

The narrative below is an example of a good application received for the 1st round of funding. The project "A translation randomized trial of culturally specific lifestyle intervention for diabetes prevention in India" was proposed by Dr Venkat Narayan (Emory University) and Dr V.Mohan (Madras Diabetes Research Foundation) and has been awarded a BRIDGES grant.

A. Purpose of Investigation and Specific Objectives

The goal of this proposal is to implement and evaluate a culturally appropriate, low-cost, and sustainable lifestyle intervention for the prevention of type 2 diabetes mellitus (T2DM) in Chennai, India. India leads the world with 40 million cases of diabetes and is projected to have nearly 80 million people with diabetes by 2030.¹ Indians and other South Asian populations are especially susceptible to cardio-metabolic diseases, including T2DM²⁻⁵ and have higher rates of cardio-metabolic risk factors (such as central adiposity and high insulin resistance), which often present at younger ages than in other populations.⁶ South Asians appear to have larger fat mass, smaller lean mass, and lower glucose disposal compared to Caucasians,⁷ further increasing their risk of developing T2DM. Prevention of T2DM is therefore a critical public health priority for South Asians.

Five separate randomized trials confirmed that T2DM can be prevented or delayed with lifestyle interventions,⁸⁻¹² cost-effective^{13, 14} programs promoting improvements in diet, increased physical activity, and weight loss. Translation of these lifestyle interventions to real-life settings, however, remains a major challenge. Messages must be tailored to the unique dietary patterns of the communities into which they are implemented, and physical activity programs should highlight indigenous exercises that are acceptable to the population. These programs should be targeted to the largest at-risk population: individuals with pre-diabetes (impaired fasting glucose and/or impaired glucose tolerance), a non-diseased population.¹⁵⁻¹⁷

Research is needed to determine optimal ways to deliver lifestyle interventions that are contextually and culturally appropriate, low-cost, feasible, and sustainable. We thus propose a diabetes prevention translation trial in Chennai, South India to widely implement the results of prior lifestyle interventions.^{8, 11} This proposal will build on our existing experience in community-based screening and prevention and in developing culturally appropriate diet and exercise interventions for South Asians. This project's innovations include training of low-cost lay interventionists and the development and evaluation of culturally appropriate nutrition education and exercise. The study aim and objectives 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 700 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 T2DM; *Secondary Outcomes:* body weight, percent body fat, body mass index, waist-to-hip ratio, 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 (QALY).

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.

Data from this study will be used for designing and advocating for the implementation of scalable, culturally specific lifestyle interventions for the prevention of diabetes in India and other South Asian countries, a region that is the epicenter of the diabetes epidemic.

B. Background

T2DM is a major public health issue in India. Indians and, in fact, all South Asians, have higher rates of T2DM than Caucasians,^{2, 3, 5} and are more likely to develop T2DM at younger ages^{18, 19} and at lower body mass indices.^{19, 20} India has the highest number of diabetes cases worldwide (40 million).^{1, 21} Another 30 million Indians have pre-diabetes and are at high risk of developing T2DM.⁵ T2DM is an economically costly disease²² and a major cause of mortality and morbidity. Indians and other South

Asians with diabetes have worse glycemic control,^{19, 23} a higher prevalence of microalbuminuria,²⁴ hypertension, retinopathy, and cardiovascular disease,²³ and a higher incidence and faster progression of renal disease than most other diabetic populations.²⁵ The prevalence of T2DM risk factors, such as insulin resistance, increased fat mass, and central obesity are high in South Asian populations.^{6, 7, 26-28} T2DM prevention is a priority for South Asian populations.

T2DM can be prevented. Excess weight and obesity are strongly related to T2DM risk.²⁹⁻³¹ Five randomized trials of lifestyle interventions, programs designed to promote weight loss and prevent diabetes through a combination of diet, activity, and behavior changes, have confirmed that diabetes incidence can be substantially reduced in people with pre-diabetes treated with lifestyle interventions.⁸⁻¹² Two of these studies, the Diabetes Prevention Program (DPP) in the US and the Finnish Diabetes Prevention Study (FDPS), showed a 58% reduction in diabetes incidence in study participants in the lifestyle group compared to those in the control group.^{10, 11} The lifestyle intervention in the Indian Diabetes Prevention Program (IDPP)⁸ had a lower effect on diabetes prevention (28.5% reduction in diabetes incidence in the lifestyle arm compared to controls). However, the IDPP had several notable differences from the DPP and the FDPS: (1) the IDPP was a work-site based program while the other programs were community-based; (2) 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 (3) the IDPP was less intensive, with less frequent contact with study staff and dietary advice (maintain energy balance, reduce total fat, saturated fat, simple sugars and refined carbohydrate intake, and increase fiber intake) was given only during monthly calls, which may not have been sufficient to lead to lasting behavior change. Creating an intervention that overcomes these challenges might improve the results and sustainability of diabetes prevention efforts in India.

