Better Together Study

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PROTOCOL TITLE: *Better Together: A patient-centered approach to improve diabetes among immigrant communities*

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REVISION HISTORY

Revision #	Version Date	Summary of Changes
1	09/03/2020	Updated recruitment methods section (added phone script to attachments)
2	10/25/21	Updated to change form to telehealth instead of in-person sessions. Updated financial tokens given to patients.
3	11/9/21	Updates incentives to match consent form
4	3/1/23	Added qualitative interview guide to participant satisfaction evaluation
5	10/25/24	Updating the protocol to reflect COVID related modifications in the data collection
6	11/13/24	There is one missed update in the objectives section that needed to be updated.
7	1/24/25	The inclusion/exclusion criteria needed to be updated to include women as well, based on COVID-related modifications
8	1/24/25	Clarifying that the secondary outcomes are all exploratory outcomes and data will be reported on participants individually.
9	2/5/25	We were unable to recruit any West African participants for this study, so we have removed this language.

Table of Contents

1. Study Summary

Study Title	Better Together: A patient-centered approach to improve diabetes among immigrant communities
Study Design	pre-post trial
Primary Objective	Feasibility and acceptability
Exploratory Objective(s)	Change in Hemoglobin A1c, Weight, Blood Pressure
Research Intervention(s)/Interactions	Health education focused on weight loss
Study Population	Immigrants from South Asia
Sample Size	48
Study Duration for individual participants	6 months
Study Specific Abbreviations/ Definitions	
Funding Source (if any)	NIMHD

2. Objectives

There has traditionally been very low uptake of diabetes education programs among immigrant men. This may be in part due to a lack of engagement of these community's social support networks. To address this, we will test: 1) that a social network-focused SMA intervention based in primary care is feasible and acceptable among South Asians with prediabetes/type 2 diabetes, and 2) that health behaviors will also improve among participants' social networks.
The aims of this project are to:
Aim 1: Implementation: Evaluate the preference, feasibility, and acceptability of social network-based (participant + social partner) versus individual-based (participant only) SMA ILI among SA immigrant participants with prediabetes/T2D through a 2-group pilot study.
Leveraging a pragmatic design approach, simulating a natural experiment, I will recruit participants with prediabetes/T2D (n=48 total) to join one of 2 kinds of 8-session/16-week SMA intervention groups at an Emory Family Medicine clinic: (1) dyads (patient + social partner; mixed gender) or (2) men-only
Primary Outcomes: recruitment and retention (preference and feasibility) and satisfaction (acceptability)
Exploratory Outcomes: pre-post changes in biometric measurements (body weight, blood pressure, plasma lipids, glycated hemoglobin), physical activity, and diet
Aim 2: Broader reach through Social Networks: Assess the behavioral outcomes of the pilot intervention amongst members of participants' social networks as potential spillover effects.
Conduct baseline and 6-month post-recruitment mapping of participants' (from Aim 2) self-identified social networks (n=5/participant) and assess the following:
Primary outcomes: change in weight control practices (e.g. physical activity, calorie counting, etc.)

Exploratory outcomes: change in weight from baseline to 6 months

3. Background

Diabetes is a major public health concern and challenging to address in current primary care practice. The burden of prediabetes and type II diabetes (T2D) in the US is growing rapidly, with 1.5 million new cases of T2D annually and 84 million currently living with prediabetes.[1] T2D now accounts for the largest portion of healthcare cost in the US, and is a major contributor to morbidity and mortality.[2] T2D can lead to complications such as renal dysfunction, peripheral and autonomic neuropathy, vision problems, and cardiovascular disease.[3] It is one of the top chronic conditions seen in primary care, accounting for over 15% of all outpatient primary care visits.[4] Over 50% of these visits are associated with multiple diagnoses, making it challenging for health professionals to address evidence-based T2D care in allotted 15 minute visits.[5] As such, preventing or delaying the onset of T2D and its related complications are major public health and health system priorities.

South Asians and Africans are growing immigrant groups at high risk for diabetes in the US. South Asian (SA) (ancestry originating from India, Pakistan, Bangladesh and other parts of South Asia) and Sub-Saharan African immigrant groups make up two of the fastest growing immigrant groups in the US.[6] SAs have higher rates of T2D and cardiovascular disease than whites.[7–9] Furthermore, SAs without diabetes have a high prevalence of T2D risk factors. Compared to whites, SAs have: higher rates of hypertension,[74] dyslipidemia, and insulin resistance.[10–12] SAs report low levels of physical activity, and the diet of the SA migrant population is low in fiber and is often high in fat and sugar.[13–16] In a British study, compared to white Europeans, SAs with T2D have worse glycemic control over time, even when the processes of care are similar.[17,18]

