FEASIBILITY OF ADMINISTERING THE NATIONAL DIABETES PREVENTION PROGRAM AT THE UNIVERSITY OF UTAH: A PILOT STUDY

by

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ABSTRACT

Large lifestyle interventions have been effective in preventing type 2 diabetes (T2D) in high-risk individuals. However, the effects of translational studies at the community level are less consistent. The purpose of this study was to determine the efficacy of the National Diabetes Prevention Program (NDPP) to reduce the risk for T2D via improvements in body weight, body composition, glucose management, and quality of life (QOL) in members of the University of Utah community who are at elevated risk for developing T2D. Forty-seven prediabetic University staff and faculty were enrolled in a year-long group-based translation of the NDPP. The intervention employed two goals: achieving > 7% weight loss, and obtaining $\geq$ 150 minutes/week of moderate intensity physical activity. After the 12-month intervention, improvements were observed in body weight (-4.82%, $p < 0.001$), BMI (-5.20%, $p < 0.001$), waist circumference (-4.56%, $p < 0.001$), hip circumference (-4.50%, $p < 0.001$), systolic blood pressure (-5.94%, $p < 0.001$), 6-minute walk distance (7.15%, $p = 0.001$), oral glucose tolerance (-8.41%, $p < 0.028$), and QOL scale (8.3%, $p < 0.001$). There were no significant effects ($p > 0.05$) on waist-to-hip ratio, diastolic blood pressure, or fasting blood glucose. A small but significant increase in HbA1c was detected. At study completion, only 28% of participants had achieved the weight loss goal, but 52% of participants had achieved the physical activity goal. There was a significant positive correlation between the number of goals met and improvements in body weight ($r_S = 0.61$, $p < 0.001$), BMI ($r_S = 0.56$, $p < 0.001$), waist circumference (r_S

= 0.39, $p = 0.007$), and hip circumference ($r_S = 0.33$, $p = 0.024$), but no association between goals met and change in glucose management variables. Despite limited effect on markers of glucose management, these results confirm the feasibility of the NDPP's lifestyle intervention to improve risk factors associated with T2D in members of the University of Utah community.

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INTRODUCTION

Type-2 diabetes (T2D), which is characterized by progressive insulin resistance and consequent hyperglycemia (Alberti & Zimmet, 1998), is associated with increased risk of hypertension (Gress, Nieto, Shahar, Wofford, & Brancati, 2000), dyslipidemia (Goldberg, 2001), microvascular diseases (UK Prospective Diabetes Study Group, 1998), nontraumatic amputations (Shojaiefard, Khorgami & Larijani, 2008), and cardiovascular disease (Haffner, Lehto, Rönnemaa, Pyörälä, & Laakso, 1998). T2D accounts for approximately 95% of all diagnosed cases of diabetes nationally (Centers for Disease Control and Prevention [CDC], 2015). Moreover, according to the most recent Centers for Disease Control and Prevention (CDC) data, T2D is the seventh leading cause of death in the U.S. (Kochanek, Murphy, Xu, & Tejada-Vera, 2016), and adults with T2D have approximately a 180% greater risk of dying prematurely as compared to their non-diabetic counterparts (Seshasai et al., 2011).

In the United States alone, an estimated 21 million people have been diagnosed with T2D, and another 8.1 million are thought to be undiagnosed cases (CDC, 2015). The estimated economic cost of diabetes is $245 billion, with $69 billion attributed to indirect costs of the disease, including work-related absenteeism, unemployment due to chronic complications of the disease, loss of productivity at work, and premature mortality (American Diabetes Association [ADA], 2013). In 2007, the projected cost for undiagnosed diabetes alone was $8.3 billion (Zhang, Dall, Mann, et al., 2009). With an

estimated 1.4 million new cases of diabetes diagnosed annually (CDC, 2015), and predictions of nearly 1 in 3 adults being diagnosed by 2050 (Boyle, Thompson, Gregg, Barker, & Williamson, 2010), it is increasingly important to identify and implement those health care pathways that effectively reduce T2D incidence in order to both improve health and reduce national health care costs.

Like T2D, prediabetes places an individual at substantially higher risk of heart disease, stroke, vision loss, amputations, kidney disease, and early mortality (Albright & Gregg, 2013; Nathan et al., 2007). Moreover, as compared to the 1% annual risk of T2D among the general population, the average annual risk of developing T2D among those with prediabetes is 5%-10% (Gerstein et al., 2007). Prediabetes is diagnosed when an individual has elevated blood glucose levels that are below the clinical cutoff of frank diabetes. Eighty-six million people in the U.S. are thought to have prediabetes (CDC, 2015), accounting for an estimated $25 billion in health care costs (Zhang, Dall, Chen, et al., 2009). While prediabetes represents a substantial health care burden in and of itself, it also identifies individuals who may benefit most from targeted diabetes-prevention efforts.

The goal of usual care treatment for T2D is to achieve and maintain optimal levels of blood glucose, circulating lipids, and blood pressure so as to delay or prevent the development of comorbidities (ADA, 2010). Effective management of blood glucose and related health indices has been shown to occur through improved nutrition, increased physical activity, weight loss, and the use of prescription medications (CDC, 2015). The relative efficacy of these methods, however, is not well understood.

The Diabetes Prevention Program (DPP) was a large randomized controlled trial

that compared the efficacy of an intensive lifestyle intervention with the use of metformin, a leading antidiabetes prescription medication, to reduce the incidence of T2D in individuals with impaired glucose tolerance (Knowler et al., 2002). The primary outcome, progression to T2D, was measured in addition to secondary cardiometabolic risk factors. The goals of the intensive lifestyle intervention (ILS) were modest weight loss of at least 7% of initial weight and an increase in moderate-to-vigorous intensity physical activity (MVPA) to at least 150 minutes per week. Over a period of 24 weeks, the ILS group attended 16 one-on-one "core sessions," led by either a nutritionist, physician, or exercise expert, which focused on educating participants and improving their behaviors related to healthy eating, increasing exercise, and other common barriers to healthy lifestyle change (Knowler et al., 2002). Following the core sessions, the maintenance phase consisted of continued group and one-on-one sessions offered every 4-6 weeks for the remainder of the nearly 3-year study period. The results of the study showed that, in comparison to a control group who only received standard health behavior education, the incidence rate of T2D was reduced by 58% and 31% in the ILS and Metformin groups, respectively. Fifty percent of the participants in the ILS group achieved the 7% weight loss goal by the end of the 24 weeks, while 74% attained the physical activity goal of at least 150 minutes of MVPA per week. Posthoc analysis of the ILS group data revealed that weight loss of 5 kg (11lb) reduced the risk of T2D by 51%, and for every kilogram lost, there was a 16% reduction in risk for T2D (Hamman et al., 2006). Those who achieved *both* goals of the ILS reduced their risk of T2D by 89% (Hamman et al., 2006). The authors concluded that, in comparison to weight loss per se, the combination of diet and physical activity-induced weight loss elicited the greatest

improvement in risk for T2D.

The Diabetes Prevention Outcomes Study (DPPOS) is a long-term follow-up to the DPP. The aim of the DPPOS was to identify whether or not the reduced risk for T2D that was observed in the original DPP intervention groups would persist over time (Diabetes Prevention Program Research Group [DPPRG], 2009). During a median follow-up period of 5.7 years, it was found that diabetes incidence rates rose in the lifestyle intervention group from 48 to 59 cases per 1000 person years, which may be partly explained by weight regain during this period (DPPRG, 2009). However, when compared with the placebo group, the 10-year cumulative incidence of T2D in the Lifestyle and Metformin groups was reduced by 34% and 18%, respectively (DPPRG, 2009). Further analysis of the DPPOS revealed that those individuals who achieved a complete reversion to normal glucose regulation had a 56% lower risk for T2D as compared to participants who remained prediabetic for the duration of the follow-up study (Perreault et al., 2012). Moreover, regression to normal glucose regulation was associated with significantly lower cardiovascular disease risk, underscoring the cumulative benefits of long-term healthy lifestyle behavior change (Perreault et al., 2014).

The success of the DPP, which was in consort with other large diabetes prevention trials, is the basis of the CDC's ongoing effort to translate healthy lifestyle intervention programs into real-world clinical care. Specifically, in 2009, the CDC's Division of Diabetes Translation began work to establish the National Diabetes Prevention Program (NDPP), which was later included in the Patient Protection and Affordable Care Act (2010). The goals of the CDC's implementation of the NDPP were

to standardize the training of the workforce responsible for teaching a version of the DPP's lifestyle intervention that was modified for delivery to small groups (~10-18 individuals) of at-risk individuals. Implementing the NDPP also established standards for program accuracy and reliability and created a central support system for community-based organizations looking to disseminate the NDPP's lifestyle program at the local level (CDC, 2016). To date, the CDC has fully recognized more than 80 NDPP programs across the country, with more than 1000 additional community programs pending recognition.

