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Mary Beth Weber Date

Translating Lifestyle Programs for Diabetes Prevention in South Asian Communities

By

Mary Beth Weber

Doctor of Philosophy

Graduate Division of Biological and Biomedical Sciences

Nutrition and Health Sciences

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B.S., University of Georgia, 1999

M.P.H., Emory University, 2002

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A dissertation submitted to the Faculty of the

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Abstract

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South Asians, people from the Indian subcontinent, are at increased risk for developing diabetes. Translating successful diabetes prevention programs to create culturally appropriate lifestyle interventions for South Asian populations worldwide is a prudent method for preventing diabetes in this population. The aims of this dissertation are to understand the determinants of lifestyle behaviors and excess weight and evaluate the ability of a culturally tailored lifestyle intervention to improve anthropometric measures related to diabetes risk in the South Asian population. This dissertation describes research using data from two different studies which seek to plan, implement, and evaluate lifestyle programs for diabetes prevention in South Asian populations: the formative research phase of the US-based South Asian Health and Prevention Education (SHAPE) study and cross-sectional and longitudinal data from the Diabetes Community Lifestyle Improvement Program (D-CLIP) in Chennai, India. A thematic analysis of verbatim transcripts from seventeen focus group discussions conducted with US South Asians showed that immigration to the US and gender expectations, particularly the desire to ensure the comfort and happiness of family members, were barriers to healthy lifestyle behaviors. Conversely, family can also be a motivator and a source of social support for healthy lifestyles. A cross-sectional analysis of D-CLIP screening data (N=1,281) assessed the relationship between factors associated with healthy weight maintenance (fruit and vegetable intake, weekly exercise, weight loss history, and weight loss and exercise self-efficacy) and body mass index (BMI) and waist circumference. Weekly fruit consumption, past weight loss experience, and weight loss self-efficacy, along with gender, age, and marital status, explained 13.7% and 25.8% of the variation in BMI and waist circumference, respectively, in this population. Finally, changes in BMI, weight, and waist circumference during the first six months of the D-CLIP randomized controlled intervention trial were compared in intervention (n=294) and control (n=304) participants. Intervention participants showed significantly greater reductions ($p<0.0001$ for all) in weight, BMI, and waist circumference (2.86 kg, 1.05 kg/m^2, and 3.72 cm) compared to controls (0.73 kg, 0.31 kg/m^2, and 1.58 cm). Based on the results of this research, recommendations for diabetes prevention in South Asian populations are proposed.

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Table of Contents

List of Tables

List of Figures

Chapter 1: Introduction

Diabetes has reached epidemic proportions globally. According to the 2011 Diabetes Atlas published by the International Diabetes Federation, 366 million people worldwide have diabetes, approximately 80% of whom live in low- and middle-income countries.[1] The majority of diabetes cases, approximately 95%, are type 2 diabetes mellitus (hereafter referred to as diabetes). India has the second highest number of people with diabetes in the world,[1] and South Asians, individuals from the Indian subcontinent, which includes India, Pakistan, Nepal, Bangladesh, Sri Lanka, Bhutan, and the Maldives, are at an acutely high risk of developing diabetes and developing diabetes at younger ages and lower body mass indices than other populations.[2-9]

Preventing diabetes in this population, therefore, is of paramount public health importance. There is strong evidence, in the form of controlled randomized trials, that diabetes can be prevented or delayed through lifestyle changes, specifically improvements in diet, increased physical activity, and weight loss. A meta-analysis of randomized, controlled, lifestyle intervention trials for diabetes prevention found that lifestyle intervention participants had a 50% decrease in 1-year diabetes incidence (relative risk = 0.55, 95% confidence interval: 0.44-0.69) compared to participants in the control or placebo study arms.[10] Translational research seeks to bridge the gap between research studies and implementation by identifying ways to deliver proven public health programs at the clinic, community, or population level.[11] Translating the US Diabetes Prevention Program (DPP) curriculum, a program that was shown to prevent or delay diabetes in a study population that included a broad range of people (both genders, a wide age range, and many different race/ethnic groups), would be a prudent method for developing diabetes prevention programs and policy for South Asians living in Asia and globally.

Before translating the DPP for a specific population, it is important to understand the unique determinants of diabetes in that community. Diet, physical activity, and weight are complicated issues. They are affected not only by available resources, but also by culture, society, genetics, and choice. A culturally appropriate intervention, incorporating the lifestyle components of a successful diabetes prevention program (e.g., the DPP), should be implemented with sensitivity to socio-cultural norms in the South Asian community. Within this intervention, messages need to be tailored to the dietary patterns, physical activity preferences, barriers, and motivators that are unique to the South Asian population, so that the intervention is both acceptable to the community and effective at reducing disease risk.

There is a paucity of data describing the decision processes around, barriers to, and motivators for lifestyle behaviors for diabetes prevention in the South Asian community. Furthermore, there has only been one major trial of a lifestyle intervention for diabetes prevention specifically for this high-risk group.[12] Additional research, especially studies testing low-cost, community-based, sustainable, diabetes prevention programs, is needed. The research described in this dissertation addresses these gaps in the literature.

The following chapters describe research that seeks to (A) understand the determinants of lifestyle behaviors and excess weight among the South Asian community; and (B) evaluate the ability of a culturally tailored, DPP-like lifestyle intervention to improve anthropometric measures in the South Asian population. The aims of the research presented here are:

Research Aim 1:

To investigate the determinants of diet and physical activity behaviors specific to the South Asian community using data from focus group discussions conducted with South Asian adults living in the metropolitan Atlanta area.

Seeking the views of potential users of a lifestyle intervention is critical in the development phase of the program to ensure that the activities and advice that comprise the intervention are culturally, socially, and practically appealing to the target community of South Asians. Focus group discussions are ideal for the in-depth exploration of community level views. The methodology and results of this analysis are presented in Chapter 4.

Research Aim 2:

To assess the correlation between select behavioral and psychosocial measurements and overweight/obesity in the South Asian population using cross-sectional data from a large diabetes prevention study in Chennai, India.

Weight reduction, through diet change and increased physical activity, is the central focus of the DPP program. Understanding the factors related to excess weight in this population is important towards planning intervention programs that address the unique risk profile for weight gain in the South Asian community. Fruit and vegetable intake, weight loss history, time spent exercising, and weight loss and exercise self-efficacy have been correlated with overweight or weight loss in other populations. Chapter 5 describes a cross-sectional analysis of data from the Diabetes Community Lifestyle Improvement Program (D-CLIP), a translational research project in Chennai, India, assessing the relationship between these factors and anthropometric markers in this study population.

Research Aim 3:

To compare changes in anthropometric markers between standard of care control subjects and intervention arm participants in the first six months of a trial of a culturally tailored, step-up, lifestyle intervention program for diabetes prevention being conducted in Chennai, India.

In the DPP trial, weight loss was shown to be the most influential determinant of diabetes risk reduction.[13] Chapter 6 describes a longitudinal analysis of the D-CLIP study, assessing the changes in anthropometric measurements (weight, BMI, and waist circumference) during the first six months of the program. Early successes or failures in terms of weight loss will help determine the efficacy of a DPP-like program in the South Asian population.

A summary of the research findings, as well as a reflection on the public health implications of this research, is located in Chapter 7. The goal of translational research is to identify programs that are sustainable and can be disseminated beyond the initial research subjects to create long-term disease prevention. The research presented in this document can be used to plan and implement diabetes prevention and weight management programs for South Asian populations.

Chapter 2: Background

Diabetes: The Scope of the Epidemic

In individuals with normal glucose tolerance (NGT), healthy pancreatic β-cells are able to maintain glucose homeostasis by increasing or decreasing insulin secretion,[14] even when there is a change in insulin action (e.g., due to weight gain); however, when the β-cells are impaired because of genetic predisposition or overuse (e.g., from continued need to produce excess insulin in response to peripheral insulin resistance[15, 16]), β-cells can become insulin resistant, leading to hyperglycemia then to prediabetes (a precursor to and risk factor for diabetes), and, ultimately, to frank diabetes. The American Diabetes Association's diagnostic criteria for prediabetes and diabetes[17] are shown in Table 1. Uncontrolled, diabetes can lead to serious secondary complications including loss of vision, peripheral and autonomic neuropathy, renal dysfunction, and cardiovascular disease.[18] Diabetes is a major public health problem, contributing significantly to morbidity and mortality, and diabetes is economically costly,[19] burdening health care systems and individuals.

Table 1: Diagnostic criteria for diabetes and prediabetes

	Fasting Plasma Glucose		2-hour Post-load Glucose*
Prediabetes	100-125 mg/dl Impaired Fasting Glucose (IFG)	Or	140-199 mg/dl Impaired Glucose Tolerance (IGT)
Type 2 Diabetes Mellitus	>125 mg/dl	Or	>199 mg/dl

*Measured during an oral glucose tolerance test (OGTT)

Worldwide the number of people affected by diabetes is staggering. The International Diabetes Federation estimates that in 2011, 366 million people worldwide had diabetes (prevalence = 8.3%), and this number is expected to rise to 552 million (prevalence = 9.9%) by 2030.[1] Because diabetes is often asymptomatic, presenting only when secondary complications arise, a large proportion of people with diabetes are unaware of their condition. The prevalence of undiagnosed diabetes is high, with the proportion of cases undiagnosed at 50% or greater, depending on the setting, gender, and age of the population. [20-24]

Diabetes in South Asians

Traditionally, diabetes was considered a disease of affluence, disproportionately affecting wealthy and urban populations; however, this is no longer the case. Approximately 80% of the number of people with diabetes live in low-to-middle income countries (LMICs),[1] and, although diabetes prevalence is still lower in rural areas compared to urban regions, this gap is shrinking.[25, 26] This shift in diabetes prevalence is attributed to the changing economic and lifestyle factors (nutrition, types of employment, decreased daily physical activity) that result from development;[27] however, in some LMIC populations, particularly South Asians, there seems to be a high baseline risk of diabetes that is aggravated by these changes in lifestyle.

Studies in the Indian subcontinent have shown increasing trends in diabetes prevalence, [28-34] and India currently has the second highest number of cases of diabetes worldwide (approximately 61.3 million people in 2011),[1] with prevalence estimates for urban populations as high as 15%.[29] South Asians, both in Asia and in the US, have higher rates of diabetes than Caucasians[2-7] and other Asian-American populations[5, 7] and are more likely to develop diabetes at younger ages[8, 9] and at lower body mass indices.[9, 35] Two studies conducted in Atlanta, Georgia, both reported an 18% prevalence of diabetes in the Asian Indian population,[36, 37] nearly two-fold higher than the national adult diabetes prevalence of 9.3%.[38] South Asians with diabetes have worse glycemic control,[9, 39] a higher prevalence of microalbuminuria,[40] hypertension, retinopathy, and cardiovascular disease,[39] and a higher incidence and faster progression of renal disease than most other populations with diabetes.[41]

Key Risk Factors For Diabetes

Diabetes, like many chronic diseases, is caused by a confluence of factors, both environmental and genetic. Lifestyle behaviors, namely excessive caloric intake and physical inactivity, lead to overweight/obesity and increased insulin resistance, which elevates the risk of developing diabetes.[42, 43] Age also is associated with increased insulin resistance, although this is mainly due to age-related obesity and inactivity; older individuals who are non-obese and physically fit are not insulin resistant compared to non-obese, fit, younger individuals.[16] Inheritance of diabetes is polygenic, and the associated gene variants act together to confer risk;[44] however, the risk conferred by most known gene variants associated with diabetes is small[45] (the exception to this is the transcription factor 7-like 2 gene [TCF7L2], a transcription factor involved in the Wnt signaling pathway[46, 47]).

It is likely that genes alone will not lead to diabetes in most people, although underlying genetic risk may explain why many at-risk (e.g., overweight) people never develop diabetes.[48] This is well illustrated by comparing Pima Indian populations living on a reservation in Arizona with those living in Mexico.[49] Both populations share the same genetic background but have very different lifestyles; adult Pima Indians living in Arizona are largely sedentary and have a high prevalence of obesity (69%), while Pima Indians living in Mexico are more physically active and less obese. The prevalence of diabetes among Mexican Pima Indians is 8.0%, which is 3-fold higher than non-Pima Mexicans (2.5%), but far lower than the 37.5% diabetes prevalence found in Arizona Pima Indians (the highest prevalence of any race/ethnic group in the US). In this population, lifestyle compounds baseline genetic risk, resulting in a 5-fold increase in diabetes prevalence. A similar pattern can be seen in populations with low genetic diabetes risk. Japanese Americans tend to weigh more than their Japanese counterparts and consume a significantly greater percentage of daily calories from animal protein,[50] and the prevalence of diabetes is approximately 4-fold higher among second-generation Japanese-Americans than among native Japanese.[51]

Reducing body weight and increasing exercise are key lifestyle factors to counter the effects of obesity on hyperglycemia. Obesity is strongly related to risk for type II diabetes;[52-54] diabetes risk increases by 12% for each unit BMI increase.[55] Overweight and obesity increase liver and skeletal muscle insulin resistance, thereby increasing diabetes risk.[42, 43, 56-59] How body fat is distributed, particularly abdominal adiposity, contributes to diabetes risk, independent of

BMI.[56, 60-62] Visceral fat, as an active endocrine organ, can lead to the development of insulin resistance and increased glucose intolerance,[63-66] and the accumulation of free fatty acids and inflammatory mediators released by visceral fat can damage tissues and possibly pancreatic beta cells.[67, 68]

A review of the data on obesity interventions concluded that low-fat diets with exercise or behavioral therapy resulted in prevention of diabetes and improved glycemic control.[52] An increase in moderate to vigorous physical activity is associated with a reduction in diabetes risk of 63-65%,[69] and even short-term interventions that increase moderate intensity exercise have reduced diabetes risk factors.[70, 71] Exercise acts directly on glucose intolerance by enhancing insulin sensitivity[72] and improving glucose uptake,[73, 74] and indirectly by decreasing concentrations of fatty acid metabolites, thereby improving insulin resistance.[57, 75] Exercise also helps to prevent diabetes by acting to promote healthy body weight.

Along with increased exercise, following a healthy diet improves insulin action and reduces hepatic glucose production, thereby countering the effects of obesity on hyperglycemia.[58] Conversely, excessive caloric intake leads to weight gain and, over time, degrades hepatic glucose control and metabolic homeostasis, and poor diet quality (e.g. low intake of dietary fiber, whole grain cereals and low-glycemic carbohydrates or high intakes of saturated and trans fats) has been linked to increased risk of cardiometabolic diseases like diabetes.[42, 76-78] A study comparing cardiometabolic disease risk across several different diet patterns showed that the healthy diet reduced the 15-year risk of diabetes and death from a coronary event or nonfatal myocardial infarction compared with the unhealthy diet (full-fat dairy products, refined grains, processed meat, and fried foods) and only the healthy diet (low-fat dairy, whole grains, fruits and vegetables, and moderate alcohol) significantly reduced diabetes risk (hazards ratio = 0.71, 95% confidence interval: 0.51-0.98).[79] Likewise, the DASH diet (a low-fat, high fiber diet rich in vegetables, fruit, and low-fat dairy products)[80] and a Mediterranean-style diet (high intake of vegetables, beans, fruits, nuts, fish and olive oils with a low consumption of meat, high-fat dairy products, and processed foods) supplemented with extra virgin olive oil or mixed nuts [81] was associated with reduction in diabetes risk.

Diabetes Risk Factors in South Asians

Even among South Asians without diabetes, the prevalence of diabetes risk factors is high. Compared to Caucasians, South Asians have higher rates of insulin resistance[3, 82] and even among those with pre-diabetes, there is a marked reduction in β-cell function.[83] South Asians have higher rates of central obesity and subcutaneous adipose tissue, and a higher percent of visceral fat[3, 65, 82, 84-89] at lower BMIs than Caucasians[2] and when comparing individuals with the same waist-to-hip ratio.[3, 87] Furthermore, South Asians report lifestyle behaviors that compound their risk of developing diabetes. South Asians report low levels of physical activity.[87, 90-92] The South Asian diet, both in Asia and in migrant populations, is often high in fat and sugar and low in fiber, and South Asians consume less fresh fruits and vegetables than other populations, despite a higher proportion of vegetarianism.[36, 93-98]

Lifestyle Interventions for Diabetes Prevention

As described above, poor dietary behaviors, low levels of physical activity, and excess body weight are all major risk factors for the development of diabetes. Lifestyle intervention programs seek to address these risk factors for diabetes through behavioral education with the goals of improving diet, increasing exercise, and/or weight loss. The methodology and results of the major, randomized, diabetes prevention-focused, lifestyle intervention trials are described below.

The Da Qing IGT and Diabetes Study

The Da Qing IGT and Diabetes Study,[99] conducted in Da Qing, China, was the first, large, randomized trial testing lifestyle education as a diabetes prevention tool. Thirty-three study clinics were randomized to provide study participants with one of four education programs: (A) standard diabetes prevention advice (control); (B) dietary counseling; (C) exercise counseling; or (D) combined diet and physical activity counseling. Physicians counseled 577 adults with IGT to follow a low-fat diet rich in vegetables and low in simple sugar intake with personalized calorie and food group intake goals and/or to increase leisure-time physical activity by 1-2 units per day (units were defined as 30 minutes of mild intensity exercise, 20 minutes of moderate intensity exercise, ten minutes of strenuous exercise, or five minutes of very strenuous exercise) depending on study arm. At six years, individuals in the diet, exercise, and diet-plus-exercise groups had reductions in diabetes incidence of 31%, 46%, and 42% respectively, compared to the control arm.[99] The beneficial effects of lifestyle intervention (either diet, exercise, or both) was shown in all participants irrespective of baseline weight,[99] although the effectiveness of lifestyle education was attenuated in individuals with higher insulin resistance (diabetes incidence was reduced 50% compared to controls in those with lowest insulin resistance compared to 30% compared to controls in those with higher insulin resistance).[100] Over time, the impact of the lifestyle program were attenuated, but still provide some protection against diabetes; after 20 years of follow-up, the cumulative incidence of diabetes, after adjustment for age and clustering by clinic, was 43% lower in the intervention group (all intervention arms combined) compared to the control group, and intervention participants had 3.6 more diabetes-free years on average than control participants.[101] The attenuation in risk reduction over time may reflect changing behaviors of study participants or might indicate that lifestyle programs can only partially prevent or delay diabetes.[102] This may be due to changes in behaviors over time, an inability of lifestyle interventions to reverse damage to β-cell function,[103] or age-related increases in insulin resistance paired with underlying β-cell defects may counteract the improvements in insulin resistance provided by lifestyle change. Future research is needed to clarify this issue.

Diabetes Prevention Studies in Japan

In Japan, an intensive lifestyle intervention was compared with a standard intervention for men with IGT.[104] At a hospital visit every 3-4 months, all participants were provided with monitoring and education on weight loss, increasing physical activity, and dietary improvement; however, in the intervention arm, participants were advised to work towards a BMI of 22 kg/m^2, while the standard intervention arm told participants to maintain a BMI of 24 kg/m^2 or less. The 4-year cumulative incidence of diabetes was 3.0% in the intensive intervention group compared to 9.3% in the standard intervention group, a 67.5% relative risk reduction ($p<0.0001$).[104] These results underlie the importance of weight loss to an ethnicity-appropriate BMI for diabetes prevention.

Another trial, the Japan Diabetes Prevention Program[105] utilized existing clinic resources to deliver diabetes prevention education. Patients with IGT, aged 30-60 years, were randomized to receive either standard of care or group and individual lifestyle education (diabetes and diabetes prevention, diet change, increasing physical activity, and weight loss for overweight or obese participants). Participants in the intervention arm showed significant decreases in BMI and increases in insulin sensitivity at three years, and, compared to controls, there was a relative risk reduction of 53% in diabetes incidence in the intervention arm, although this was not significant.[105]

The Finnish Diabetes Prevention Study

The Finnish Diabetes Prevention Study (DPS)[106] was a multicenter study (number of centers = five) comparing standard care with an intensive lifestyle intervention for diabetes prevention. Intervention participants (N = 522 overweight men and women with IGT) were counseled individually at seven face-to-face sessions with between session phone calls to educate participants on how to reach the study goals to: (1) lose ≥5% of their baseline weight; (2) increase physical activity to 30 minutes or more per day of moderate physical activity; reduce dietary fat so that (3) total fat constituted less than 30% of total energy and (4) saturated fat was less than 10% of total energy; and (5) increase dietary fiber intake to at least 15 g/1000 kcal. Participants were also encouraged to attend voluntary group sessions (e.g., lectures, cooking classes, supermarket visits), and they were given the option of following a very low calorie diet at months 6-7 to boost weight loss.

Participants in the DPS lifestyle intervention had a 58% reduction in diabetes incidence compared to controls.[106] After 7-years median follow-up, the reduction in relative risk of diabetes was lower, but still significant at 36%.[107] Although the number of study goals achieved by participants was an important factor in how effective the program was for diabetes prevention, even participants who only obtained one goal showed reductions in diabetes incidence; regardless of which goals were reached, the incidence of diabetes per 100 person-years was 8.4, 7.1, 5.5, 5.8, and 2.0 for participants reaching 0, 1, 2, 3, and 4-5 of the study goals, respectively.[107]

The Diabetes Prevention Program

The Diabetes Prevention Program[108] was a 27-site study conducted in the US randomizing 3,234 ethnically diverse, overweight adults (aged 25 years or more) with IGT and elevated FPG (FPG 90-125 mg/dl) to standard of care, an intensive, one-on-one, individualized lifestyle intervention program, or metformin (850 mg twice per day). A fourth study arm (troglitazone) was discontinued due to potential liver toxicity of the drug. Case managers met with participants in the lifestyle arm once per week for sixteen weeks then once per month for eight months and provided training on diet (reduction of total fat intake), physical activity, and behavior change (e.g. increasing social support, goal setting) with the goals for participants to lose 7% or more of their baseline weight and increase physical activity to 150 minutes or more per week. Case managers were also provided with a toolkit to help participants reach study goals, which included items such as free gym memberships and meal replacement shakes.

Participants in the DPP lifestyle intervention showed a 58% reduction in diabetes incidence compared to controls.[109] The lifestyle intervention was effective in all race/ethnic groups and across ages, with older individuals showing the greatest reduction in diabetes incidence compared to controls (71% for individuals aged 60 or more years, compared to 48% for those aged 25-44 years).[109] The increased benefits for older populations are likely due to lifestyle interventions overcoming age-related increases in peripheral insulin resistance.[110] The lifestyle program was also effective across BMI levels; however those with the lowest BMIs had the greatest reduction in diabetes risk: 65% reduction in diabetes incidence compared to controls for people with BMIs of 22 - <30 kg/m^2, compared to 51% for those with BMIs of ≥35 kg/m^2.[109] Finally, lifestyle interventions can overcome genetic susceptibility to diabetes,[12, 109] further supporting the importance of lifestyle change for diabetes prevention.[111]

The Indian Diabetes Prevention Programme

In the Indian Diabetes Prevention Programme (IDPP),[12] 531 South Indians aged 35-55 years with IGT were randomized to receive either (A) standard health advice (control arm), (B) lifestyle modification, (C) metformin, or (D) lifestyle modification plus metformin. Recruiting was conducted at worksites and potential participants included employees and their family members. Lifestyle education was taught at randomization and again two weeks later over the phone and included instruction on healthy eating (reducing total calorie, fat, and refined carbohydrate intake, increasing fiber intake, and avoiding sugar) and physical activity for participants who did not already have active lifestyles (e.g. their jobs involved physical labor or they walked or biked 30 minutes or more per day already). Monthly phone calls and in-person sessions every six months were used to maintain motivation for lifestyle change. Participants in the drug or drug plus lifestyle arm were given metformin twice daily at 250 mg per dose.