Cumulatively, these findings in SA immigrant communities challenge the well-accepted "healthy immigrant effect" phenomenon (that immigrants are on average healthier than native-born persons), suggesting that more tailored T2D prevention and management strategies are greatly needed to narrow the disparities in outcomes between these and other US populations.[25,26]

Intensive lifestyle interventions (ILIs) can improve diabetes self-management and health outcomes. Six large trials showed that intensive lifestyle interventions (ILIs), group-based programs designed to promote weight loss through a combination of diet, activity, and behavior change, decrease T2D incidence in people with prediabetes and reduced complications among people with T2D.[27–31] Two of these studies, the Diabetes Prevention Program (DPP) in the US and the Finnish DPP, showed a >50% reduction in T2D incidence in study participants in the ILI group compared to those in the control group.[27,30] Additional analyses have shown that the effects of lifestyle interventions are long-lasting, even when participants gain back some of the weight lost during the program.[27,29,30,32] The effects of the DPP intervention are also cost-effective.[33–35] The LookAHEAD trial, a weight-loss intervention in patients with T2D, showed improved quality of life, glycemic and lipid control, blood pressure, and reduction in overall cost.[36] Based on the findings of these and other studies, expert organizations, including the American Diabetes Association recommend lifestyle changes such as weight loss and increased physical activity for the prevention and treatment of T2D.[37]

Immigrant men face systems and societal barriers to engage in ILIs. While no sex differences have been found in treatment effect for intensive lifestyle interventions for T2D prevention,

uptake of men in such programs is low, ranging from 20-40%.[27,38–40] Immigrant men in particular, may face additional barriers to access such programs due to poor healthcare access (lack of health insurance and no usual source of care), compared to immigrant women and US-born men.[41,42] Men are less likely than women to identify disease prevention strategies and lifestyle as influencing their health.[43]

Preliminary data from my qualitative study in the SA Muslim immigrant community in Atlanta suggests that immigrant men do not prioritize lifestyle change, citing a lack of perceived control to make decisions about what is eaten in the home. One male focus group participant remarked, "If my wife tells me to eat, I have to eat. I have no choice." At the same time, spouses and family members can provide motivation for healthy lifestyle choices. Another male participant noted, "I think husband and wife it does [motivates] automatically. Like the other day I came home and my wife was walking outside in the subdivision and she told me, "Do you want to join me for half an hour?" So let me go and join. Part of the kinda bonding."

Strategies to improve the reach of diabetes prevention and management programs for men, particularly immigrant men, are needed and our data suggest that engagement of social networks, particularly family and other household members is important.[39]

Family and social networks could be an important factor to improve patient activation, especially for South Asian and African immigrant men. Social networks, defined as someone with social or family ties to an individual, affect health through myriad mechanisms including social support, social influence, social engagement, and access to resources.[44] Previous work from my mentorship team shows, that spouses of people with newly diagnosed T2D have twice the annual incidence of T2D in the year after their partner's diagnosis compared to the national average (16.4 vs 8.1 per 1000 persons from 2007-2011).[45] Moreover, social networks, participation through social support, may be able to be leveraged to improve health behaviors. In a number of studies, participants with high levels of social support were more engaged in health behavior changes, and social support has been shown to improve patient activation for behavior change.[46–50] In a sub analysis of untreated spouses of participants in the LookAHEAD ILI were more likely to lose >5% of their body weight and engage in positive dietary changes, when compared to control group untreated spouses.[51]

However, to date, most research, guidelines, and approaches to diabetes prevention and care have focused on individual self-management. We have not explored the potential for "collateral health effects" of interventions–for example, people who are socially connected with each other.[52] Interventions that ignore participant's social structure may overlook the potentially valuable support created by one's social context (e.g., helping reinforce positive behaviors). Not engaging with social connections might even increase the barriers to behavior change as social connections may influence unhealthy lifestyle choices. Family members and friends can potentially be negative influences, hindering a patient's health goal.[53,54] Targeting social network influencers in programs could harness their knowledge and motivation in such a way that they enhance behavior change in both participants and their social influencers and potentially sustain behaviors, given the ongoing relationships of participants and social influencers.

Typical SA immigrant populations are culturally close-knit communities, with strong family and social ties.[55,56] Several studies have identified cultural and family priorities as barriers

to health behaviors such as physical activity among SAs.[57,58] Lawton et al report that among SA men, there is a pervasive belief that time outside of work should not be spent on leisure activities such as exercise, but used to help family members or spend time with children.[57] In a qualitative study of perceptions of cardiovascular risk among SAs in California, participants noted that dietary practices were a central part of the family unit. They felt that giving foods, particular high in butter and milk, were considered a nurturing act by a mother or wife.[59] Furthermore, social gatherings are an integral part of cultural identity for SA diaspora, and these events often center on food, which is often high in sugar and oil and low in fiber.[57,60] Similarly Sub-Saharan African immigrant communities have high levels of social cohesion, often relying on family support and social networks for health concerns.[61] A qualitative study of African immigrants in Manitoba, Canada cites how more established immigrants who have lived abroad in Canada often serve as an important support system for new arrived immigrants.[62] A study of African immigrant offspring, note that social and religious gatherings are central part of their culture, and foods, often high in oils and starches, are central to these celebrations.[63] Thus, these cultural and social influences shared among SA and African immigrants may be better addressed in an ILI that targets participants and their social influencers.