In the state of Utah, 4.4% of the population has been diagnosed with T2D and 32.7% of Utahans are thought to be prediabetic (Dall et al., 2014). Moreover, the estimated total cost related to diabetes was predicted at nearly 1.7 billion dollars, with 272 million dollars being accounted for by prediabetes (Dall et al., 2014). Despite being one of the most active states in the nation, it is estimated that 56.9% of the state's population are overweight, 22.5% are obese, and 48.1% do not get adequate physical activity (CDC, 2010). The University of Utah Diabetes Prevention Program (UUDPP) was developed as a pilot project to implement the CDC's NDPP for at-risk members of the community. Though this pilot study was designed to initially target members of the University of Utah and their families, if successful, the architects of the study intend to expand the project to include members of the greater Salt Lake City region. The purpose of the current study is to evaluate and report the UUDPP's efficacy to reduce the risk for T2D and improve cardiometabolic health among members of the University of Utah community who are at an elevated risk for developing T2D. Data from this year-long pilot project will be compared with similar worksite translational studies of the DPP

(Amundson et al., 2009; Mau et al., 2010) as well as those of the landmark Diabetes Prevention Program (Knowler et al., 2002) and will be used to guide expansion of the NDPP within the state of Utah.

Study Aims and Hypotheses

The purpose of this feasibility study was to determine the efficacy of the National Diabetes Prevention Program to reduce the risk for type 2 diabetes via improvements in body weight, body composition, and other markers of cardiometabolic health, and to improve quality of life in members of the University of Utah Community who are at elevated risk for developing type 2 diabetes. Therefore, we proposed the following aims:
Aim 1: To determine whether 12-months of the National Diabetes Prevention Program lifestyle intervention reduces risk for type 2 diabetes by improving body weight, body composition, glucose regulation, blood pressure, physical activity, and quality of life.

Hypothesis 1: We hypothesize that there will be significant reductions in type 2 diabetes risk via improvements in body weight, body composition, glucose regulation, blood pressure, physical activity, and quality of life after 12 months of the National Diabetes Prevention Program lifestyle intervention.

Aim 2: To determine whether those participants who achieve the weight loss or physical activity goals of the National Diabetes Prevention Program lifestyle intervention have greater improvements in body composition, glucose regulation, blood pressure, and quality of life as compared to those participants who do not achieve the intervention's weight loss or physical activity goals.

Hypothesis 2: We hypothesize that those participants who achieve the weight loss

or physical activity goals of the National Diabetes Prevention Program lifestyle intervention will have greater improvements in body composition, glucose regulation, blood pressure, and quality of life as compared to those participants who do not achieve the intervention's weight loss and physical activity goals.

REVIEW OF LITERATURE

Prevention of Type 2 Diabetes

The outcomes of the DPP study aligned with those of previous reports from the Malmö Feasibility Study, The Da Qing Diabetes Prevention Trial, and the Finnish Diabetes Prevention Study, each of which implemented similar behavior-based interventions in groups of individuals who were at high risk of developing T2D (Eriksson & Lindgärde, 1991; Pan et al., 1997; Tuomileto et al., 2001). Additionally, both the Finnish Diabetes Prevention Study and the DPP have elicited long-term follow-up data regarding the efficacy of the original interventions to promote sustained health improvements and persistent protection again T2D (DPPRG, 2009; Lindstrom et al., 2006). Moreover, the DPP has prompted multiple translational studies and investigations into its efficacy in different racial and ethnic subsets of the U.S. population (Ackermann, Finch, Brizendine, Zhou, & Marrero, 2008; Kramer et al., 2009). Together, these studies are informing the clinical practice and public health care policies we now use to support those with prediabetes. Still, further research is warranted as rates of diabetes have yet to recede.

Some of the earliest research targeting long-term T2D prevention came out of the Malmö Feasibility Study (Eriksson & Lindgärde, 1991). This 6-year prospective cohort study was designed to evaluate the feasibility of a clinical diet and exercise program to reduce the incidence of T2D in individuals with impaired glucose tolerance. Participants

were organized into diabetic and prediabetic treatment groups, in addition to prediabetic and normal controls. The treatment program consisted of 6 months of dietary counseling, and 6 months of physical activity instruction offered in groups of 10-15, or disseminated on an individual basis. After 5-years, the authors reported an average weight loss of 2.3-3.3 kg, compared to an increase of 0.2-2.0 kg in the control, and a 63% lower risk of T2D among those in the intervention group as compared with controls (RR= 0.37, $p < 0.003$).

Eriksson and Lindegärde (1991) concluded that the study's combination of physical activity and weight reduction was effective at reducing risk of T2D development and improving the symptoms and complications of diagnosed diabetes, and could be maintained long term. The authors also proposed that this intervention could be translated to a large-scale community-based effort.

The Da Qing Diabetes Prevention Trial (Pan et al., 1997) began shortly after the release of the Malmö study's findings. At this time, the prevalence of diabetes in China was increasing rapidly in response to the country's economic development and a greater predominance of modernized vs. traditional lifestyle (Pan, Yang, Li, & Liu, 1997). This controlled clinical trial aimed to examine the independent and combined effects of diet and exercise on incidence of T2D in those with impaired glucose tolerance in China (Pan et al., 1997). The goals of the dietary group were to restrict caloric intake for those with a BMI ≥ 25 kg/m^2 so as to elicit weight loss at a rate of 0.5-1.0 kg/month until a BMI = 23 kg/m^2 was achieved. The exercise-only group was instructed to increase activity by 1-2 units of exercise per day, with one unit equating to 30 minutes of mild, 20 minutes of moderate, 10 minutes of strenuous, or 5 minutes of very strenuous activity. The intervention goals for the diet and exercise combination group included both goals from

the diet- and exercise-only groups. All intervention groups received weekly counseling for 1 month, followed by monthly counseling for the following 3 months, and then once every 3 months for the remainder of the study. At the end of the 6-year study, results revealed a 67.7% incidence of diabetes in the control group, and 46% in the combined group. The diet-only and exercise-only groups also showed significantly lower incidence rates, 43.8% and 41.1%, respectively, indicating that either group was effective in reducing the incidence of diabetes. As compared with the control group, the diet, exercise, and combined intervention groups showed reductions in risk of 31%, 46%, and 42%, respectively.

Like China, Finland experienced a significant increase in the prevalence of T2D during the 1980s and 1990s, and it was estimated that there was a 97% increase in the number of individuals diagnosed with diabetes from 1988-2002 (Niemi & Winell, 2006). The Finnish Diabetes Prevention Study, which was published 4 years after the Da Qing Trial, was designed to determine the feasibility and efficacy of a lifestyle modification intervention to prevent the onset or delay T2D at the community level (Tuomileto et al., 2001). In this study, participants were randomly assigned to treatment or control groups. Members of the treatment group received individual counseling on reducing weight by at least 5%, limiting total intake of fat to < 30% of total energy consumed, reducing intake of saturated fat to < 10% of the total energy consumed, increasing fiber consumption, and accumulating at least 30 minutes of moderate intensity exercise each day. Counseling sessions were offered 7 times throughout the year, with telephonic counseling provided every 3 months for the remainder of the intervention. Control group participants were given information on the goals of the intervention, but were not given any individualized

programming to help them accomplish those goals.

After the 1st year, Tuomileto et al. (2001) found that the mean weight loss was greater in the intervention group as compared to the control group (4.7 ± 5.4% vs. 0.9 ± 4.2%, $p < 0.001$). After 2 years, weight reduction remained significantly greater in the treatment group ($p < 0.001$). After the completion of the study and an average follow-up period of 3.2 years, the cumulative incidence rates of diabetes were 11% in the intervention group and 23% in the control group, which coincided with a 58% risk reduction in those who completed the intensive lifestyle modification intervention. This reduction in risk was identical to that of DPP, and in line with the 42% reduction in risk observed in the Da Qing's combined exercise and diet modification group (Knowler et al., 2002; Pan et al., 1997).

Similar to the DPPOS, the extended follow-up of the Finnish Diabetes Prevention Study was designed to assess the long-term effects of the lifestyle intervention and its sustained efficacy in reducing the development of T2D (Lindstrom et al., 2006). Results revealed that after a mean follow-up of 7 years, the cumulative incidence rate of T2D in the intervention group was 4.3 cases per 100 person years (95% CI 3.4–5.4), relating to a 43% reduction in risk. Though there was a trend toward an increase in the overall risk of progressing to T2D following the initial intervention period, the absolute risk of the original group differences persisted compared to follow-up.

