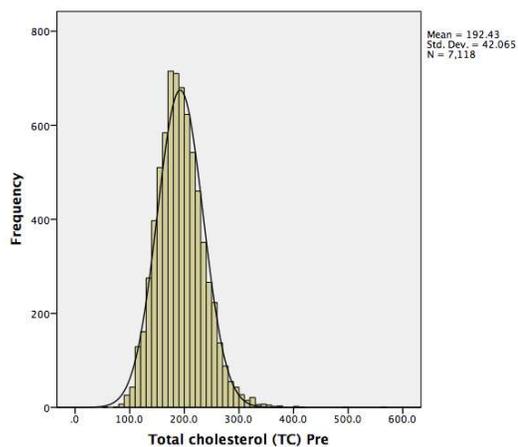
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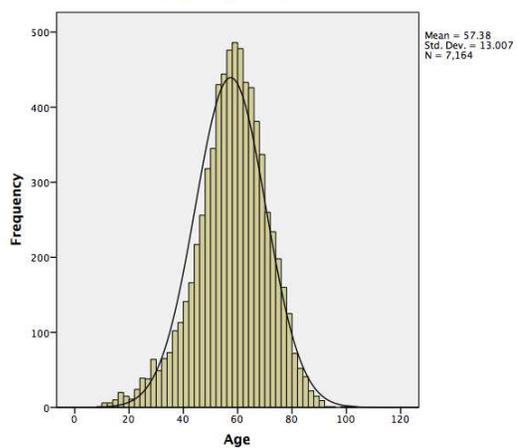
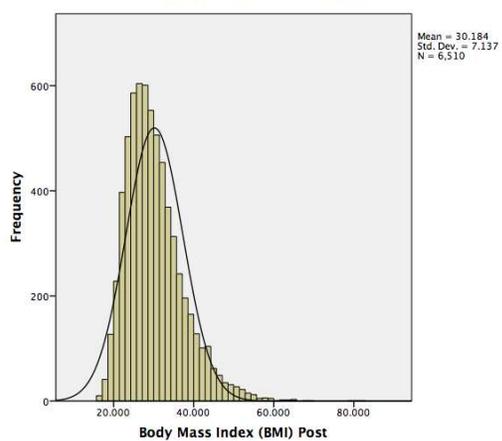
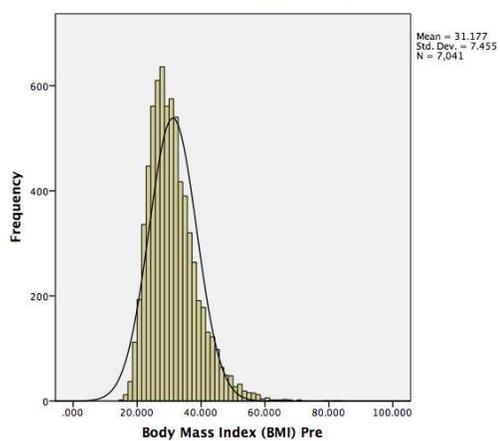
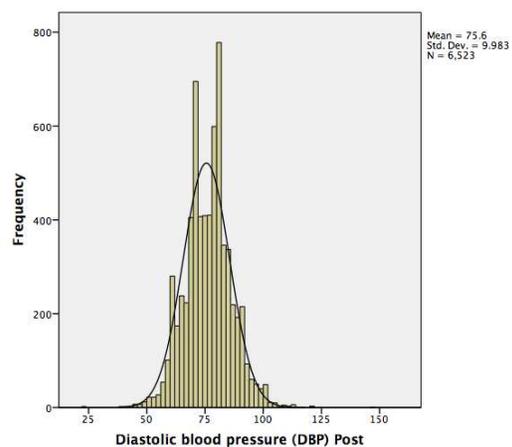
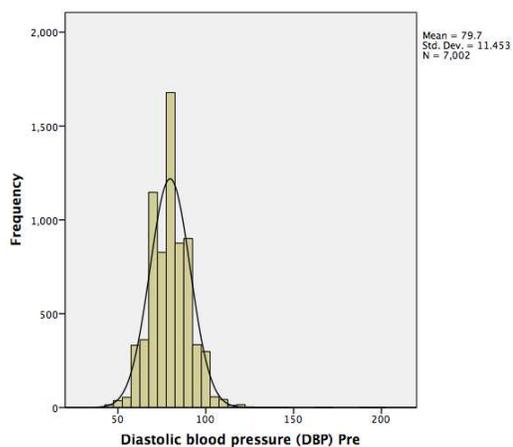
## Appendix A: Results of G\*Power Computation of Sample Size



## Appendix B: Histogram of Study Variables of the Population







## Appendix C: Data Use Agreement

### **DATA USE AGREEMENT**

This Data Use Agreement (“Agreement”), effective as of July 1, 2015 (“Effective Date”), is entered into by and between Janie Unruh (“Data Recipient”) and Complete Health Improvement Program (“Data Provider”). The purpose of this Agreement is to provide Data Recipient with access to a Limited Data Set (“LDS”) for use in research in **accord with laws and regulations of the governing bodies associated with the Data Provider, Data Recipient, and Data Recipient’s educational program.** In the case of a discrepancy among laws, the agreement shall follow whichever law is more strict.