Shared medical appointments (SMAs) may be a model to incorporate the power of social networks for intensive lifestyle education delivery. Group-based clinic visits, such as SMAs are a promising, sustainable strategy to increase patient access by seeing a larger volume of patients in shorter a time frame and increase efficiency of the time health professionals spend with patients. In this model, individuals with a similar medical condition participate in a longitudinal multidisciplinary group visit with a portion of the visit dedicated to personalized care. The visits generally involves 12 to 16 patients in a 1 to 2 hour visit in which a portion of the visit is facilitated by a team (for example a physician/nurse/advanced practice provider/nutritionist) in a group setting and a portion is individualized for each patient.[37] The rationale for the group format is that it provides additional support that improves patient activation to make changes, thus SMAs focus on educational interventions such as self-management, medication management, or nutrition.[38-40] Interventions testing the SMA model have been shown to be feasible in several chronic health conditions, including heart failure and diabetes (T2D) self-care, and are associated with lower direct medical costs and higher guideline adherence in T2D care.[5,41] Furthermore, these visits are reimbursed by all payers, creating a sustainable approach to deliver ILI curriculum. Yet, to date the SMA model does not incorporate patients' health influencers, who may be critical in providing support to initiate and sustain behavior change and have not targeted the specific needs of immigrant men.

Preliminary/Relevant Data

In our pilot study, we focused on a dyad-based group ILI with SA Muslims. We successfully recruited 7 patients and their support partners in 5 days, using physician referrals and chart review, supporting feasibility of the proposed study. For those that were called and declined participation, 30% reported that their support partner, typically a spouse, could not commit to attend the sessions. Of the 7 patients enrolled, 3 were men, and their support partners included 1 adult son and 2 wives. Of the 4 female patients, support partners included 3 husbands and 1 female friend. Pilot data show high levels of male participation (43%), and in most dyads (6 of 7), both partners have prediabetes or T2D, and the mean age of participants is

51 (age range 23-72). Retention of participants is >80% retention at midpoint of the 16-week, bi-weekly intervention. Survey data suggest high levels of satisfaction with the group-based format (5/5 on Likert-like scales) and engagement of the support partner (5/5).

Supporting our choice to offer a male-only group, in a pilot translation study of the DPP for a predominantly African American group in New York City, in which participants in an all-male group program lost a mean 4% of body weight, participants reported interest for both male-only or mixed gender groups.[39,64]

Rationale for the proposed study

The literature regarding social network-focused interventions for T2D prevention and management is limited. To date, studies have tended to focus on involving family members when intervening to address chronic conditions in pediatric populations.[65,66] Current standard of care is individual-focused T2D self-management and prevention education at the time of diagnosis, and few published studies have explicitly targeted adult participants and their social contacts.[67] Systematic reviews of family interventions to address adult T2D note that many interventions do not involve communities and patients in their study design phase.[67,68] Understanding the cultural and family environment have been identified as key factors in considering how to tailor interventions for racial/ethnic minority populations.[69,70] *Our study addresses these gaps by focusing on SA and WA immigrant men as model populations to examine preferences, feasibility, and acceptability for an SMA intervention based in primary care and developed with user-driven input and changes in healthy lifestyle practices among participants' social networks.* The findings of this study should have relevance to other chronic conditions, such as hypertension and cardiovascular disease, and for other socially-cohesive subpopulations (e.g., Latinos, Native Americans, and rural whites).

4. Study Endpoints

This study has 2 aims, the first is a culturally tailored lifestyle intervention for South Asian immigrants in Atlanta. The second aim examines spillover effects of the intervention among participants' self-identified spillover effects. The endpoints are as follows:

Aim 1:

Primary Outcomes: I will examine outcomes in both patients (**P**) and social partner (**SP**) for those in the mixed gender arm of the intervention Specifically, I will report on:

1. *Recruitment and retention (preferences and feasibility)*: preference by group of the study (e.g. which group of the study are participants choosing), rate of recruitment, number of sessions attended; for dyads, this would include sessions attended together and separately, over the 6 month study period
2. *Participant perceptions of ILI (acceptability):* questionnaires at conclusion of program to evaluate: (1) satisfaction with the program and (2) suggestions for program improvement