Further analysis of the Finnish Diabetes Prevention Study follow-up identified a positive association between the number of intervention goals achieved and the magnitude of the reduction in incidence of T2D over the 7-year period (Lindstrom et al., 2006). Summarily, Lindstrom et al. (2006) found that those who achieved 4 or 5 of the

lifestyle modification goals of the original intervention reduced their risk for T2D by 77% (HR = 0.23, $p = 0.0004$). Similarly, Hamman et al. (2006) found a positive relationship between the number of goals achieved in the DPP and improvement in risk. They concluded that achieving all of the DPP goals conferred an 89% reduction in risk for developing T2D (HR = 0.11, $p < 0.0001$). Of the existing large diabetes prevention studies, the Da Qing Trial was the only one to directly assess the isolated impact of exercise and diet on risk reduction. Interestingly, they found that a greater reduction in risk for diabetes was observed in the exercise-only group when compared to the diet or combined intervention groups (Pan et al., 1997). Specifically, they found that the exercise-only group experienced a 46% ($p < 0.0005$) reduction in risk of developing diabetes compared to the 42% ($p < 0.005$) reduction in the combined group, and 31% ($p < 0.03$) reduction in the diet-only group.

Global estimates have indicated that several native and migrant Asian Indian populations in South Africa, India, Singapore, and Fiji are among those with the highest prevalence of diabetes and prediabetes (11->20%) (King & Rewers, 1993). The Indian Diabetes Prevention Program (IDPP) was developed in response to the earlier large diabetes intervention trials, with the aim to determine whether a lifestyle intervention could also be effective at reducing the rate of diabetes progression in an Asian Indian prediabetic population (Ramachandran et al., 2006). Participants with confirmed impaired glucose tolerance were randomized to one of four groups. Group 1, the control group, received health information and advice regarding the risk of progressing from prediabetes to T2D. Of the three intervention groups, Group 2 undertook a lifestyle modification intervention, Group 3 was given metformin, and Group 4 was given the combination of

both the lifestyle intervention plus metformin. The lifestyle group received advice about achieving at least 30 minutes of moderate intensity physical activity per day, nutritional advice about dietary modifications for the reduction of total caloric intake, and guidelines on how to make healthier eating choices (Ramachandran et al., 2006). Unlike previous lifestyle interventions, no specific weight loss goal was given. Monthly phone calls and in-person coaching sessions provided every 6 months were provided to all participants receiving the lifestyle intervention (Groups 2 and 4), for the duration of the study (Ramachandran et al., 2006). Following the 3-year intervention period, the cumulative incidences of T2D was 55% in the control group (95% CI 46.0-63.6), 39.3% (95% CI 30.4-48.5), 40.5% (95% CI 32.0-49.7), and 39.5% (95% CI 30.9-48.9) in the intervention alone, the metformin, and the combined intervention groups (Groups 2, 3, and 4), respectively (Ramachandran et al., 2006). Though effective at reducing diabetes incidence, there were no significant differences between intervention groups, with risk reductions of 26.4-28.5% when compared with the control group. Though a significant increase in weight from baseline was observed in the control group ($p < 0.01$), an increase in weight was also observed in the intervention only group (Group 2) at 24 months ($p = 0.035$) despite their reduced risk for T2D. There were no significant weight changes in the other groups ($p > 0.05$) (Ramachandran et al., 2006).

Though the IDPP (Ramachandran et al., 2006) resulted in significant reductions in the progression to T2D among prediabetic participants, the magnitude of the effect of the lifestyle intervention (28.5%) was markedly less than that from the other large diabetes prevention studies. The overall risk reductions of 58% in both the Finnish and DPP studies and the 42% reduction in risk from the Da Qing study all provided stronger

evidence for effective primary prevention of T2D (Knowler et al., 2002; Pan et al., 1997; Tuomileto et al., 2001). As the authors of the IDPP noted, the rate of progression from prediabetes to diabetes was significantly higher in the Indian controls (18.3% per year) as compared with the controls of the Finnish (6% per year), the DPP (11%), and the Chinese Da Qing control groups (11.3%) (Ramachandran et al., 2006). It should also be noted that the IDPP did not employ a weight loss goal among its intervention groups. Considering that weight loss was established as *the* most important factor in the reduction of risk observed in the Finnish and DPP studies, the subsequent lack of weight loss among the intervention groups in the IDPP may partially explain the reduced effectiveness in the IDPP's intervention as compared with those of the Finnish Diabetes Prevention Study and the American DPP (Knowler et al., 2002; Ramachandran et al., 2006; Tuomileto et al., 2001).

Scaling up the DPP

Despite an impressive reduction in T2D risk following implementation of an intensive lifestyle intervention, the DPP was not designed as a cost-effective model for large-scale dissemination of diabetes prevention practices. Rather, the DPP was a time and resource-intensive intervention that provided, among other aides, fitness facility access and one-on-one counseling and has been estimated to cost $1,399 per participant (Ali, Echouffo-Tcheugui & Williamson, 2012; Knowler et al., 2002). Several translation studies have been conducted to investigate how to modify the DPP ILS for community-level application. The DEPLOY study assessed the feasibility of training existing YMCA wellness instructors to deliver a group-based adaptation of the original "core sessions" of

the DPP (Ackermann, Finch, Brizendine, Zhou, & Marrero, 2008). After 12 months, participants exhibited significantly greater reductions in body weight (-6% vs. baseline, $p < 0.05$) and improvements in total cholesterol (-13.5 mg/dl vs. baseline, $p < 0.05$) as compared to controls that participated in usual YMCA wellness programming. Moreover, the magnitude of weight lost was in line with the original, more intensive DPP study (Knowler et al., 2002). Another study assessed the viability and effectiveness of a clinic-based system of patient-referral to community-based lifestyle intervention programs (Ackermann, 2010). Ackermann (2010) found that a two-stage screening process to identify high risk individuals, and clinical testing of both fasting and 2-hour oral glucose tolerance, were deemed feasible even for the large volume of potential participants. Additionally, Ackermann et al. (2006) reported that economic modeling of these group-based practices and screening procedures indicated that even if these large-scale community-level efforts prove to be only half as effective as the original DPP, the outcomes would still likely be cost effective.

Mechanisms Underlying the NDPP's Lifestyle Intervention

The goals of the DPP were twofold: weight loss and increased physical activity. Specifically, participants were encouraged to achieve and maintain weight loss of 7% of baseline body weight through modifications in both diet and exercise (Knowler et al., 2002). Initial dietary modification included the reduction of total fat intake, not caloric restriction per se. However, this change in fat intake was intended to promote a consequent caloric deficit through healthier eating habits (DPPRG, 2002). Targeted caloric-reduction goals were introduced several weeks after the initial dietary

modification phase, and they tasked participants with reducing total caloric intake by 500-1000 kcal per day so as to achieve weight loss of approximately 1-2 pounds per week. To help them reach these goals, participants were taught strategies for self-monitoring of fat and calorie intake, healthier food selection and preparation, and restaurant choice. These dietary modifications coincide with the National Institutes of Health clinical guidelines for weight loss and the reduction of cardiovascular disease risk in overweight and obese adults (Klein et al., 2004; Pi-Sunyer et al., 1998).

The other primary goal of the DPP was to increase participant physical activity to at least 150 minutes of moderate intensity exercise per week. This physical activity goal was designed to incur a weekly exercise energy expenditure of at least 700 kcals (DPPRG, 2002). This physical activity goal was chosen because previous research has supported its effectiveness for the prevention of T2D and its sustainability in long-term prospective studies (DPPRG, 2002; Helmrich, Ragland, Leung, & Paffenbarger, 1991; Wing et al., 1988). Moreover, this volume of physical activity is in line with current national recommendations for the purpose of reducing risk for cardiovascular and metabolic diseases and the prevention of unhealthy weight gain (Haskell et al., 2007; Pate et al., 1995; Physical Activity Guidelines Committee, 2008).

The DPP's Steering Committee designated weight loss and increased physical activity as the primary focus of the program's lifestyle modification efforts in direct response to the outcomes of the Malmö Study (DPPRG, 2002), which reported that weight loss and improved cardiorespiratory fitness were significantly and independently correlated with improvements in insulin sensitivity. Moreover, the Malmö study found that the improvements in fitness and body weight contributed equally to the reductions in

T2D incidence with partial correlations (r^2) of 0.04 ($p < 0.03$) and 0.05 ($p < 0.011$) for weight loss and increased oxygen consumption, respectively (Eriksson & Lindgarde, 1991). In contrast, the DPP Study (Hamman et al., 2006), and the Finnish Diabetes Prevention Study (Tuomileto et al., 2001) established that weight loss per se was *the most* important factor for the prevention of T2D in individuals with impaired glucose tolerance or prediabetes. In a posthoc analysis of the DPP intensive lifestyle group, Hamman et al. (2006) determined that diabetes risk was not affected by either the average annual change in self-reported physical activity (MET hours/week) or average reduction in caloric intake (total kcal/day) when these variables were assessed independently of weight loss. However, in those individuals who did not meet the weight loss goal, successfully meeting the physical activity goal still conferred a 44% reduction in T2D incidence ($p = 0.012$). Similarly, in the Finnish Diabetes Prevention Study, Tuomileto et al. (2001) reported a 70% reduction in the incidence of T2D in those participants who did not lose more than 5% of their body weight but who did achieve the goal of getting more than 4 hours per week of moderate intensity exercise. Further analysis of the Finnish study found that obtaining at least 2.5 hours/week of walking conferred a 63-69% decrease in T2D risk, which was independent of BMI (Laaksonen et al., 2005). Furthermore, the odds ratio for developing T2D for those subjects in the intervention group who did not reach the 5% weight loss goal but did achieve the exercise goal during the first year was 0.2 (95% CI, 0.1-0.6) (Laaksonen et al., 2005). Moreover, the authors of the Malmö Study indicated that those in the intervention group who lost weight *and* improved their cardiorespiratory fitness were reported to have greater reductions in T2D risk as compared to those who achieved only weight loss or improved fitness (Eriksson &

Lindgarde, 1991). Thus, though weight loss is not essential to improve risk for diabetes, there appears to be a dose-response relationship between the magnitude of improvement in body weight and physical activity, and the diabetes-preventive effect of intensive lifestyle modification.