Even with the differences in study design, the effects of lifestyle interventions in the DPP, the FDPS, the IDPP, and other studies are cost-effective^{13, 14, 32} and long-lasting (3 or more years follow-up), even when participants gain back some of the weight lost during the program.^{9-11, 33} Policy documents from expert organizations, including The Disease Control Priorities project (DCP-2),³⁴ the European Society of Cardiology and European Association for the Study of Diabetes,³⁵ the Canadian Diabetes Association,³⁶ the American Diabetes Association¹⁷, and the International Diabetes Federation,¹⁶ recommend lifestyle changes such as weight loss and increased physical activity for the prevention of T2DM among those with pre-diabetes.

There is clearly an urgent need for culturally specific, community-based, sustainable lifestyle interventions in South Asian countries for the prevention of T2DM. A successful lifestyle intervention created for India, a large, diverse, and populous South Asian country with large numbers of T2DM cases, increased morbidity from T2DM, and the presence of many potentially interrelated T2DM risks factors, could be used as a template for similar lifestyle programs throughout South Asia and in South Asian populations globally. Interventions that seek to control obesity and increase physical activity may be the most effective way to prevent diabetes in Indians.³ Translating lifestyle interventions to the community to create a culturally tailored lifestyle intervention would be a prudent means of applying effective strategies to this population.

Successes of culturally specific interventions are widespread.^{37, 38} Researchers have long noted that when people are approached in a culturally sensitive way, they are more receptive to health messages,^{39, 40} and the Indian community is no different.^{41, 42} 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.

Lifestyle programs also need to address the barriers to behavior change within a community. Much of the research on barriers to lifestyle change in South Asian Communities has been conducted in the United Kingdom, and it is important to note that barriers for Indians in India might differ. Traditional foods are an important part of the social culture of Indian life,⁴¹ and the food choices are influenced by many factors, including religion, region of origin within India, and health messages received.⁴³ Programs seeking to modify diet must be sensitive to the cultural beliefs and norms regarding food. Migrant South Asian women report the following barriers to physical activity: modesty issues which preclude exercising in mixed-gender groups; traditional dress, which may be unsuitable for

many types of exercise; family objections to exercise participation; unwillingness to exercise beyond a comfortable threshold; and not viewing exercise as culturally appropriate.^{38, 41, 44} Conversely, women from South Asian countries cite many of the same motivating factors for exercise as other populations: weight loss, a way to maintain independence, and the need for the social activity that exercise can provide.⁴⁴ In general, social support is one of the greatest motivating factors for lifestyle change in this community and should be used to strengthen any lifestyle program directed at this population.⁴⁵

Members of the study team, both in the US and India, have experience in diabetes screening, prevention trials, and translation research. The researchers at Emory University are creating a culturally appropriate lifestyle intervention for diabetes prevention in South Asians in Atlanta, the majority of who are of Asian Indian origin. This program builds on the core components of the DPP lifestyle intervention, modifying the existing program to include culturally appropriate nutrition information and advice and exercises (yoga and folk dances). Results of focus group discussions with members of the South Asian community will inform the final intervention design and will also provide insight into the development of the project described in this proposal.

The research team in India, located at the Madras Diabetes Research Foundation (MDRF) in Chennai, India, just completed the Prevention, Awareness, Counseling and Evaluation Diabetes program (PACE), a large four-phase project that: increased diabetes awareness by distributing educational materials to over a million people; performed large-scale diabetes and pre-diabetes screening on over 75,000 people with free blood sugar tests; and implemented an exercise program for diabetes prevention.⁴⁶ The exercise intervention, which randomized study centers to receive training on yoga, walking, both yoga and walking, or neither (controls centers), showed that exercise interventions are both possible and effective in this population. The program, although short in duration, showed that walking alone significantly decreased fasting plasma glucose (unpublished data). Diabetes materials, developed specifically for PACE and including a diabetes documentary, posters, and booklets, are valuable resources that can be used in other projects, including the one described in this proposal.

In summary, the increased risk for developing T2DM and the high prevalence of T2DM risk factors in India and all of South Asia must be urgently addressed. Lifestyle interventions are an effective and cost-effective means for preventing T2DM. There is a need for an effective lifestyle intervention in South Asia for the prevention of T2DM, and India is the ideal location to develop such an intervention. The study team, with experience in diabetes screening and prevention in Indian populations both in the US and India, proposes a randomized translation trial of a DPP-like intervention for the prevention of T2DM in India which is culturally appropriate, low-cost, community-based, scalable and sustainable.

C. Detailed Plan of Investigation

	Months											
	01-03	04-06	07-09	10-12	13-15	16-18	19-21	22-24	25-27	28-30	31-33	34-36
Prepare and translate manuals, study materials, obtain IRB approval	█											
Train of lay interventionists	█											
Recruitment & screening		█	█	█	█	█	█	█	█	█	█	█
Baseline testing & randomization			█	█	█	█	█	█	█	█	█	█
Intervention:				█	█	█	█	█	█	█	█	█
Active intervention (4 months)				█	█	█	█	█	█	█	█	█
Maintenance (2 months)					█	█	█	█	█	█	█	█
Follow-up (6-12 months)							█	█	█	█	█	█
Close out, data analysis, intervention evaluation, final reports, and publications												█
Dissemination of results												█

This proposal describes the implementation and evaluation of a community-based, culturally appropriate, low-cost, and sustainable lifestyle intervention for the prevention of T2DM among people with pre-diabetes in India using a randomized controlled trial.