Exploratory Outcomes: To evaluate changes in T2D-related risk behaviors in Ps, changes in the following at baseline (BL), 6 months (conclusion of ILI), and 6 months will be measured:

1. *Anthropometric measurements (body weight, body mass index (BMI), abdominal waist circumference)*: Weight will be measured in kilograms using a calibrated, standardized scale, and height will be measured using a standardized stadiometer. BMI will be calculated using the standard formula. Waist circumference will be measured by the World Health Organization recommended method.[113]
2. *Hemoglobin A1c (A1c):* Point-of-care testing (POCT) with well-validated clinical instrument
3. *Blood pressure:* Blood pressure will be measured using standard procedures with a manual cuff
4. *Plasma lipids:* POCT with well-validated clinical instrument
5. *Physical activity:* Participants will be asked to keep daily activity logs (e.g. minutes of exercise and types of exercises performed daily)
6. *Diet:* Changes in diet will be measured using the Rapid Eating and Activity Assessment for Participants short version (REAP-S), a validated short food frequency questionnaire (FFQ).[71(p)]

Aim 2: Assess the behavioral outcomes of the pilot intervention among participants' social contacts as potential spillover effects.

Primary outcomes will include change from baseline to 6- months in weight control practices (e.g. physical activity, calorie counting, etc.), based on a 30-item questionnaire previously used in a similar intervention.[51]

5. Study Intervention / Design

Describe the study intervention that is being evaluated, and/or the nature of interactions proposed.

6. Procedures Involved

Aim 1:
3.1 Overview: To evaluate preferences, feasibility, and acceptability of a virtual SMA ILI for SA and WA immigrant men on health behaviors and glucose control in a pre-post pilot study. Participants with T2D or prediabetes will be given a choice of 1 of 2 groups of the study: (1) dyads (patient + support partner; mixed gender) or (2) men-only (no social partner). Groups will be stratified by ethnicity, thus a total of 4 groups.

3.2 Study Design and Setting: This is a pragmatic, pre-post, pilot study. Participants will meet in groups of 12 for the SMA intervention at the conference room at the Emory Family Medicine Center in Dunwoody, Georgia. The group size of 12 is the recommended size for SMAs.[37] Leveraging a pragmatic, quasi-experimental design, simulating a natural experiment, the ILI will occur on a rolling basis, as recruitment is completed by group.
3.3 Intervention Development: The intervention will be refined based on feedback from the qualitative data analyses from Aim 1. Based on previous work by our team, the intervention was modified to be delivered in group telehealth sessions over 6 months. Each session will last

60-90 minutes, and participants will engage in a total of 6 televisit sessions. Sessions will consist of a group-based program for all participants, followed by a personalized care plan, led by a physician, Dr. Shah, or an advanced practice provider. For those that choose the dyad-based group, their social partner must commit to attend all in-person sessions. The sessions will take place at a time most convenient to participants and a time that can be integrated into the routine clinic schedule, likely a weekend morning or weekday evening. Based on my pilot study and previous work of my mentorship team, the sessions will be modeled on the Diabetes Prevention Program[27,72,73] and will include:

- Basic skills in healthy eating and physical activity, tailored for SA and WA immigrants
- Coping skills and managing the external environment (e.g. social or family situations that are specific SA and WA immigrant groups)
- Building social support so dyads/participants can learn effective ways to support one another to make and sustain health behaviors.

3.4 Recruitment: I and a research assistant will identify eligible participants through chart review and referrals from the Emory Family Medicine Center. We will contact eligible adult patients via phone to confirm their diagnosis, explain details of the study, obtain verbal consent, and recruit the patient and social partner, if choosing the dyad group (we will suggest who to include, based on our qualitative work) to participate. I anticipate screening 200 patient charts to identify a total of 48 eligible, consenting participants.

Eligibility (Inclusion and Exclusion Criteria): Based on reviews done at screening, men and women >18 years of age with a diagnosis of T2D or prediabetes will be invited to participate.

3.5 Enrollment: Individuals and their support person (if choosing the mixed gender arm) meeting eligibility criteria will receive detailed study information and be invited to participate. Informed consent forms will be available in English. All subjects will be reassured that their participation is voluntary and they are free to withdraw at any time, without consequences to their existing care. Participants will receive $20 gift cards for each data collection survey, and a total fo $75 if they complete all surveys and attend all sessions as a token of appreciation.

The following additional protocol adds a qualitative element to Aim 1, primary outcome 2: Participant perceptions of ILI (acceptability): questionnaires at conclusion of program to evaluate: (1) satisfaction with the program and (2) suggestions for program improvement

We will employ a type of in-depth interviewing style known as semi-structured interviews. Semi-structured interviews and semi-structured interview guides allow some flexibility in the administration of the guide, as compared to a structured interview guide. This will allow for in-depth data collection to generate valid data on this topic.