The mechanisms by which physical activity confers improvements in glucose metabolism underlie the independent effects of exercise on T2D incidence. At rest, insulin is required to facilitate the removal of glucose from the blood and its intake into the cells of the body for storage and use for energy (Alberti & Zimmet, 1998). Muscle tissue is the principle site of this insulin-mediated glucose "disposal," and glucose transport across the cellular membrane into the muscle has been identified as a rate-limiting step for glucose uptake in both normal and diabetic subjects (Shepherd & Kahn, 1999). As such, dysfunction of any of the processes involved in insulin-mediated glucose uptake by skeletal muscle substantially increases an individual's risk of hyperglycemia and subsequent diabetes. In fact, muscle insulin resistance, which is characterized by impaired glucose transport into the muscle tissue, is a significant predictor of subsequent T2D (Haffner, Lehto, Rönnemaa, Pyörälä, & Laakso, 1998). During contraction (i.e., physical activity and exercise), however, muscle tissue is able to take up glucose from the blood independent of insulin. Even in insulin-resistant T2D, glucose uptake by the working muscle is preserved via contraction-related glucose transport function (Goodyear & Kahn, 1998; Musi et al., 2001). Therefore, muscle action during physical activity represents a key moderator in acute glucose management and an important component in lifestyle modification for both the prevention and treatment of T2D.

Acute and chronic exercise has been shown to increase insulin sensitivity in

muscle, adipose, and liver tissue, thus improving systemic glucose metabolism even at rest (Goodyear & Kahn, 1998). Devlin et al. (1987) reported increases in insulin sensitivity following acute bouts of vigorous intensity endurance exercise, while Perseghin et al. (1996) reported improvements in glucose uptake of up to 40% in response to endurance exercise-induced glucose transport into muscle tissue. However, these benefits have been shown to diminish quickly, with insulin sensitivity decreasing 48-72 hours following the last bout of exercise (King et al., 1995).

Reductions in the highly metabolically active visceral adipose tissue depot are mechanistically linked with increases in insulin sensitivity following weight loss (Kahn, 2003). Visceral adiposity promotes increases in circulating nonesterified fatty acids, ectopic fat deposition and proinflammatory cytokines (TNF-α, IL-6), which are thought to impair insulin-receptor function and subsequent insulin-mediated glucose uptake in a variety of tissues, including adipose, muscle, pancreas, and liver (Johnson et al., 2009; Petersen & Pedersen, 2009). Fortunately, visceral fat appears to be particularly sensitive to exercise-induced sympathetic stimulation of lipolysis and is preferentially mobilized (and thus reduced) in response to exercise training even when exercise does not elicit changes in body weight (Johnson et al., 2009; Vissers et al., 2013).

In addition to its direct effects on insulin sensitivity, physical activity significantly impacts the most common comorbidities of T2D. Observational studies have shown that endurance, resistance, or a combination of endurance and resistance exercise can reduce blood pressure in those with diabetes (Cauza et al., 2005; Cohen et al., 2008). Cauza et al. (2005) demonstrated positive effects of exercise on blood pressure with as little as 90 minutes of MVPA per week, which is below the dose of exercise employed by the DPP.

Additionally, exercise has been associated with reductions in very low-density lipoprotein (VLDL) and triglyceride levels, and substantial increases circulating high-density lipoproteins (HDL) (Department of Health and Human Services [DHHS], 1996; Kraus et al., 2002). Though the biggest improvements in blood lipids have been observed following high-volume exercise, positive changes have been observed at doses similar to that of the DPP, including improvements in low-density lipoprotein (LDL) particle size and triglyceride concentrations (Kraus et al., 2002).

Current national physical activity recommendations (150 minutes per week of moderate activity or 75 minutes a week of vigorous activity), which are in line with the physical activity goals of the DPP, aim to prevent unhealthy weight gain and reduce risk for chronic diseases including cardiovascular disease and T2D (Physical Activity Advisory Committee, 2008). Without concomitant reductions in caloric intake, however, larger volumes of activity are likely needed for clinically relevant weight loss of 5% or more, and though the exact dose (or volume) of physical activity required to prevent T2D is not yet known, data from the Nurses' Health Study, the Iowa Women's Health Study, the Study of Eastern Finns, and the DPP suggest that approximately 150 minutes of moderate intensity exercise reduces the risk for T2D by 25-36% (Physical Activity Advisory Committee, 2008).

METHODS

Experimental Design

We used an experimental research design to determine the effects of the 12-month UUDPP lifestyle intervention on our dependent variables, which included changes in body weight, waist and hip circumferences, blood pressure, quality of life, physical activity, fasting blood glucose, serum HbA_{1c}, and 2-hour oral glucose tolerance test (OGTT). Each of our dependent variables was measured at baseline and at the completion of the 12-month intervention. Our main independent variable was participation in the UUDPP lifestyle intervention. In a secondary analysis, we explored changes in the association between our dependent variables according to whether participants did or did not meet the weight loss and physical activity goals of the NDDP intervention (secondary independent variables).

Participants

Members of the University of Utah faculty and staff and their immediate family who were at high risk for developing T2D were recruited to volunteer to participate in this study. Volunteers were overweight or obese (BMI $\geq$ 24 kg/m^2, or $\geq$ 22 kg/m^2 if Asian), and were given physician's clearance to participate in onsite-supervised exercise. Qualified volunteers were screened to determine their risk for T2D by completing the CDC prediabetes-screening test, which provided a risk score in response to questions

regarding risk of gestational diabetes, family history, BMI, and age. A score ≥ 9 indicated high risk for prediabetes. According to CDC NDPP administrative guidelines (CDC, 2011), at least 50% of participants had to be diagnosed as prediabetic according to one of the following methods: 2-hour OGTT (plasma glucose 140-199 mg/dl), fasting plasma glucose (100-125 mg/dl), or Hemoglobin A1c (HbA1c) (5.7-6.4). Accordingly, no more than 50% of the participants could qualify with a CDC prediabetes screening test score ≥ 9 without qualifying blood values. Volunteers previously diagnosed with gestational diabetes mellitus automatically qualified for participation even if they did not present with current indicators of prediabetes.

Exclusion criteria included diagnosis of T2DM, pregnancy, lack of medical clearance for participation, severe cardiac disease (New York Heart Association class III or greater), uncontrolled hypertension (> 165/95 mmHg), and any orthopedic problems that would preclude participation in the physical activity intervention. Participants were required to be willing to undergo screening tests, including tests of fasting blood sugar, oral glucose tolerance, blood lipids, and Hemoglobin A_{1c}.

Recruitment and Participant Identification

Recruitment was started following approval by the University of Utah Institutional Review Board. Flyers and study information were disseminated to University Hospital and campus departments/divisions through in-person discussions with faculty and staff, and via an informational video intended for use during staff/faculty meetings. Medical providers at the University of Utah also referred patents for study participation. The email address dpp@utah.edu was used on all fliers and recruitment

materials, and all prospective volunteers were directed to contact the UUDPP email.

All interested volunteers were contacted via phone by a study lifestyle coach for prescreening. The phone-based prescreening process was standardized by the NDPP (CDC, 2011), and was used to identify risk of T2D (see Appendix). Qualified volunteers were invited to attend an in-house screening at the University of Utah (at either HPER-East or the Health Professions Education Building) to further discuss the study details, provide answers to any volunteer questions, and to obtain informed consent. Paper copies of all signed informed consent documents, which included contact information for study administrators, were supplied to enrolled participants. If the volunteer did not wish to provide consent to study participation, she/he was invited to participate in the Diabetes and Senior Health (DASH) supervised exercise program as well as the nutrition and behavior modification education classes offered at the University of Utah through the PEAK Health and Fitness clinic.

Procedures

Upon receiving signed informed consent, demographic information, including contact and address information, ethnicity, race, marital status, living situation, education level, and employment status, was collected and participants were scheduled for a subsequent appointment at the University of Utah Hospital's Center for Clinical and Translational Science (CCTS), where they underwent fasting tests of blood glucose, serum HbA1c and a 2-hour OGTT, in accordance with the CDC guidelines (CDC, 2014). This appointment required participants to fast for the 12 hours preceding their appointment. Appointments were scheduled for approximately 3 hours so as to provide

adequate time for arrival and orientation, participant questions, and all necessary testing procedures. Participants were offered a meal following their OGTT. The CCTS sent all test results to the principle investigator or co-investigator via encrypted email.