Compared to the DPP and the DPS, the IDPP lifestyle intervention was less effective, although participants did show a significant reduction in diabetes risk: compared to the control arm, there was a 28.5% reduction in diabetes incidence in the lifestyle modification arm, a 28.2% reduction in the lifestyle plus metformin arm, and a 26.4% reduction in the metformin arm.[12] A pooled analysis of participants in the IDPP and the IDPP-2 (which compared the IDPP lifestyle intervention with placebo or pioglitazone) studies showed that the lifestyle intervention was equally effective for diabetes risk reduction in participants with isolated IGT and those with both IGT and IFG.[112]

The lower risk reduction in this study could be due to several reasons. First, Asian Indian populations show a high rate of conversion to diabetes. The glucose intolerance of participants in the IDPP program may have already progressed to a point where moderate lifestyle change is not sufficient for diabetes prevention. Second, there was no significant loss in weight (in fact, all groups gained weight over the course of the study), and waist circumference did not change significantly from baseline to end of follow-up.[12] In other populations, weight loss has been shown to significantly reduce diabetes risk. Third, not all participants were asked to increase physical activity; those with "active" jobs or who walked or biked to work were not counseled to increase their daily activity. Fourth, the IDPP was a work-site based program (instead of community-based), and participants might have been less motivated to make lifestyle changes. Finally, the IDPP program was less intensive. Participant-staff interactions were less frequent than other studies and dietary advice was only provided during monthly calls, which may have not been sufficient to result in lasting behavior change. Even so, the IDPP intervention was shown to be cost effective and efficient for diabetes prevention in India; the numbers of individuals needed to treat to prevent one case of diabetes were 6.4 with lifestyle intervention, 6.9 with metformin, and 6.4 with lifestyle plus metformin.[113]

Summary of Lifestyle Interventions for Diabetes Prevention

As detailed above, lifestyle interventions are effective tools for diabetes prevention or delay, with participants showing significant reductions in diabetes risk compared to controls, even after they gain back some or all the weight lost during the lifestyle program.[99, 106, 107, 109, 114] In addition to reducing diabetes risk in high-risk individuals, lifestyle interventions improve aerobic capacity, blood pressure, whole body insulin sensitivity, insulin responses, markers of inflammation (CRP, IL-6, and plasminogen activator inhibitor), and plasma lipid levels.[58, 103, 115-118] Lifestyle interventions, at various levels of intensity (from the very intensive DPP to the less intensive IDPP), are cost-effective for preventing diabetes.[119-121] Based on these findings, expert organizations, including the American Diabetes Association[122] and the International Diabetes Federation[123] recommend lifestyle changes (e.g., increased physical activity, weight loss) for diabetes prevention.

Common Components of Successful Lifestyle Intervention Programs

The most successful of the lifestyle trials described above have several unifying features; in each, participants were counseled on:

(1) Weight loss: The DPS and the DPP showed the highest reduction in diabetes incidence and both promoted weight loss (5% in DPS and 7% in the DPP). Weight loss is accomplished by inducing a calorie deficit through increasing physical activity, decreasing calorie intake, or, ideally, both. In the DPP lifestyle intervention group, BMI, waist and hip circumference, weight, and waist-to-hip ratio predicted diabetes incidence in both sexes, and diabetes risk reduction in the lifestyle intervention arm was significantly predicted by weight, BMI, and waist reduction in women and by weight, BMI, waist-to-hip ratio, waist circumference, and subcutaneous and visceral fat reduction in men.[124] Furthermore, weight

loss was determined to be the most important factor in diabetes risk reduction.[13]

(2) Increasing physical activity: Most lifestyle interventions recommend at least 150 minutes per week of moderate to vigorous physical activity.[69, 99, 124, 125]

(3) Following a healthy, well-balanced diet: In the DPS, consuming a low-fat, high fiber diet had a dose-dependent effect on sustained weight loss and was associated with reduced diabetes risk.[126]

(4) Tools for behavior change: Successful diabetes prevention programs included information on health behavior change that is based on proven behavioral health theories (e.g. Prochaska's Stages of Change Model[127] and the Health Beliefs Model[128]).

Translation of the DPP for the South Asian Population

Narayan and colleagues define translational research as "comprehensive, applied research that strives to translate the available knowledge and make it useful in everyday clinical and public health practice."[11, 129] In other words, translational research seeks to bridge the gap between basic science and effectiveness studies and implementation of proven research in clinics and the commuity.[129-132] Translational research using the curricula developed for the DPS and the DPP is underway. These studies have shown promising results with participants displaying weight loss, and, in some studies, reductions in blood pressure, FPG, plasma lipids, or diabetes risk.[133-138]

There is a lack of data on lifestyle programs for diabetes prevention in the South Asian population. Given that the DPP intervention study was successful across race-ethnic groups, including Asian Americans,[109] and given the elevated risk for diabetes in South Asian populations, translating the DPP curriculum for this population seems a prudent course of action. South Asians are a large, multicultural population, which includes people from a variety of religious, ethnic, and language groups, and these differences affect lifestyle choices like dietary composition, acceptability of engaging in behaviors like smoking or overeating, and how and even if people choose to exercise.

The behavior change component of the DPP[108, 139] helps participants to improve health behaviors through promoting social support, teaching skills to remove barriers and problem solve, and increasing self-efficacy. In translating the DPP for the South Asian community, researchers must understand the role of culture in decision processes around diet and physical activity. When people are approached in a culturally sensitive way, they are more receptive to health messages,[140, 141] and the South Asian community is no different.[97, 142] Culturally tailoring an intervention shows the community that the problem applies to them and gives the community a sense of ownership. Community members may be more likely to enroll in a program that includes familiar activities. Ownership and investment in the program should increase sustainability because community members who feel the project has been developed with their input and is relevant to their lives may be more likely to continue the program after the study is completed. Furthermore, culturally appropriate advice can be easier to utilize immediately, as participants do not have to modify the advice on their own to account for common food and activity choices in their community.

Similarly, since weight loss is a pivotal component of the DPP curriculum, when translating the DPP in the South Asian population, it is important for researchers to understand how behavioral factors associated with weight gain/loss in other groups (e.g., weight loss history, consumption of fresh fruit and vegetables) act in this population so that they can promote behaviors that will have the greatest impact on weight. Research is needed to understand behavioral choices in South Asians in India and the US in order to plan successful, acceptable, and sustainable diabetes prevention programs for these communities.

Chapter 3: Methods

This dissertation reports data from two different translational research programs of diabetes prevention through lifestyle intervention: (1) a formative research study and pre-post pilot trial of a DPP-like program among South Asians living in metropolitan Atlanta, Georgia (the South Asian Health and Prevention Education Program, SHAPE) and (2) a large, randomized controlled trial being conducted in Chennai, India called the Diabetes Community Lifestyle Improvement Program, or D-CLIP. The methods for each study are described below. Data analysis methods pertinent to each study question are presented in the appropriate chapters (chapters 4-6).

The SHAPE study

The SHAPE Study (clinicaltrials.gov NCT01084928) is a formative research project to determine the best way to educate South Asians living in the US about diabetes prevention, weight management and lifestyle change. The goals of the SHAPE project are (1) to develop a culturally specific lifestyle intervention program based on the DPP curriculum and adapted based on community feedback gathered during focus group discussions; and (2) to test the acceptability, feasibility, and effectiveness of this program in a small, pilot, pre-post intervention trial. The SHAPE study is funded through several sources: a grant from the National Institute of Diabetes, Digestive, and Kidney Diseases (NIDDK) at the National Institutes of the Health (the primary funder), an Emory University Office of University Community Partnerships grant, and with funds provided through a partnership with the American Diabetes Association, Atlanta and Northeast Georgia Chapter. The Emory University Institutional Review Board approved all study procedures.

Formative Research to Inform the SHAPE Program

There is little published research available describing the lifestyle and diabetes/obesity prevention behaviors of South Asian Americans. It was therefore imperative, before modifying the DPP curriculum for this population, to gather qualitative information on these issues in the South Asian community. The aim of the qualitative arm of the SHAPE study is: t*o develop and refine a lifestyle intervention for diabetes prevention for South Asians living in the US that is culturally specific and scalable, based on the components of the DPP and data from focus group discussions.* The study objective is to conduct focus group discussions with the South Asian community to identify community perceptions and behaviors regarding diet, exercise, obesity, and diabetes; identify strategies to develop culturally specific activities for diabetes prevention; and gauge community interest in planned intervention components. These data will be used to shape the components of a lifestyle intervention that is culturally appropriate for the South Asian community.

The study team recruited men and women, aged 25 years or older, living in metropolitan Atlanta who self-identify as South Asian for focus group discussions (FGD). The South Asian community in Atlanta is diverse, and recruitment was conducted at locations and through organizations that are familiar to a wide range of South Asian sub-communities to identify people from a broad cross-section of the community. Further, targeted recruitment was conducted through specific organizations (e.g. religious centers and specific cultural groups like the Greater Atlanta Tamil Society) to identify individuals from the larger cultural groups that make up the bulk of Atlanta South Asians. The selection of recruitment sites and populations was done based on the suggestions of a community advisory group, a team of community leaders, South Asian physicians, and other researchers with a stake in the Atlanta South Asian community.

Specific recruitment strategies, and FGD, data collection, and analysis methods are described in Chapter 4. Briefly, FGD, stratified by gender and age (25-39 years old, and aged 40 years or older) were held at locations familiar to the Atlanta South Asian community. Each discussion was led by a trained moderator who matched the study participants for gender. FGD were recorded using a digital recorder.

Two sets of FGD were held. Although both sets of FGD covered similar topics, the primary focus of the discussion differed slightly. The first set of FGD focused on the following key areas (See Appendix A: Focus Group Discussion Questions, Set #1 for FGD questions):

1. *Views of Diabetes and Overweight – Are obesity and diabetes major health issues in the South Asian community? What are the perceived causes and consequences of diabetes/obesity?*
2. *Diabetes and Obesity Prevention – How do members of the South Asian community prevent diabetes/weight gain?*

3. *Barriers to Physical Activity and Diet Change – What activities are common in the South Asian community? What is viewed as healthy/unhealthy in the South Asian American diet? What are barriers to and benefits of physical activity/exercise and diet change within the South Asian community?*
4. *Suggestions for the Intervention Program – What components would community members find attractive in a lifestyle intervention?*

Once saturation was reached for many of the issues around diabetes, obesity, diet and physical activity, the moderator's guide was changed and a second set of focus group discussions was held focusing on the following issues (See Appendix A: Focus Group Discussion Questions, Set #2 for FGD questions):

1. *Suggestions for the Intervention Program – What components would community members find attractive in a lifestyle intervention?*
2. *Perceptions of Planned Intervention Components and Activities (physical activity in general and specific activities, diet/nutrition education tools)*

The verbatim transcripts of the FGD were analyzed as described in Chapter 4. Data from the FGD were used to modify the DPP curriculum to make it culturally appropriate and targeted to the needs and preferences of the South Asian community, while maintaining the core structure and health education base of the original program. An analysis of the role of culture in diet and exercise choices in this population and recommendations for how this information can be used to promote a healthier lifestyle for South Asians can be found in Chapter 4.

The SHAPE Pilot Study

The SHAPE pilot study aims to implement the culturally specific, DPP-like lifestyle intervention for diabetes prevention amongst the South Asian population with pre-diabetes, in a pilot study with 25 individuals. Because the pilot study classes are on going and the analysis of the results is outside of the scope of this document, the pilot study will not be described here. Results of the SHAPE pilot study will be used to develop an R18 proposal to test a definitive, randomized controlled trial of a culturally appropriate lifestyle intervention for the prevention of diabetes in South Asians.

The D-CLIP Trial

D-CLIP (clinicaltrials.gov # NCT01283308) is a randomized translation trial of a DPP-like intervention for the prevention of diabetes in India, which is culturally appropriate, low-cost, community-based, scalable, and sustainable. Currently, all study participants have completed classes and are in study follow-up. The trial is being conducted in Chennai (formerly Madras), India's fourth largest city and the largest city in Southern India. Study classes and testing take place at Dr. Mohan's Diabetes Specialities Centre/Madras Diabetes Research Foundation (MDRF). This project is supported by a BRiDGES Grant from the International Diabetes Federation. BRiDGES, an International Diabetes

Federation project, is supported by an educational grant from Eli Lilly and Company. The aim and objectives of the D-CLIP trial are:

Aim: To evaluate the effectiveness, cost-effectiveness, and sustainability of a community-based diabetes prevention program in Chennai, India using a randomized controlled trial, with 600 people with "pre-diabetes" randomized to either standard lifestyle advice or a culturally specific, low-cost, intensive lifestyle intervention.

Objective 1: To evaluate effectiveness of the lifestyle intervention by assessing between group changes in the following:

Primary Outcome: incidence of diabetes

Secondary Outcomes: body weight, body mass index, waist circumference, fasting glucose, blood pressure, plasma lipids, activity, and diet.

Objective 2: To evaluate the cost-effectiveness of the lifestyle intervention by assessing the incremental costs and benefits per case of diabetes prevented and per quality-adjusted life-year.

Objective 3: To evaluate the sustainability of the lifestyle intervention by assessing participants' perceptions of the acceptability of program components through focus group discussions with active study participants and telephone interviews with participants who left the program.

The study methodology is described in detail elsewhere[143] (see Appendix B: Weber MB, Ranjani H, Meyers GC, Mohan V, Narayan KM. A model of translational research for diabetes prevention in low and middle-income countries: The Diabetes Community Lifestyle Improvement Program (D-CLIP) trial. Prim Care Diabetes. Apr 2012;6(1):3-9.). An overview of the study population and protocol is provided here.

Study Population

The study population is defined as people with pre-diabetes who are 20 years or older and lived in Chennai, India at the time of recruitment. Approximately 20,000 people were recruited and participated in first-level screening (capillary blood glucose, height, weight, and waist circumference measurements and a short questionnaire). From these, 1,281 people attended clinic-based screening. This identified 599 people who were eligible and willing to participate in the randomized trial. Inclusionary criteria are shown below:

- Live in or near Chennai, India
- Aged 20-65 years
- A BMI ≥23 kg/m^2 and/or a waist circumference >90 cm for men and >80 cm for women
- No prior diabetes diagnosis, except for gestational diabetes
- At high risk of developing diabetes (pre-diabetes) with baseline fasting glucose of 100-125 mg/dl and/or 2-hour post-load glucose of 140-199 mg/dl
- Not currently pregnant

- No evidence or history of heart disease, serious illness, cancer diagnosis within the last five years, or other conditions that may impede or prohibit participation.
- Willingness to consent to randomization

Participants who did not fit these inclusionary criteria were excluded from randomization into the D-CLIP study.

The D-CLIP Lifestyle Intervention

Eligible participants for the D-CLIP trial were randomized to receive either standard of care (control arm) or a step-up diabetes prevention program (intervention arm), as described below.

Participants randomized to the control group received standard lifestyle advice for a patient presenting with pre-diabetes at the study center. Shortly after randomization, they met with a clinic physician and a dietician and attended two lectures on diabetes prevention (one exercise class and one class on weight loss and diet change for diabetes prevention). Control participants received publicly available literature (flyers, brochures, etc.) developed by the study center for diabetes prevention classes.

Intervention arm participants attended group, lifestyle classes (behavior/diet change classes and a physical activity class) weekly during the active intervention period (months 0-4 after randomization) and at least four times during the maintenance period in months 5-6 after randomization (during the 2-month maintenance period, participants could select from eight weekly classes, attending at least half). Class materials were developed by professional nutritionists, fitness instructors, and health educators from MDRF and Emory using the DPP curriculum as a starting point and modifying it based on the experience of the study team and guidelines and information published by the American Diabetics Association on general nutrition, the Association of Physicians of Indian Origin on nutrition for Indian diets,[144] and the Indian Council of Medial Research on the management of diabetes.[145] Like the DPP, participants were taught health behaviors and techniques to reach the study goals of a 7% weight loss and an increase in physical activity to at least 150 minutes per week. All classes were team-taught by a professional health educator (for lifestyle classes) or an exercise trainer (for exercise classes) and a trained lay interventionist. Additional peer support was provided through the use of peer support groups, who worked together in class and were encouraged to provide support outside of the classroom. The composition of the peer support groups (e.g., live in same neighborhood, same gender) differed by intervention class and reflected the opinions of class participants. Intervention participants who remained at highest risk of developing diabetes after four months of lifestyle intervention (FPG values of 100 mg/dl or more and HbA_{1c} measures of 5.7% or more) were prescribed metformin at a dose of 500 mg twice per day. Metformin, a glucose-lowering drug, has been shown to reduce diabetes incidence in individuals with pre-diabetes.[12, 109]

Study Testing

Data collected during the in-clinic screening visit will serve as baseline data for the participants in the randomized trial and as a source of cross-sectional data on the Asian Indian population in Chennai. Participants in the randomized trial return to the clinic for additional study testing at 4 months (after completion of active intervention period classes), 6 months (after completion of maintenance classes), 12 months, and every six months until the close of the study. Data collection methods are shown in table 2.

Table 2: D-CLIP trial study testing

	Month of Study				
Test or instrument name	0	4	6	12, 24, etc.	18, 30, etc.
Pen and Paper Surveys[1]	■	■	■	■	■
Food Frequency Questionnaire	■			■	
Height and Weight, Waist Circumference, Percent Body Fat	■	■	■	■	■
Blood Pressure	■	■	■	■	■
Fasting Plasma Glucose and Insulin	■	■	■	■	■
Post-Challenge Glucose and Insulin (30 minute and 2 hour)	■			■	
$HbA1_c$	■	■	■	■	■
Lipid Profile	■	■	■	■	■
CBC/Haemogram	■			■	

1. Includes questionnaires to measure participant demographics, behaviors, psychosocial measures (e.g. self-efficacy, quality of life), general health, and health-related costs

The primary outcome of the D-CLIP trial is diabetes incidence (the proportion of individuals progressing from pre-diabetes to diabetes at each time point as defined by a FPG≥126 mg/dl or a 2-hour post-load glucose of ≥200 mg/dl). Secondary outcomes include changes in anthropometric measurements (percent body fat, body weight, body mass index, waist circumference), plasma lipids, blood pressure, fasting glucose, and reported activity and diet. Although not primary outcomes, the researchers will also measure changes in the following over the course of the study: weight loss and exercise stage of change and self-efficacy; health status; and perceived benefits of and barriers to exercise and healthy eating. Secondary objectives include assessment of program cost and cost-effectiveness and program acceptability.

Data analysis for the D-CLIP trial will include qualitative analysis of verbatim transcripts from focus group discussion and interviews with study participants and drop-outs, respectively, and quantitative analysis of questionnaire, clinical, and biological data. This dissertation includes a cross-sectional analysis assessing the relationship between baseline BMI and behavioral variables (Chapter 5) and a longitudinal analysis of changes in BMI, weight, and waist circumference in the first six months of the D-CLIP trial (Chapter 6). Pertinent data analysis techniques are described in each chapter.

CHAPTER 4: Barriers to and Opportunities for Lifestyle Change to Prevent Diabetes in US South Asians

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Abstract

South Asian Americans are a growing immigrant group with an elevated risk of developing diabetes. Diabetes can be prevented or delayed through improvements in lifestyle behaviors, namely increasing physical activity and making the diet healthier. Little is known about cultural barriers to and motivators for lifestyle change in US South Asians. This paper reports the results of focus group discussions with adult South Asian Americans. The study aims are to describe how cultural preferences and social norms affect lifestyle choices around diet and physical activity in this community and to make recommendations for tailoring diabetes prevention programs for US South Asians. A thematic analysis was conducted using verbatim transcripts of the focus group discussions (N = 17). Key issues influencing lifestyle behaviors in this community were immigration to the US, and the subsequent changes in physical activity and diet, and gender expectations. Men and women are expected to focus primarily on caring for the family, ensuring their comfort and financial security, and this takes priority over other activities including health promotion. This focus on family and the importance of socializing with them can be used as a tool to promote behavior change and increase social support for healthy lifestyle

behaviors. Lessons from this study can be used to create culturally tailored lifestyle programs for diabetes prevention in the South Asian American community.

Introduction/Background

The South Asian population (individuals from India, Pakistan, Bangladesh, Nepal, Sri Lanka, Bhutan, or the Maldives) is a rapidly growing immigrant ethnic group in the US. The state of Georgia has seen a particularly rapid increase in the number of residents of South Asian origin; for example, between 2000 and 2005, the Indian American sub-population grew by 72%, to nearly 80,000 people.[146]

Diabetes is a major health issue in the US; from 2005 to 2050, the prevalence of diagnosed diabetes in the general US population is expected to more than double from 5.6% to 12.0%.[147] In the US, the prevalence of diabetes is significantly higher in Asian Indians compared to other Asian groups and non-Hispanic whites,[5-7] and South Asians are more likely than other populations to develop diabetes at younger ages.[8, 9, 85]

Lifestyle interventions, programs designed to promote weight loss and prevent diabetes through diet, activity, and behavior change, decrease diabetes incidence in individuals with pre-diabetes.[12, 99, 106, 109, 148] To date, there is limited research testing proven diabetes prevention programs in South Asian migrant populations. The Diabetes Prevention Program, a multi-center trial in the US which tested individual lifestyle counseling or metformin for diabetes prevention in high-risk individuals, showed that lifestyle was effective in all race/ethnic groups, including Asians,[109] but the number of South Asians in the study was small. No studies have addressed delivering diabetes prevention at the group or population level to South Asian Americans.

Being exposed to a new environment, as well as the challenges of balancing traditional beliefs and practices with US culture, makes lifestyle changes particularly difficult for migrant groups. For lifestyle programs to be most effective they need to be culturally appropriate and address the barriers to lifestyle change that are unique to the South Asian American community. There is a need for research to determine the specific barriers to lifestyle change affecting this population. This study aims to (1) describe how cultural preferences and social norms affect lifestyle choices around diet and physical activity in the South Asian American community and (2) make recommendations for how to tailor diabetes prevention programs to the US South Asian population.

Research Design and Methods

Study Participants and Procedures

Individuals aged 25 years or older and who self-identified as South Asian were eligible to participate in the study. Focus Group Discussions (FGD) were conducted to obtain in-depth, community-level information from a variety of viewpoints[149] about beliefs and behaviors around lifestyle and diabetes prevention among South Asian Americans. FGD (N=17) were stratified by gender and age (25-39 years [younger group] or 40 years or older [older group]). Stratification of study participants helps ensure data quality by minimizing the development of hierarchies within the group whereby some members feel reluctant to share their true feelings.[149, 150] For example, deference to elders is an important South Asian cultural value,[151] so separating FGD by age helps to promote more open discussion. Age and gender can also affect beliefs, lifestyle behaviors, and acculturation.[152, 153] Similarly, diabetes risk increases with age and a minority of diabetes cases (17.4%) are diagnosed before age 40;[154] the difference in diabetes prevalence between younger and older age groups might affect self-perceived risk of and knowledge about diabetes and prevention practices. Stratifying groups by age and gender may make between-group differences in knowledge, beliefs, and behaviors clearer.

Participants were purposively recruited to identify a diverse range of participants that reflect the heterogeneous South Asian population, which includes people of different nationalities, religions, and cultural backgrounds. Recruitment strategies were informed by the study's community advisory board, which is made up of influential members of the South Asian community. Targeted recruitment of younger participants was done by distributing fliers about the study at meetings or through listservs of South Asian community organizations. Older study participants were recruited in person at South Asian shopping centers and grocery stores. Participants from both age groups were recruited through an advertisement placed in a local South-Asian magazine and at health fairs planned by organizations in the South Asian community and a South Asian-targeted diabetes education event held by the American Diabetes Association.

Data Collection

Seventeen FGD were conducted by trained moderators (five with older females, and four each with younger males, younger females, and older males). FGD were held at locations that are familiar to the South Asian community in Atlanta (e.g., university classrooms for younger participants and Indian restaurants for older participants). Moderators were matched to the gender of study participants to retain homogeneity in the group composition, thereby promoting a more open discussion.[155] Also, Moderators were not members of the South Asian community to encourage participants to provide more explicit information about relevant cultural issues, as they will need to be explained to an "outsider" rather than a member of their own community who would "know how things are done."[156] After obtaining informed consent, participants took part in a 60-90 minute discussion. FGD were digitally recorded. After the discussion, each participant was asked to complete a short survey to collect individual-level information, e.g., demographic data, migration history, and history of diabetes.

Data Analysis

De-identified survey data was entered into Excel to calculate means and frequency distributions for variables. A trained, master's level research assistant created verbatim transcripts from the digital recordings. De-identified textual data, comprised of the verbatim transcripts, were managed using MAXqda (version X). The textual data was reviewed and inductive codes were developed. To determine code validity and inter-coder reliability, data were coded by two coders independently and compared for consistency. A *thematic analysis* of the data was conducted by developing thick descriptions of core issues on influences on diet and physical activity behaviors in the South Asian community. The data were compared using structured comparisons to identify specific issues relevant to particular sub-groups of South Asian participants (e.g., different issues raised by men and women). Outliers were examined (e.g., individuals who chose to follow a healthy lifestyle by improving the quality of their diet or being more physically active) to identify potential influences or triggers to lifestyle changes. The researchers continued to revisit the data to assess the validity of the core issues and their relationship to the outcomes of interest in this study. The Emory Institutional Review Board approved the study protocol.

Results

A total of 109 individuals participated in the seventeen FGD (mean group size = 6.4). Demographic characteristics of study participants are shown in Table 3 (page 50). Older participants were more likely than younger participants to be married or report a history of diabetes, while younger participants, as a whole, were more educated. All of the older participants were born outside the US, while the younger groups included both first and second-generation South Asian Americans (14-83% US-born, depending on group).