The participant list will be pulled from the Better Together study and the community health workers from the Better Together study. Ten people from the Better Together study and their support person will be interviewed as dyads. The people selected for the interviews will be done purposively. We will aim to have balance in gender of the participant with diabetes – aiming for 5 male participants and 5 female participants. Some questions in the attached interview guide pertain to the individual with diabetes, some will be directed at the support person, and some will

be answered by both. All three CHWs will be interviewed separately, totaling to 10 dyad interviews and 3 CHW interviews.

We expect data saturation to be achieved with the 13 interviews and will then qualitatively analyze these data. Interviews will be transcribed using rev.com and a deductive coding process rooted in social support theory will be employed. A codebook will be developed with the initial set of codes matching the social support constructs. Inductive codes will be drawn from the emerging stories and themes from the interviews as needed. A second coder will independently code all transcripts.

Aim 2:

4.1 Overview: To test the hypothesis that a social network-focused ILI SMA will have spillover effects among participants' social networks I will prospectively assess the influence of behavioral weight loss treatment on participant's self-identified social contacts who influence their lifestyle practices. I will conduct baseline and 6-month post-recruitment mapping of participants' (from Aim 2) self-identified social contacts (n=5/participant). Based on the high rates of cardio-metabolic risk factors in SA and WA immigrant communities, we anticipate that participants' social contacts will have elevated cardio-metabolic risk at baseline.[59,61,74–76]

4.2 Participants: We will utilize an **egocentric approach**. During enrollment of participants (egos) in Aim 2, we will use a name generator prompt to ask egos to identify social contacts who most influences their lifestyle behaviors (listing 5 alters).[77] Alters will be asked to participate in surveys as baseline and at 6-months. Alters will be excluded if they lack proficiency in English, are < 18 years of age, or cannot provide written consent.

4.3 Study Design: Paper surveys and weight assessments at baseline and at 6 months months will be conducted via home visits with alters (if geographically feasible). The alters will receive $20 for each assessment.

7. Data and Specimen Banking

No specimens will be stored. •All hard copies of surveys and consent forms will be stored in a locked file cabinet in a locked cabinet at the Emory Family Medicine Clinic at Dunwoody.

- Electronic data will be stored on a password protected, Emory University laptop, in a password protected electronic file.
- Every measure will be taken to prevent loss/theft of data, including limiting the number of people who have access to files and not allowing hard copies to of data to be taken from the clinic.
- We will make the data of our work available through presentations of the results, including the methods, results, and plans for further investigation at regional, national, and international meetings and conferences for researchers and clinicians. We will also work with our community advisors to disseminate the results to local communities and other stakeholders with interest in our findings.
- Publication of data shall occur during the project, if appropriate, or at the end of the project, consistent with standard scientific processes. We have budgeted for publication in open access journals to improve availability of our findings. Following NIH policy, the research data documenting, supporting, and validating research findings will be made available after the main findings from the final research data set have been accepted for publication via the procedure below. We will ensure adequate protections of the privacy of human subjects by removing all

personal identifiers and protected health information and ensuring IRB oversight of data sharing.

- Participants will be informed during consent that completely de-identified data (i.e., free of all 18 types of HIPAA identifiers) will be available to qualified researchers. Within 18 months of study completion, we will make datasets available to investigators who submit a written request to the PI. The only contingency on the use of the data will be ethical guidelines (e.g., requirement for completion of appropriate human subjects' protection training courses, secure data storage). The NIH will be notified of any data transmissions. De-identified data will be shared with requesting researchers via secure, electronic mail.

8. Sharing of Results with Participants

See above, study findings will be made available via community stakeholders, presentations, and publications. Participants pre-post biometric results will be shared with individual participants at the end of study.

9. Study Timelines

The timeline of the proposed Study 2 and 3 (Aims 1 and 2) is summarized in the table below. The timeline begins after notice of award. Of note, there is a separate qualitative study (Study 1) to culturally tailor all study related materials (this has been previously submitted to the IRB and is exempt). Thus, the proposed aims in the protocol begin at month 12 after notice of award.

Overall Project	**Expected completion post-award**
Aim 1: Pragmatic Pilot Study	
Finalized data collection protocol	Month 12
Finalized intervention protocol	Month 12
Approvals for Aim 2 consent forms	Month 13
IRB approval for Aim 2	Month 14
Registration on ClinicalTrials.gov	Within 1 month of IRB approval for Aim 2 (Month 15)
Recruitment of research coordinators	Month 1
Completion of training of research coordinators	Month 2
Recruitment of advance practice provider (APP)	Month 12
Completion of training of APP	Month 14
Anticipated start of recruitment for trial participants	Month 15
Anticipate start of first group sessions	Month 16
Anticipated completion of 50% of group sessions	Within 14 months of recruitment start (Month 30)