Participants with prediabetes confirmed by either the CDC Prediabetes Screening Test (see Appendix) or by qualifying blood testing were contacted by a UUDPP research assistant or Lifestyle Coach to schedule an appointment for baseline testing. At this appointment, a UUDPP Lifestyle Coach collected information on the participant's medical history and biometric data, measured their cardiovascular fitness, and guided the participant on how to complete surveys of their quality of life, dietary intake, and self-report physical activity. Resting heart rate was calculated via radial pulse for 30 seconds, multiplying the counted heart rate by two. Body weight (kg) was assessed using a self-calibrating digital scale (Seca 840 Bellissima-digital, Snoqualmie, WA), and height was measured via stadiometer (Seca 216 Accuhite, Snoqualmie, WA). To determine the weight loss goal that would be incorporated in the lifestyle intervention program, 7% of baseline weight was calculated per the NDPP guidelines. Resting blood pressure was measured using a standard aneroid sphygmomanometer and stethoscope. Waist and hip circumferences were measured in accordance with WHO guidelines (World Health Organization [WHO], 2011), and a waist-to-hip ratio was calculated. To estimate cardiovascular fitness, a 6-minute walk test was administered (Enright, 2003). This test was used because it is perceived as safe, easy to measure, and applicable to an ambulatory obese population (Beriault et al., 2009). Additionally, participants were instructed on and completed three survey instruments. All surveys are included in the Appendix. The validated Rapid Assessment of Physical Activity (RAPA) assessed

participants' self-reported physical activity levels (Topolski, et al., 2006). Two assessments of quality of life, the Quality of Life Scale (QOLS) and the Single Item Quality of Life, were administered (Burckhardt & Anderson, 2003), as management and lowering of blood glucose levels has been shown to be effective in improving overall wellbeing or quality of life (Rubin & Pevrot, 1999). The quality-of-life scales were evaluated based on the sum score of all responses. The baseline appointment took approximately 1 hour. The follow-up appointment at approximately 12 months consisted of the same battery of tests as baseline, including blood testing.

UUDPP Intervention

Following baseline testing, participants were assigned to a group of no more than 15 participants. Groups were scheduled to attend 22 education classes at either the Health Professions Education Building (HPEB), the Annex building, Human Resources building, or Orson Spencer Hall at the University of Utah. The curriculum of the group education classes was developed by the CDC to target physical activity, healthy eating, and other healthy behavior modifications. The classes were led by trained and certified CDC NDPP Lifestyle Coaches. Classes were provided via weekly sessions for the first 8 weeks (classes 1-8), followed by bimonthly sessions for the following 4 months (classes 9-16). During the final 6 months, groups met only once per month (classes 17-22). At the beginning of each class, participants were asked to report total minutes of moderate intensity physical activity performed during the previous week. At study completion, an average of self-reported weekly physical activity during the last 6 months of the intervention was used to determine whether participants had reached their physical

activity goal of > 150 min of MVPA per week. Lifestyle Coaches also measured and recorded participant weight, and collected their food recall journals for subsequent review. The coaches encouraged participants to work toward the goals of 7% weight loss and to increase physical activity to at least 150 minutes of moderate intensity activity throughout the group education and discussion sessions, and through any individual contact they had with the participants during the intervention period.

Optional supervised exercise sessions were made available to participants each Tuesday and Thursday from 3:00-8:00 PM via the DASH exercise program held at the Skaggs Patient Wellness Center. Participants were encouraged to exercise on their own in this environment; however, additional instruction was available. Those who chose not to participate in the supervised physical activity were instructed to exercise on their own time. Those who did participate in the DASH supervised exercise program were instructed to acquire additional activity minutes on their own so as to meet the intervention's physical activity goal.

Sample Size Justification and Study Attrition

Using a priori estimates, a total sample size of 46 was chosen to detect significant intervention-related change in body weight (Amundson et al., 2009) with a statistical power of 80% and at an alpha level of 0.05. This variable was selected due to the relationship between weight change and improvements in glucose regulation demonstrated by the large diabetes prevention trials previously reviewed. Though we oversampled and enrolled a total of 69 participants so as to accommodate anticipated drop out, we experienced an attrition rate of 32% and were left with 47 participants at

study completion. Participant flow through the enrollment, follow-up, and analytical phases of the study is presented in detail in Figure 1. Herein, we present data analysis for the 47 participants with complete weight and body composition data. Of these, we report missing data for one participant in each, the 6-minute walk distance and HbA1c measures. Similarly, two participants did not have complete fasting blood glucose data, and three participants were missing 2-hour OGTT data.

Statistical Methods, Data Analysis, and Interpretation

Descriptive statistics were used to determine the normality of our primary dependent variables, including body weight, BMI, waist circumference, waist-to-hip ratio, blood pressure, 6-minute walk distance, QOL, and fasting tests of blood glucose, serum HbA_{1c}, and 2-hour OGTT. To determine the effect of participation in the 12-month diabetes prevention program on these variables, paired *t*-tests were used for normally distributed variables, and Wilcoxon Signed Rank tests for those variables that did not meet the assumptions of the parametric *t*-test. To summarize the responses of our dependent variables, change scores were calculated as postintervention score minus preintervention score. 12-month changes in data from the RAPA, which elicits yes or no answers to a series of 9 questions about participant physical activity habits, was assessed using the McNemar Test for differences on a dichotomous dependent variable between two related groups. To determine if achievement of the intervention's weight loss or physical activity goals resulted in group differences in changes in body composition, glucose regulation, blood pressure and quality of life, we used a repeated measures analysis of variance with the preintervention values as covariates so as to control for any

regression to the mean effects. Spearman Rho correlations were used to assess bivariate relationships between those variables that were not normally distributed; Pearson Product Moment correlations were used for all other variables. A p-value < 0.05 was used to designate statistical significance. Posthoc calculations of effect-size and statistical power were performed to determine practical significance and the likelihood of Type-II error, respectively.

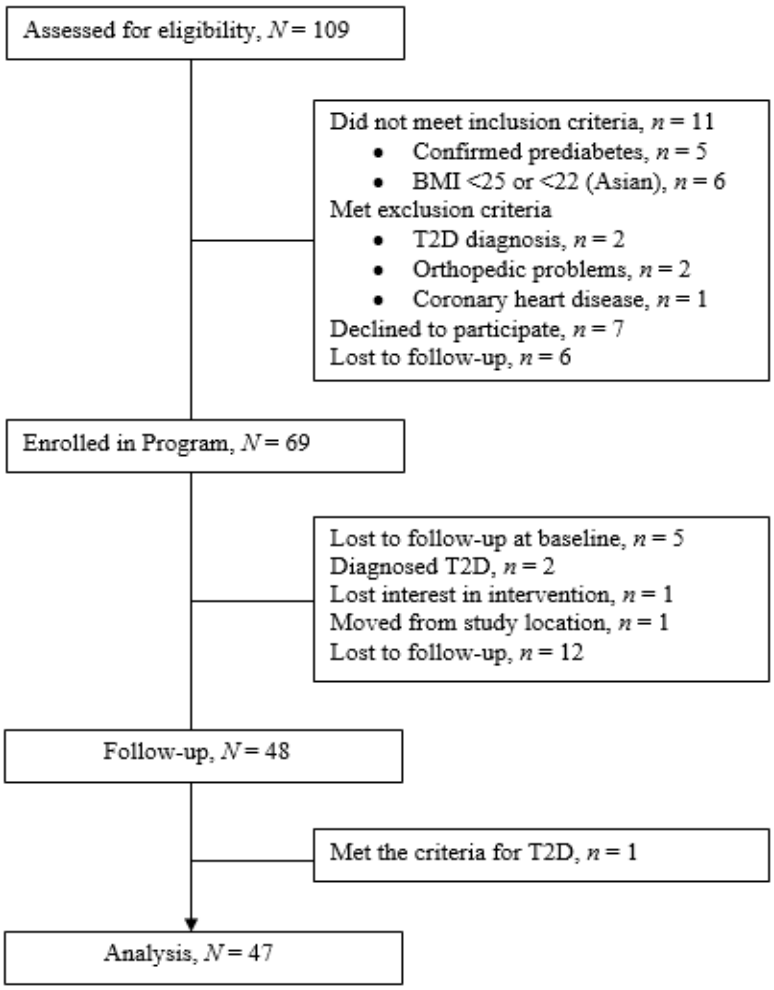

Figure 1. Participant flow diagram

RESULTS

Participant demographics are presented in Table 1. Of the 47 total participants, the majority were female (78.7%), non-Hispanic/Latino (91.5%), and White (97.9%). The mean age of participants was 47.71 ± 11.15, and nearly half (42.6%) were educated at the bachelor's degree level.