Power and Sample Size: With a sample of size of **315** people per study arm, this study will have **80%** power to detect a 38.3% reduction (from 18.3%⁸ to 11.3%) in T2DM incidence in the intervention

arm (one-side $\alpha = .05$). Therefore, the researchers plan to randomize 700 people with pre-diabetes to the intervention or control arm of the study (350 per arm, allowing for a 10% loss to follow-up in each arm).

Figure A: Study Timeline

Timeline: The study timeline is shown in Figure A. The study will last 36 months with: protocol planning and training of lay interventionists in months 1-6; recruitment and screening beginning in month 5 and continuing until 700 people have been randomized into the study; and baseline testing and randomization of participants beginning in month 8. Individuals who are eligible for study enrollment will begin the intervention no more than 1 month after randomization. Each month, 60-70 people will be randomized to either the control or the intervention arm. One intervention "cohort" of approximately 25-35 people will be created monthly, and each cohort will go through the lifestyle classes together. The intervention will consist of 16 weeks of the active intervention program, 8 weeks of a less-intensive maintenance period, and follow-up. The intervention will commence in month 8 and run until month 30 (thus, allowing 22 months to randomize and treat 700 subjects with a minimum of 12 months total follow-up, including the intervention period).

C.1. Recruitment, Screening, and Baseline Testing

Eligibility and Exclusionary Criteria: The study will take place in Chennai (formerly Madras), India's fourth largest city and the largest city in Southern India, with a population of 7 million. Chennai is the home of MDRF, the location of all study testing and lifestyle classes. We estimate screening 5000-7000 people using casual capillary blood glucose and a short questionnaire to recruit 1,500 people for baseline testing. This is based on a calculated positive predictive value of 30% for using a casual blood glucose of greater than or equal to 120 mg/dL to test for pre-diabetes.⁴⁷ Inclusion and exclusion criteria were guided by previous diabetes prevention trials.^{8, 10, 48} **Based on measurements done at screening and baseline, the study will include men and women who have the following characteristics (all others will be excluded from the study):**

- Live in or near Chennai, India and have a confirmed age greater than or equal to 25
- A BMI ≥ 22 kg/m²† and/or a waist circumference >90 cm for men and >80 cm for women
- No prior diabetes diagnosis, except for gestational diabetes
- A high risk of developing diabetes (pre-diabetes) as defined by a casual capillary glucose greater than or equal to 120 (measured during screening) AND Baseline fasting glucose of 100-125 mg/dL and/or 2-hour post-load glucose of 140-199 mg/dL
- Not pregnant and no history of heart disease, serious illness, cancer diagnosis in the last five years, or other conditions that may impede or prohibit participation
- Willingness to consent to randomization

†The researchers plan to enroll Indian men and women with a BMI ≥ 22 kg/m². Many studies have indicated that this lower cutoff is more appropriate for Asian populations, because of increased disease risk and percent body fat at lower BMI's.^{20, 49} Study participants in the intervention arm will be counseled to lose 7% of their body weight over the course of the 16-week study and 8-week maintenance period. The research team feels that this is a reasonable weight-loss goal based on the following: (1) excess body weight is common in this community^{8, 50} (in the CURES study 45.9% of those sampled had a BMI ≥ 23 kg/m²), and most of the randomized participants will likely have BMI ≥ 25 kg/m²;⁴⁹ (2) participants in the DPP lifestyle intervention successfully met weight goals over a relatively short period of time;¹¹ and (3) eliminating 500 calories/day or expending enough energy to burn 500 calories/day while making no other changes will result in a weight loss of 0.545 kg per week. If participants maintain this minimal level of change for the 16 weeks of the intervention, they could lose 7% of their body weight over the course of the study.

Recruitment and Screening: Study participants will be recruited from several sources: (a) MDRF's epidemiologic databases with several thousand subjects (b) Dr. Mohan's Diabetes Specialties Centre's electronic medical records system, which holds records for over 150,000 diabetic (one of the world's largest) and over 2,500 pre-diabetic patients; (c) free diabetes risk factor screening and recruitment days at temples, mosques, and churches and other public places; and (d) advertisements in newspapers, on television, and at colleges and worksites. Men and women attending screenings will be

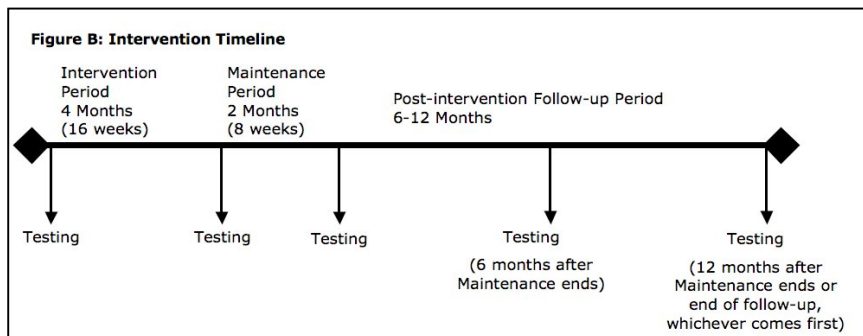
told about the study and offered the chance to participate if they are eligible. Dr. Mohan and his team at MDRF have considerable experience and expertise in recruitment and retention in India: for example, 26,001 subjects were recruited from within the corporation limits of Chennai City for the urban component of the CURES (a response rates of >90%).⁵ PACE screened over 75,000 individuals,⁴⁶ and, for the international DREAM study, MDRF contributed the largest number of pre-diabetic subjects from any single center in the world.⁵¹