Anticipated completion of 100% of groups sessions	Within 26 months of recruitment start (Month 42)
Follow up visit completion of 50% of group session participants	Within 26 months of recruitment start (Month 42)
Follow up visit completion of 50% of group session participants	Within 38 months of recruitment start (Month 50)
Completion of primary endpoint and data analyses	Month 60
Final study report and manuscript submission	Over last 10 months of study, from Months 50-60
Final results in ClinicalTrials.gov	At time of manuscript acceptance
Aim 2: Social Network Analysis	
Finalized data collection protocol	Month 12
Approvals for Aim 3 informed consent forms	Month 13
IRB approval for Aim 3	Month 14
Anticipated start of recruitment for social network members (alters)	Month 16
Completion of data collection of alters	Approximately 6 months after last group session completed (Month 50)
Completion of data analyses	Month 60
Manuscript submission	Over last 10 months of study, from Months 50-60

10. Subject Population

Aim 1:

Based on reviews done at screening, men with a diagnosis of T2D or prediabetes will be invited to participate if they meet all of the following inclusion criteria: (1) age > 18 years; (2) confirmed diagnosis of prediabetes or T2D (documented A1c of ≥ 5.7% or FBG of >100); (3) a family member or peer willing to participate and attend all sessions as a social partner (if enrolling in dyad arm); and (4) proficiency in English(if in dyad, at least one member of each dyad), and (5) willingness to provide written consent. Individuals will be excluded from participation if they have any of the following: (1) type 1 diabetes or diabetes secondary to other conditions (e.g. steroid-induced, pancreatic insufficiency, or chemotherapy-induced); (2) malignancy or life-threatening illness with life expectancy of <5 years; (3) end-stage disease or serious illness that prohibits participation (e.g. end-stage renal disease or class IV congestive heart failure); (4) inability to perform unsupervised physical activity; (5) pregnancy; (6) diagnosed cognitive deficits or limited decision-making capacity; (7) alcohol or substance abuse; or (8) homelessness or no fixed address.

Aim 2:

For the second aim, participants will be identified through participants in Aim 1. The eligibility criteria are as follows:

Proficient in English
Age greater than or equal to 18 years

11. Vulnerable Populations

- NA

12. Local Number of Participants

For Aim 1, our goal is to recruit 48 participants. We anticipate screening 200 patient charts to identify a total of 48 eligible, consenting participants. For Aim 2, we anticipate that each participant will identify 4 social contacts (i.e. alters), and these will mostly consist of household members, based on a previous study.[77] Of these, we conservatively expect 3 alters per participant to compete baseline and follow up surveys. A previous study of SA's in an urban setting in India reported a 97% response rate.[77] This would provide a sample size of 140 (97% of 48 participants x 3 alters/participant).

13. Recruitment Methods

All recruitment will be done via chart review of patients seen at the Emory Dunwoody Family practice, via chart review. Patients who met eligibility criteria from chart review will be contacted by phone or email (See phone scripts). For Aim 2, participants will be identified from participants in Aim 1.

Incentives: For Aim 1: All subjects will be reassured that their participation is voluntary and they are free to withdraw at any time, without consequences to their existing care. Participants will receive $75 gift cards for completing all surveys and attending sessions.

For Aim 2: Paper surveys and weight assessments at baseline and at 6 months will be conducted via home visits with alters (if geographically feasible). Participants will receive $20 for each assessment.

14. Withdrawal of Participants

Participants will be notified at the time of consent that they are free to withdraw from the study at any time. If during study participation, and participants develop conditions that do not allow participation in physical activity, such as unstable angina, stroke, or physical disability, they will be withdrawn from the study for their safety, without consent. For those that withdraw or are asked to withdraw, data collected to that point will be included unless participants request their data be withdrawn as well.

15. Risks to Participants

This study has minimal risks. There are no concerns for serious adverse events. Other potential risks include pain with finger pricking for blood sample collection. However, we are using standard clinical technique for point of care lab collection, thus this is an acceptable risk in the population. There is a risk of loss of confidentiality of study data. We will, however, take measures to ensure that this does not happen by the following measures: storing data on a locked, password protected electronic file and using a study ID number in place of personal information when possible.

16. Potential Benefits to Participants

The potential benefits to participants in Aim 1 include improved knowledge of diabetes management and prevention, better glycemic control, and improved weight management. We hypothesize that participants in Aim 2 will also received some benefit from the intervention through contact with participants in Aim 1. This will include improved weight control practices.