The Role of Immigration in Lifestyle Behaviors

Participants reported that immigration to the US contributed to their unhealthy lifestyle choices and led to weight gain. They reported that it is easier to choose to be inactive in the US than in South Asia because of the prevalence of cars, elevators, and climate-controlled environments in the US. Also, there is a larger variety of brands and types of foods available in the US compared to India and cooking ingredients like oils, sugar, dairy products, and spices are much cheaper, so participants report using more of these foods and ingredients, resulting in higher fat and calorie intake. Older men and women report that the faster pace of life in the US makes it more difficult to cook using traditional, more time-consumptive methods. Instead, people rely on processed, canned, and frozen foods, behaviors that older participants believe are less healthy and cause weight gain.

Participants reported that South Asian women are responsible for food preparation and men are rarely taught to cook. Men, usually migrate to the US alone, and therefore rely on pre-prepared food for their meals, much of which is high in calories and fat. Because of this, migration can be especially detrimental to the diet of South Asian men. The majority of participants follow a vegetarian diet, although the definition of "vegetarian" varies widely from pure vegetarian to diets including fish or even chicken. Older men report that there were only limited vegetarian options when they moved to the US over twenty years ago, and so they relied on whatever vegetarian food was available, without any consideration of how healthy or unhealthy the food item was:

> *When we came here there was no vegetarian food so you change that habit to something different. Whatever was available; you have to eat something. Pizza … we eat so much of [it] without even knowing or recognizing the impact of the food. That was available*

> *in the majority … not only restaurants, but at the company place … What do you eat? That's the only thing you have!* (Older Male)

Although there are more vegetarian items available now in the US, males who immigrated more recently still rely on pre-prepared, frozen foods or eat at restaurants, choices that are high in fat, sodium, and calories, because they lack cooking skills and knowledge.

The Role of Gender in Lifestyle Behaviors

Men described themselves as providers for their family, obtaining material resources and financial support for their spouse, children, and sometimes extended family. Participants reported that they are expected by the South Asian community to provide for their family by getting a good job (which means first excelling at school), being successful at work, and saving money. These responsibilities leave little time for men to focus on their health, for example:

> *There are a lot of issues like family, children, fee structure, planning finances, so health takes a backseat in that. It's not like we- we don't … want to be healthy, we want to look good but, uh, the emphasis is- is currently on career, family, so that sort of thing* (Young Male).

Men reported that they work long hours, leaving little time for exercise, and, during a busy workday, they often skip meals leading to overeating later. Furthermore, South Asians value saving money now over saving health later, for example:

> *You [are] willing to pay when you get sick. You'll pay tons of dollars to the doctor, but if you say, here, to buy a gallon of milk it'll cost you two dollars extra every day, you aren't willing to do that and so we end up paying much higher value later on.* (Older Male)

To obtain a good career and material success, academic success is very important to South Asian men. One man described that South Asians "would rather have a Ph.D. and a lot of money and die a little early" (Older Male).

Marital success is also critical for South Asian men. Career, salary, and education are seen as important qualities in a good husband and necessary to attract a suitable wife, as this quote describes:

> *The need of excelling is … because of … the arranged marriage system. So the girls' train of thought is, "oh look, he- he has a good education, he has a Ph.D., he has a- a 100K job, just marry him." You know? It's like that's- that's a- it's a decision made. So the need for looking attractive, I- that's not what's there-* (Young Male)

To reach these goals, men were encouraged as children to spend time on studying and not on sports. Because of this cultural emphasis on studying over athletics, men, particularly older men, report that they never developed a love for exercise so it is difficult for them to exercise now. Older men also reported that in arranged marriages, spouses often lose interest in each other sexually by the time their children reach middle school, therefore they have no reason to exercise to be attractive to their partner, further discouraging them from starting or maintaining an exercise program.

Similarly, South Asian women reported little pressure to maintain their physical appearance after marriage, with young women saying that many South Asian women "let themselves go" after having a baby. South Asian culture dictates that women are responsible for the family and caring for the household, placing the needs of others above themselves. Young women report that many South Asians view exercise only as a weight loss tool, and taking time from caring for the family to exercise for health, pleasure, or other reasons is questioned. Young, divorced women reported that the only reason they had time for exercise is because they did not have a spouse to care for as "if he is another baby," a social conviction that older women reported they perpetuated, even when it meant giving up time for themselves:

> *We Indian people spoiled our men by giving everything in their hands, so they are lazy so they want us to pay more attention then we go. And we say, oh I am going to gym – no, no, no, I need you here. I need this thing, and I need this thing to be done.* (Older Female)

Although women are responsible for food preparation in South Asian homes, they still find if difficult to improve the diet of their families. All participants reported that Indian culture is "based around food," and food plays an integral role in family life, socializing, and celebrating. Participants reported that although South Asian diets can be healthy, South Asian Americans choose the less healthy foods more often (e.g., fried snacks, more oily and fatty foods), add in less healthy ingredients (e.g., lots of cheese, extra oil or ghee), cook healthy foods in unhealthy ways (e.g., frying, over-cooking vegetables), eat large portion sizes, and rarely make tradeoffs by choosing healthy foods to counterbalance the unhealthy. Taste is the primary driver of food choice, and oil is associated with tasting good: "oil is the king. I mean, to make it taste, uh, delicious" (Young Male). In fact, participants in each FGD defined "healthy" and "delicious" as opposites, and people, especially men, felt that lowering the fat in South Asian food would make it less, or even un-, palatable. Since women wish to please their families by creating food they like, many women report difficulties in changing traditional South Asian recipes to be healthier. Those who attempted to lighten South Asian foods (e.g., lower fat, calories, sugar, or sodium) often met with resistance from their families and friends. Lightened recipes are considered less presentable and tasty, and women report being called a "*scrooge*" if they use less oil in cooking. One woman relayed the following story:

> *I went to a party … and there was a layer of [oil] in a big tray … so me and my friend … we just drained the oil out. And the lady who had cooked it, she saw us take-draining oil out so she took the food back in, put the oil back in and brought it out …. there's some stubborn people like that.* (Older Female)

In addition, women use food as a tool to show love and approval to family members, giving or denying food accordingly:

> *Food in our culture means love, it means affection, it means caring, and um. I remember when my mom was really pissed off at us, like the food kinda stops and when she kinda wants to like get into our lives, like, the food starts pouring in.* (Young Female)

Women, therefore, often provide their loved ones with large servings to show affection and people have grown accustomed to eating these large portions.

Overcoming Barriers to Healthy Lifestyle Behaviors

Some participants reported following a healthy lifestyle even though exercise, diet change, and weight loss are uncommon in their community. As described above, in the South Asian culture, caring for one's family is a person's primary responsibility. For participants who were able to make healthy lifestyle choices, this focus on family was a motivator for and not a barrier to lifestyle improvement. Adapters of healthy lifestyle behaviors reported that they were motivated to exercise and follow a healthy diet by a desire to be better able to care for themselves and their family and to prevent disease and disability so they would have more quality time with their loved ones.

Furthermore, participants reported that they are motivated to pass on knowledge about healthy lifestyle choices to others (e.g., children and parents) to improve the health of their families and communities. Participants reported that, ideally, the entire family will adopt lifestyle changes together, and that one health conscience individual can work to promote change in the entire family, for example:

> *I brought some ground rules when my parents were here* [in the US]. *I mean, I used to listen to my parents, um, when I was in India, and in terms of whatever food they gave, but when I came here, and when I educated myself, I brought this rule: Okay, you have to eat this in the breakfast, eat this thing in the lunch, eat this, eat this thing in the dinner. And, after when they went back* [to India], *they're still following it. So if somebody is really strong in a family, they can probably bring this change.* (Young Male)

Healthy changes may also be enacted without the expressed cooperation of all family members. Women reported that overcoming their family's reluctance to change their diet caused them to make changes to foods and recipes without their family's knowledge: these women described how they enacted gradual changes in the diet, e.g., slowing increasing spice while decreasing oil. These women reported that their families never noticed the changes and now enjoy healthier foods.

South Asians who make healthy lifestyle choices credit the support of friends and family for making and maintaining these changes. Many individuals who reported following an active lifestyle sought out activities with built-in social support (e.g., group sports for young men, family walks for older men and women, or exercise classes for women) to help them maintain motivation for the lifestyle choices, and most reported that they had friends and family who encouraged them either by words or example. Given the strong work imperative of South Asian men, male participants reported that workplace exercise programs would allow them to have time to exercise and would be very appealing, especially if attending was considered part of their job:

> *Speaker 1: "If the employer say that tomorrow this is going to be on PEP or performance appraisal everybody will be work out. Eh-heh." [Laughter].*
>
> *Speaker 2: "Yeah."*
>
> *Speaker 3: "I excel."* (Young Male Participants)

Discussion

South Asian Americans in this study reported a high prevalence of unhealthy lifestyle behaviors that increase their risk of developing diabetes: a lack of physical activity and a diet that favors high fat, high calorie foods and large portion sizes. These behaviors have been reported in other studies of South Asian migrant populations in the United Kingdom, Canada, and the US.[157-166] Participants in this study reported that immigration influences some of these unhealthy lifestyle choices; in the US, it is easier than it was in South Asia to be sedentary and unhealthy food is inexpensive and plentiful in the US. Entering a new environment, and the subsequent changes in behavior, have been linked to weight gain and increased risk of diabetes in various migration populations, including South Asians.[167-169] Although many components of immigration cannot be changed, for example exposure to new foods, many of the barriers to healthy lifestyle that result from migration can be mitigated by providing South Asian communities with training in increasing physical activity and decreasing sedentary behavior and nutritional information that is specific for South Asian foods and recipes.

As a pluralist society,[161, 170, 171] South Asians prioritize the needs of the community over self, spending time with their family and providing them with comfort and financial security before caring for their own health. The lifestyle behaviors of South Asian men and women are strongly influenced by cultural expectations for educational, financial, and marital success and by gendered expectations on the roles of men and women in South Asian communities (focus on work for men and caring for the family and the household for women). For South Asian Americans, these cultural traditions remain and cause difficulty for following a healthier lifestyle.

However, South Asian participants in this study do not view these obstacles as insurmountable. Diabetes prevention programs can leverage the same cultural influences that currently pose barriers to healthy lifestyle choices into positive forces of change using the experiences of South Asians who have been successful in adopting healthy lifestyle behaviors. First, because participants reported that a primary reason for improving their health was to better enable them to provide their families with the care needed and so that they were not a burden on their loved ones, diabetes prevention programs should stress positive outcomes that affect the entire family and one's role in the family unit, for example, being healthy enough to help with the grandchildren. Enrolling the entire family, or at least spouses, would help reinforce the message that change is good for the entire family and might make it easier for the family to accept changes. Study participants reported that social support was vital for starting and maintaining diet change and physical activity in their community, and families or spouses that changed their lifestyles together were particularly successful at improving diet and physical activity patterns. Diabetes prevention programs in this community should incorporate tools to create and promote social support such as training South Asian community members as peer educators, dividing participants into peer support groups, or inviting friends and family members to participate in classes or the program. Physical activity programs and educational material should focus on increasing activities of daily living, which would not require taking time from other responsibilities, and structured exercise programs could teach activities that can be done as a family or a group (e.g., group walks, team sports). Diet classes should focus on teaching techniques for reducing fat intake and portion sizes while maintaining the flavor profile of the south Asian diet (e.g., adding flavor with spices instead of fat). Lastly, programs should be designed that work into people's busy schedules, for example, work-based programs or weekend classes.

Strengths of this study are that it included South Asians, aged 25 years and above, with and without diabetes, from various countries and regions of South Asia, of different religious traditions, and with a range of education levels. The research team conducted 17 focus group discussions, which allowed them to talk to over 100 members of the South Asian community in Atlanta. Nevertheless, this study has at least two limitations. First, the logistics of recruitment made it impossible for the research team to recruit younger participants quickly enough to host separate groups for first and second-generation South Asians; the difference in place of birth might have affected lifestyle behaviors, and this difference could not be adequately captured in this study. Second, conducting focus group discussions in English means that the results of this study may not apply to South Asians who do not speak English. The researchers believe that this is not the case, however, since study participants were describing behaviors of the entire population. However, acculturation affect lifestyle behaviors such as diet and physical activity, and the researchers cannot rule out the possibility that English-speaker participants are more acculturated than other members of the South Asian community.

Conclusion

In the US, where food is plentiful, portions are large, unhealthy ingredients are cheap and readily available, and the environment supports sedentary activity over active lifestyle choices, South Asians, with their focus on family, society, and food, are at a uniquely high risk for weight gain and developing cardiometabolic diseases like diabetes. This study showed that, although immigration and traditional gender roles can act as barriers to following a healthy lifestyle, they can also motivate South Asians to change their diet and physical activity behaviors. This information can be used to design culturally appropriate and community accepted diabetes prevention programs.

Chapter 4 Tables

Table 3: Demographic characteristics of SHAPE focus group discussion participants by age and gender

Age-Gender Group*	# of Groups	Hindu (%)	Married (%)	US Born (%)	Mean Years Living in the US	Home Ownership (%)	History of Diabetes** (%)	Education Level
Older Males	4	62.5%	94.3%	0%	22.1	65.7%	55.6%	Primary School or Higher
Older Females	5	69.2%	72.0%	0%	25.1	77.0%	48.5%	Primary School or Higher
Younger Males	4	67.8%	42.8%	24.3%	10.6	48.0%	7.0%	College or Higher
Younger Females	4	80.3%	37.8%	29.0%	11.8	72.3%	0%	College or Higher

*Younger age group includes participants aged 25-39 years. Older age group includes participants aged 40 years or older.
** History of diabetes includes type 2 diabetes or gestational diabetes.

CHAPTER 5: Correlates of BMI and Waist Circumference and Healthy Lifestyle Factors in Asian Indians

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Abstract

Excess body weight is an important risk factor for type 2 diabetes mellitus, a major cause of morbidity and mortality worldwide. Understanding the factors related to higher weight and waist circumference are important for preventing weight gain and treating overweight individuals. This study used screening data from the Diabetes Community Lifestyle Improvement Program, D-CLIP, a randomized controlled trial of a diabetes prevention program in Asian Indians, a population with a markedly high risk of developing diabetes. The researchers assessed the relationship of certain factors associated with healthy weight maintenance (weight loss and exercise self-efficacy, fruit and vegetable intake, weekly exercise, past experience with weight loss) with Body Mass Index (BMI) and waist circumference by estimating unadjusted correlations and conducting bivariable and multivariable linear regression modeling. Exercise self-efficacy and weight loss self-efficacy were positively and significantly correlated with average minutes per week exercising ($R = 0.26$, $P<0.0001$ and $R=0.26$, $P<0.0001$ for the exercise self-efficacy subscales, sticking to it and making time, respectively) and fruit and vegetable intake ($R = 0.07$, $p <0.05$ and $R= 0.12$, $p<0.0001$, respectively, for weight loss self-efficacy). Weekly fruit consumption,

past weight loss experience, and weight loss self-efficacy, along with gender, age, and marital status, explained 13.7% and 25.8% in the variation in BMI and waist circumference, respectively, in this population. Further research is needed to determine if factors associated with BMI and waist circumference in this cross-sectional analysis are related to longitudinal changes in anthropometry.

Introduction/Background

India has the second highest number of people with diabetes worldwide.[1] Compared to other populations, Asian Indians get diabetes at younger ages and a lower body mass index (BMI) and fare worse once they have diabetes.[8, 9, 35, 39-41] Excess body weight is a major risk factor for the development of type 2 diabetes, the predominant form of diabetes. India is experiencing a rise in the prevalence of overweight and obesity; from 2005 to 2030, the number of individuals in India classified as overweight or obese is predicted to increase from 88.3 million to 342.8 million.[172] These estimates probably underestimate the true magnitude of this problem, since they are based on the traditional BMI cut-points for overweight and obesity (25-29.9 kg/m^2 and ≥ 30 kg/m^2), instead of the lower BMI ranges recommended for Asian Indians (overweight: 23-24.9 kg/m^2 obesity: ≥ 25 kg/m^2).[173]

Although the cause of weight gain in most individuals is clear – excess calorie intake, insufficient calorie expenditure, or both, the underlying factors that contribute to these behaviors are varied and complex. Food and activity choices are determined by preference, culture, the environment, and psychosocial factors. Understanding how these factors relate to weight in different populations is important for developing lifestyle intervention programs that are culturally appropriate and provide populations and patients with tools for prevention that are meaningful to them.

The Diabetes Community Lifestyle Improvement Program (D-CLIP)[174] is a community-based, randomized, controlled, translational research study being conducted in Chennai, India testing a step-up model of diabetes prevention. Community-level screening on almost 20,000 people was followed by extensive screening/cross-sectional data collection on 1,281 people to identify a sample of 602 overweight men and women with impaired fasting glucose (IFG, fasting plasma glucose of 100 to 125 mg/dl), impaired glucose tolerance (IGT, 2 hour glucose of 140-199 mg/dl during an 75-g oral glucose tolerance test), or both. This analysis reports on data collected at the D-CLIP detailed screening visit, which included the initial sample of 1,281 individuals (344 normoglycemic, 206 with isolated IFG, 201 with isolated IGT, 273 with IGT and IFG, and 255 with type 2 diabetes).

The analysis in this paper was conducted to better understand the relationship between select factors related to weight maintenance and weight in Asians Indians. The aims of the analysis were to answer the following questions: In a sample of Asian Indian adults attending a screening visit for a randomized trial of a diabetes prevention lifestyle program: (1) Do behavioral markers (fruit and vegetable consumption, past weight loss experience, and exercise) and certain psychosocial measures (exercise and weight loss self-efficacy) correlate with adiposity as measured by BMI or waist circumference; and do these correlations differ depending on gender, marital status, income, or education level? (2) What is the relative association of fruit and vegetable consumption, past weight loss experience, exercise, and exercise and weight loss self-efficacy with BMI and waist circumference?

Research Design and Methods

Study Participants and Procedures

The Emory Institutional Review Board and the Madras Diabetes Research Foundation's (MDRF) Ethical Committee approved the D-CLIP study protocol. All subjects provided informed consent at each of two screening visits and before randomization into the trial. Details of the D-CLIP methodology are described elsewhere.[174] Briefly, men and women, aged 20-65 years, were recruited for the study at community-wide and targeted screening events in the community and at housing complexes, places of worships, schools, and workplaces, through hand-searching of clinic records, and by direct referral by physicians or other study participants. Recruited individuals participated in first level screening, which included a short survey, a random capillary blood glucose test, and anthropometric measurements. Individuals with a random capillary blood glucose of greater than or equal to 110 mg/dl, and no major health issues were invited to the clinic for further screening tests at the clinic. This analysis includes participants attending clinic-based screening for the D-CLIP study (n = 1,281).

Data Collection

The clinic-based screening visit included completion of an in-person survey, anthropometric measurements, and laboratory tests. Testing was conducted at the Translational Research Center at MDRF. All staff were trained in proper collection methods, and the study testing staff included dieticians, health educators, and phlebotomists. Data collection methods pertinent to this analysis are described below.

Study Questionnaire: All study questionnaires were self-administered and were available in either English or Tamil. The main questionnaire was created by study staff specifically for the D-CLIP trial. Demographic information (e.g., age, gender, marital status, income, highest education obtained), diet and physical activity behaviors, and weight loss history were self-reported in the study questionnaires. Current physical activity behaviors were assessed by asking about number of days per week exercising, average length of each exercise session, type of activities done, and location of activities. Average fruit and vegetable intake was assessed by the following questions: In a typical week, how many days do you eat fruit/vegetables? Weight loss history, methods tried in past weight loss attempts, and outcomes of prior weight loss attempts were self-reported in the study questionnaire. In addition, the study questionnaire packet included previously validated survey instruments; those used in this analysis are described below.

Exercise self-efficacy was measured using an instrument developed by Sallis and colleagues to measure self-efficacy for exercise behaviors.[175] This survey instrument measures an individual's perception that he/she has the ability to exercise in twelve different situations (e.g., when feeling depressed, on weekends, when there are excessive demands at work) and provides scores for exercise self-efficacy on two scales: sticking to it (adhering to an exercise regime regardless of mood and situation) and making time for exercise (prioritizing exercise over other time demands). Questions are scored by participants on a 5-point Likert-like scale, ranging from “I know I cannot” to “I know I can.”

Weight loss self-efficacy was measured using the Weight Efficacy Life-style Questionnaire (WEL).[176] The WEL assesses an individual’s ability to resist overeating in different situations (e.g., at parties, when anxious, while watching television) by asking them to record how confident they are that they can avoid overeating in certain situations using a 10-point Likert-type scale (from not confident to very confident). The WEL provides a total weight loss self-efficacy score as well as scores on five subscales indicating the individual’s ability to resist eating in different situations: the negative emotions scale, the availability scale, the social pressure scale, the physical discomfort scale and the positive activities scale.

Anthropometric Measurements: Body weight was measured in kilograms without shoes or heavy clothing or jewelry using a standardized, calibrated scale. Height was measured barefoot using a standardized stadiometer. BMI was calculated by dividing the weight in kilograms by the height in meters squared. Waist circumference was measured while participants were standing using a non-elastic measuring tape at the midway point between the lowest point of the costal margin and the highest point of the iliac crest.[177] Overweight was defined using Asian-specific cut-points: a BMI of 23 kg/m^2 or greater or a waist circumference of greater than or equal to 80 cm for women or 90 cm for men.[173]

Data Analysis

All analyses were conducted in SAS, version 9.3 (Cary, N.C). Variables of interest were first checked for normality; since all variables were roughly normal, no transformations of continuous variables were necessary. Exercise self-efficacy scores (making time and sticking to it) and weight loss self-efficacy score and subscale scores were calculated. Variables for calculated average minutes of exercise per week and a categorical variable for past weight loss experience (have not attempted weight loss, lost weight and maintained some or all of the loss, lost weight but gained back some or all of the weight, lost and regained weight many times [weight cycling], or did not lose any of the desired weight) were created. Population distributions or means for demographic and anthropometric variables were measured.

Pearson correlation coefficients were calculated to quantify the relationships between BMI or waist circumference and behavioral factors (days per week consuming fruit or vegetables, past weight loss experience, and average minutes of exercise per week) and self-efficacy scores (weight loss and exercise self-efficacy). Correlations were compared across subgroups of the study population by stratifying by gender, marital status, income, and education. Correlations were also calculated between covariates (WEL total score and subscale scores, exercise self-efficacy scores, fruit and vegetable intake, experience with past weight loss attempts, and minutes per week exercising) to look for relationships between the independent variables.

Bivariable linear regression using SAS's proc glm function was used to assess the relative importance of self-efficacy, behavioral factors, and demographic factors (age, gender, monthly household income, education, and marital status) in determining BMI and waist circumference in this population. Backwards elimination modeling techniques were used to assess the best-fit model explaining waist circumference and BMI in this population. The full model, including all possible two-way interactions among demographic factors, behavioral variables, and self-efficacy scores, was run with SAS's proc glm function and the highest order term with the largest non-significant p-value was removed. This procedure was repeated until the best-fit model was established. For both the BMI model and the waist circumference model, all interaction terms were dropped during the elimination process. Models containing either WEL total score or WEL subscale scores were run separately. Models with the WEL total score had better fit than models with the subscales, so results for the subscales are shown for correlation analysis only.

Results

Sample characteristics of the 1,281 people who completed the D-CLIP screening are shown in Table 4 (page 66). The mean BMI was 27.40 ± 3.75 kg/m^2 for the entire sample and was significantly higher in females (28.64 ± 4.02 kg/m^2) than in males (26.69 ± 3.39 kg/m^2). Because the goal of screening was to identify a sample of participants for a diabetes prevention study with a focus on weight loss, most individuals attending screening were overweight (46.5% of the sample) or obese (44.3% of the sample). The mean waist circumference was

97.06 ± 8.44 cm for men and 88.55 ± 8.45 cm for women, corresponding to 85.4% of the sample being centrally overweight by Asian-specific waist circumference cut-points.

Pearson correlation coefficients and p-values for the associations between BMI or waist circumference and behavioral factors and self-efficacy scores are shown in Table 5 (page 67). Lower BMI and waist circumference corresponded with higher weight loss self-efficacy ($p < 0.005$ for both outcomes), more frequent fruit and vegetable consumption ($p < 0.05$ for all), and having either no past weight loss attempts or successful past weight loss attempts where the individual lost weight and maintained some or all of the loss ($p < 0.001$ for both outcomes). Exercise self-efficacy and average minutes per week exercising were significantly correlated with waist circumference, but not BMI, with more minutes per week exercising and higher exercise self-efficacy being associated with higher waist circumference ($p < 0.05$ for all).