Screening for enrollment will be conducted at the health screenings and the MDRF offices. Potential study participants will be asked to fill out a short survey to determine height, weight, pregnancy status, age, and history of diabetes, cardiovascular disease, severe lung disease, cancer, and functional difficulties and have their blood glucose measured by a finger-stick, capillary blood glucose (CBG) test. It is estimated that about 5000-7000 will be screened with CBG and that 1500 people will be interested in the study and eligible for baseline testing using the above eligibility criteria.

Baseline Testing and Randomization: Baseline testing will determine eligibility for the intervention and gather baseline data for study participants. A list of study tests and instruments can be found in Table 1. All participants who are eligible for the intervention after baseline testing and agree to randomization will be randomized to receive either the culturally appropriate lifestyle intervention (intervention arm) or standard lifestyle advice (control arm).

C.2. The Intervention

Control Arm: Participants randomized to the control group will receive standard lifestyle advice. They will be asked to attend one group class where they will learn basic information on diabetes prevention, weight loss, diet, and exercise consistent with expert recommendations for a healthy lifestyle, including losing 5-10% of their excess body weight, following standard dietary recommendations to reduce calorie and fat intake, and exercising at least 150 minutes per week. Control participants will receive publicly available literature (flyers, brochures, etc.), which are consistent with the information given in class. The control participants will have no contact with study staff besides the one class and at study testing days.



Intervention Arm: Figure B shows the intervention timeline. The key components of the lifestyle intervention are:

- 1. Lay Interventionists:** Community volunteers will be interviewed and recruited for training as lay interventionists. They will be trained on lifestyle coaching, diabetes prevention, and diet and exercise change by members of the study staff. These men and women will assist in teaching lifestyle classes and provide support and guidance to study participants. The study team plans to recruit and train at least 12 lay interventionists during months 1-6 of the study.
- 2. Lifestyle Classes:** Participants will attend group lifestyle classes weekly during the intervention period and biweekly during the maintenance period. The DPP lesson plans⁵¹ will be used as a starting point for developing culturally appropriate lifestyle curricula. During the intervention period, classes will focus on diabetes, diabetes prevention, increasing physical activity/decreasing sedentary activities,

and making diet and behavior modifications for weight loss and disease prevention. Recommended diet modifications will focus on decreasing total calories and fat by avoiding fried foods and sugar-sweetened beverages, increasing fiber intake, reducing glycemic load mainly by switching from refined white rice to unrefined brown rice, and reducing sugar intake. Maintenance period lifestyle classes will cover maintaining weight loss and continuing lifestyle changes made during the intervention period. Professional nutritionists and fitness instructors from MDRF and Emory will guide DPP modifications and will refer to information published by the American Dietetics Association on general nutrition, the Association of Physicians of Indian Origin on nutrition for Indian diets,⁵² and guidelines on the management of diabetes from the Indian Council of Medical Research.⁵³ Local resources, such as Research Society for Study of Diabetes in India, will also be consulted. All classes will be held at MDRF and will be team-taught by a professional health educator and a trained lay interventionist.

3. Aerobic Exercise Component: Participants in the intervention arm will be asked to exercise at least 150 minutes per week, *in addition to their normal activity*. **The exercise intervention component will be designed to increase adherence and acceptability by creating a program of activity that is flexible and culturally appropriate.** Participants will be asked to walk on their own or with walking groups organized by the study team and led by a lay interventionist at least three times per week. Walking has been shown to be an effective exercise for decreasing diabetes risk.^{8, 11} Participants will be allowed to do alternate forms of aerobic exercise if they chose. A culturally appropriate aerobics DVD, (developed by Aarti Patel) using Indian styles of dance, will be modified and made available as another exercise option.

4. Stretching and Strength Training Exercise Component: Study participants will be taught to include stretching and strength training exercises after every workout. At group walking classes, the lay interventionist will lead the group in resistance-type, strength training exercises (using their own body weight to gain muscle strength) and yoga-style stretching. The Lead Fitness Instructor (Mr. Balaji) will teach several one-hour classes on yoga-style stretching and strength training each week. The strength training will focus on teaching participants to use every day objects (i.e. food cans or sand bags) as weight training tools. At a minimum, participants must attend these classes biweekly during the intervention period and monthly during the maintenance period.

5. Follow-up Period: During the post-intervention follow-up period, there will be no contact between study staff and participants to reinforce the objective of implementing a lifestyle intervention in a real-life setting. The length of *post-intervention follow-up* will vary from 6 months for the last intervention cohort to 12 months for the first group enrolled in the study.