In response to the 12-month long NDPP lifestyle intervention, there were significant improvements in body weight (-4.82%, $p < 0.001$), BMI (-5.20%, $p < 0.001$), waist circumference (-4.56%, $p < 0.001$), hip circumference (-4.50%, $p < 0.001$), systolic blood pressure (-5.94%, $p < 0.001$), 6-minute walk distance (7.15%, $p = 0.001$), and OGTT (-8.41%, $p < 0.028$; Table 2). By contrast, there were no significant changes in waist-to-hip ratio, diastolic blood pressure, and fasting blood glucose (Table 2). Additionally, there was a significant *increase* in serum HbA_{1c} (1.45%, $p = 0.035$; Table 2). Over the course of the 12-month intervention, the proportion of participants who met national physical activity recommendations by engaging in at least 30 minutes per day of moderate intensity physical activity on at least 5 days each week increased from 15% at baseline to 52% at study completion ($p = 0.001$; Figure 2). Similarly, the proportion of participants who engaged in strength training at least 1 day per week increased from 34% to 60% ($p = 0.002$), and the proportion of participants who performed activities to improve flexibility also increased from 43% to 67% ($p = 0.001$; Figure 2). Pairwise analysis of the QOLS revealed a significant increase in quality of life ($p < 0.001$), while

no change was observed in the single-item QOL ($p = 0.47$; Table 2).

In evaluating the degree to which participants were successful during the UDPP, we assessed whether or not participants met the study's goals for weight loss (lose 7% of baseline body weight) and/or physical activity (achieve and maintain 150 minutes of MVPA each week). We determined that 10 participants successfully achieved both goals, 3 participants achieved the weight loss but not the physical activity goal, 29 participants achieved the physical activity but not the weight loss goal, and 5 participants were not able to achieve either goal. As a result, we had significant group size differences and small sample sizes that precluded statistical group comparisons. As an alternative, we used the Spearman Rho correlation coefficient to assess the bivariate association between the number of goals met given as a continuous variable and the change in all biometric and glucose variables. In this analysis, we found a significant positive correlation between the number of goals met and improvements in body weight ($r_S = 0.61$, $p < 0.001$), BMI ($r_S = 0.56$, $p < 0.001$), waist circumference ($r_S = 0.39$, $p = 0.007$), and hip circumference ($r_S = 0.33$, $p = 0.024$). However, we found no statistically significant relationships between the number of goals met and any of the markers of glucose metabolism ($p > 0.05$).

Table 1. Baseline characteristics of participants completing lifestyle intervention

Characteristics	*N* = 47
Sex	
Male, *n* (%)	10 (21.3)
Female, *n* (%)	37 (78.7)
Age, mean ± SD	47.71 ± 11.15
Ethnicity	
Hispanic/Latino, *n (%)*	4 (8.5)
Not Hispanic/Latino, *n* (%)	43 (91.5)
Race	
White, *n* (%)	46 (97.9)
Asian American, *n* (%)	1 (2.1)
Marital Status	
Single, *n* (%)	9 (19.1)
Married, *n* (%)	29 (61.7)
Divorced, *n* (%)	8 (17.0)
Widowed, *n* (%)	1 (2.1)
Living Situation	
Lives alone, *n* (%)	4 (8.5)
Lives with spouse, *n* (%)	18 (38.3)
Lives with partner, *n* (%)	2 (4.3)
Lives with spouse and children, *n* (%)	11 (23.4)
Lives with children, *n* (%)	3 (6.4)
Lives with other, *n* (%)	9 (19.1)
Education Status	
High school or GED, *n* (%)	2 (4.3)
Some college or technical school, *n* (%)	8 (17.0)
Associates degree, *n* (%)	6 (12.8)
Bachelor's degree, *n* (%)	20 (42.6)
Master's degree, *n* (%)	7 (14.9)
PhD degree, *n* (%)	3 (6.4)
Other advanced degree, *n* (%)	1 (2.1)

HS-high school, GED- general education development

Table 2. Changes in weight, body composition, blood pressure, cardiorespiratory fitness, fasting blood glucose, 2-hour OGTT, HbA1c and quality of life following 12 months of UDDP intensive lifestyle intervention. (Values are means ± *SD*)

Variable	*N*	Baseline	Follow-up	*p*-value
Weight (kg)	47	99.71 ± 25.00	94.90 ± 24.05	<0.001[a]
BMI (kg/m^2)	47	35.59 ±7.48	33.74 ±7.13	<0.001[a]
Waist (cm)	47	108.78 ± 18.92	102.82 ± 17.61	0.001[a]
Hip (cm)	47	121.81 ± 17.74	116.33 ± 15.65	<0.001[a]
Waist:Hip Ratio	47	0.89 ± 0.11	0.89 ± 0.11	0.958
SBP (mmHg)	47	125.83 ± 12.21	118.36 ± 10.67	<0.001
DBP (mmHg)	47	78.74 ± 10.94	76.77 ± 7.86	0.21
6-minute walk (m)	46	512.28 ± 85.59	548.94 ± 77.22	0.001[a]
FBG (mg/dL)	45	93.65 ± 8.90	92.22 ± 7.80	0.20[a]
2-Hr OGTT (mg/dL)	44	122.41 ± 36.17	112.12 ± 25.83	0.03
HbA_{1c} (%)	46	5.53 ± 0.31	5.61 ± 0.27	0.04
QOLS (score)	47	70.11 ± 11.45	75.91 ± 10.08	<0.001
S-I QOL (score)	47	2.80 ± 0.69	2.87 ± 0.58	0.47[a]

SBP-systolic blood pressure, DBP-diastolic blood pressure, FBG- fasting blood glucose, OGTT-oral glucose tolerance test, HbA_{1c}-glycated hemoglobin A_{1c}, QOLS-Quality of life scale, S-I QOL-single-item quality of life.
[a]p-value from Wilcoxon Sign-Rank Test

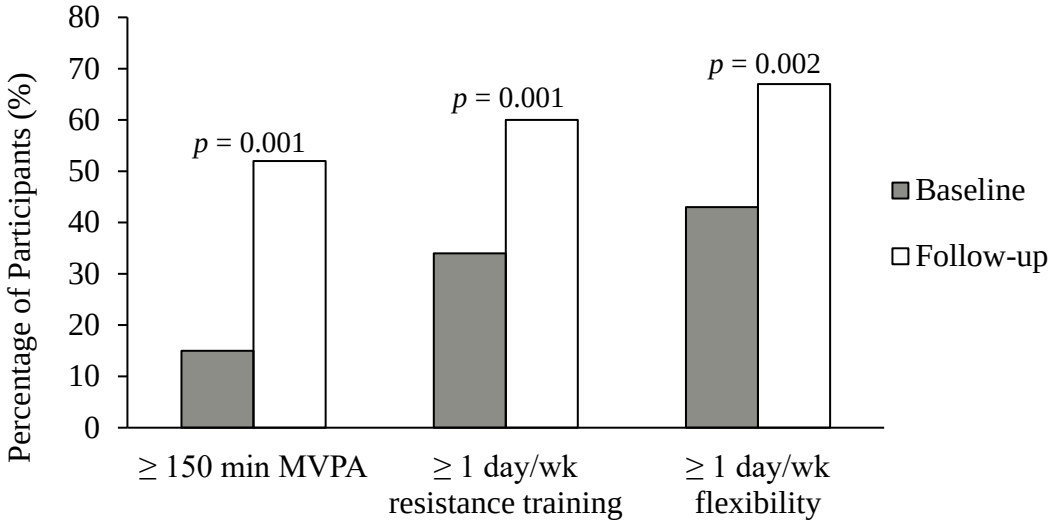

Figure 2. Effects of the 12-month NDPP intervention on select RAPA outcomes

DISCUSSION

The purpose of this study was to determine whether a year-long diabetes prevention program, based on the guidelines of the National Diabetes Prevention Program, would be effective in improving glucose regulation, body composition, body weight, blood pressure, physical activity, and quality of life in those at high risk for developing T2D at the University of Utah. To our knowledge, this study is only the second diabetes prevention program translation study in the state of Utah, and the first to be conducted for higher education staff and faculty.

The primary finding from this study was that, following the lifestyle intervention, participants experienced improvements in measures of body weight and body composition, blood pressure, physical activity status, and quality of life. Our second aim was to determine whether those who achieved one or more of the study goals (weight loss and increased physical activity) would achieve greater improvements in these dependent variables as compared with those who did not achieve the study goals. Though we were unable to detect group differences, we identified a direct relationship between the number of study goals achieved and the degree of improvement in body weight, BMI, and waist and hip circumferences.

The average weight loss of the participants in the current study was 4.8%, which was lower than that observed in the lifestyle intervention groups of the DPP (6.9%) and Finnish Diabetes Prevention Study (7.2%), respectively (Knowler et al., 2002; Tuomileto

et al., 2001; Figure 3). However, our findings align well with those from other DPP translational studies, which reported weight losses of 1.5% to 6.7% (Aldana et al., 2005; Amundson et al., 2009; Kramer et al., 2009; Whittemore et al., 2009; Figure 4). Though each of these studies was based on the original DPP, only the studies by Aldana et al. (2006) and Kramer et al. (2009) conducted follow-up testing at 1 year, while the others reported outcomes measured at 6 months of follow-up (Amundson et al., 2009; Whittemore et al., 2009). Though our reported average weight loss was small, the DPP established that even a small amount of weight loss strongly predicts improvements in T2D risk, with a 16% reduction in risk for every kg of lost weight (Hamman et al., 2006).