The magnitude of the correlations was largely similar across gender, education, marital status, and monthly household income group, although the correlations were not significant in all subgroups. Some notable exceptions were as follows. Those with incomes of greater than 35,000 Rupees per month displayed higher correlations between BMI and minutes per week exercising ($R = -0.14$, $p = 0.05$) and vegetable intake ($R = 0.14$, $p = 0.05$) and between waist circumference and fruit intake ($R = -0.18$, $p = -0.18$), vegetable intake ($R = -0.19$, $p = -0.19$), weight loss self-efficacy ($R = -0.27$, $p < 0.0001$) and past weight loss experience ($R = 0.25$, $p < 0.001$) compared to the entire sample or the other income groups. Individuals who were never married (single) had stronger correlations between waist circumference and BMI and weight loss self-efficacy ($R = 0.27$, $p = 0.01$ and $R = 0.32$, $p = 0.003$, respectively) compared to the entire group or to married, divorced/separated, or widowed participants. Correlations between BMI and fruit intake, vegetable intake, weight loss self-efficacy and waist circumference and weight loss self-efficacy were significant in men, but not women, while the correlation between waist circumference and making time for exercise was significant in women only.

Table 6 (page 68) lists the Pearson correlation coefficients for the relationships among behavioral and self-efficacy variables. Fruit and vegetable consumption were significantly and positively associated with weight loss self-efficacy ($p < 0.01$), exercise self-efficacy ($p < 0.01$), and each other ($p < 0.0001$). Exercise in minutes per week was significantly and positively associated with exercise self-efficacy ($p < 0.0001$), fruit and vegetable consumption ($p < 0.05$) and past weight loss experience ($p < 0.0001$). Past weight loss experience was positively and significantly associated with exercise self-efficacy ($p < 0.01$).

Bivariate modeling indicated that age, gender, education, household income, marital status, fruit intake, weight loss history, and weight loss self efficacy were independently associated with BMI, and gender, education level, household income, vegetable intake, past weight loss experience, exercise self-efficacy (both the making time and sticking to it scales), weight loss self-efficacy, and minutes per week exercising were correlated with waist circumference (Table 7, page 69). Multiple regression models indicated that 13.7% of the variability in

BMI in this population could be explained by the following factors: gender (β = 1.86 ± 0.21, p <0.001, for female gender); age (β = -0.20 ± 0.01, p = 0.13); marital status (β = -0.30 ± 0.90, p = 0.74 for single; β = 0.82 ± 0.81, p = 0.31 for married; and β = 1.0 ± 1.0, p = 0.32 for separated/divorced); number of days per week consuming fruit (β = 0.91 ± 0.31, p = 0.003 for 0-2 days per week; β = 0.48 ± 0.28, p = 0.09 for 3-5 days per week); weight loss experience (β = -1.54 ± 0.27 p < 0.0001 for have not attempted weight loss; β = -0.80 ± 0.32, p = 0.01 for lost weight and maintained some or all of the loss; β = 0.49 ± 0.35, p = 0.16 for lost weight but gained back some or all of the loss; β = 0.67 ± 0.39, p = 0.09 for weight cycling); and weight loss self-efficacy (β = -0.01 ± 0.00, p = 0.003) (Figure 1, page 70). The final multivariate model (Figure 2, page 71) predicting waist circumference in this population contained the following factors, the same as in the model for BMI: gender (β = -8.72 ± 0.49, p <0.001, for female gender); age (β = 0.04 ± 0.03, p = 0.12); marital status (β = -3.55 ± 2.10, p = 0.09 for single; β = -0.51 ± 1.88, p = 0.79 for married; and β = 0.30 ± 0.13, p = 0.90 for separated/divorced); number of days per week consuming fruit (β = 1.85 ± 0.72, p = 0.01 for 0-2 days per week; β = 0.97± 0.66, p = 0.14 for 3-5 days per week); weight loss experience (β = -3.61 ± 0.62 p < 0.0001 for have not attempted weight loss; β -2.39 ± 0.74, p = 0.001 for lost weight and maintained some or all of the loss; β = 1.77 ± 0.80, p = 0.03 for lost weight but gained back some or all of the loss; β = 0.90 ± 0.90, p = 0.32 for weight cycling); and weight loss self-efficacy (β = -0.02 ± 0.01, p = 0.003). These variables together explain 25.8% of the variability in waist circumference.

Discussion

In this study of overweight and obese Asian Indian adults, weekly fruit intake, past weight loss experience, and weight loss self-efficacy were significantly associated with BMI and waist circumference. Low fruit intake, weight loss with regain of weight, and weight cycling were associated with higher waist circumference or BMI, while having no history of past weight loss attempts, having lost and maintained weight loss in the past, and higher weight loss self-efficacy were associated with lower BMI or waist circumference. Other factors explaining BMI and waist circumference in this population were gender (with females having higher BMI but lower waist circumference than men), age (with BMI decreasing but waist circumference increasing as age increased), and marital status (with single status being protective against high BMI and waist circumference, married status associated with higher BMI but lower waist circumference, and separated/divorced with higher BMI and waist circumference).

Fruit and vegetable consumption has been shown to be low in India.[178, 179] The inverse association between fruit and vegetable consumption and waist circumference and BMI found in this study is consistent with previous work in South India.[180] In the final adjusted models for BMI and waist circumference in this analysis, fruit consumption, but not vegetable consumption, was associated with adiposity. Fruit and vegetable consumption in this population are different behaviors and could reflect differences in health-seeking behaviors. Vegetables are readily available and used liberally in regional cooking, whereas fruits are more expensive and largely seasonal. People consuming fruit regularly are making a special effort to purchase and consume fresh fruits, and these people might be more focused on health and weight maintenance.

Correlations among study variables indicated that individuals with higher self-efficacy were more likely to engage in healthy behaviors (consuming fruits and vegetables more days per week and exercising more average minutes per week), which has also been shown elsewhere.[181, 182] The association between excess weight and weight loss self-efficacy and a history of weight loss seen in this study are also consistent with other studies.[181, 183, 184] These results show that self-efficacy plays an equally important role in health behaviors in India, a low- to middle-income country (LMIC), as it does in Western populations. In longitudinal weight-loss studies, high baseline self-efficacy and increases in self-efficacy during the program have been shown to predict greater weight loss in study participants.[185, 186] Longitudinal studies are needed to determine if baseline self-efficacy also predicts weight loss over time in Asian Indians and if improvements in self-efficacy over time predict great changes in weight; data from the D-CLIP randomized trial can help answer these questions. Furthermore, research is needed in rural areas and other LMICs to determine if these findings are consistent across all populations and settings.

Although exceptions exist,[187] most studies show a positive association between exercise self-efficacy and lower weight.[183, 188, 189] In this study, exercise self-efficacy was not significantly related to baseline BMI, and the correlation with baseline waist circumference was no longer significant after adjustment for other variables, even though exercise self-efficacy significantly correlated with average minutes per week exercising. Although day-to-day physical activity is traditionally high in India, exercising for fitness or health is not a common concept. In this environment, measuring exercise self-efficacy using questions that are designed for societies where exercise is the cultural norm may not be appropriate. Further, the simple measure of exercise used in this study (average minutes per week), might have not been sufficient to truly capture exercise and cannot be used to stratify people based on day-to-day activity, which may be more important in this setting. Understanding the role of physical activity behaviors and views is important for effectively promoting physical activity to at-risk South Asians, particularly as leisure-time exercise will need to increase as day-to-day physical activity declines with increasing urbanization.[178]

This study has several weaknesses. First, the use of simple markers for fruit and vegetable consumption and, as mentioned above, physical activity, may not be accurate measures of these behaviors. Second, the measure of exercise did not take into account type of activity or intensity, which might affect the results. These findings should be verified using more rigorous measures of dietary intake and daily activity. In addition, the instruments used in this study to measure exercise and weight loss self-efficacy have not been specifically validated for this population; however, both have been used successfully in a variety of settings and populations,[190-197] and the WEL was used in the DPP study, which included a diverse study sample including South Asians.[181]

Despite these limitations, this study has at least three major strengths.

First, the study population is large, including over 1,200 individuals. Second, the study population is diverse and includes individuals across the spectrum of glucose intolerance with a range of educational levels and incomes. Third, there is a paucity of reported data on correlates of excess adiposity in the South Asian community, particularly in regards to psychosocial measures like self-efficacy, so this study fills a gap in the existing literature on the Asian Indian population.

Conclusion

Understanding the reasons for how and why people gain weight or maintain weight above public health recommendations, whether they are biological, behavioral, cultural, or psychosocial, is important for effectively reaching patients and populations. This study shows that health behaviors such as low fruit consumption, a history of unsuccessful weight loss, and low self-efficacy for weight loss are important associates of having a higher BMI or waist circumference in South Asians. Further studies are needed to gain a fuller picture of the psychosocial and behavioral factors influencing excess weight in this population and how the factors in this and other studies relate to weight gain or loss over time. India is undergoing demographic, nutritional, and epidemiological transitions, and these changes are particularly evident in urban environments.[198] The rates of overweight and obesity, and related health issues, are likely to rise. Responding now to find effective, culturally tailored tools for prevention of these conditions should be a public health priority.

Chapter 5 Tables and Figures

Table 4: Study sample characteristics: means and proportions for demographic and anthropometric variables in South Asian adults attending screening for the D-CLIP study

Variable	N (%) or Mean (SD) (N= 1,281)
Age (years)	44.31 (9.26)
Gender	
Male	815 (63.62%)
Female	466 (36.38%)
Highest level of school	
Primary school or less	118 (9.24%)
High school	365 (28.49%)
Undergraduate Degree/Technical School	465 (36.30%)
Post-graduate	329 (25.68%)
Monthly income (Indian Rupees)	
< 10,000	326 (25.45%)
10,000-15,000	244 (19.05%)
15,001-25,000	206 (16.08%)
25,001-35,000	163 (12.72%)
>35,000	203 (15.85%)
Marital Status	
Single, never married	85 (6.64%)
Married	1142 (89.15%)
Divorced/Separated	35 (2.73%)
Widowed	19 (1.48%)
Weight in kilograms	73.33 (11.70)
Body mass index in kg/m^2	27.40 (3.75)
Waist circumference in centimeters	
Male	97.06 (8.44)
Females	88.55 (8.45)

Table 5: Association of body mass index (BMI) and waist circumference (WC) with health beliefs and behaviors in South Asian adults attending screening for the D-CLIP study

	N (%)	Score Means ± SD	BMI R*	P**		WC R*	P**
Weight loss self-efficacy							
Total Score	1280 (99.9)	117.78 ± 38.50	-0.10	< 0.001		-0.09	< 0.001
Negative Emotions Scale		24.41 ± 9.25	-0.05	0.06		-0.07	0.02
Availability Score		21.94 ± 9.52	-0.12	<0.0001		-0.10	< 0.001
Social Pressure Score		23.11 ± 8.79	-0.12	<0.0001		-0.10	< 0.001
Physical Discomfort Score		24.59 ± 8.79	-0.05	0.09		-0.06	0.03
Positive Activities Score		23.73 ± 9.30	-0.06	0.02		-0.06	0.03
Exercise Self-Efficacy							
Sticking to it	1260 (98.4)	3.37 ± 1.03	-0.02	0.57		0.07	0.01
Making Time	1262 (98.5)	3.74 ± 1.01	-0.02	0.50		0.07	0.01
		BMI Means ± SD			**WC Means ± SD**		
Fruit Consumption							
0-2 days/week	418 (32.7)	27.71 ± 3.64	-0.07	0.01	94.74 ± 9.45	-0.06	0.02
3-5 days/week	661 (51.6)	27.36 ± 3.74			93.75 ± 9.22		
6-7 days/week	200 (15.7)	26.84 ± 3.93			93.02 ± 9.71		
Vegetable Consumption							
0-2 days/week	36 (2.8)	27.49 ± 3.58	-0.06	0.03	95.38 ± 11.96	-0.08	0.01
3-5 days/week	469 (36.7)	27.71 ± 3.70			94.82 ± 9.26		
6-7 days/week	772 (60.5)	27.20 ± 3.77			93.39 ± 9.27		
Past Weight Loss Experience							
Have not attempted weight loss	505 (39.5)	26.45 ± 3.67	0.20	<0.0001	91.87 ± 9.46	0.17	< 0.0001
Lost weight and maintained some or all of loss	218 (17.0)	27.10 ± 3.56			93.30 ± 8.68		
Lost weight but gained back some or all of loss	172 (13.5)	28.49 ± 3.48			97.52 ± 8.98		
Weight cycling	118 (9.2)	28.94 ± 3.70			95.23 ± 8.96		
Did not lose any weight	266 (20.8)	28.03 ± 3.72			95.50 ± 9.18		
Average Weekly Exercise							
0-29 minutes	668 (52.3)	27.47 ± 3.66	-0.04	0.16	93.23 ± 9.48	0.07	0.01
30-89 minutes	163 (12.8)	27.79 ± 3.97			94.78 ± 8.63		
90-149 minutes	139 (10.9)	27.08 ± 3.92			94.74 ± 10.20		
150 minutes or more	308 (24.1)	27.17 ± 3.73			94.75 ± 9.05		

*Pearson Correlation Coefficients. **P value for significant of correlation between BMI or waist circumference and variable of interest.

Table 6: Pearson Correlation Coefficients for associations between independent variables in South Asian adults attending screening for the D-CLIP study

	WEL Negative[2]	WEL Availability[2]	WEL Pressure[2]	WEL Discomfort[2]	WEL Activities[2]	Sticking to It[3]	Making Time[3]	Fruit intake	Vegetable Intake	Weight loss history	Exercise minutes/ week
WEL[1] Total	0.84*	0.83*	0.85*	0.84*	0.86*	0.27*	0.27*	0.07#	0.12*	-0.02	0.03
WEL Negative[2]		0.54*	0.60*	0.75*	0.64*	0.15*	0.18*	0.03	0.10^	-0.02	-0.02
WEL Availability[2]			0.72*	0.53*	0.69*	0.27*	0.24*	0.06#	0.12*	-0.03	0.03
WEL Pressure[2]				0.63*	0.66*	0.24*	0.25*	0.05	0.10^	-0.05	0.03
WEL Discomfort[2]					0.66*	0.20*	0.21*	0.06#	0.08^	-0.01	0.03
WEL Activities[2]						0.28*	0.28*	0.10^	0.11*	0.01	0.06#
Sticking to it[3]							0.73*	0.09^	0.08^	0.10^	0.26*
Making Time[3]								0.11^	0.10^	0.13*	0.26*
Fruit Intake									0.22*	0.02	0.19*
Vegetable Intake										0.01	0.07#
Past Weight Loss Experience											0.18*

1. Weight Efficacy Life-style Questionnaire total score.[176] 2. Weight Efficacy Life-style Questionnaire subscale scores.[176] 3. Subscales of the exercise self-efficacy instrument.[175] * P<0.0001 ^<0.005 # <0.05

Table 7: Beta Coefficients and F statistics for bivariate models using BMI or waist circumference as outcomes in South Asian adults attending screening for the D-CLIP study

	BMI			Waist Circumference		
Independent Variable	**F (p)**	**Beta (p)**		**F (p)**	**Beta (p)**	
Age	4.72 (0.03)	-0.02 (0.03)		2.06 (0.15)	0.04 (.15)	
Gender (Male = referent)	85.02 (<.0001)	1.95 (>0.0001)		301.43 (<.0001)	-8.51 (<.0001)	
Education (postgraduate = referent)	3.23 (0.02)	Primary	0.62 (0.12)	4.45 (0.004)	Primary	-2.85 (0.01)
		High School	0.28 (0.53)		High School	-1.95 (0.01)
		Undergraduate/Technical	0.42 (0.12)		Undergraduate/Technical	-0.52 (0.44)
Household Income, Rs./Month (>35,000 = referent)	2.95 (0.01)	<10,000	0.62 (0.10)	3.20 (0.01)	<10,000	-0.20 (0.83)
		10,000-15,000	0.59 (0.14)		10,000-15,000	0.20 (0.84)
		15.001-25,000	1.30 (0.002)		15.001-25,000	-0.73 (0.48)
		25,001-35.000	1.01 (0.02)		25,001-35.000	1.92 (0.08)
Marital Status (Widowed = referent)	3.06 (0.03)	Single	-0.74 (0.44)	2.52 (0.06)	Single	0.45 (0.85)
		Married	0.34 (0.70)		Married	2.15 (0.32)
		Divorced/Separated	1.29 (0.22)		Divorced/Separated	-1.24 (0.64)
Fruit Intake, times/week (6-7 = referent)	3.65 (0.03)	0-2	0.86 (0.007)	2.61 (0.07)	0-2	1.72 (0.03)
		3-5	0.52 (0.09)		3-5	0.73 (0.34)
Vegetable Intake, times/week (6-7 = referent)	2.75 (0.06)	0-2	0.29 (0.64)	3.79 (0.02)	0-2	1.99 (0.21)
		3-5	0.51 (0.02)		3-5	1.42 (0.01)
Weight Loss Experience (Attempted, but did not lose weight = referent)	20.02 (<0.0001)	Have not attempted	-1.58 (<0.001)	15.78 (<0.0001)	Have not attempted	-3.63 (<0.001)
		Lost and maintained loss	-0.93 (0.01)		Lost and maintained loss	-2.20 (0.01)
		Lost weight but regained	0.45 (0.20)		Lost weight but regained	2.01 (0.02)
		Weight cycling	0.91 (0.02)		Weight cycling	-0.27 (0.79)
Exercise Self-Efficacy – Sticking to It	0.32 (0.60)	-0.06 (0.57)		6.52 (0.01)	0.65 (0.0108)	
Exercise Self-Efficacy – Making Time	0.45 (0.50)	-0.07 (0.50)		6.93 (0.01)	0.68 (0.009)	
Weight Loss Self-Efficacy	11.81 (0.001)	-0.01 (0.006)		10.96 (0.001)	-0.02 (0.001)	
Minutes/Week Exercising (>150 min/week = referent)	1.39 (0.24)	0-29 minutes	0.31 (0.24)	2.82 (0.04)	0-29 minutes	-1.52(0.02)
		30-89 minutes	0.62 (0.09)		30-89 minutes	0.03 (0.97)
		90-149 minutes	-0.09 (0.82)		90-149 minutes	-0.01 (0.99)

Figure 1: Influence of behavioral and personal factors on body mass index (BMI) in South Asian adults attending screening for the D-CLIP study

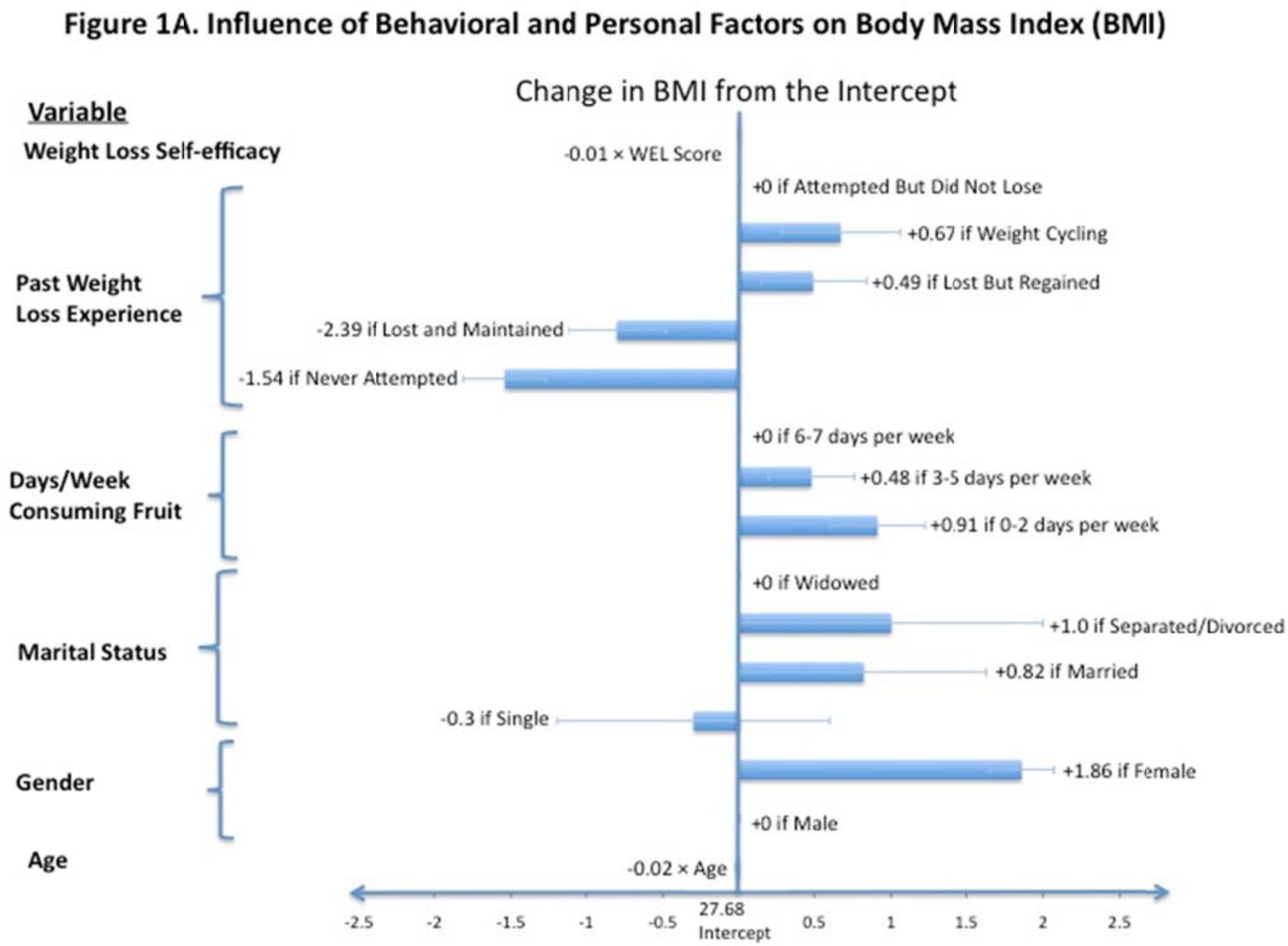
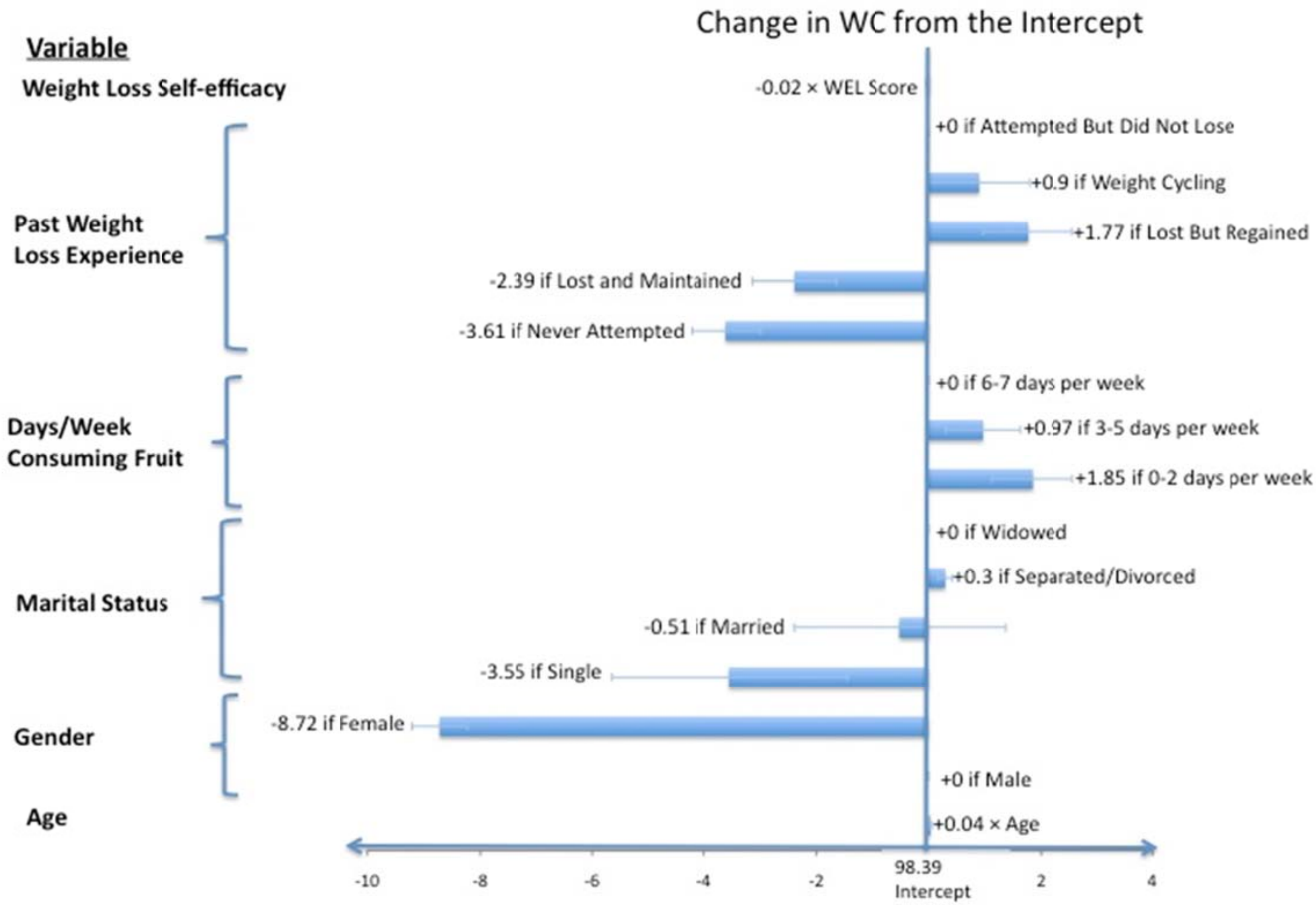


Figure 2: Influence of behavioral and personal factors on waist circumference (WC) in South Asian adults attending screening for the D-CLIP study



CHAPTER 6: Changes in Anthropometric Measurements in Asian Indians Enrolled in a Lifestyle Intervention Program: Six Month Results of the D-CLIP Trial

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Abstract

The Diabetes Community Lifestyle Improvement Program (D-CLIP) is a randomized, controlled, translation trial in Chennai, India testing a step-up model of diabetes prevention (six months of weekly lifestyle classes plus metformin for those not responding by four months). Mixed methods modeling was used to compare change over time for weight, waist circumference, or BMI in control (n = 304) and intervention participants (n = 294), and heterogeneity in the effect of the intervention on each outcome by age category, BMI category, glucose intolerance category, education, income, and gender was evaluated. Mean decreases in waist circumference, weight, and BMI between months 0 and 6 were as follows: for controls, 1.58 cm, 0.73 kg, and 0.31 kg/m^2, respectively; and, for intervention participants, 3.72 cm, 2.86 kg, and 1.05 kg/m^2, respectively. Change in all anthropometric outcomes between 0 and 6 months was significantly greater in intervention participants than in controls ($p < 0.0001$ for all outcomes). Results were consistent across sub-groups of the study populations, except that

intervention participants with isolated impaired fasting glucose (IFG) at baseline showed significantly greater reductions in waist circumference than individuals with isolated impaired glucose tolerance (IGT) or IGT+IFG ($p = 0.02$, change in waist circumference: iIFG 4.33 cm, iIGT 2.58 cm, IFG+IGT 4.04 cm). Six-month results from the D-CLIP trial show participation in a low-cost, culturally tailored lifestyle program for diabetes prevention can help Asian Indians at high risk for diabetes to lose weight and decrease waist circumference.