6. Peer Support Groups: Participants in the intervention group will be placed into peer support groups of 4-6 people. This type of “**buddy system**” has been shown to increase compliance in intervention studies^{54, 55} and cross-sectional studies of exercise participation.⁵⁶⁻⁵⁸ The Task Force on Community Preventive Services “strongly recommends” mechanisms to increase social support networks, including pairing participants with exercise buddies, as a means to increase physical activity.⁵⁹ The support groups will be encouraged to talk to one another outside of class to offer support. Members of the peer groups will work together during small group activities in the lifestyle classes.

Study Testing: All participants will attend study testing at screening, baseline, post-intervention (4 months after randomization), and post-maintenance (6 months after randomization). Follow-up testing will occur for all participants at 6 months after maintenance ends (12 months after randomization), and, if the individual was enrolled in the study before month 17, again at the end of follow-up (8-12 months after maintenance ends, 14-18 months after randomization). Participants in the intervention arm will have anthropometrics and capillary blood glucose measured monthly throughout the intervention to track progress. Study participants will be asked to arrive at each testing appointment after having fasted overnight for at least 10 hours. All study testing will be conducted at MDRF by trained nursing or study staff. Study tests and instruments are shown in Table 1.

Table 1: Study Tests and Instruments

Test or instrument name	Screening	Baseline	Week 4, 8, and 12	Post-Intervention	Post-Maintenance	Follow-up
Screening questionnaire						
Capillary glucose						
Brief medical history questionnaire						
Weight and height						
Fasting plasma glucose						
Oral glucose tolerance test						
Blood chemistry and blood count						
Glycosylated Hemoglobin (HbA1c)						
EKG						
Plasma lipids						
Waist, hip, and abdominal sagittal circumference						
Percentage body fat						
Exercise/diet self efficacy						
Exercise/diet stage of change						
Exercise/diet behaviors, risks, benefits, barriers (health beliefs)						
Food frequency questionnaire						
3 day food record						
Activity Logs						
Class Attendance Records						
24 hour dietary recall						
Depression and anxiety - patient health questionnaire						
Social support questionnaire						
Quality of life (Quality of well-being scale)						
Measures of cost (from patient and staff surveys, chart reviews)						

Objective 1: To evaluate effectiveness of the lifestyle intervention by assessing between group changes in the primary and secondary outcomes.

Measurement of the primary outcome – Diabetes Incidence: At baseline and follow-up visit(s), a 75-g oral glucose tolerance test will be administered to measure both 2-hour post-load glucose (2HG) and fasting plasma glucose (FPG). After the intervention and maintenance periods, blood glucose will be measured by a FPG test. Diabetes is diagnosed by a $FPG \geq 126$ mg/dL or a $2HG \geq 200$ mg/dL. Diabetes incidence will be calculated by determining the proportion of individuals progressing from pre-diabetes to diabetes at each time point.

Measurement of secondary outcomes – percent body fat, weight, body mass index, waist-to-hip ratio, fasting glucose, blood pressure, plasma lipids, activity, and diet: The following methods will be used to measure the secondary outcomes. The timing of study tests is shown in Table 1.

- Percent body fat:** Percent body fat will be measured using bioelectrical impedance (Beurer machine).⁶⁰
- Body Weight:** Weight will be measured in kilograms using a standardized, calibrated scale. Weight loss in kilograms and percent weight loss will be calculated.
- Body Mass Index:** Height will be measured using a standardized stadiometer. BMI will be calculated.
- Waist-to-hip ratio:** The circumference of the waist and hip will be measured following the protocol used in the DPP.⁶¹ The waist-to-hip ratio will be calculated.
- Fasting Glucose:** Measurement of blood glucose levels is described above (see measurement of preliminary outcome). Glycosylated hemoglobin (H_{A1c}) will be measured to determine long-term glucose control.
- Blood pressure (BP):** BP will be measured using standard procedures with an electronic BP apparatus.

- g. *Plasma lipids*: Plasma levels of HDL, LDL, triglycerides, apolipoproteins A and B, and total cholesterol will be measured from a venous blood sample.
- h. *Activity*: Participants in the lifestyle arm will be asked to fill out daily activity logs. Questionnaires given to all study participants will measure recent average activity and exercise behaviors.
- i. *Diet*: Changes in “normal diet” will be assessed by comparing the results of a 12-month food frequency questionnaire (FFQ) from baseline and end of follow-up. The study will use a FFQ developed for and validated by MDRF in Chennai.⁶² Diet behaviors will be measured using questionnaires given on each testing day. Participants in the intervention arm will also be given a three-day food record once per month and asked to fill it out for the three days before the next lifestyle class.

Other tests and instruments: Although not primary outcomes, the researchers will also measure changes in the following over the course of the study: pulse rate (measured by EKG), diet and exercise stage of change and self-efficacy; affect and anxiety; and perceived benefits of and barriers to exercise and healthy eating. These measurements will be determined through validated questionnaires.

Objective 2: To evaluate the cost-effectiveness of the lifestyle intervention.