1. **Definitions.** Due to the study’s affiliation with Laurente, a USA-based company, unless otherwise specified in this Agreement, all capitalized terms used in this Agreement not otherwise defined have the meaning established for purposes of the USA “HIPAA Regulations” and/or “FERPA Regulations” codified in the United States Code of Federal Regulations, as amended from time to time.
2. **Preparation of the LDS.** Data Provider shall prepare and furnish to Data Recipient a LDS in accord with any applicable laws and regulations of the governing bodies associated with the Data Provider, Data Recipient, and Data Recipient’s educational program.
3. **Data Fields in the LDS.** **No direct identifiers such as names may be included in the Limited Data Set (LDS).** In preparing the LDS, Data Provider shall include the **data fields specified as follows**, which are the minimum necessary to accomplish the research: for all CHIP participants between the dates of January 2006 and September 2012: total cholesterol, low density lipoproteins, high density lipoproteins, triglycerides, fasting plasma glucose, body mass index, systolic blood pressure, diastolic blood pressure, weight (pre- and post- CHIP results in U.S. measurements), height, marital status, age/DOB, gender, religious preference, family history of diabetes, self-selection of type 2 diabetes, and dates of attendance.
4. **Responsibilities of Data Recipient.** Data Recipient agrees to:
  - a. Use or disclose the LDS only as permitted by this Agreement or as required by law;
  - b. Use appropriate safeguards to prevent use or disclosure of the LDS other than as permitted by this Agreement or required by law;
  - c. Report to Data Provider any use or disclosure of the LDS of which it becomes aware that is not permitted by this Agreement or required by law;
  - d. Require any of its subcontractors or agents that receive or have access to the LDS to agree to the same restrictions and conditions on the use and/or disclosure of the LDS that apply to Data Recipient under this Agreement; and

- c. Not use the information in the LDS to identify or contact the individuals who are data subjects.
5. Permitted Uses and Disclosures of the LDS. Data Recipient may use and/or disclose the LDS for its Research activities only.
6. Term and Termination.
  - a. Term. The term of this Agreement shall commence as of the Effective Date and shall continue for so long as Data Recipient retains the LDS, unless sooner terminated as set forth in this Agreement.
  - b. Termination by Data Recipient. Data Recipient may terminate this agreement at any time by notifying the Data Provider and returning or destroying the LDS.
  - c. Termination by Data Provider. Data Provider may terminate this agreement at any time by providing thirty (30) days prior written notice to Data Recipient.
  - d. For Breach. Data Provider shall provide written notice to Data Recipient within ten (10) days of any determination that Data Recipient has breached a material term of this Agreement. Data Provider shall afford Data Recipient an opportunity to cure said alleged material breach upon mutually agreeable terms. Failure to agree on mutually agreeable terms for cure within thirty (30) days shall be grounds for the immediate termination of this Agreement by Data Provider.
  - e. Effect of Termination. Sections 1, 4, 5, 6(e) and 7 of this Agreement shall survive any termination of this Agreement under subsections c or d.
7. Miscellaneous.
  - a. Change in Law. The parties agree to negotiate in good faith to amend this Agreement to comport with changes in federal law that materially alter either or both parties' obligations under this Agreement. Provided however, that if the parties are unable to agree to mutually acceptable amendment(s) by the compliance date of the change in applicable law or regulations, either Party may terminate this Agreement as provided in section 6.
  - b. Construction of Terms. The terms of this Agreement shall be construed to give effect to applicable federal interpretative guidance regarding the HIPAA Regulations.
  - c. No Third Party Beneficiaries. Nothing in this Agreement shall confer upon any person other than the parties and their respective successors or assigns, any rights, remedies, obligations, or liabilities whatsoever.

- d. Counterparts. This Agreement may be executed in one or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.
- e. Headings. The headings and other captions in this Agreement are for convenience and reference only and shall not be used in interpreting, construing or enforcing any of the provisions of this Agreement.

IN WITNESS WHEREOF, each of the undersigned has caused this Agreement to be duly executed in its name and on its behalf.

## DATA PROVIDER

## DATA RECIPIENT

Signed: *L Kent*Signed: *Janie Unruh*Print Name: LILLIAN KENTPrint Name: Janie UnruhPrint Title: DATA PROVIDER AND  
LECTURER / RESEARCH FELLOW

Print Title: PhD Candidate

AT LIFESTYLE RESEARCH CENTRE,AVON DALE COLLEGE OF HIGHER EDUCATION