Introduction/Background

Risk of diabetes increases with increasing body mass index (BMI).[55] Independent of BMI category, waist circumference, an indirect measure of visceral fat, has been shown to be strongly associated with increased risk of impaired fasting glucose (IFG), a precursor and risk factor for diabetes.[199] Conversely, decreases in weight and waist circumference are associated with diabetes prevention. The US Diabetes Prevention Program (DPP) and the Finnish Diabetes Prevention Study (DPS) show that diabetes prevention can be achieved through promoting weight loss.[106, 107, 109] In the DPP, a multi-center study which included participants from multiple race-ethnic groups and across ages, reductions in weight, BMI, and waist circumference significantly predicted diabetes reduction,[124] and weight loss was determined to be the most important factor in reducing diabetes incidence.[13]

The Diabetes Community Lifestyle Improvement Program (D-CLIP) is an on-going, randomized, controlled, translation trial in Chennai, India comparing standard of care for diabetes prevention and a step-up, diabetes-prevention program.[174] India has the second-highest number of cases of diabetes of any country in the world,[1] with diabetes affecting Indians at younger ages and lower BMIs than other populations.[8, 9, 35, 85] The D-CLIP translational research study seeks to mitigate the disproportionate diabetes risk in this population.

The D-CLIP lifestyle intervention program was developed by modifying the DPP curriculum to be culturally appropriate, so it may be possible that weight loss or changes in BMI or waist circumference in D-CLIP are harbingers of reductions in diabetes incidence. It is therefore important to assess changes in these measures in the D-CLIP study population at the end of the lifestyle class period (month 6 of study enrollment). The aims of this manuscript are to: (1) assess the ability of the D-CLIP lifestyle program to enable participants to lose weight, decrease BMI, and reduce their waist circumference by comparing changes in these measures over the first six months of the study in participants in the standard of care and intervention arms of the trial; and (2) test the effectiveness of the program for weight loss in different subgroups of the study population by looking for heterogeneity in changes in waist circumference, weight, and BMI in intervention and control group participants by the following variables: gender, age category, education level, household income, BMI level, and level of glucose intolerance.

Research Design and Methods

Study Participants and Procedures

The methods for the D-CLIP study have been described elsewhere.[174] Briefly, the D-CLIP trial is an ongoing, randomized study comparing diabetes incidence (the primary outcome) and changes in glucose, lipids, anthropometry, and self-reported diet and physical activity in participants receiving standard of care treatment and participants enrolled in a step-up, lifestyle intervention program adapted from the DPP.[114, 139] The lifestyle intervention includes six months of lifestyle education (four months of active classes teaching skills for behavior change and two months of classes on maintaining behavior change) focusing on weight loss, increasing physical activity, and reducing dietary fat intake and, for participants who remain at highest risk of conversion to diabetes at four months or later, metformin prescribed at 500 mg twice per day. The Emory Institutional Review Board and the Madras Diabetes Research Foundation's Ethical Committee approved the D-CLIP study protocol. All subjects provided informed consent at each of two screening visits and before randomization into the trial.

Almost 20,000 individuals were screened in the community and, of these, 1,281 were invited for clinic-based screening to identify a sample of 599 overweight (BMI ≥ 23 kg/m^2 and/or a waist circumference of >80 cm in women or >90 cm in men) men and women with isolated impaired glucose tolerance (iIGT), isolated impaired fasting glucose (iIFG), or both (IFG+IGT) for randomization into the study. This analysis includes testing data entered up until January 1, 2012.

Data Collection

Testing was conducted at the Translational Research Center at MDRF. All staff were trained in proper collection methods, and the study testing staff included dieticians, health educators, and phlebotomists. Data collection methods pertinent to this analysis are described below.

Demographic information (e.g. age, gender, monthly household income, highest education obtained) was self-reported at baseline. Age categories were created in 15-year increments (20-35 years, 36-50 years, and 50 years or higher); these age divisions were selected to correspond to differences in life stage and behaviors, which could affect weight outcomes.

Height, weight, and waist circumference were measured at baseline, month four (at the end of the active intervention classes), and month six (at the end of maintenance classes). Height in meters was measured barefoot using a standardized stadiometer, and body weight in kilograms was measured using a standardized, calibrated scale after the participant removed shoes and any heavy clothing or jewelry. BMI was calculated by dividing the weight in kilograms by the height in meters squared. Waist circumference was measured while participants were standing using a non-elastic measuring tape at the midway point between the lowest point of the costal margin and the highest point of the iliac crest.[177] BMI categories were created for analysis as follows, corresponding to Asian-specific cut-points for overweight/obesity:[173] (1) normal BMI, which included individuals with a BMI of 22 kg/m^2 or less; (2) overweight BMI, which included individuals with a BMI of 23-27.5 kg/m^2; and (3) obese BMI, which included individuals with a BMI of greater than 27.5 kg/m^2.

Glucose was measured fasting and at two-hours during a 75-gram oral glucose tolerance test at baseline. Glucose categories were defined as follows: iIFG included participants with a fasting plasma glucose of 100-126 mg/dl (six individuals had fasting plasma glucose levels of 126 mg/dl); iIGT included participants with a 2-hour, post-load glucose of 139-200 mg/dl (two individuals had 2-hour glucose levels of 200 mg/dl, and one had a 2-hour glucose of 139 mg/dl); and IGT+IFG included individuals with both IGT and IFG or a fasting glucose of 127 mg/dl (N = 1) or a 2-hour glucose of 201-205 mg/dl (N = 14).

As shown above, 24 individuals with glucose levels above the diabetes cut-off and one with normal glucose tolerance were randomized into the study. All analyses were conducted with and without these individuals. In addition, one hundred and one participants were missing test results for both the four and six month visits. This is because the data had not been entered/collected at the time of analysis or the participant did not return to the clinic for either visit. All analyses were run with and without these individuals.

Data Analysis

All analyses were carried out using the SAS program (Version 9.3, Cary, NC). First, success of randomization was evaluation by comparing the means (using paired t-tests) or proportions (Mantel-Haenszel chi-square tests or ANOVA) of key demographic and clinical variables between participants in the intervention and standard of care control study arms. The outcomes of interest for the analysis in this paper were study arm differences in waist circumference, weight, and BMI, measured at zero, four, and six months. Change in waist circumference, weight, and BMI in intervention and control participants was calculated by subtracting the six-month value from the baseline value, and the mean change for each measurement was compared across income level, education, gender, BMI level, and level of glucose intolerance using an ANOVA or a Mantel-Haenszel chi-square test. Mixed methods models (using SAS's proc mixed function) were run to assess change over time for each study outcome comparing controls and intervention participants. Heterogeneity in the effect of intervention arm on each outcome by age category, BMI level, glucose intolerance level, education, monthly household income, and gender was evaluated by adding these variables to the model individually and testing the three-way interactions between study arm, time, and each individual factor.

Results

The study population is described in Table 8 (page 86). This analysis included 599 study participants, 304 randomized to the standard of care arm (control) and 295 randomized to receive the lifestyle intervention program. There was no significant difference between study arms for distribution or means of age, gender, education level, monthly household income, level of glucose intolerance, or anthropometric measurements. Eighty-three percent (N=498) of the 599 participants returned for either the four or six month testing visit, and 395 participants (66%) attended both the four and six month visits. The attendance rate for intervention arm participants was 83%.

When the analyses were run with or without individuals with missing data from months four and six or individuals with glucose levels outside of the pre-diabetes cut-offs, there was only a very small difference in the magnitude of results, and no difference in direction or significance level, so the results reported in this chapter include the full sample.

Mean decreases in waist circumference, weight, and BMI between months zero and six were as follows: for controls, 1.58 cm, 0.73 kg, and 0.31 kg/m^2, respectively; and, for intervention participants, 3.72 cm, 2.86 kg, and 1.05 kg/m^2, respectively (Figure 3, pages 87-89). Means did not differ significantly between subgroups of the study population except for the following: change in waist circumference, weight, and BMI each differed significantly by glucose intolerance categories in the intervention arm participants (change in waist circumference: iIFG 4.33 cm, iIGT 2.58 cm, IFG+IGT 4.04 cm, $p = 0.03$; change in weight: iIFG 3.30 kg, iIGT 2.09 kg, IFG+IGT 3.05 kg, $p = 0.02$; change in BMI: iIFG 1.20 kg/m^2, iIGT 0.77 kg/m^2, IFG+IGT 1.14 kg/m^2, $p = 0.03$); mean change in BMI was significantly higher in females in the intervention arm (change in BMI: females 1.30 kg/m^2, males 0.92 kg/m^2, $p = 0.01$); and changes in BMI and weight were significantly higher in females than males in the control arm (change in BMI: females 0.50 kg/m^2, males 0.18 kg/m^2, $p < 0.001$; change in weight: females 1.29 kg, males 0.37 kg, $p = 0.03$).

Changes in waist circumference, weight, and BMI in months zero, four, and six of the D-CLIP trial for standard of care and intervention participants are shown in Figure 4 (page 90). Mixed methods model testing indicated that the interaction of study arm by time was significant in all outcomes ($F [2, 597] = 16.42$, $p < 0.0001$ for waist circumference, $F [2, 890] = 31.72$, $p < 0.0001$ for weight, and $F [2, 597] = 31.63$, $p < 0.0001$ for BMI). These results show that participants in the lifestyle intervention program had significantly greater losses in BMI, waist circumference, and weight loss in the first six months of the D-CLIP trial compared to participants in the control arm. In models including gender, monthly income, education, glucose intolerance level, BMI level, or age category, three-way interactions between the variable, study group, and time, were tested. The only significant interaction found was the interaction between study arm, time, and glucose intolerance group in the model predicting change in waist circumference ($F [94, 593] = 2.82$, $p = 0.02$), indicating that change in waist circumference depends on study arm, time in the study, and initial glucose intolerance level.

Figure 5 (page 91) shows a more dramatic reduction in waist circumference in intervention arm participants with iIFG than other subgroups. Baseline weight, BMI, and waist circumference were lower, but not significantly lower, in individuals with iIFG than in participants in the other glucose intolerance groups; however, the distribution of people by BMI category differed significantly by glucose intolerance level (Mantel-Haenszel chi square test p-value = 0.02). Participants in the iIFG group were more often in the overweight BMI category (60.2% of iIFG participants were overweight while 34.4% were obese) compared to participants in the iIGT or IFG+IGT groups who were more often obese (57.0% in the iIGT group and 55.1% in the IFG+IGT group were obese and 38.4% and 38.8%, respectively, were in the overweight BMI category).

Discussion

Results from the D-CLIP trial at six months show that a low-cost, group-based diabetes prevention program, based on the US DPP, can successfully educate Asian Indians in Chennai, India at high risk of developing diabetes to lose weight and decrease waist circumference. This study is the first large randomized trial to include not only individuals with IGT, but also those with isolated IFG. Thus, findings of the D-CLIP trial add to the literature on diabetes prevention by showing the effects of lifestyle education on the broader at-risk population.

At six months, participants in the D-CLIP lifestyle intervention showed significant improvements in weight, waist circumference, and BMI compared to the control participants, losing an average of 2.86 kg of weight, 1.05 kg/m^2 of BMI, and 3.72 cm of waist circumference. By month six, intervention participants lost four times more weight, two times more waist circumference, and three times more BMI than control participants. Control participants also showed a decrease in measures of adiposity in the first six months of the study, but these values seemed to be increasing in months four to six. The improvement in these measures in the control participants may therefore reflect short-term behavioral improvements brought on by the control treatment and being a participant in a diabetes-prevention trial.

Only the DPP, a study population with baseline BMI of 34.0 kg/m^2, reported weight loss at six months; participants in the DPP lifestyle intervention lost approximately seven kg at month six (control participants' weight loss was close to zero kg).[109] Changes in measures of adiposity in the major diabetes prevention lifestyle trials at one year are shown in Figure 6 (page 92). Weight loss (2.9 kg) and percent weight loss (3.8%) in the D-CLIP lifestyle intervention participants were less than that seen in the DPP or the DPS (7 kg, 7% and 4.2 kg, 4.7%, respectively);[109, 200] however, mean weight and BMI were lower in D-CLIP participants at baseline, so a smaller weight loss may be more attainable. In diabetes prevention studies in Asian populations in India, China, and Japan,[12, 99, 104] weight loss was similar to or less than that seen in D-CLIP. Even with no weight loss, the IDPP and the Da Qing study showed significant reductions in diabetes incidence.[12, 99] If weight loss is an important factor in diabetes prevention in Asian populations, the D-CLIP study with a small, but significant weight loss in intervention participants, might reduce diabetes incidence to a larger degree than other studies in Asian populations. Furthermore, D-CLIP intervention participants displayed a decrease in waist circumference (3.7 cm) at six months that exceeds the one-year loss in waist circumference in the DPP (2.7 cm).[124] In Asian Indians, abdominal adiposity is common and can present at lower BMIs than in other ethnicities,[2] so a decrease in waist circumference might be a better representation of loss of adiposity than weight.

Interactions between study group and gender, monthly income, education, glucose intolerance level, baseline BMI level, or age category were not significant for any of the outcomes, indicating that the effects of the intervention on adiposity outcomes did not differ in any of these sub-groups. However, the magnitude of change in the outcome measures was affected by some of these variables. In the intervention arm, the decrease in BMI was significantly greater in females (1.30 kg/m^2) than in males (0.92 kg/m^2), and intervention females had greater losses in BMI (0.50 kg/m^2) and weight (1.29 kg) than control males (0.18 kg/m^2 and 0.37 kg). This may indicate greater improvements in behavior change (higher calorie or fat reduction or higher increases in physical activity) in women, even with only minimal health education, although this needs to be confirmed with further analysis.

The change in all outcomes in the intervention arm differed significantly based on baseline glucose intolerance level with participants with iIGT showing the least improvement of any group in terms of weight, waist circumference, or BMI. Furthermore, baseline glucose level modified the relationship between waist circumference and study group, whereby intervention arm participants with iIFG lost more waist circumference than the other groups. These results may indicate that glucose level plays an important role in weight loss in this population, with individuals with more advanced glucose intolerance or established insulin resistance have a greater difficulty with weight loss. If so, this might indicate that weight loss interventions should be instigated earlier in the natural history of diabetes in the South Asian populations. Alternatively, this could be due to difference in baseline adiposity by glucose level. Participants with iIFG in this study had smaller mean weight, waist circumference, and BMI than individuals with iIGT or IGT+IFG and were more often overweight than obese. In this population, participants who are more obese may find weight loss more difficult.

The D-CLIP study has several strengths. First, it is a large, well-randomized, trial with high attendance rates at follow-up testing and intervention classes. Second, D-CLIP is testing a culturally tailored lifestyle program for diabetes prevention in Asian Indians, a high-risk population. Third, recruitment was community-based,[201] and the study includes individuals in the full range of pre-diabetes, iIFG, iIGT, and IFG+IGT, so findings can be applied to the larger at-risk population. Finally, lessons learned from this study may be applied to other populations, particularly in Asia, where diabetes risk begins to increase at lower BMIs and where the nutrition transition and economic changes are creating environments that are more obesogenic.[178, 198]

This analysis has two major weaknesses. First, because of the close proximity in time of the study visits (months zero, four, and six), some individuals were unwilling to attend both follow-up visits, and so some participants are missing data at these time points. The use of mixed methods modeling with SAS's proc mixed function, however, allows for individuals to have missing data at any time point without removing the entire subject from the analysis, so the effects on the results should be minimal. Furthermore, analyses run without individuals missing data for both visits four and six had results that were nearly identical to those including the entire sample. Second, a few individuals (n=24) with glucose levels outside of the diabetic range were accidentally included in the trial; however the results of analyses excluding these people were not different than those reported here.

Conclusion

Initial weight loss in lifestyle trials, even as early as six months, has been shown to be an important predictor of program success and retention.[202] Results from other diabetes prevention trials worldwide show that lifestyle change, with or without weight loss, can prevent diabetes; however, programs with weight loss showed the largest reduction in diabetes incidence.[106, 109] Initial reductions in weight and waist circumference in the D-CLIP study population show that the lifestyle program can successfully lead to changes in behavior in the Asian

Indians and might be an important first step towards reducing diabetes incidence in this high-risk population.

Chapter 6 Tables and Figures

Table 8: Baseline characteristics of D-CLIP study participants (N=599)

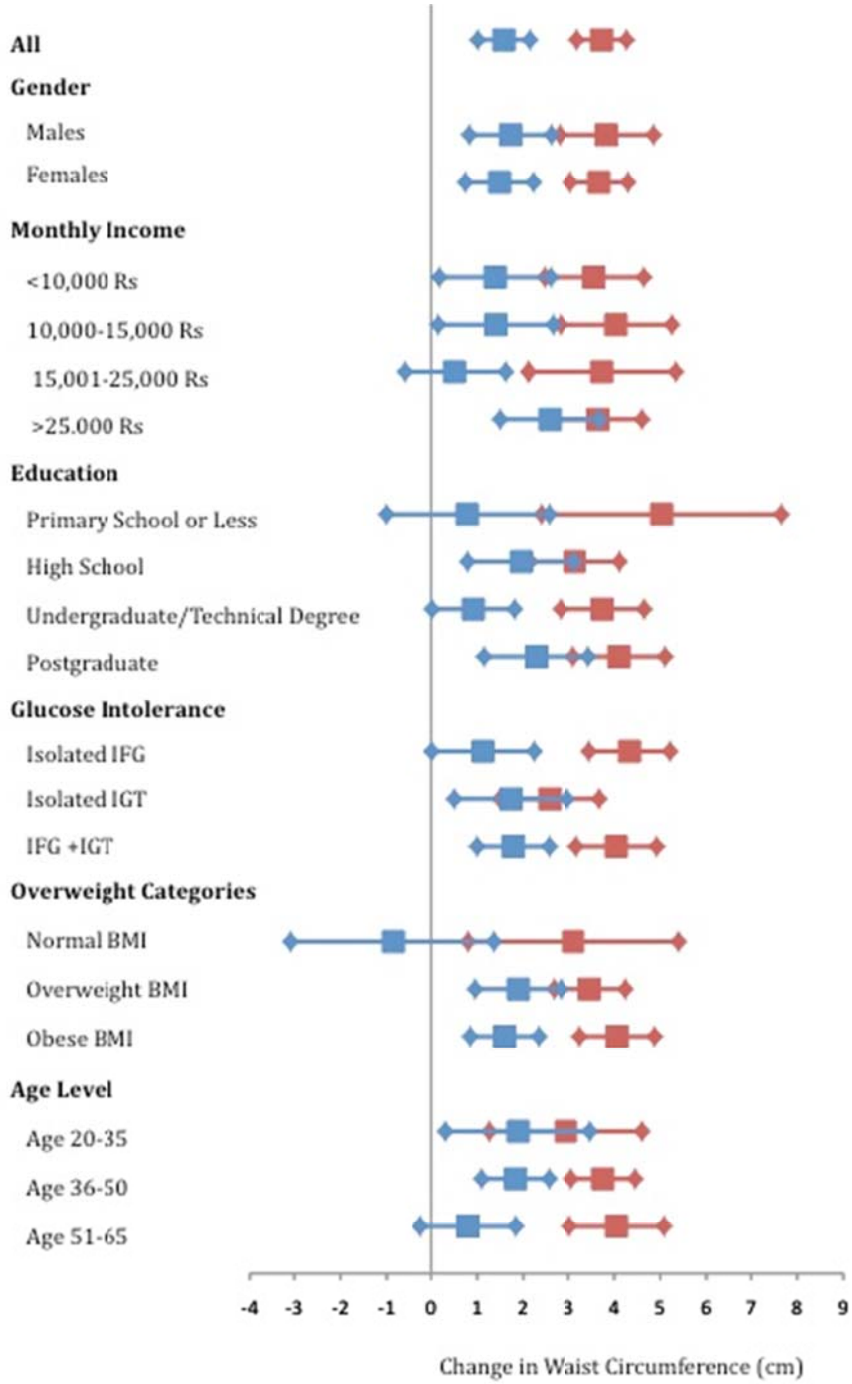
Variable	Standard of Care N = 304	Intervention N = 295
	N (%) or Mean ± SD*	
Age (years)	43.80 ± 9.33	44.48 ± 9.05
20-35 years	61 (20.1%)	50 (17.0%)
36-50 years	169 (55.6%)	166 (56.3%)
51-65 years	74 (24.3%)	79 (26.8%)
Gender –percent male	194 (63.8%)	188 (63.7%)
Education Level		
Primary School or Less	28 (9.2%)	22 (7.5%)
High School	85 (28.1%)	94 (31.9%)
Undergraduate/Technical Degree	111 (36.6%)	102 (34.6%)
Postgraduate	79 (26.1%)	77 (26.1%)
Household Income:		
<10,000 rupees/month	72 (25.6%)	81 (30.5%)
10,000-15,000 rupees/month	57 (20.3%)	63 (23.7%)
15,001-25,000 rupees/month	60 (21.4%)	40 (15.0%)
>25.000 rupees/month	92 (32.7%)	82 (30.8%)
Mean Waist Circumference (cm)	94.88 ± 8.60	94.63 ± 9.50
Mean Weight (kg)	74.72 ± 11.28	74.53 ± 11.34
Mean BMI (kg/m^2)	27.77 ± 3.64	27.92 ± 3.71
Overweight Categories		
Normal BMI	18 (5.9%)	16 (5.4%)
Overweight BMI	139 (45.7%)	134 (45.4%)
Obese BMI	147 (48.4%)	145 (49.2%)
Glucose Intolerance Level**		
Isolated IFG	87 (28.6%)	93 (31.5%)
Isolated IGT	88 (29.0%)	86 (29.2%)
IGT+IFG	129 (42.4%)	116 (39.3%)

* There is no significant difference between standard of care and intervention participants for any variables.