In comparison to other translational studies, Mensink, Feskens, Saris, De Bruin, and Blaak (2003) and Aldana et al. (2005) saw significant reductions in glucose tolerance following a lifestyle intervention program. Significant improvement in glucose tolerance was also observed in the current study, though no significant changes were observed in fasting glucose values, and a significant increase in HbA_{1c} was detected.

The CDC's criteria for enrollment in translational programs employing the NDPP are quite broad, presumably for the purpose of improving public health. By making inclusion in these community-based programs fairly lenient, a greater number of individuals may benefit from the program's healthy lifestyle modifications. Unfortunately, though, these criteria have the potential to limit the ability to research the efficacy of these programs without an epidemiological scale sample size. In posthoc analyses looking at potential differences based on how participants were screened for prediabetes, we grouped subjects on the basis of whether or not they met the clinical diagnostic criteria for prediabetes (2-hr OGTT = 140-199 mg/dl, fasting plasma glucose =

100-125 mg/dl, or HbA1c = 5.7-6.4). We found that 52% of our participants met at least one of these clinical criteria. The remaining participants (n = 21) were designated as prediabetic, and thus eligible for study participation, according to the CDC's screening instrument, which includes current weight, age, and family history of T2D. In comparing these groups, we found that those with clinically diagnosed prediabetes were older (p = 0.003) and had higher baseline values for fasting glucose (p = 0.005), 2-hr OGTT (p = 0.007), and HbA1c ($p < 0.001$). Despite covarying for these baseline group differences, there were no differences between groups for change in weight, BMI, waist or hip circumferences, blood pressure, 6-minute walk distance, fasting glucose, or 2-hr OGTT following the 12-month lifestyle intervention ($p > 0.05$). However, we did detect significant group differences for change in HbA1c ($p < 0.002$). Specifically, we found that those with clinically confirmed prediabetes experienced no significant changes in their HbA1c levels following the intensive lifestyle intervention. In contrast, those diagnosed as prediabetic using the CDC screening instrument experienced a significant increase in HbA1c following the intervention (p = 0.003). Though this represents only a 2.6% increase (0.1359 points) in HbA1c levels, it is interesting to note these group differences. It is possible that, when compared with those who may not be clinically prediabetic, individuals with clinically confirmed prediabetes may be more sensitive to the metabolic improvements that can occur as a result of participation in the lifestyle intervention. As such, it may be inappropriate to utilize clinical measures of glucose management to evaluate the efficacy of the NDPP in participants without clinically confirmed prediabetes. Why those individuals who qualified for study participation via the CDC's screening instrument alone experienced deterioration of their glucose

management as measured by the increase in HbA1c levels remains unclear and further investigation is warranted.

The effect of achieving the NDPP's study goals on participant health outcomes was investigated by Hamman et al. (2006). In their posthoc analysis of the DPP, the authors determined that achieving all of the goals of the DPP proved most effective at reducing risk of T2D. Specifically, Hamman et al. (2006) found that there was a 46% reduction in T2D risk for participants who met the physical activity goal only, nearly an 80% reduction for those who achieved the weight loss goal only, and an 89% reduction in risk for those who achieved all goals of the DPP (Hamman et al., 2006). It is important to note that even though only 27.7% of the participants in the current study achieved the weight loss goal, the majority (83.0%) of participants achieved the physical activity goal. There are many known and independent benefits of physical activity improving the complications related to prediabetes and diabetes. Independent of weight change, physical activity can improve insulin sensitivity and glucose metabolism; and reduce visceral adipose tissue concentrations, blood pressure, and cholesterol, to name a few (Cauza et al., 2005; Goodyear & Kahn, 1998; Kahn, 2003; Kraus et al., 2002).

One of the primary strengths of this study was the inclusion of physical activity measures. A significant increase in physical functioning was determined using the 6-minute walk test. Mau et al. (2010) also found a significant increase in 6-minute walk distance in a DPP translation study for a Polynesian population. Additionally, we found significant improvements in self-reported measures using the RAPA. Though self-report data are known to be subject to participant bias, the improvements in the RAPA were supported by improvements in the 6-minute walk distance following the intervention

period. Furthermore, improvements in cardiovascular fitness are associated with reductions in the risk for T2D, cardiovascular disease, and all-cause mortality independent of weight loss (Eriksson & Lindgärde, 1991; Helmrich, Ragland, Leung, & Paffenbarger, 1991).

Another strength of the current study was the inclusion of an assessment of participant quality of life. It has been thought that those at risk for T2D may experience decreases in quality of life (Florez et al., 2012). This study found significant improvements in the total score related to quality of life in the QOLS following the lifestyle intervention, which is in line with improvements observed in the original DPP (Florez et al., 2012).

There were several limitations in this study. This sample of participants had low diversity, and was primarily female, which does not represent the broader population of individuals at risk for developing T2D. In fact, 15.5 million (13.6%) of those with T2D are male, while 13.4 million (11.2%) are female (CDC, 2015). Additionally, group meeting attrition over the course of the study and loss of participants to follow-up may have contributed to our difficulty in conducting group data analyses. Also, we did not assess any form of motivation in this study, and so we could not control for any self-selection bias.

Future research should include measures of motivation, and whether it may be cost effective to provide one-on-one counseling with a wellness coach. Finally, future research in Utah should include greater diversity and additional male representation. Utah has the fifth highest population of Polynesians in the U.S. (Hixon, Hepler, & Kim, 2012), and when compared to the general population, Pacific Islanders have an 11% greater

prevalence of diabetes (Schiller, Lucas, Ward, & Peregoy, 2012). Thus, there is a need for targeted diabetes prevention research with the Polynesian population in Utah.

In conclusion, this pilot study demonstrated that the NDPP was effective at improving risk factors associated with prediabetes, in particular with reducing body weight and increasing physical activity in a sample of individuals from the University of Utah community. It is therefore suggested that the program be continued and that it be expand to the greater Salt Lake City region.

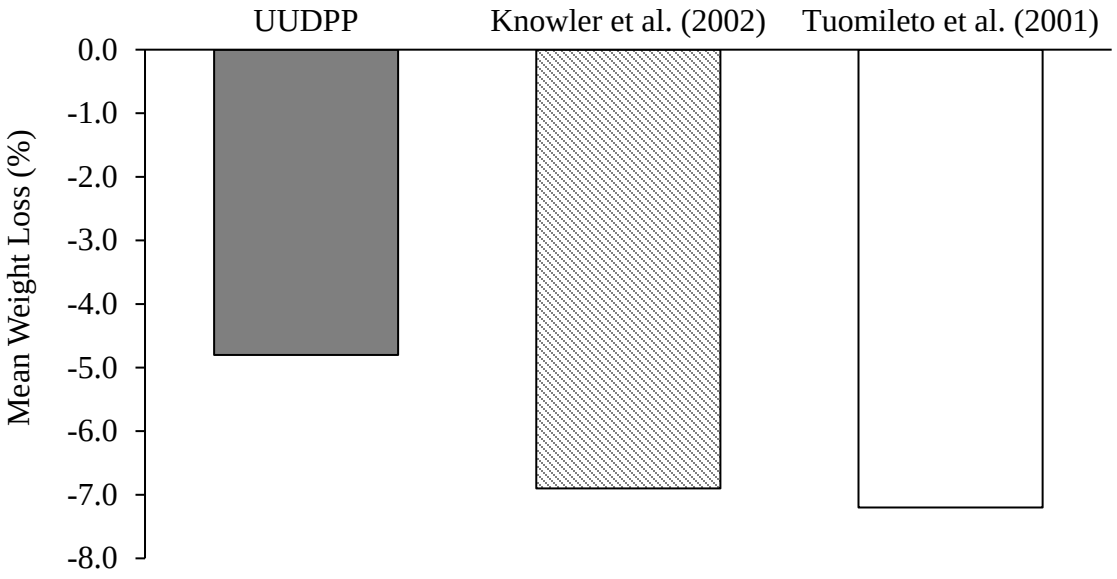

Figure 3. Mean weight loss of the UUDPP participants compared to large, national prevention studies.