17. Data Analysis, Management and Confidentiality

Aim 1 Analysis:

Power calculation: The sample size (12 participants per group) was chosen based on recommendations in the literature for optimal size for a SMA model.[78,79] Given our primary outcomes are preferences, feasibility, and acceptability, we do not expect to be powered to find differences between groups, but rather to collect preliminary data to support a larger, more definitive pragmatic evaluation. However, a lifestyle program to treat diabetes among SA immigrants in New York City provides a conservative power estimate for this study.[80] They found a 0.5 percentage point difference in HbA1c. Using this group as a known population with a baseline A1c of 7.8 with a standard deviation of 1.3, a fully powered study to detect a similar difference with an alpha (Type I error rate) of 0.05 and a beta (Type II error rate) of 0.20, would require 37 participants per group. This is beyond the scope of this pilot study/training award. Instead, we will accept an alpha of 0.20 and a beta of 0.40, which defines a targeted recruitment of 11 participants per group (n=44); thus our target of 12 per group (n=48) would power us for these parameters. The Emory Family Medicine Clinic sees approximately 11,000 unique patients annually. We conservatively estimate that approximately 10% are of WA or SA origin and 30% of this population will have T2D or prediabetes, thus we would have 330 eligible participants from which to recruit 48. This number is feasible as it would require enrollment of 6 participants weekly for 8 weeks.

Quantitative Data Analysis: De-identified, quantitative data will be entered into a Redcap database. Regular data audits will ensure the accuracy of the electronic data. Analyses will be conducted using the Stata 15 statistical software package. Descriptive analysis will be performed for all baseline variables, and outliers will be investigated for data errors. A probability of <0.05 will be considered statistically significant for all tests. All 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 pre-post comparisons will be made using t-tests or chi-square tests. Analyses will be intention to treat. When appropriate, hierarchical linear models will be created, to account for repeated measures in the same person and the clustering of participant into dyads, to look at pre- and post-intervention changes (comparing baseline to 6-month follow up). However, modeling will be limited by the small sample size of the study. All data will be presented before and after adjustment for confounding and interaction (including, for example, age, gender, and education). Primary Outcome Analyses: Preferences will be assessed by quantifying number enrolled in each group. Feasibility will be assessed by quantifying rate of enrollment, number of sessions attended by participants (for dyad arm, will assess P and SP individually and together). Acceptability will be assessed by quantifying Likert-like scales of satisfaction with each session and overall intervention. Exploratory Analyses: Participant anthropometric and biochemical markers will be assessed individually and modeled over time using hierarchical

modeling to account for clustering. Changes in glycemic control and lipids from baseline to 6 months for P will be done using similar methods as above to account for clustering; for dyad arm, if SP also has diabetes or prediabetes, their change in glycemic and lipid control will be assessed individually and compared to their baseline measure. This pilot data will be used to determine an effect size for sample size estimates for a larger, pragmatic, randomized trial.
Aim 3:
Power calculation: We anticipate that each participant will identify 4 social contacts (i.e. alters), and these will mostly consist of household members, based on a previous study.[77] Of these, we conservatively expect 3 alters per participant to compete baseline and follow up surveys. A previous study of SA's in an urban setting in India reported a 97% response rate.[77] This would provide a sample size of 140 (97% of 48 participants x 3 alters/participant). Given, the small sample size of the intervention participants, we do not expect to be powered to find differences in weight loss practices among alters, however this data will provide a signal of spillover, pilot data, and necessary training for the PI for a larger fully powered study with a control group.
Analysis: After appropriate data checks (as described in section 3.8 above), descriptive analyses will be performed for all baseline variables, and outliers will be investigated for data errors. Chi squared tests will be used to assess pre-post differences in WCSS items. Partial correlations, controlling for relevant baseline values from egos and alters will be used to examine associations between egos and alters in changes in weight and behaviors (as assessed by the WCSS items). When appropriate, hierarchical linear models will be created, to account for repeated measures in the same person and the clustering of alters by household, to look at baseline to 6-month changes in weight management behaviors.

All patient-related data will be held in confidence by the investigator and if released will be identified only by a study ID number. Data will be stored and analyzed in a manner to preserve confidentiality; data will be de-identified and stored in a secured REDCap database with access limited to authorized personnel. Source documents and paper documents will be stored in a locked drawer within another locked room; only authorized personnel will have access to these records.
This study will comply with Emory's Data Security Policy (http://it.emory.edu/security/security_awareness/encrypt.html). All sensitive data and data that contains HIPAA identifiers will be stored on a hard drive, disk, or thumb drive that is encrypted, password-protected, and kept in a locked office. All data will be extracted and analyzed by the study team. Only aggregate data will be printed or published. Once the study is complete all data will be destroyed.

18. Provisions to Monitor the Data to Ensure the Safety of Participants

In Study 2 of this proposed project (Aim 1), the intervention is an educational behavior change program that is based on the successful lifestyle principles tested in the Diabetes Prevention Program (DPP) study and the Action for Health in Diabetes (Look AHEAD) study. Despite the very low potential for injury to research subjects, we will engage an independent data safety and monitoring board (DSMB) for assistance with oversight.