** The following people with glucose levels outside of the pre-diabetes range were included: in the isolated IFG group, six individuals with fasting plasma glucose of 126 mg/dl were included; in the isolated IGT group, one individual with a 2-hour plasma glucose of 139 mg/dl and two individuals with 2-hour plasma glucose of 200 mg/dl were included; and in the IGT+IFG group, one individual with a fasting plasma glucose of 127 mg/dl and fourteen individuals with 2-hour plasma glucose of 201-205 mg/dl were included.

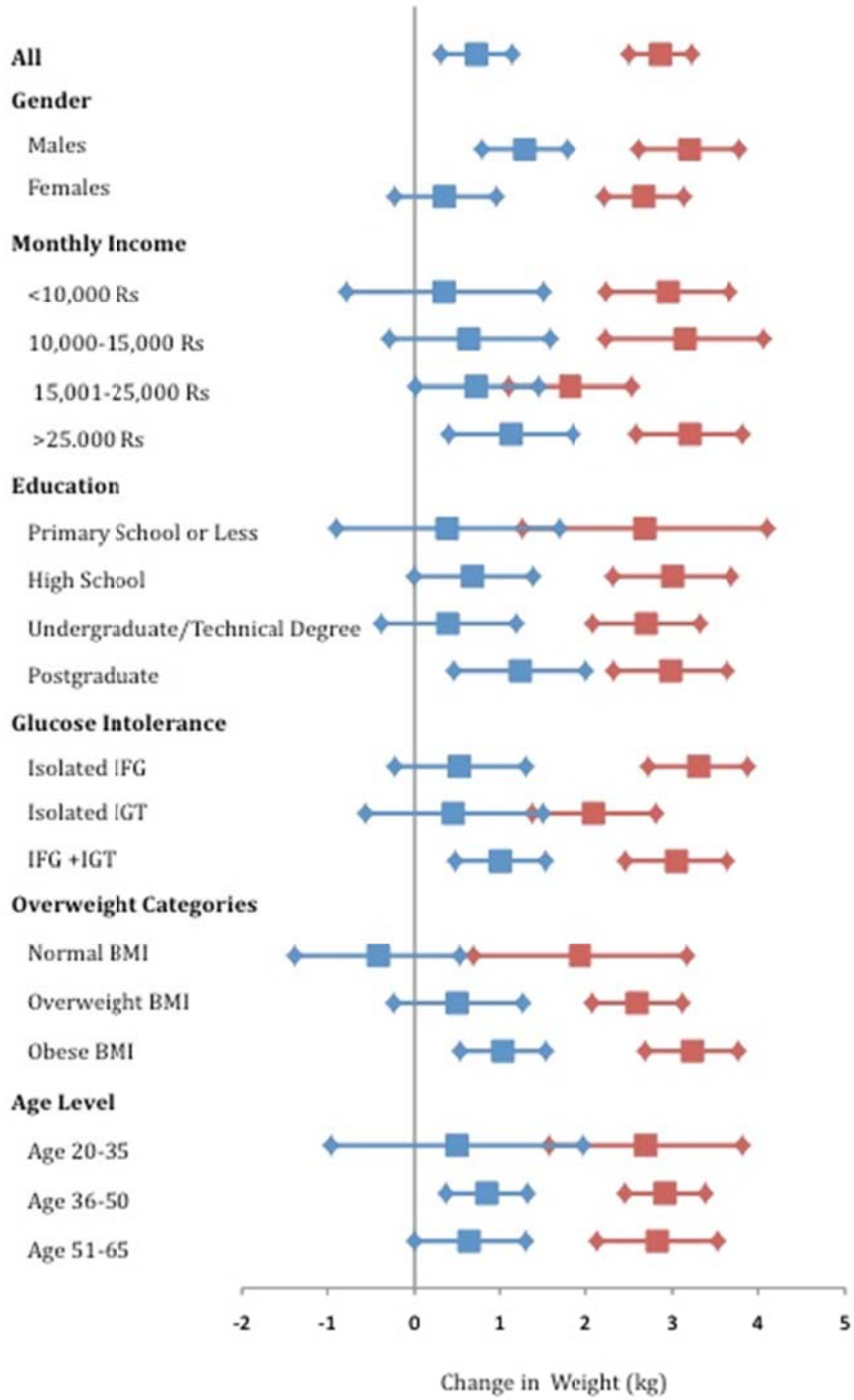
Figure 3: Plot of heterogeneity in change in waist circumference, weight, and BMI in controls and intervention participants from 0 to 6 months in subgroups of the D-CLIP study population

3A: Waist circumference means and 95% confidence intervals for control (blue) and intervention (red) participants*



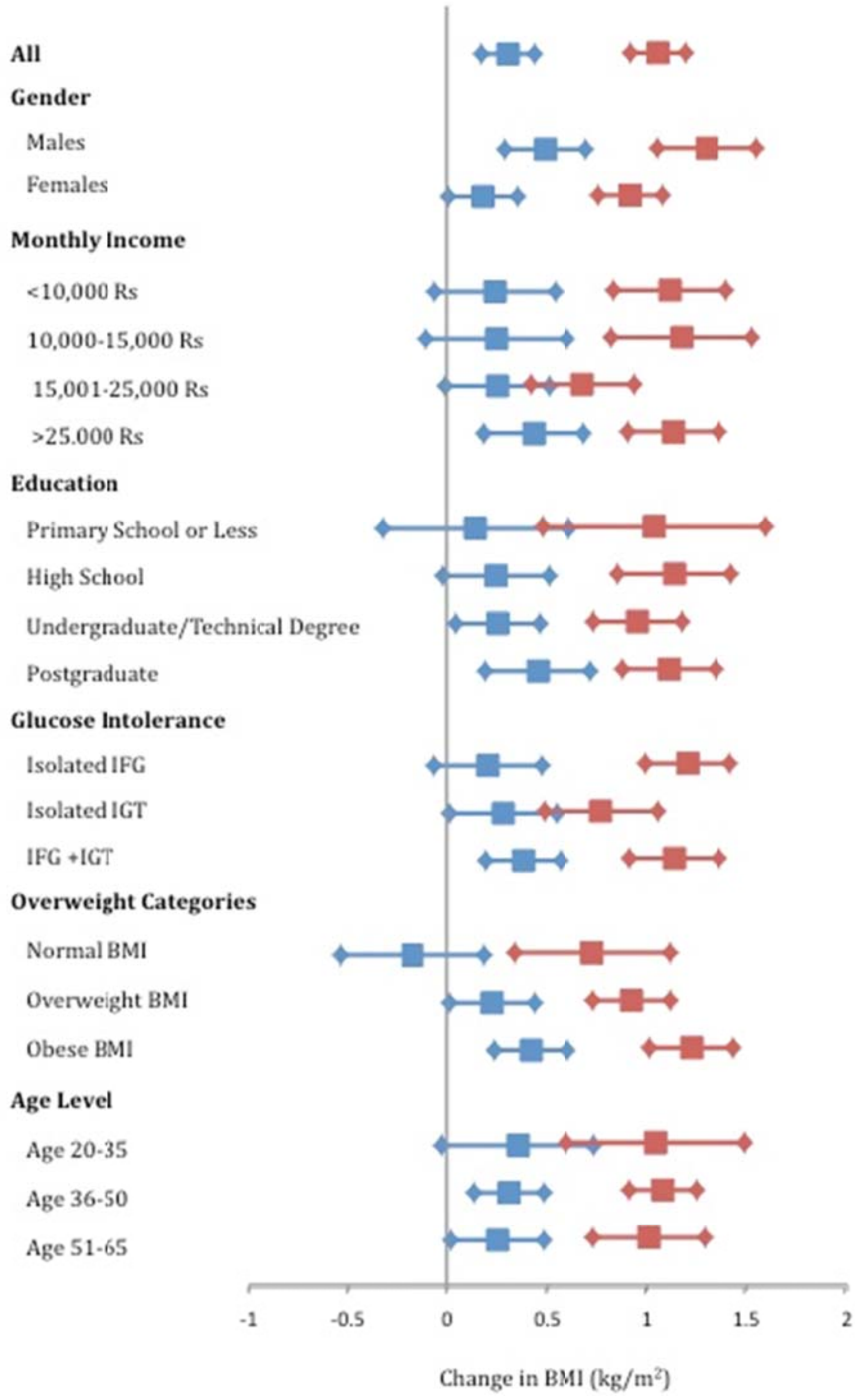
* Mean change in waist circumference differs significantly by glucose intolerance level (p = 0.03) in the intervention participants. Other subgroup means did not differ significantly for control or intervention arm participants.

3B. Weight means and 95% confidence intervals for control (blue) and intervention (red) participants**



** Among intervention arm participants, there was a significant difference in change in weight between glucose intolerance categories (p = 0.02). Weight differed significantly by gender in controls (p = 0.02). Other subgroup means did not differ significantly for control or intervention arm participants.

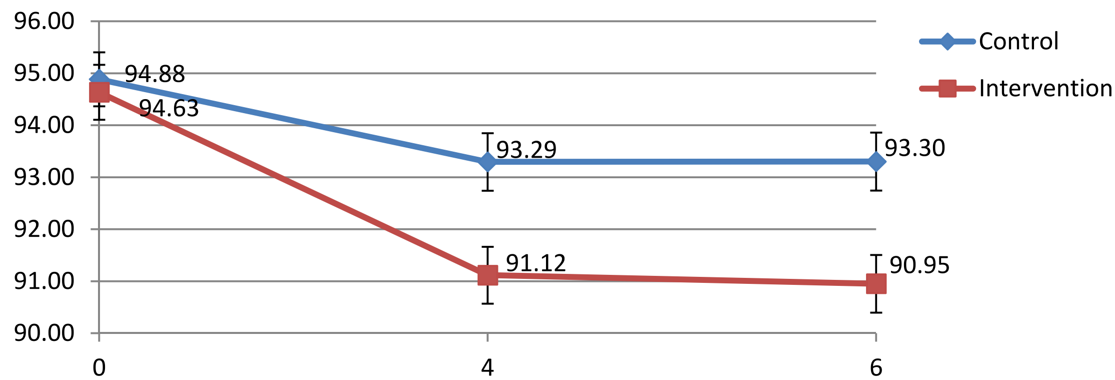
3C. BMI means and 95% confidence intervals for control (blue) and intervention (red) participants***



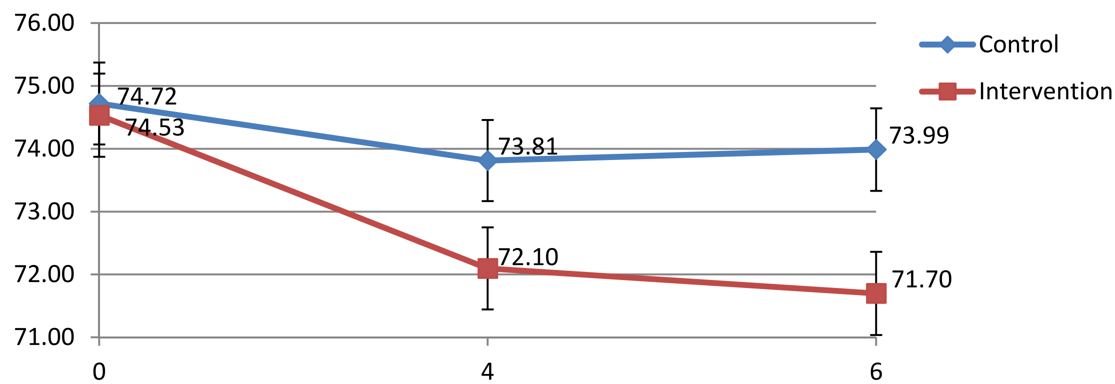
***Mean change in BMI differed significantly by gender in controls (p = 0.02) and intervention participants (p = 0.01) and among glucose intolerance groups (p = 0.03) in the intervention arm participants. Other subgroup means did not differ significantly for control or intervention arm participants.

Figure 4: Changes in outcome measures during months 0-6 in D-CLIP participants*

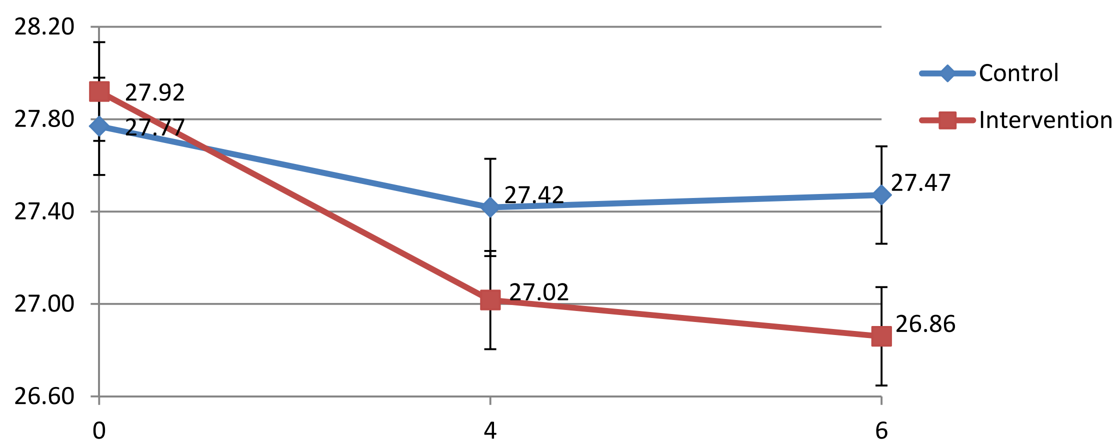
4A: Waist Circumference



4B: Weight

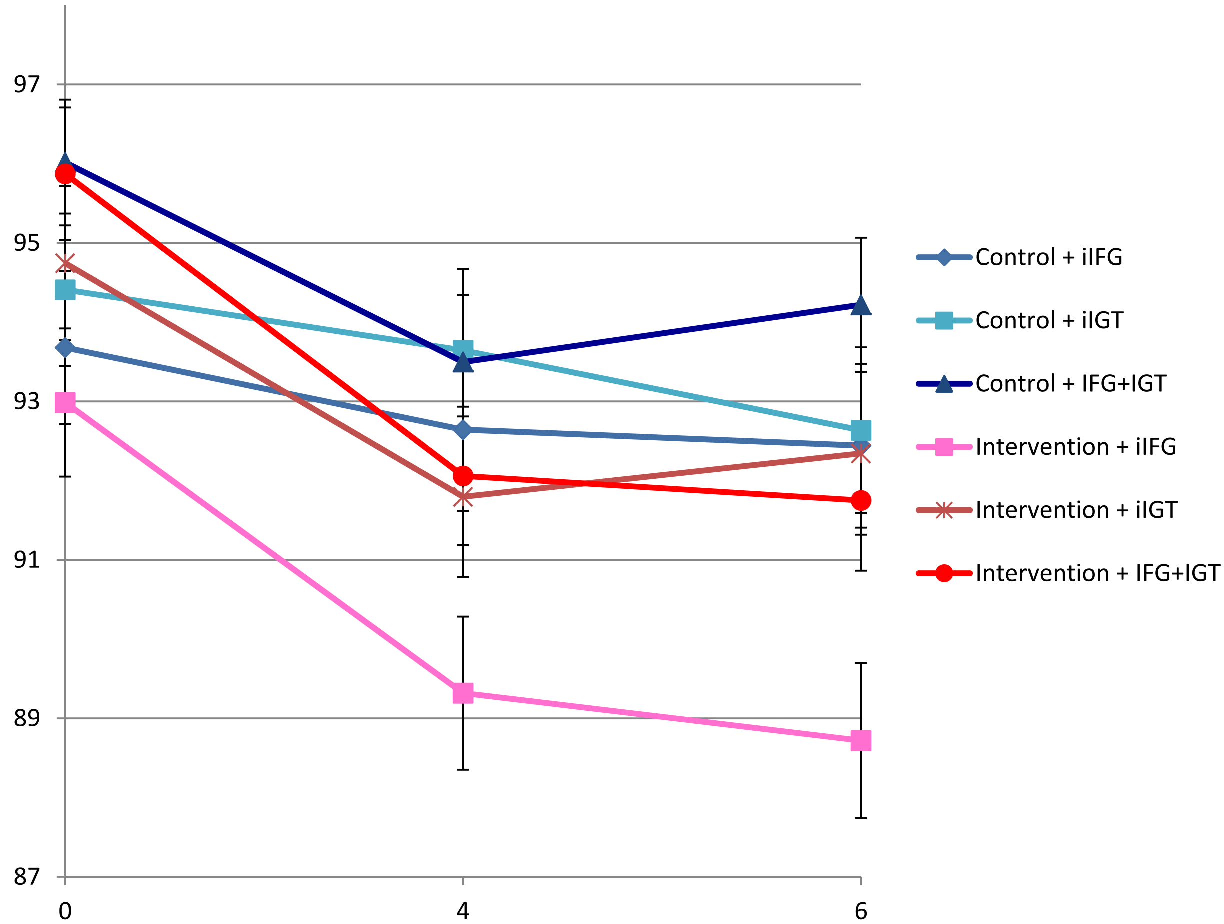


4C: BMI



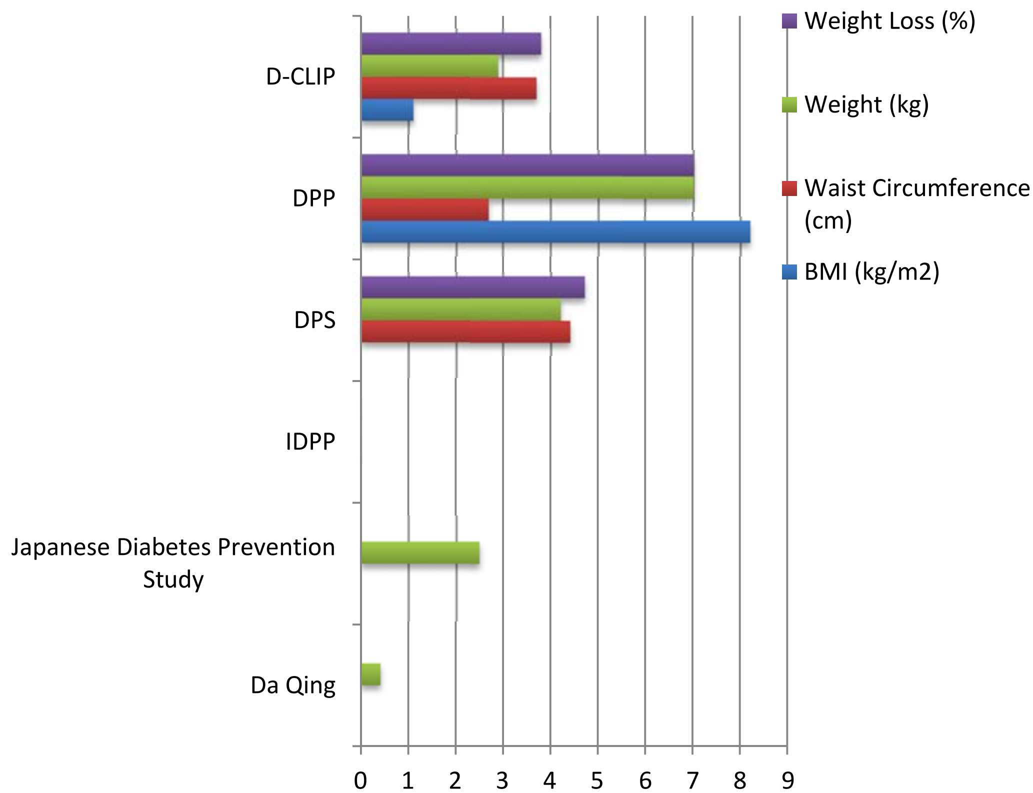
*At each time point, the least squares mean is shown with error bars representing the standard error.

Figure 5: Change in waist circumference during months 0-6 by glucose intolerance groups for intervention and control participants in the D-CLIP trial



*At each time point, the least squares mean is shown with error bars representing the standard error.

Figure 6: Change in measures of adiposity in lifestyle participants in D-CLIP at six months and other major diabetes prevention trials at one year



*Weight loss for the DPP (Diabetes Prevention Program) was from Knowler WC, et al. NEJM. 2002;346:393-403.[109] Changes in BMI and waist circumference were from Fujimoto WY, et al. Diabetes. 2007;56:1680-1685.[124] Data for the DPS (Diabetes Prevention Study) were from Tuomilehto J, et al. NEJM. 2001;344:1343-1350.[200] Data for the IDPP (Indian Diabetes Prevention Programme) were from Ramachandran A, et al. Diabetologia. 2006;49:289-297.[12] Data for the Japanese diabetes prevention study were from Kosaka K, et al. Diabetes Research and Clinical Practice. 2005;67:152-162.[104] Data for Da Qing (the Da Qing IGT and Diabetes Study)[99] were reported in Norris SL. Am J Prev Med. 2005;28:126-139.

**Change in BMI was not reported in the DPS, IDPP, the Japanese diabetes prevention study, or the Da Qing Study. Change in waist circumference was not reported in the Japanese diabetes prevention study or the Da Qing study. In the Japanese diabetes prevention study and the Da Qing study, baseline weight was not reported, so percent weight loss could not be calculated.

Chapter 7: Summary and Conclusions

Summary of Findings

The research presented in this dissertation aims to describe the determinants of lifestyle behaviors and excess weight in South Asian populations and evaluate the ability of a culturally tailored lifestyle intervention program to improve measures of adiposity in South Asians. The analyses were conducted using data from the formative research phase of the US-based South Asian Health and Prevention Education (SHAPE) study and cross-sectional and longitudinal data from the Diabetes Community Lifestyle Improvement Program (D-CLIP) in Chennai, India. Both studies seek to develop, implement, and formally evaluate culturally tailored lifestyle intervention programs for diabetes prevention in South Asian populations.

First, a thematic analysis was conducted using data collected during seventeen focus group discussions with South Asian Americans in the metro-Atlanta area in Georgia. Participants reported that the changes in lifestyle and environment after immigration to the US and a desire to adhere to traditional gender roles, particularly those that focused on caring for one's family, were barriers to healthy lifestyle behaviors. However, participants also reported that they were able to use family as a motivator and source of social support for healthy lifestyle changes. Next, cross-sectional screening data from the D-CLIP trial was analyzed to determine the relationship between BMI or waist circumference and factors associated with healthy weight maintenance (fruit and vegetable intake, weekly exercise, weight loss history, and weight loss and exercise self-efficacy). In this population, weekly fruit consumption, past weight loss experience, and weight loss self-efficacy, along with gender, age, and marital status, explained 13.7% and 25.8% of the variation in BMI and waist circumference, respectively. Lastly, six-month longitudinal data in the D-CLIP randomized trial was analyzed to assess changes in measures of adiposity (BMI, weight, and waist circumference) in control and intervention participants. Intervention participants showed significantly greater reductions in weight, BMI, and waist circumference compared to controls ($p<0.0001$ for all). Mean changes in measures of adiposity between months zero and six were as follows: for intervention participants, weight decreased by 2.86 kg, BMI decreased by 1.05 kg/m^2, and waist circumference decreased by 3.72 cm and for control participants, weight decreased by 0.73 kg, BMI decreased by 0.31 kg/m^2, and waist circumference decreased by 1.58 cm. The effects of the intervention were consistent across gender, income level, educational attainment, baseline BMI category, and age category. However, there was some difference in outcome by baseline glucose intolerance level, with intervention participants with iIFG showing a significantly greater improvement in waist circumference than individuals with iIGT or IFG+IGT.

Immigration has been correlated with weight gain and increased diabetes risk in various migrant populations.[167-169] For participants in the study presented here, immigration resulted in changes in physical activity levels because the US environment is more conducive to being sedentary, and cooking ingredients and foods are less expensive and more abundant in the US than in South Asia leading to higher caloric intake. Male participants were especially affected by changes in diet, largely due to the fact that they lacked the knowledge on how to cook and therefore relied on prepared foods (e.g., frozen meals or take-out pizza), which tend to be higher in calories and dietary fat.

South Asian society is pluralist,[161, 170, 171] meaning that individuals prioritize the needs of their community over their own needs. In the case of South Asians, family, both nuclear and extended family plays a pivotal role in South Asian culture; The first priority of both men (by providing financial security through working) and women (by caring for the home and family) is securing the comfort and happiness of their families. Participants reported that time spent on these activities made it difficult to include exercise in their daily routine. Women found altering the diet of their family difficult because South Asians associate oil with flavor and are accustomed to large portions, and women were reluctant to prepare food that their family did not want. These behaviors and barriers have been reported in other South Asian populations in Canada, Europe, and the US,[36, 97, 157-166, 203-206] indicating that this aspect of culture is constant, regardless of the country of residence.