Evaluation of Cost-Effectiveness: We will determine the cost-effectiveness of an intensive lifestyle program 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 will be calculated and expressed as a ratio. The perspective of this economic evaluation will be a single payer system. We will also conduct the analysis from a societal perspective in the sensitivity analysis. All analyses will be within the time frame of the trial. **Quality of life** will be measured as utility values (1=perfect health; 0=death) from the Quality of Well-being Scale.⁶³

Costs: The direct medical and non-medical costs and indirect costs associated with the lifestyle intervention over 18 months will be included. *Direct medical costs* will include the cost of: implementing the lifestyle interventions, intervention side effects, and medical care (hospital costs, emergency room, urgent care, outpatient services, telephone calls to providers, and medications). *Direct non-medical costs* will include the value of time spent by participants traveling to and attending interventions, time spent exercising, shopping and cooking healthy foods and the cost of equipment, food, and transportation. To estimate cost of lost productivity, the researchers will estimate costs arising from being absent from work or usual activity due to the intervention, illness, injury, or premature mortality. The research team will summarize the incremental cost of the lifestyle intervention relative to the standard lifestyle advice cost.

Information on costs will be from medical records and participant surveys. Secondary data sources will be used as much as possible to reduce the burden of data collection for economic analysis. Unit costs for study participant time will be based on the average national wage rate. Unit costs for outpatient services, outpatient procedures, laboratory tests, and consultations will be estimated using charges. The unit cost of labor, fringe benefits, equipment and supplies consumed will be assessed from secondary sources. The unit cost of medications will be derived from average wholesale prices. The unit cost of time will be based on actual salaries.

Objective 3: To evaluate the sustainability of the lifestyle intervention.

Evaluation of Recruitment, Adherence, and Program Acceptability: To evaluate recruitment, databases will be created to 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 will be recorded at all exercise and lifestyle classes by asking each participant to sign-in upon arrival, and participants in the lifestyle arm will be asked to fill out exercise logs daily and 3-day food records once per month. Completed exercise logs and food records will be collected at each lifestyle class, photocopied, and returned to the study participant. The number and type of exercise sessions done weekly will be recorded.

The acceptability of the intervention will be assessed through focus group discussions with participants who received the lifestyle intervention. During the maintenance period, 20% of participants in the lifestyle intervention will be randomly selected and asked to return to MDRF for one of 8 focus group discussions. Focus groups will be comprised of 8-10 people of the same gender and moderated by

a trained facilitator of the same gender as the participants. Focus group discussions will last 45-60 minutes and will focus on seeking participants' experiences of the lifestyle intervention. Each discussion will be led by a member of the study team who was not a teacher in the lifestyle classes to encourage honest feedback. The participants will be encouraged to share their experience in the lifestyle program in the following areas: (a) positive aspects/benefits of the lifestyle program; (b) negative aspects of/problems with the program; (c) suggestions for the future (what about the program should change or stay the same?); and (d) monetary "worth" of the program (what would they be willing to pay for the program?). The focus group discussions will be audio recorded and transcribed.

Participants who drop out or withdraw from the program will also be contacted and interviewed by phone or home visit to determine (a) their reasons for leaving the study, (b) likes and dislikes about the intervention, and (c) suggestions for improving the intervention.

The data from the focus groups discussions and phone/home interviews will be used to: (1) complement the quantitative evaluation of the intervention by seeking experiential feedback on each component of the lifestyle intervention from the perspective of the 'user'; (2) assess the acceptability and sustainability of the program for the community; and (3) to further develop future translation programs for large-scale implementation.

C.3. Data Analysis Plan

Data Quality: Study forms and biological samples will be labeled with a unique study identifier. Study forms will be duplicated and the copy will be used for double data entry. All quantitative data will be entered into a Microsoft Access database and audited for accuracy. Coded forms will be kept separately from the code list to maintain confidentiality. Study staff will check missing and outlier values monthly. All forms will be stored in a locked file cabinet in a locked office.

The accuracy and validity of activity logs will be assessed by comparing the group classes recorded on the activity log and attendance records for the classes. A member of the study team will call 20% of study participants per month to do an unannounced 24-hour dietary recall to test the validity of the food records. The call will occur on one of the three days per month the participants are recording their dietary intakes.

Extensive training of all study staff will be key to ensuring data quality. Dr. Hennink, an experienced researcher in qualitative and quantitative data collection, will train focus group moderators and survey administrators via videoconference. All medical testing will be done at MDRF, and all MDRF staff members are highly trained and qualified.

Qualitative Data Analysis: Qualitative data will comprise the verbatim transcripts of all focus group discussions. Audiotapes of focus group discussions will be transcribed, and the transcriptions audited for accuracy. The transcripts will be de-identified prior to analysis. The MAXqda (2007) program will be used to manipulate textual data for analysis. Analysis of the textual data will follow the grounded theory methodology,^{64, 65} whereby key themes are identified inductively from the textual data. These themes will then be compared using structured comparisons to identify specific issues relevant to sub-groups of participants, for example different issues raised by men and women or by younger and older participants.