At each in-person session, participants will be asked about any potential adverse effects (e.g., injuries, chest pain associated with exercise) and report these to the study investigators. These adverse events will then be reported to the single institutional review board (IRB) and the DSMB. Detailed procedures for the notification of any abnormal findings of clinical relevance as well as non-emergency and emergency referrals will be developed and implemented. As part of the informed consent process, individuals will be informed of their rights regarding injury sustained during study procedures and if study-related injury does occur, participants will be offered treatment according to prevailing local health policies.

DSMB – The PI will identify four independent scientists or clinicians who are not part of the mentorship team, to serve as a DSMB for the study. The DSMB will be charged with external oversight, monitoring conduct, data integrity, and patient safety. Prior to recruitment for Aim 1, the DSMB will review the protocol and monitoring plans. Following this, the DSMB will mainly monitor for adequate recruitment milestones, the occurrence of adverse events related to participation in the study, and for effectiveness (or lack thereof) of the intervention.

The following adverse events will be monitored: death, dropout, clinical deterioration, hospitalizations related to cardiovascular disease, other major surgical procedures (e.g., amputation), development of serious substance abuse, and emergence of new medical diagnoses posing significant risk to subjects.

The PI will convene DSMB meetings prior to recruitment and at 6-month intervals thereafter until the participants that were recruited last have completed their 6-month follow-up visits. The DSMB meetings will be via teleconference and the study has budgeted for honoraria for the DSMB members. At these meetings, the PI will present recruitment updates and data regarding patient safety and adverse events. Any events arising in the interim between DSMB meetings will be communicated to the DSMB electronically. Following DSMB meetings, the PI will compile the suggestions and discussion and share any concerns with the study investigators, the IRB, and the National Institutes of Health.

In the unlikely event that we observe a high number of serious adverse events (e.g., heart attacks) that are deemed related to the intervention, premature discontinuation of the study may be recommended by the external DSMB or the IRB via consensus of the PI and mentorship team. Similarly, if an individual is hurt by the study, and the intervention is linked and decreases the likelihood of the participant completing the study, provisions will be made to remove him/her from the study.

Aim 2:
Participants in Study Record 3 (Aim 3) are not participating in an intervention, and are completing a pre-post paper survey and weight measurements. There is no potential for side effects or injury. As such, a data safety and monitoring board (DSMB) is not applicable to this study aim.

19. Provisions to Protect the Privacy Interests of Participants and Confidentiality of Participants' identifiable data

All study personnel will have completed the mandatory CITI human subjects research training before commencing any study-related activities.

The informed consent form for this study has been created by the Emory School of Medicine Office of Science and Research in accordance with Federal guidelines, including the Health Insurance Portability and Accountability Act (HIPAA).

We anticipate that all subjects will have the capacity to give informed consent.

All patient-related data will be held in confidence by the investigator and if released will be identified only by a study ID number. Data will be stored and analyzed in a manner to preserve confidentiality; data will be de-identified and stored in a secured REDCap database with access limited to authorized personnel. Source documents and paper documents will be stored in a locked drawer within another locked room; only authorized personnel will have access to these records. All study related data will be destroyed within 3 years of study completion.

Economic Burden to Participants
All study related costs are covered by the study, we do not anticipate economic burden to participants. We will offer sessions during hours that are convenient to participants to avoid disruption of work schedules.

20. Consent Process

• Informed consent will be obtained in person through review and written signature of our informed consent document; this will occur just prior to the focus group discussion.
• No waivers will be required
• No vulnerable populations are included
•We aim to ensure comprehension by reviewing and summarizing the informed consent in person with participants and allowing time to ask questions

Non-English-Speaking Participants

- Given the limited funding of this proposed study, all focus groups discussion will be conducted in English.
- English proficiency is included in the inclusion criteria.

21. Setting

For Aim 1, all research related activities will take place at Emory Family Medicine Clinic at Dunwoody. For Aim 2, when geographically feasible, surveys and weight assessments will done via home visit. If this is not feasible, this will be conducted remotely via phone or an approved video conference platform.

22. Resources Available

- Our research team has connections with the local South Asian immigrant populations. In a previous pilot of South Asians in Atlanta, in a 5-day period, our team was able to recruit 14 eligible participants, thus our study is feasible.
- The timeline is attached above. We will have 48 months to complete this study
- The team has access to high-speed internet access with Dell docking station and laptop computer, each equipped with major word processing, citation manager (Endnote), Adobe professional, and statistical software (SPSS, Stata, matlab, MAXQDA, Microsoft Excel). All computers have connectivity to the Emory University secure network, which includes extensive access to online services, and medical journals. The team also has access to 2 digital audio-recording devices.
- All study team members must complete CITI training and will have access to all needed protocols and materials via a secure platform such as Emory Box.

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