Gender roles have been shown to influence health behaviors in non-South Asian populations as well;[207] however, because social expectations for men and women vary slightly in different cultures, there are some differences in the barriers to healthy lifestyle choices for men and women between cultural groups. For example, both African American and South Asian American men report that their role as family provider is a major barrier to physical activity. South Asian males report that, because of work and family commitments, they lack the time to exercise, even though they believe exercise to be a valuable activity for their health. African American men, on the other hand, report that the effort exerted for work and family care leaves them with no energy to exercise.[208] Furthermore, African American men with diabetes describe many components of diabetes self-care, including following a healthy lifestyle as "unmasculine," which leads them to avoid these behaviors.[209] Also, Women from many ethnic groups report that household chores and childcare limit their ability to be physically active (for examples, see these studies of Latin American women[210] and Australian mothers of young children[211]); however, South Asian women are unique in reporting that caring for their husbands was a major factor influencing lifestyle behaviors.

Even so, some participants reported following a healthy lifestyle. For most of these individuals, they were able to overcome barriers to physical activity and diet change by using family as a motivator for health behaviors and diabetes prevention. Participants who adopted healthy lifestyles included their family in their efforts, were motivated to change by their desire to be better able to function as part of the family, and relied on family and friends to provide social support for their behaviors. The importance of social support for South Asians seen in this study population has been reported elsewhere,[36] indicating that efforts to promote lifestyle change should use built-in or newly created social support networks to ease the transition to healthier behaviors in South Asians.

Sedentary lifestyles paired with diets high in calories and fat can lead to excess body weight. However, weight gain is a complex issue, and the determinants of overweight/obesity go beyond simply "over-eating" and "not exercising." Among individuals attending a screening visit for the D-CLIP study, lower fruit consumption, having lost weight and regained the loss, or weight cycling were associated with higher BMI or waist circumference, while having lost weight and maintained some or all of the loss or having never attempted weight loss were associated with lower BMI and waist circumference. Higher weight loss self-efficacy was associated with lower BMI and waist circumference. The associations between fruit intake, history of weight loss attempts, and weight loss self-efficacy with adiposity has been seen in other populations.[180, 181, 183, 184] This indicates that these factors may play an important role in adiposity regardless of race/ethnicity. However, interpretation of these results should be conducted with caution since the analysis was cross-sectional and direction of association cannot be determined.

Number of days per week consuming vegetables, exercise self-efficacy, and average minutes per week exercising were not associated with BMI or waist circumference in the D-CLIP data. In this population, the behaviors of vegetable and fruit consumption might differ. Vegetables are used frequently in cooking and are readily available. Fruits, on the other hand, are available seasonally and are relatively expensive. People consuming fruit regularly are making a special effort to purchase and consume fresh fruits, and these people might be more focused on health and weight maintenance. Unlike the D-CLIP study, most studies have shown a negative association between weight and exercise self-efficacy.[183, 188, 189] The lack of association in this study may be due to an actual lack of association or could be because the survey instrument used is not appropriate for this population. Average minutes per week exercising, as calculated in this analysis, may be an oversimplification of the behavior and may not accurately reflect the amount of exercise. Also, exercise in minutes per week ignores other important components of physical activity such as type of activity or exercise intensity.

The greatest reductions in diabetes risk (58% in the DPP and DPS interventions compared to controls) are seen in lifestyle intervention programs that promote weight loss.[106, 109] The two largest diabetes prevention trials in Asia, the Da Qing IGT and Diabetes Study in China[99] and the Indian Diabetes Prevention Programme,[12] did not include a weight loss goal for participants, and weight loss was close to zero in both studies. Even so, both programs showed reductions in diabetes incidence compared to controls; however, these reductions were smaller than those seen in the DPP and DPS studies (31%, 46%, and 42% in the diet, exercise, and diet and exercise arms of the Da Qing study and 28.5% in the IDPP). There is no reason to assume, however, that weight loss would not be beneficial to Asian populations. South Asians have high rates of central obesity which present at lower BMIs than other populations[2] and have more visceral fat than Caucasians when matched for waist-to-hip ratio.[3, 87] A diabetes prevention program in South Asians, which includes a weight loss component, might result in reductions in diabetes incidence that are closer to that seen in the DPP and DPS.

Results from the D-CLIP trial at six months show that a low-cost, group-based diabetes prevention program, based on the US DPP, can successfully decrease adiposity in Asian Indians in Chennai, India at high risk of developing diabetes. The six-month weight loss among intervention participants in the DPP, the only large, diabetes prevention trial to report six-month weight loss, was seven kilograms (7% of baseline weight),[109] over twice that reported here for the

D-CLIP trial (2.86 kg, 3.8%). The lower weight loss in D-CLIP compared to the DPP might be because mean weight and BMI were lower in the D-CLIP study than the DPP, so a smaller weight loss may be more attainable. Since, even without weight loss, the IDPP and the Da Qing study showed that diabetes incidence can be reduced in Asian populations without weight loss,[12, 99] the weight loss in the D-CLIP study might be an indicator that the D-CLIP trial can reduce diabetes to a larger degree than the other studies in Asian populations. Furthermore, the significant decrease in waist circumference at six months in D-CLIP intervention participants exceeded the decrease in waist circumference in the DPP at one year.[124] Since abdominal obesity is a common diabetes risk factor in South Asians,[2] improved waist circumference may be a better marker of loss of adiposity, and possibly diabetes risk reduction, than weight loss.

Six-month results from the D-CLIP trial show that intervention participants with IFG had greater reductions in waist circumference over time than other participants in the D-CLIP lifestyle intervention. This might indicate that individuals with less insulin resistance, those who are earlier in the natural history of diabetes, respond better to weight loss efforts and that prevention programs should include participants with IFG, the earliest stage of pre-diabetes. Since none of the other large, randomized trials of lifestyle programs for diabetes prevention included participants with iIFG, there is no basis of comparison for these results. However, lifestyle participants in the DPP had an increase in fasting glucose over time that was significantly lower than the fasting plasma glucose increase in the placebo group,[109] indicating that lifestyle change might also be effective for individuals with IFG. Continued follow-up of the D-CLIP trial might help clarify this issue.

Limitations

The research presented in this dissertation has several potential limitations. First, the dissertation includes qualitative data collected from South Asian migrants living in the United States and cross-sectional and longitudinal data from a diabetes intervention study in Chennai India. Data from both sites was used in making public health recommendations for diabetes prevention in the South Asian community in this discussion section. However, these populations may not be comparable and combining the findings may not be appropriate, particularly in regards to behaviors and the reasons for these behaviors. Many of the lifestyle behaviors and barriers to and motivators for healthy lifestyle choices reported in this dissertation are consistent with the results of published studies in other South Asian populations globally,[36, 97, 157-166, 203-206] even though these populations differ in where they reside, degree of acculturation, and income and education level. This might indicate that these populations are more alike than different in their reasons for certain behavioral choices, and that lessons learned in one South Asian population could apply to South Asians living in another setting.

Second, we assessed the correlations between BMI and waist circumference and behavioral and psychosocial factors using cross-sectional analysis of screening data from the D-CLIP trial. Since it is impossible to determine temporality from cross-sectional data, it is unclear if the factors associated with increased measures of adiposity, low fruit intake, unsuccessful weight loss history, and weight loss self-efficacy, are a cause or consequence of excess weight.

Third, Ineligible participants, namely those with glucose levels outside of the pre-diabetic range (N = 24) were accidently included in the D-CLIP intervention trial. Follow-up analyses were conducted with and without these individuals, and there was not a substantial change in the magnitude and no change in the direction or significance of results. In a community-based, translational program like D-CLIP, inclusion of borderline individuals, although not ideal, may provide valuable results. In a real-world setting, such as a physician's office, individuals with borderline diabetes may be treated as if they have pre-diabetes. The recommended course of action for such an individual is reduction in weight if needed, increased physical activity, diet improvement, and prescription of an anti-glycemic drug like metformin,[17] the same protocol used in the D-CLIP study. Although the sample size is small and will lack statistical power, outcomes for this subgroup of the D-CLIP sample could provide insights into how the treatment recommendations affect body weight and glucose levels in people with glucose values on the borderline between prediabetes and diabetes.

Fourth, we assumed that weight loss in the intervention arm was due to behavioral changes made because of the intervention. Without assessing if behavioral change took place (e.g., fat/calorie reduction and increases in physical activity), the decrease in adiposity shown in intervention arm participants could be due to other factors (e.g., illness, use of prescription drugs including weight loss drugs or medications with weight loss as a side effect, or other weight loss techniques such as herbal supplements, purging, or skipping meals). Future analyses will include those to measure changes in behavior as well as other possible behaviors and events that could lead to changes in weight or body fat distribution.

One possible cause of weight loss in the intervention participants could be use of metformin. In the DPP,[109] participants in the metformin arm (dose = 850 mg twice per day) showed reductions in weight that exceeded those in the placebo arm but were significantly less than in intervention arm participants (mean weight loss at three years was 2.1 kg in the metformin arm, compared to 5.6 kg in the intervention arm and 0.1 kg in the placebo arm). The weight loss among metformin participants may be partly explained by weight loss due to gastrointestinal symptoms, which occurred significantly more frequently among metformin users than other study participants. In the IDPP,[12] on the other hand, there was no weight loss in any study arm, including the metformin or metformin plus lifestyle arms of the study (dose = 250 mg twice per day). When the longitudinal analysis presented in this dissertation was conducted, data on metformin use was not available, so it was not possible to compared weight loss in participants who were or were not taking metformin. The goal of the D-CLIP trial is to test a step-up model of diabetes prevention, not to measure the relative contribution of metformin to lifestyle. However, it is valuable to assess what benefits metformin adds to lifestyle in terms of improving study outcomes, particularly given the conflicting results presented by the DPP and IDPP. Future analyses will include comparisons of intervention arm subjects who are or are not prescribed metformin.

Finally, the research presented here, particularly the D-CLIP follow-up analysis, assumes that weight loss in South Asians will result in a reduction of diabetes risk. This may not be true, but evidence from other study populations, plus the fact that adiposity, particularly abdominal adiposity, has been shown to be a diabetes risk factor in South Asians and other populations, seem to indicate that weight loss is still important for diabetes risk reduction in South Asians. In the DPP lifestyle intervention group, diabetes risk reduction was significantly predicted by weight, BMI, and waist reduction in women and by weight, BMI, waist-to-hip ratio, waist circumference, and subcutaneous and visceral fat reduction in men.[124] In the Look AHEAD trial, a lifestyle intervention for people with diabetes, among participants in the intensive lifestyle intervention, changes in weight and fat mass, as well as decreases in hepatic fat, best predicted improvements in peripheral insulin sensitivity.[212] Future analysis of D-CLIP follow-up data is needed to determine if the lifestyle intervention will prevent diabetes as well as decreasing measures of adiposity.

Suggestions for Improving Studies like SHAPE and D-CLIP

Several changes and additions to the SHAPE and D-CLIP studies could have increased the strength and richness of the findings and would be beneficial additions to similar studies conducted in the future. First, because of recruitment constraints, it was not possible to conduct separate focus group discussions with first and second generation South Asians. Difference in place of birth and the associated exposures during childhood and young adulthood of South Asians born in Asia and in the US could result in differences in lifestyle behaviors and adherence to cultural norms. These differences may not have been evident in groups that included both first and second-generation participants. Also, qualitative data was gathered using only focus group discussions. The inclusion of some in-depth qualitative interviews would have made the data on barriers to and lifestyle behaviors richer. In particular, interviews could have been used to explore further the behaviors of South Asians who are already following a healthy lifestyle or among migrants to the US with different levels of acculturation. Future studies like the SHAPE trial that seek to understand lifestyle behaviors in under-studied ethnic minority groups or migrant populations should consider including a variety of qualitative data collection techniques.

Behaviors around diet and physical activity are influenced by multiple factors, including the environment; measuring the availability of resources (e.g., safe and accessible places to walk, access to low-fat or healthier foods) would held to explain the associations between behaviors and adiposity in South Asian populations. Similarly, qualitative data collection in SHAPE indicated the importance of gender roles, immigration, and social support in lifestyle behaviors. Future studies assessing barriers to and motivators for lifestyle behaviors and behavior change should include tools to measure history of immigration, social support, and work and household responsibilities.

In this dissertation, we reported that select psychosocial (weight loss self-efficacy), behavioral (past weight loss history and fruit intake), and demographic (age, gender, and marital status) factors influenced 13.7% and 25.8% of the variability in BMI and waist circumference in the D-CLIP study population. These results are similar to those seen in other studies; for example, in the DPP, 15% of the variance in BMI was explained by three psychological factors related to eating (binge eating severity, dietary restraint, and craving).[181] It is important that future analyses of D-CLIP and SHAPE data and other studies in this population assess other factors that might explain more of the variability in BMI and waist circumference. Researchers have shown that diet and physical activity behaviors only partially explain weight; some examples of other factors that have been shown to influence body weight or distribution of body fat are hormone levels, genetics, sleep deficit, environmental factors, psychological factors, and birth weight.[213-217] Understanding how these factors interact in the South Asian population to influence adiposity is important, and studies should include tools to measure these factors.

Finally, including more rigorous tools for measuring behaviors and adiposity would strengthen the studies presented here and future studies in this population. Diet should be measured using a validated, culturally appropriate food frequency questionnaire or multiple 24-hour recalls. Physical activity should be measured as accurately as possible, ideally with an accelerometer, or, alternatively, with daily activity logs or a validated survey instrument. Full-body bio-impedance, air-displacement techniques, or underwater weighting are better assessments of body fat than weight or BMI, and, instead of waist circumference measurements, abdominal CT-scans could be used to better measure visceral fat. However, these more technical tools for measuring adiposity are more expensive and may not be possible or practical in developing countries or in field-based studies.

Strengths and Innovations

The research presented in this dissertation uses a mixed methods approach to describe the behavioral and psychosocial factors related to lack of physical activity, poor diet, and their frequent outcome, excess adiposity, in South Asians. Combining both qualitative and quantitative methodologies provides a richer picture of behaviors and attitudes around diabetes prevention and weight gain and loss than could be expected from a purely quantitative study.

This research contributes not only to the literature on translation of diabetes prevention programs, particular in LMIC setting. In LMICs like India, obesity and related diseases like diabetes are likely to become even more common as development moves forward and the nutritional landscape changes. Understanding how to treat and prevent weight gain in LMIC populations, like South Asians, is important to counteract the changes in lifestyle that are occurring or expected to occur as the nutrition and economic transitions progress. Furthermore, South Asians are a rapidly growing ethnic minority group in the US, so lessons learned about diabetes and diabetes prevention in South Asian populations could be used to plan programs among US migrants.

D-CLIP is a large, well-randomized trial with good retention and attendance rates. The D-CLIP trial is unique in that it includes individuals in the full range of pre-diabetes (iIFG, iIGT, and IFG+IGT) and tests the recommendations for diabetes prevention put forth by the American Diabetes Association[17] to treat with lifestyle change followed by metformin prescription for individuals who remain at high risk of developing diabetes. In order to create long-term diabetes prevention in South Asia, the D-CLIP trial includes tools to promote dissemination and sustainability of the project; namely the use of trained peer educators, creation of culturally tailored study materials that can be easily reproduced and disseminated, and inclusion of peer-support networks made up of study participants.

Public Health Implications

Gaps in the Published Literature

Few published studies specifically address the elevated risk of developing diabetes in South Asian populations. There is only limited research that addresses barriers to[36, 97, 203, 204] and motivators for[205] the lifestyle behaviors of South Asian populations, and studies on self-efficacy and other psychosocial factors influencing behaviors are mainly in the areas of HIV prevention, medication adherence, and tobacco use. Furthermore, there are only a handful of published intervention trials directed towards diabetes prevention in South Asian populations,[206, 218, 219] and only one large randomized trial of a lifestyle intervention for this high-risk group, the IDPP.[12]

The IDPP is an important study in that it was the first large, randomized trial to show that lifestyle interventions could affectively reduce the incidence of diabetes in Asian Indians with IGT. However, the lifestyle intervention in the IDPP[12] had a lower effect on diabetes prevention (28.5% reduction in diabetes incidence in the lifestyle arm compared to controls) than other diabetes prevention trials such as the DPP or the DPS (both showed a 58% reduction in diabetes incidence in the intervention arm compared to controls). Several notable differences in the IDPP compared to the DPS and DPP might explain this: (1) the IDPP did not promote weight loss; (2) the IDPP was a work-site based program while the other programs were community-based; (3) IDPP participants with "active" jobs or who walked or biked to work were not counseled to increase their daily activity, so these people would not have done any added exercise; and (4) the IDPP was less intensive, with less frequent contact with study staff, and dietary advice was given only during monthly calls, which may not have been sufficient to lead to lasting behavior change.

The research presented here, in particular the D-CLIP trial, seeks to overcome these challenges by delivering a community-based intervention program with weekly contracts with participants for six months and a goal to increase planned physical activity (activity that is done outside of activities of daily living) to at least 150 minutes per week. The three analyses presented here fill the gaps in the literature by describing the South Asian community's self-perceived barriers to and motivators for exercise and diet change, exploring associations between psychosocial factors and behaviors and markers of adiposity, and assessing the ability of a culturally tailored lifestyle program to achieve weight loss and decrease BMI and waist circumference in intervention participants.

Recommendations for Diabetes Prevention in the South Asian Community

The research presented in this dissertation can be used to develop diabetes prevention programs for the South Asian community that are accepted by community members and address the unique risk profile of South Asian populations. These programs should include the following components:

- Diabetes prevention programs should promote **weight loss** as a first step in diabetes prevention. In the D-CLIP trial, setting goals for intervention participants to increase physical activity to at least 150 minutes per week and decrease total fat intake were the basis for weight loss. Data analysis assessing if participants made these changes is outside of the scope of this dissertation; however, intervention participants were able to lose weight and decrease BMI and waist circumference significantly more than control participants, so the educational program resulted in sufficient behavior change to bring about this weight loss.
- These programs should include people in the **full range of glucose intolerance**. D-CLIP intervention participants with iIFG had the greatest improvements in waist circumference, which indicates that even in the early stages of glucose intolerance lifestyle programs can have beneficial effects on health.
- Exercise is not a cultural norm in the South Asian community. Diabetes prevention programs should include **exercise instruction**, preferably in the form of group exercise classes to increase social support for physical activity. In the D-CLIP trial, participants attended weekly exercise classes where they learned about improving cardiovascular fitness, strength training using their own body weight or household objects (e.g., water bottles), and stretching. According to informal discussions with participants

and feedback received during end of study focus group discussions (data not shown), these classes were well received by participants.

- South Asian focus group discussion participants reported that caring for their family's needs was their primary concern, and it was difficult for them to make lifestyle changes that their family did not support or facilitate. Including the entire **family** in a diabetes prevention program, or at least inviting them to some of the classes, could help to overcome the barriers that exist because study participants want to please their families (e.g., family members may be more accepting of foods made with less oil if they understood why participants were modifying recipes).
- Diabetes prevention programs for South Asians should incorporate tools to increase **social support**. South Asian culture values family (nuclear and extended) and socializing with family and friends are important components of a South Asian's life. South Asians who have healthy friends and family in their support network reported that they were more likely to engage in diet change and physical activity. Teaching lifestyle classes in group settings and promoting group interaction inside and outside of class time would provide a built-in social support network for healthy lifestyle change. Larger classes can be divided into smaller peer support groups to ease interaction between participants. Classes can include the family or friends of the target participant to help foster social support in the individual's day-to-day life. Training community members as peer educators, as was done with the Dia-ambassadors in the D-CLIP trial, is another way to promote social support. Informally, participants in the D-CLIP and SHAPE intervention programs

report that the social support provided by the classes is important for starting and maintaining lifestyle change.

- Traditional foods are an important part of the South Asian culture,[97] and programs that seek to modify diet must be sensitive to the importance of certain foods and eating habits. Classes should teach tools for fat and calorie reduction that **improve the nutritional content of food without sacrificing flavor**. For example, curries can be flavored with spices instead of oils and low-fat yogurt can be substituted for full fat in many meals without a noticeable difference in flavor.
- Fruit and vegetable intake in South Asians is low, even though there are a high proportion of people who are vegetarian.[178, 179] In the research presented here, and in other studies in South Asians,[180] **fruit and vegetable intake** was inversely associated with BMI and waist circumference. Lifestyle programs in this community should promote increasing intake of fresh fruits and vegetables, particularly as a replacement for foods with higher fat and calories.
- In this dissertation, high **self-efficacy** for weight loss was correlated with better health behaviors (higher fruit and vegetable intake, exercising more minutes per week). Higher self-efficacy was also associated with lower BMI and waist circumference. Education programs in this population should include components of the health-beliefs model, particularly promotion of self-efficacy.

Future Directions

Longitudinal analyses of the D-CLIP trial data are needed to determine if this culturally tailored lifestyle intervention program can prevent diabetes, improve cardiometabolic markers, and result in long-term weight reductions. In addition, longitudinal data analysis can elucidate the roles of baseline self-efficacy and change in self-efficacy in weight change in the D-CLIP study population. Most prospective studies of self-efficacy show that higher self-efficacy and improvements in self-efficacy partially mediate changes in BMI, weight, and waist circumference;[195, 220-222] however, a few studies have found that higher baseline self-efficacy scores were associated with less weight loss, possibly reflecting overconfidence or lack of experience with the difficulties of weight loss in these individuals.[221]

It would be beneficial to investigate some of the emerging factors associated with diabetes or weight gain in the South Asian population. For example, stored blood samples from the D-CLIP trial could be used to investigate the association of gene variants associated with diabetes or obesity and program success. One such gene is the PERIOD2 gene, a gene associated with the circadian clock. Certain polymorphisms in PERIOD2 have been associated with abdominal obesity, extreme snacking, skipping meals, stress eating, and withdrawal from a weight loss program in Caucasians.[223] Similarly, assessing the role of non-genetic associates of weight gain, such as sleep debt, would be valuable.

Cost and cost-effectiveness analyses and a qualitative assessment of program acceptability are planned for D-CLIP. The results of these analyses can aid in dissemination of the D-CLIP program and promotion of the program to health officials and policy-makers in India and throughout South Asia. Other avenues of future research include modifying the D-CLIP curriculum to rural or impoverished communities in India and throughout South Asia.

The SHAPE pilot study is ongoing, but once completed it will offer the opportunity to compare the findings of the D-CLIP trial with a South Asian population in the US. Furthermore, lessons learned from the SHAPE focus group discussions and the pilot study, as well as programmatic lessons learned in D-CLIP, will be used to plan a large, randomized trial of a lifestyle intervention for diabetes prevention in South Asian migrants living in the US.

Conclusion

The research presented in this dissertation seeks to address the disparity in diabetes risk seen in South Asian populations by describing culturally-specific barriers to a healthy lifestyle, assessing the association between adiposity and behavioral and psychosocial factors, and evaluating changes in adiposity in participants in a culturally-tailored lifestyle intervention program in South Asians. The data presented in these studies can inform the development of diabetes prevention programs for South Asian populations. Application of these findings can help to ease the burden of diabetes in South Asian countries and in South Asian migrant populations and can serve as a model for translational research projects in other low- and middle-income countries.

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Appendices

Appendix A: SHAPE Study Focus Group Discussion Questions

Focus Group Discussion Questions, Set #1

Diabetes and Obesity

1. What are the most common health issues affecting the South Asian Community in Atlanta?
    i. Which of these health issues are the biggest problems for women in your community?
    ii. Which of these health issues are the biggest problems for men in your community?

2. Let's talk about diabetes.
    i. What do you know about diabetes?
    ii. What are some of the causes of diabetes in the South Asian community?
    iii. What can South Asian people do to prevent diabetes?

3. Now let's talk about obesity.
    i. What do you know about obesity?
    ii. What are some of the causes of obesity in the south Asian community?
    iii. What can South Asians do to prevent weight gain and obesity? [PROBE: Do people in your community use any of these methods to lose weight?]