Quantitative data analysis: Analysis of quantitative study data, including assessment of changes in primary and secondary outcomes, will be conducted in SAS, version 9.1 (SAS Institute, Cary, N.C). A probability of <0.05 will be considered statistically significant for all tests. Continuous variables will be tested for normality, and non-normal values will be categorized or transformed. Descriptive analysis will be performed for all variables and unadjusted comparisons between study arms will be made using T-tests (for continuous variables) or Chi-square Tests (for discrete variables). When appropriate, longitudinal models will be created to look at change over time for outcome variables, and changes over time will be plotted. All data will be presented before and after adjustment for confounding and interaction.

Randomization will be assessed by comparing baseline variables between the two study arms. Recruitment will be evaluated by comparing the sample sizes of individuals: screened for the study; passing the screening criteria; at baseline; agreeing to be randomized; and enrolling in the study. Percent retention will be measured by subtracting the number of individuals in each arm of the study returning for testing at the end of the intervention period and the end of the maintenance period or the end of follow-up from the

total number enrolled in the study and dividing by total enrollment. A participant will be considered adherent to the intervention if he or she attended 95% or more of the required classes and turns in at least 95% of diet and exercise records.

The effectiveness of the program will be measured in terms of differences between study arms in incidence of diabetes, changes in body size and composition, biomedical measures, and diet and activity. Diabetes incidence will be compared between study arms using Cox's longitudinal models to look for changes over time. The researchers will present both adjusted and unadjusted models. Similarly, longitudinal models will be used to plot and analyze changes in secondary outcomes, body weight (in kg), percent body fat, waist-to-hip ratio, abdominal saggittal diameter (in meters), fasting glucose (in mg/dL), blood pressure (in mmHg), blood lipids (including high and low density lipoproteins, total serum cholesterol, triglycerides, in mg/dL), activity (in METs/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).

Cost-Effectiveness Analysis: Two sets of outcomes will be used to measure cost-effectiveness: Cost-effectiveness analysis (CEA) (*incremental cost per case of diabetes prevention*) and cost-utility analysis (CUA) (*incremental cost per quality-adjusted life-years (QALY)*). QALY will be calculated using utility values derived from the Quality of Well-being scale. The basic formulae to calculate incremental CEA ratio and CUA ratio of the intensive lifestyle intervention compared to standard advice are:

$$ICER_{CEA} = (\text{Mean Cost}_{\text{intervention}} - \text{Mean Cost}_{\text{standard advice}}) \div (\text{Mean Effect}_{\text{intervention}} - \text{Mean Effect}_{\text{standard advice}})$$

$$ICER_{CUA} = (\text{Mean Cost}_{\text{intervention}} - \text{Mean Cost}_{\text{standard advice}}) \div (\text{Mean QALY}_{\text{intervention}} - \text{Mean QALY}_{\text{advice}})$$

The cost-effectiveness of the lifestyle intervention is represented by the ratio of incremental cost to increment effectiveness. In addition, sensitivity analyses will be performed in order to examine effects of key parameters on cost-effectiveness ratios.

C.4. Key Personnel

Emory University has formalized an institutional relationship with MDRF to create the MDRF-Emory Global Diabetes Research Center (GDRC) at Chennai. Drs. K.M. Venkat Narayan and V. Mohan are Co-Directors of this new center. The proposed study will be a collaboration between investigators at Emory University and the MDRF/GDRC, Chennai, India.

Dr. K.M. Venkat Narayan – Co-Principal Investigator is Hubert Professor of Global Health and Epidemiology and Professor of Medicine at Emory University (Atlanta, GA, USA). Formerly Chief of the Diabetes Epidemiology and Statistics Branch at the Centers for Disease Control and Prevention (CDC), he has led a number of large national epidemiological, intervention, translation research, and economic studies. He has over 190 publications, and is an investigator in several multi-center trials, including the DPP. Dr. Narayan also led a culturally specific lifestyle intervention trial in the Pima Indians.

Dr. V. Mohan – Co-Principal Investigator is a diabetologist and researcher and is director of MDRF with over 350 publications. MDRF is involved with several ongoing epidemiological and clinical studies and has both capacity and local know-how in population-based research in South India. Dr. Mohan initiated, designed and conducted several population-based studies, notably, CUPS,⁶⁶⁻⁷⁰ CURES,^{5, 71-76} and PACE,^{46, 77} and the WHO-ICMR NCD Risk Factor Surveillance and Integrated Diseases Surveillance Project of the Indian Government.

Dr. Monique Hennink – Co-Investigator is Rollins Associate Professor in the Rollins School of Public Health, Emory University. She is a recognized authority in qualitative research techniques, with methodological expertise in qualitative research design, conduct, and textual data analysis. She has conducted evaluation research and in-depth studies amongst South Asian populations.

Mary Beth Weber, MPH – Co-investigator is a third year doctoral student in the Nutrition and Health Sciences Program at Emory University. She holds a MPH in Epidemiology from Emory University. Ms. Weber has experience in project coordination, study design, collecting and analyzing quantitative data, health promotion, and health policy and is leading a lifestyle intervention study among South Asians in Atlanta.

Dr. Ping Zhang, PhD – Consultant is Senior Economist at the Division for Diabetes Translation, CDC, and has led or is leading the economic evaluation for several large diabetes studies: DPP, IDDP, ACCORD, and has extensive experience in measurement of costs, quality of life, and economic modeling.