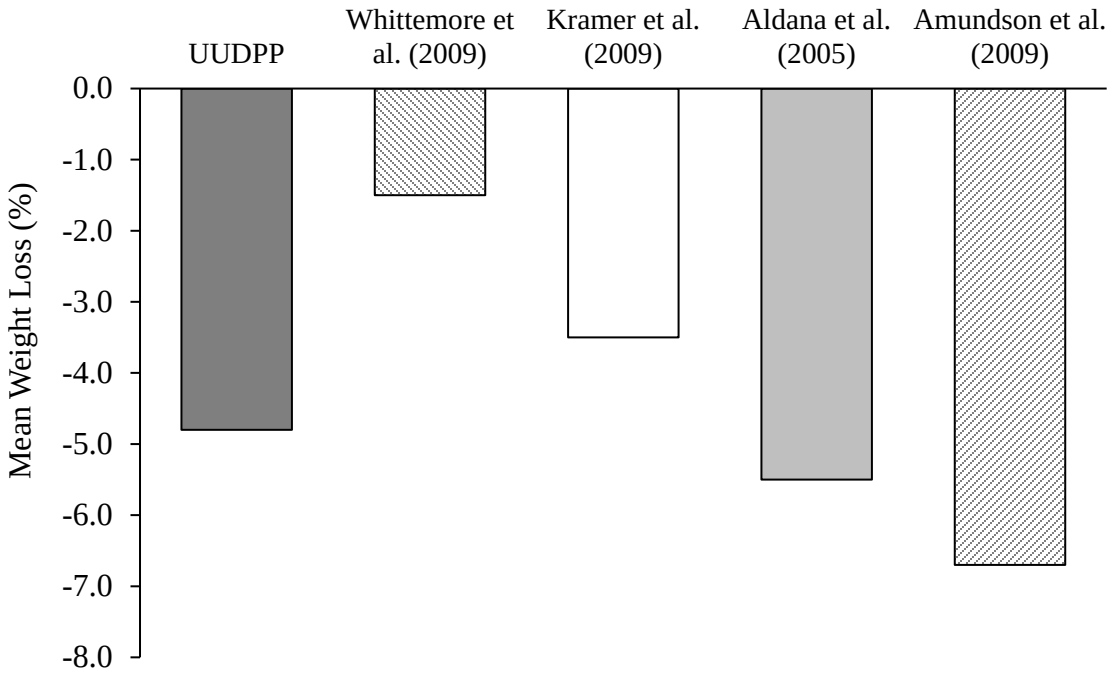

Figure 4. Mean weight loss of UUDPP participants compared to other DPP translation studies.

APPENDIX

QUESTIONNAIRES

University of Utah Diabetes Prevention Program Phone Screening Questionnaire

Name _____ **Gender** _____ **Date** _____

Phone number _____ **DOB** _____ **Age** _____

1) Do you work at the University?	YES	NO[x]
2) Where do you work at the University? _____		
3) Do you have Type 2 diabetes?	YES[x]	NO
4) Females: Are you pregnant?	YES[x]	NO
5) Are you overweight?	YES*	NO ___
a. What is your height/weight (no shoes or clothes) _____		
b. BMI ≤24 (≤ 22 if Asian)	YES[x]	NO
6) Are you being treated for high blood pressure?	YES	NO
a. Is your blood pressure > 165/95 mmHg?	YES[x]	NO
7) Do you have heart disease?	YES[x]	NO
8) Do you have any significant orthopedic problems that limit activity?	YES[x]	NO
9) Do you have any trouble concentrating or following directions?	YES[x]	NO
10) If you exercise with us, are you willing to have an ETT if required by your MD?	YES	NO[x]
11) Are you willing to commit to a 12 month intensive program?	YES	NO[x]
12) Are you 65 years of age or older?	YES*	NO ___
13) Are you younger than 65 and get little or no exercise daily?	YES*	NO ___
14) Are you between 45 and 64 years of age?	YES*	NO ___
15) Do you have a parent with T2DM?	YES*	NO ___
16) Do you have a brother or sister with T2DM?	YES*	NO ___
17) Females: Have you ever had a baby weighing more than 9 lbs?	YES*	NO ___
18) Females: Have you ever had gestational diabetes?	YES	NO
19) Have you ever been told you have pre-diabetes (IFG or IGT)	YES	NO
20) Do you have a documented high 2 hr OGTT or FBS or HbA1c?	YES	NO
21) If you do not have documented pre-diabetes, are you willing to undergo an 8 hour fast followed by a 2 hour OGTT?	YES	NO[x]
22) Are you being treated for high cholesterol?	YES	NO
a. Have you ever had your Triglyceride level measure 250 mg/dl or greater?	YES	NO
b. Have you ever had your HDL measure 35 mg/dl or lower?	YES	NO
23) Are you physically active less than 3 days/week?	YES	NO
24) Are you a member of any of the following ethnic groups?		
a. Asian American	YES	NO
b. African American	YES	NO
c. Hispanic/Latino American	YES	NO

d. Native American YES NO
e. Pacific Islander YES NO

Anyone aged 45 years or older should consider getting tested for diabetes, especially if they are overweight. If they are younger than 45, but are overweight and have one or more additional risk factors (see above), they should consider getting tested.

*Components of the CDC Prediabetes Screening Test. A score of 9 or higher indicates a high risk for Prediabetes.
[x] Indicates exclusion criteria

In order to be eligible to consent, subjects must score a 9 or higher on the starred questions and have no exclusionary criteria.

ELLIGIBLE? **YES** **NO**

IF NOT, WHY NOT? _____

RISK SCORE _____ **AT RISK?** **YES** **NO**

INTERESTED? **YES** **NO**

IF NOT, WHY NOT? _____

IN-HOUSE SCREEN DATE _____

NAME OF PHONE SCREENER _____

Rapid Assessment of Physical Activity

Physical Activities are activities where you move and increase your heart rate above its resting rate, whether you do them for pleasure, work, or transportation.

The following questions ask about the amount and intensity of physical activity you usually do. The intensity of the activity is related to the amount of energy you use to do these activities.

Examples of physical activity intensity levels:

Light activities • your heart beats slightly faster than normal • you can talk and sing	 Walking Leisurely  Stretching  Vacuuming or Light Yard Work
Moderate activities • your heart beats faster than normal • you can talk but not sing	 Fast Walking  Aerobics Class  Strength Training  Swimming Gently
Vigorous activities • your heart rate increases a lot • you can't talk or your talking is broken up by large breaths	 Stair Machine  Jogging or Running  Tennis, Racquetball, Pickleball or Badminton

How physically active are you? *(Check one answer on each line)*

		Does this accurately describe you?	
RAPA 1			
1	I rarely or never do any physical activities.	Yes ☐	No ☐
2	I do some **light** or **moderate** physical activities, but not every week.	Yes ☐	No ☐
3	I do some **light** physical activity every week.	Yes ☐	No ☐
4	I do **moderate** physical activities every week, but less than 30 minutes a day or 5 days a week.	Yes ☐	No ☐
5	I do **vigorous** physical activities every week, but less than 20 minutes a day or 3 days a week.	Yes ☐	No ☐
6	I do 30 minutes or more a day of **moderate** physical activities, 5 or more days a week.	Yes ☐	No ☐
7	I do 20 minutes or more a day of **vigorous** physical activities, 3 or more days a week.	Yes ☐	No ☐
RAPA 2 3 = Both 1 & 2			
1	I do activities to increase muscle **strength**, such as lifting weights or calisthenics, once a week or more.	Yes ☐	No ☐
2	I do activities to improve **flexibility**, such as stretching or yoga, once a week or more.	Yes ☐	No ☐

ID # _____

Today's Date _____

Quality of Life Scale

Please read each item and circle the number that best describes how satisfied you are at this time. Please answer each item even if you do not currently participate in an activity or have a relationship. You can be satisfied or dissatisfied with not doing the activity or having the relationship.

	Delighted	Pleased	Mostly Satisfied	Mixed	Mostly Dissatisfied	Unhappy	Terrible
1. Material comforts home, food, conveniences, financial security	7	6	5	4	3	2	1
2. Health - being physically fit and vigorous	7	6	5	4	3	2	1
3. Relationships with parents, siblings & other relatives- communicating, visiting, helping	7	6	5	4	3	2	1
4. Having and rearing children	7	6	5	4	3	2	1
5. Close relationships with spouse or significant other	7	6	5	4	3	2	1
6. Close friends	7	6	5	4	3	2	1
7. Helping and encouraging others, volunteering, giving advice	7	6	5	4	3	2	1
8. Participating in organizations and public affairs	7	6	5	4	3	2	1
9. Learning- attending school, improving understanding, getting additional knowledge	7	6	5	4	3	2	1
10. Understanding yourself - knowing your assets and limitations - knowing what life is about	7	6	5	4	3	2	1
11. Work - job or in home	7	6	5	4	3	2	1
12. Expressing yourself creatively	7	6	5	4	3	2	1
13. Socializing - meeting other people, doing things, parties, etc	7	6	5	4	3	2	1
14. Reading, listening to music, or observing entertainment	7	6	5	4	3	2	1
15. Participating in active recreation	7	6	5	4	3	2	1
16. Independence, doing for yourself	7	6	5	4	3	2	1

Single-Item Quality of Life Questionnaire

Single Item Quality of Life Measure Visit# _____ ID# _____

Please think about your life as a whole. How satisfied are you with it?

Are you:

completely satisfied

very satisfied

somewhat satisfied

not very satisfied

not at all satisfied

Please circle one

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