Physical Activity and Diet

4. I would like to change topics now and talk about some health behaviors. Let's start by talking about exercise.
    i. What do you think about when you hear the word "exercise"?
    ii. What kind of activities do you consider to be exercise?
    iii. What activities do South Asian [women/men] in your community do for exercise?
    iv. How common is exercising in your community?
    v. Why do people in your community exercise? [PROBE: Describe someone in your community who exercises – who are they, when do they exercise]
    vi. Many people do not exercise. What are the reasons that South Asian [men/women] do not exercise? [PROBE: cost, time, dislike exercise]
    vii. We are planning a program to improve health in your community, which will include information on exercise. How would you want to learn about exercise? [PROBE: Classes/online, format of classes, Language of classes/materials, location of classes, timing of classes, length of classes, instructor, types of information to include]

5. I'd like to talk about the South Asian diet now.
   i. What makes the South Asian diet healthy? [PROBE: Describe a plate of healthy food]
   ii. What makes the South Asian diet unhealthy? [PROBE: Describe a plate of unhealthy food]
   iii. How could these unhealthy eating habits be changed for someone trying to lose weight? (PROBE: portion size, buffets, fats)
   iv. What are some of the difficulties in changing eating habits?
   v. How could these difficulties be overcome?
   vi. Earlier I mentioned that we are planning a program to improve the health of South Asians. The goal of this program will be to prevent diabetes and will include information on nutrition. How would you want to learn about nutrition? [PROBE: Classes/online, format of classes, Language of classes/materials, location of classes, timing of classes, length of classes, instructor, types of information to include]

Focus Group Discussion Questions, Set #2

Class Structure

1. As I mentioned before, we are planning a diabetes prevention program for South Asians living in Atlanta. This program will have separate lessons on eating a healthy diet and on staying active, both as ways to be healthier, lose weight, and prevent diabetes. How should this information be presented to study participants? [Probes: What are your thoughts on online classes or podcasts? If the classes were in person, how often should class be held? Where should classes be held?]

Diet and Nutrition Education

2. What diet and nutrition topics do you think are important for South Asians?

3. Based on feedback from other discussion groups, we have thought of some ideas for the classes on healthy diet. I would like to get your feedback on some of these ideas. What do you think about a cooking class as a way to encourage people to change their cooking habits? [Probe: Whom would this type of demonstration appeal to? Would you rather watch someone else cook or help with the cooking?]

4. What do you think about giving people in the class a recipe book with healthy South Asian meals? [Probes: Would you use it? What should be included?]

5. What are some other ideas for ways to present information about healthy diets that South Asians would enjoy?

Physical Activity Education – 20 minutes

6. Now, I want you to think about a time that you were being physically active and were having fun. Can you describe this experience to me? [Probes: What activity were you doing? Did the activity require any sort of equipment? How long would did the exercise or activity last? Where were you (home, gym, community center, indoors, outdoors)? Were you by yourself, or were you with other people?]

7. The SHAPE team has also started planning the exercise education portion of the program. Currently, we are planning to offer group classes that focus on using Garba and Dandiya as forms of exercise. What do you think of this idea? [Probe: Would this be an exercise class you would want to participate in? What do you like about the idea? What do you dislike (if anything)? Who would this type of class appeal to? How often would you be willing to come to an exercise class like this? Where should the classes be held?]

8. Besides the group classes, we will also give people other opportunities to exercise. For example, we will provide people with an exercise DVD they can do at home. What do you think about that idea? [Probe: Would you use it? Who would an exercise DVD appeal to? What should be on the DVD? Should the people on the DVD all be South Asian?]

9. What are some other ideas for ways to present information about activity and exercise that South Asians would enjoy?

Appendix B: Article Attachment Pending Permission of Journal

Weber MB, Ranjani H, Meyers GC, Mohan V, Narayan KM. A model of translational research for diabetes prevention in low and middle-income countries: The Diabetes Community Lifestyle Improvement Program (D-CLIP) trial. *Prim Care Diabetes*. Apr 2012;6(1):3-9.

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Original research

A model of translational research for diabetes prevention in low and middle-income countries: The Diabetes Community Lifestyle Improvement Program (D-CLIP) trial

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ABSTRACT

Aims: The Diabetes Community Lifestyle Improvement Program (D-CLIP) aims to implement and evaluate in a controlled, randomized trial the effectiveness, cost-effectiveness, and sustainability of a culturally appropriate, low-cost, and sustainable lifestyle intervention for the prevention of type 2 diabetes mellitus in India.

Methods: D-CLIP, a translational research project adapted from the methods and curriculum developed and tested for efficacy in the Diabetes Prevention Program, utilizes innovated methods (a step-wise model of diabetes prevention with lifestyle and metformin added when needed; inclusion of individuals with isolated glucose tolerance, impaired fasting glucose, and both; classes team-taught by professionals and trained community educators) with the goals of increasing diabetes prevention, community acceptability, and long-term dissemination and sustainability of the program. The study outcomes are: diabetes incidence (primary measure of effectiveness), cost-effectiveness, changes in anthropometric measures, plasma lipids, blood pressure, blood glucose, and HbA_{1c}. Program acceptability and sustainability will be assessed using a mixed methods approach.

Conclusion: D-CLIP, a low-cost, community-based, research program, addresses the key components of translational research and can be used as a model for prevention of chronic diseases in other low and middle-income country settings (clinicaltrials.gov number, NCT01283308).

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1. Introduction

Effective implementation of evidence from proven clinical and public health interventions for diabetes prevention [1–4], particularly in low and middle-income countries (LMIC), is a challenge. Translational research can identify the best ways to deliver successful prevention programs to communities. These trials of community-level implementation of proven policy should attempt to incorporate the standards for translational research and program dissemination [5–8]; namely the integration of tools to measure program effectiveness, efficiency, reach, and community-level outcomes.

Herein, we describe the Diabetes Community Lifestyle Improvement Program (D-CLIP), which addresses the implementation issues of translational research to prevent diabetes in India, a large LMIC with a markedly high prevalence of Type 2 diabetes mellitus (T2DM) [9–11]. Based on the strength of the evidence for behavioral and pharmacological interventions for T2DM prevention [1–4,12–15], expert groups such as the American Diabetes Association and the International Diabetes Federation promote the use of lifestyle programs first, followed by the appropriate addition of oral hypoglycaemic agents like metformin in individuals non-responsive to lifestyle change, for diabetes prevention in the larger at-risk population: individuals with impaired glucose tolerance (IGT), impaired fasting glucose (IFG), or both, a more encompassing group than those evaluated in efficacy studies. Because these policies are difficult and costly to implement and scale up in their tested forms, the level of real-world implementation is rudimentary. D-CLIP tests the effectiveness of implementing these policies (lifestyle plus metformin when necessary) in a wide range of individuals at risk for developing diabetes, including those with IFG, IGT or both, in a LMIC setting.

2. Methods

2.1. *Study participants*

Inclusion and exclusion criteria for D-CLIP were selected to minimize the risk of adverse events while reaching the broadest population of individuals with pre-diabetes. Men and women, aged 20–65 years with no major concomitant health issues who are overweight (using South Asian-appropriated cut-points defined by the World Health Organization [16], a Body Mass Index, BMI, of $\geq 23\,kg/m^2$ and/or a waist circumference ≥ 90 cm for men and ≥ 80 cm for women) and are at high risk of developing T2DM because of the presence of pre-diabetes (baseline fasting plasma glucose, FPG, indicating IFG: 100–125 mg/dL and/or 2-h post-load glucose indicating IGT: 140–199 mg/dL) are eligible for the D-CLIP study [17]. Individuals who are pregnant or breast-feeding or have previously or newly diagnosed diabetes or a history or evidence of heart disease, serious illness, or conditions which would impede participation in an unsupervised physical activity and diet change program are excluded from the study.

Recruitment occurs at large-scale community screenings; at targeted screenings at housing/apartment complexes, local businesses (workplaces/offices), places of worship (temples,

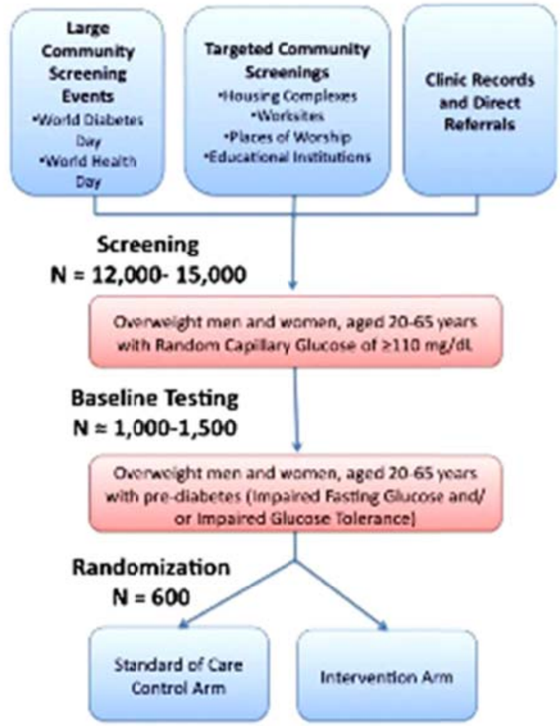


Fig. 1 – D-CLIP study recruitment.

churches), and educational institutions (faculty and staff at schools and colleges); through clinic records at the study site; and through direct referral by health care providers at the clinic and through study participants (see Fig. 1). Screening includes a short survey, anthropometric measurements, and a random capillary blood glucose (RCBG) test. Individuals with RCBG of greater than or equal to 110 mg/dL are asked to attend baseline testing. It is estimated that about 12,000–15,000 people will be screened with RCBG and, subsequently, 1000–1500 people will be eligible for baseline testing.

2.2. *Intervention*

Control arm participants receive the standard of care treatment for patients with pre-diabetes at the study site. They meet with a physician and a dietician, attend two classes (a lecture on diabetes prevention through weight loss and diet change and an exercise class), and receive handouts reinforcing prevention of T2DM through increased physical activity and weight loss.

Individuals enrolled in the intervention arm participate in a step-wise model of T2DM prevention with the goal of reducing diabetes risk through (1) weight loss of at least 7% and (2) 150 min or more per week of moderate level physical activity. Participants attend 16 weekly sessions on lifestyle change and physical activity instruction followed by 8 weeks of maintenance classes of which participants attend at least half. The D-CLIP curriculum is based on the DPP lesson plans [18], modified to be group-based and culturally appropriate. Each class lasts 90–120 min with the first half of class teaching lifestyle skills and the second focusing on physical activity. During the intervention period, classes focus on diabetes prevention, increasing physical activity/decreasing sedentary activities, dietary improvement (focusing on a reduction in dietary fat consumption), and behavior modifications for weight loss and disease prevention. Maintenance period lifestyle classes cover maintaining weight loss and continuing lifestyle changes made during the intervention period. The physical activity lessons teach participants about increasing day-to-day physical activity and training them on more formal exercises, including aerobic exercise and strength training using their body weight and every day objects (e.g. water bottles).

All classes are team-taught by professional health educators and exercise trainers and lay interventionists. Lay interventionists, termed Dia-ambassadors, are community volunteers who are trained by the study staff to teach about diabetes prevention and lifestyle change. Dia-ambassadors remain active with these groups throughout the duration of the study, assisting the professional educators in teaching classes, providing peer-to-peer guidance and support to participants, and arranging opportunities for exercise and socializing outside of class. Peer support groups provide additional social support; group members work together during small group activities in the classes and are encouraged to contact each other outside of class time.

Intervention arm participants who remain at highest risk of T2DM (FPG values of 100 mg/dl or more and HbA1c measures of 5.7% or more) after four or more months in the program are given metformin in addition to continuing the lifestyle program. Metformin dosages start at 500 mg per day, and, when appropriate, increase to 1000 mg per day (given as 500 mg twice per day). Based on the high rates of conversion to diabetes in South Asians with pre-diabetes [19], it is anticipated that approximately 50% of the individuals in the lifestyle arm will be prescribed metformin over the course of the study.

During the follow-up period (post-lifestyle and maintenance classes), study staff contact with all participants is minimal. The health educators are available by phone or email to answer questions; the center holds occasional exercise refresher courses; and SMS text messages are sent to intervention group participants with reinforcing messages and to control group members reminding them to return for follow-up. Social support tools are maintained during follow-up: Dia-ambassadors continue to offer support to the participants, peer support groups are encouraged to maintain contact with one another, and participants have access to an online community, which they can use to post information, questions, and concerns for other participants.

2.3. *Data collection*

Study measurements for the primary and secondary outcomes are listed in Table 1. All testing visits occur after an overnight fast of at least 8 h. Unless otherwise indicated, methods for testing and sample analysis are as described previously for other studies at the intervention site [20].

Diabetes incidence, the primary outcome, is the cumulative proportion of individuals who progress to diabetes at each time point. A 75-g oral glucose tolerance test [21] with blood draws for glucose and insulin at 0, 30, and 120 min is conducted at baseline and at the annual follow-up visit. At the 4th and 6th month visits and at mid-year follow-up visits, fasting glucose and insulin are measured alone. Diabetes is diagnosed by a FPG $\geq$ 126 mg/dL or a 2-h glucose $\geq$200 mg/dL [17].

The secondary outcomes, of body weight, waist circumference, percent body fat [22], blood pressure, glycosylated hemoglobin (HbA1c), and plasma levels of high density lipoprotein (HDL), low density lipoprotein (LDL), triglycerides, and total cholesterol are measured in all study participants at each testing visit. To understand the effect of the intervention on basic pathophysiological pathways, differences in the changes in beta cell function [as measured by the Oral Disposition Index [23], calculated as $(\Delta I0\text{–}30/\Delta G0\text{–}30) \times (1/\text{fasting insulin})$] and insulin resistance (using the Homeostasis Model Assessment of Insulin Resistance, HOMA-IR [24]) are calculated. Questionnaires given to all study participants measure recent average activity and exercise behaviors. Changes in average diet are assessed by comparing the results of a 12-month food frequency questionnaire (FFQ) from baseline to the end of the intervention period and during follow-up. The FFQ used in D-CLIP was developed for and validated by the study site in Chennai [25]. Diet behaviors are measured using questionnaires given on each testing day. Participants in the lifestyle arm are asked to fill out daily activity and food intake logs ("Keeping Track Booklets").

The cost-effectiveness of the intensive lifestyle program, from the perspectives of a single payer system and society, will be compared with standard lifestyle advice by conducting incremental cost-effective analyses in which the net costs and net effectiveness of the intensive lifestyle program and the standard lifestyle advice is calculated and expressed as a ratio. All analyses are within the time frame of the trial. The direct medical and non-medical costs and indirect costs associated with the lifestyle intervention over 36 months are included. Information on costs are from medical records, participant surveys, and assessment of intervention costs (personnel, equipment) [26].

To evaluate recruitment, databases track how many individuals are screened for the study, return for baseline measures, agree to randomization, and enroll in the study. To measure program adherence, attendance is recorded at all exercise and lifestyle classes by asking each participant to sign-in upon arrival. The participants' Keeping Track Booklets are analyzed to assess changes in physical activity and diet and feedback is provided to the study participants. Adherence to metformin is assessed using a questionnaire and pill counts at each study visit.

Program acceptability is assessed through focus group discussions (FGD) with participants who receive the lifestyle intervention. After every third lifestyle cohort has begun maintenance classes, the study staff invites a sample of men and women from each of the previous three classes to participate in a FGD. Four men and four women are selected from each class so that a total of 12 men and 12 women are invited for the FGD at each time point. If one group does not have four men or women, participants are over-sampled from the other groups. The participants are encouraged to share their experience in the lifestyle program focusing on:

Table 1 – D-CLIP measurements for main study outcomes.

Measurement	Intervention period testing			Follow-up period testing	
	Baseline	4 months	6 months	Annual[a]	Mid-year[b]
Pen and paper tests					
Questionnaires to measure behaviors, quality of life, general health, and health-related costs	✓	✓	✓	✓	✓
Food Frequency Questionnaire	✓			✓	
Anthropometry					
Weight	✓	✓	✓	✓	✓
Waist circumference	✓	✓	✓	✓	✓
Percent body fat	✓	✓	✓	✓	✓
Blood pressure	✓	✓	✓	✓	✓
Biochemical testing					
Fasting plasma glucose	✓	✓	✓	✓	✓
Post-challenge glucose (30 min, 2 h)	✓			✓	
HbA1c	✓	✓	✓	✓	✓
Lipid profile	✓	✓	✓	✓	✓
Fasting insulin assay	✓	✓	✓	✓	✓
Post-challenge insulin (30 min, 2 h)	✓			✓	
CBC/Haemogram	✓			✓	

[a] Annual testing includes testing visits every 12 months, beginning in month 12 and continuing through end of study.
[b] Mid-year testing includes testing visits every 12 months, beginning in month 18 and continuing through end of study.

(a) positive aspects/benefits of the lifestyle program; (b) negative aspects of/problems with the program; (c) suggestions for the future; and (d) monetary "worth" of the program. The FGD are audio recorded and transcribed. Participants who drop out or withdraw from the program are contacted and interviewed by phone or home visit to determine (a) reasons for leaving the study, (b) likes and dislikes about the intervention, and (c) suggestions for improving the intervention.

2.4. *Statistical analysis*

D-CLIP is randomizing 600 people to receive either the culturally appropriate lifestyle intervention plus metformin when needed or standard lifestyle advice (control arm) with a mean follow-up time of 36 months. Assuming an alpha of 0.05, a 10% loss to follow-up, and a 9% per annum conversion to T2DM (V. Mohan, unpublished data) in the control group, the sample of 300 people per group will have an 80% power to detect a 35% difference in diabetes incidence between groups.

Quantitative analyses are conducted in SAS, version 9.2 (SAS Institute, Cary, NC). A probability of <0.05 is considered statistically significant for all tests. Continuous variables are tested for normality, and non-normal values are categorized or transformed. Descriptive analyses are performed for all variables and unadjusted comparisons between study arms are made using t-tests or Chi-square tests. All data are presented before and after adjustment for confounding and interaction.

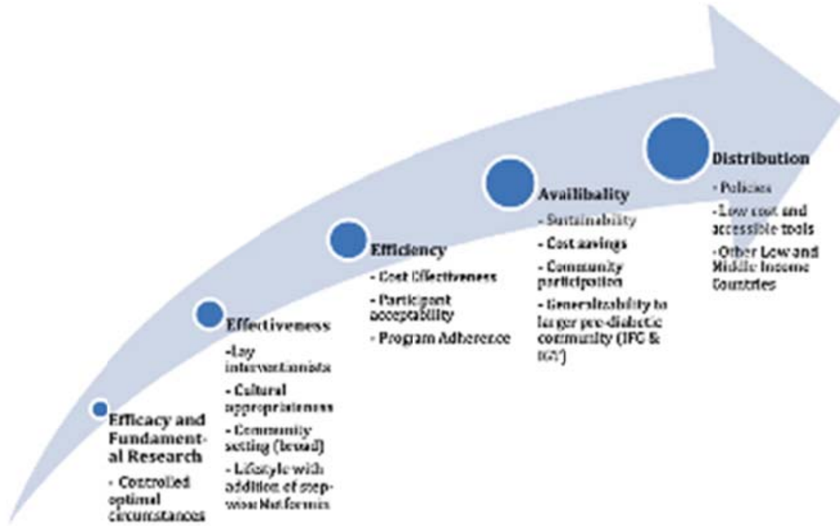
Program effectiveness is measured in terms of differences between study arms in the cumulative incidence of diabetes and, secondarily, in changes in body size and composition, biomedical measures, and diet and activity. Cox's proportional hazards models are used to assess differences in changes between the groups over time for dichotomous outcomes, and multiple measures analysis of variance are used for continuous outcomes. These longitudinal models of continuous outcomes include changes in secondary outcomes, body weight (in kg), percent body fat, fasting glucose (in mg/dL), blood pressure (in mmHg), blood lipids (including HDL, LDL, total serum cholesterol, triglycerides, in mg/dL), activity (min/day), and diet (specifically percent of calories from macronutrients, daily consumption of fat and fiber in grams per day, adjusted and unadjusted for total energy intake, and total calories/day).

Two sets of outcomes are used to measure cost-effectiveness: cost-effectiveness analysis (CEA) (*incremental cost per case of diabetes prevented*) and cost-utility analysis (CUA) [*incremental cost per* quality-adjusted life-years (QALY)]. The cost-effectiveness of the lifestyle intervention is represented by the ratio of incremental cost to increment effectiveness. In addition, sensitivity analyses are performed in order to examine effects of key parameters on cost-effectiveness ratios [26].

Qualitative data is comprised of the verbatim transcripts of all FGD. Audiotapes of FGD are transcribed verbatim, and the transcriptions audited for accuracy. The transcripts are de-identified prior to analysis. The MaxQDA (2010) program is used to manipulate textual data for analysis. Grounded theory methodology [27,28] is used to identify key themes in the data, and these themes are then compared using structured comparisons to identify specific issues relevant to sub-groups of participants (e.g. males versus females).

2.5. *Ethical considerations*

Emory University's Institutional Review Board and Madras Diabetes Research Foundation's Ethics Committee approved the D-CLIP protocol. Written informed consent is obtained



Adapted from Detsky AS, Naglie IG. A clinician's guide to cost-effectiveness analysis. Ann Intern Med. Jul 15 1990;113(2):147-154.

Fig. 2 – Steps of research evaluation.

Adapted from Detsky and Naglie [5].

from study participants at screening, baseline testing, and randomization. The D-CLIP study is registered at clinicaltrial.gov (trial number, NCT01283308).

3. Discussion

Both lifestyle change and metformin have been described as highly efficacious and cost-effective methods for diabetes prevention in clinical trials [1,4,29,30]; however, the use of metformin for highest risk individuals, added step-wise in conjunction with lifestyle intervention, has not been tested in a community-based trial. The D-CLIP study uses a step-wise model of diabetes prevention where participants attend four months of diet, exercise, and weight loss education, and, afterwards, receive metformin only if they remain at a markedly high risk of converting from pre-diabetes to T2DM (individuals with both IFG and IGT).

Diabetes prevention trials to date have included only individuals with IGT [2–4] or individuals with both IGT and IFG [1]. None have addressed the wider, at-risk population with either IGT or IFG alone and especially those with FPG between 100 and 110 mg/dl. By recruiting people with IGT, IFG, or both, D-CLIP advances the generalizability of diabetes prevention to a much wider population of people with prediabetes than evidence from efficacy trials. Broader societal public health nutrition and activity interventions delivered to all people, including those with normoglycemia, would be desirable and complimentary to lifestyle approaches delivered to those at high risk due to their prediabetes; however, evidence for broader, societal approaches to diabetes prevention remain forthcoming (for example, see Saariso et al. [31]). Furthermore, the rate of progression to diabetes among those with normoglycemia is very small compared to that among those with prediabetes [32], and therefore, extending D-CLIP to people without prediabetes would not be feasible and the type of intervention needed for those with prediabetes is very different to that needed for those with normoglycemia.

Detsky and others describe evaluation of health care interventions as flowing from fundamental research/development through five steps (see Fig. 2): (1) can the intervention achieve its goal in optimal circumstances (efficacy); (2) can the intervention produce the desired results in usual circumstances (effectiveness); (3) is the program cost-effective and does it yield a maximal health benefit with limited resources (efficiency); (4) showing availability of the services in a particular environment for the people who need them; and (5) how a policy change resulting in dissemination of this program will affect the population as a whole (distribution analysis) [5,8]. D-CLIP incorporates these steps by using proven efficacy research on diabetes prevention to create a low-cost lifestyle intervention and testing the effectiveness and generalizability of this program in a wider, community setting.

D-CLIP contains elements that will ease the transition from experiment to clinical and public health practice. Involving the community in project implementation by training lay interventionists and tailoring the intervention components to be culturally appropriate gives the community a sense of program ownership. Successes of culturally specific interventions are widespread [33–36], and D-CLIP includes examples that are culturally-appropriate, lessons that are designed to address barriers within the local community and culture to diet and activity changes, and an exercise program which focuses on activities familiar to study participants.

D-CLIP was designed to be low-cost and easily sustainable to facilitate program maintenance by local governments or community organizations. Trained lay interventionists assist in teaching lifestyle classes and provide support to participants. Lay educators have been used successfully in LMIC to disseminate health information and reduce disease burden [37], and using volunteer interventionists, instead of relying on professional educators, minimizes the burden on the health-care system, avoiding the lost opportunity costs of taking staff from other health programs. Similarly, peer support groups rely on participants, and not paid health educators, to provide encouragement and have been shown to improve adherence to behavior change [38-42]. By educating lay volunteers, empowering participants to lead and teach, and creating study materials that can be easily disseminated and sustained, D-CLIP can continue within the community after the study is complete. Furthermore, the results of the cost-effectiveness and program feasibility (program enrollment, attendance, and adherence to intervention goals and recommendations) and acceptability (feedback on components of the lifestyle intervention from the perspective of the user) analyses will be given to policy-makers and community, state, and country leaders who make decisions about health spending to find methods for sustaining and disseminating D-CLIP.

T2DM is affecting the populations in LMICs at a rapidly increasing rate [11]. D-CLIP, a randomized controlled trial testing the effectiveness, cost-effectiveness, generalizability, and sustainability of a culturally tailored, low-cost, step-wise model of diabetes prevention for South Asians, attempts to address this gap through the use of translational research, community outreach, and low-cost educational programs. If successful, D-CLIP can be used as a model of translational and implementation research for low-cost and sustainable chronic disease prevention in LMIC communities.

Conflict of interest statement

The authors have no conflict of interest to declare.

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