R. Balaji, Lead Exercise Interventionist - is a qualified and experienced Fitness Consultant and is Chief Manager of Dimensions, one of the foremost gyms in Chennai. He has trained hundreds of diabetic patients at MDRF in stretching and other exercises without use of expensive equipment.

Aarti Patel – Consultant is certified by the American Council on Exercise (ACE) as a Personal Trainer, a Group Fitness Instructor, and a Lifestyle and Weight Management Consultant and owns *Aarti Fitness*. Ms. Patel brings personal insight about weight loss and exercise to her work, based on her own 40-lb weight loss. She is the lead instructor for a diabetes prevention project among South Asians in the US.

Reena Oza-Frank, MS-MPH, RD, Nutritionist - earned her undergraduate degree from The Ohio State University in nutrition science and a dual master's program (MS-MPH) at The University of Tennessee-Knoxville in Public Health Nutrition and Community Health Education. She is a registered dietitian with experience working as a research nutritionist and as a clinical diabetes educator

Dr. Suresh Somannavar – Study Coordinator - is Head of the Department of Community Medicine at MDRF. He has extensive research experience in conducting community-based studies, including PACE.

S. Poongothai - is Chief Clinical Research Officer at MDRF. She has been involved in coordinating and leading over 45 international and national clinical trials. Ms. Poongothai will coordinate recruitment.

M. Deepa - is Chief of Epidemiology at MDRF. She has extensive knowledge on epidemiological studies, data management, data quality control, analyzing data, and writing research articles and has individually monitored conducting of large trials like CURES and the WHO-ICMR NCD Risk Factor Surveillance.

R. Guha Pradeepa - is Senior Executive, Research Projects and Publications at MDRF and has extensive experience in coordinating research projects, including PACE and the MDRF/WDF Rural Diabetes Telemedicine project.

4. Sustainability and Future Impact

Translation and Sustainability: Narayan and colleagues define **translation research** as “comprehensive, applied research that strives to translate the available knowledge and make it useful in everyday clinical and public health practice.”^{15, 78} Our project is designed to be translation research and, as such, contains elements that will ease the transition from “experiment” to clinical and public health practice. For instance, involving the community in project implementation by training lay interventionists and tailoring the intervention components to be culturally appropriate will give the community a sense of ownership of the program. Similarly, extending the intervention to a wider, more generalizable group of people with pre-diabetes and building a relevant economic assessment are keys to a translation trial.

All community interventions, especially translation research, should be designed with **sustainability** in mind. Although the intervention will end, several products and services will remain in the community:

- a. Materials created for the program, including, but not limited to, brochures and fliers promoting dietary changes, increases in daily activity, and diabetes education appropriate for Indians, will be available on the study website for downloading after the study is completed.
- b. Lay interventionists will be empowered to continue educating their peers on diabetes prevention, weight loss, and diet, exercise, and behavior changes and disseminate the lifestyle intervention throughout Chennai after the program is completed. This continued education of the community will be encouraged by directing the lay interventionists to resources in the community, like the MDRF, where they can obtain educational materials or arrange classes to train others on making positive lifestyle changes. The study interventionists will oversee this dissemination program and data on uptake will be collected.
- c. The walking groups are designed so that a study participant or a lay interventionist can continue to run them long after the intervention has ended.
- d. Results from the study, including the cost-effectiveness analysis and plans for a scalable, culturally appropriate lifestyle program for the prevention of diabetes in India, will be presented

to individuals involved in setting health policies for India, in the hopes that this program can be implemented on a wider scale in other communities in India and other South Asian countries.

- e. Results and experiences from the study will be communicated to the community using the local newspapers, radio shows, and television.

Innovations: This project has eight major innovative aspects. (1) Study participants will be organized into peer support groups, which will function as a tool to improve adherence and success. (2) The study will train lay interventionists to help deliver the program and increase opportunities for program sustainability. (3) The content of the lifestyle classes will be designed specifically to address the barriers to healthy eating and increased physical activity for Indians. (4) Nutrition classes will focus specifically on Indian foods and modifying Indian diets to reduce consumption of sweetened drinks and fried foods, portion sizes, fat, calories, and glycemic load (primarily by switching from refined white rice to unrefined brown rice) and increasing fiber intake. (5) The exercise program will focus on popular cultural activities such as walking and yoga and will teach participants to reduce time spent doing sedentary activities (e.g., watching television). (6) Participants will be trained on how to incorporate stretching and strength training, using every day objects, into their exercise routines. (7) The exercise program is designed to be sustainable; intervention participants will be encouraged and enabled to use community locations for peer-led walking groups after the intervention is complete. (8) The cost-effectiveness analysis can be used in making policy decisions for program dissemination.

Future Impact: This proposal describes an innovative, sustainable, low-cost, culturally tailored lifestyle intervention for T2DM prevention in Indians, a population at increased risk for developing T2DM. Results of this study will be used to plan a scalable, community-based, culturally appropriate lifestyle intervention for diabetes prevention that can be implemented in India and throughout South Asia, a region of the world with alarmingly high rates of diabetes and diabetes-related complications.

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