Protocol and Baseline Characteristics for A Community Health Worker-led hypertension and diabetes management program for South Asians in Atlanta: The DREAM Atlanta Study

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Abstract

Background: South Asians are disproportionately affected by type 2 diabetes (DMII) and comorbid hypertension (HTN). Community health worker (CHW) interventions have been shown to improve chronic disease outcomes, yet few have been tailored for South Asians. This paper describes the study protocol and baseline characteristics of an evidence-based CHW intervention to improve blood pressure (BP) control among South Asian adults with diabetes and comorbid HTN in Atlanta, GA

Methods: A total of 195 South Asian adults were randomized to treatment and control groups, and of these 190 completed baseline surveys (97 treatment group and 93 control group). The treatment group receives five group education sessions on DMII and HTN management and two one-on-one goal setting sessions.

Measures: Primary outcomes include feasibility, acceptability, and BP control (systolic blood pressure [SBP] <130 and diastolic blood pressure [DBP] <80). Secondary outcomes included changes in glycated hemoglobin (HbA1c), weight, diabetes self-efficacy, diet, and physical activity.

Baseline Results: Of the enrolled sample, 56% are female and mean age is 56.0 (±11.7). All participants are foreign-born. Mean SBP was 139.2 and mean DBP was 84.7. Intervention outcomes are measured at baseline and 6-month endpoint for both study groups.

Conclusions: To our knowledge, this study is the first to document the efficacy of a HTN and DMII management intervention among South Asian adults in Atlanta, GA. Future findings of the submitted protocol will fill an important gap on the translation and adaption of evidence-based interventions that have relevance to immigrant and minority populations.

Clinical Trials Registration: NCT04263311

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Background:

Hypertension (HTN) is an extremely common comorbid condition in Type II diabetes (DMII). Uncontrolled HTN among individuals with diabetes significantly increases the risk of microvascular and macrovascular complications. Such comorbidities may be amplified in racial and ethnic minority groups that experience a disproportionate burden of cardiovascular disease (CVD) risk factors. South Asian Americans, which includes individuals with ancestry from India, Bangladesh, Pakistan, Nepal, Bhutan, the Maldives, and Sri Lanka, have been found to have a higher diabetes and HTN prevalence compared with non-Hispanic whites and other racial/ethnic minority groups.[1–7] Comorbidities of diabetes and HTN are also a significant issue for this population; for example, a national study of South Asians in the United States (U.S.) found that 60% of individuals with diabetes also had comorbid hypertension.

Combined 5-year data from the American Community Survey (ACS) found that nearly 5.4 million South Asian individuals (alone or in combination with other ethnicities) lived in the U.S. in 2017, and between 2010 and 2017, the South Asian community grew by 33.1% .[8] Combined 5-year data from 2019 found that an estimated 162,157 individuals self-reporting as Asian Indian, Bangladeshi, or Pakistani ethnicity lived in Georgia (GA), a growth of 55% from 2010.[9, 10] GA comprises one of eight states in the "Stroke Belt," an area of the country that is disproportionally affected by CVD.

Despite the growing population of South Asians in GA and the known density of stroke in the Southeast, there is a lack of culturally and linguistically adapted interventions for comorbid diabetes and HTN management specific to South Asian subgroups. Data has shown that South Asian subgroups have a high prevalence of diabetes and hypertension compared to other Asian subgroups.[11, 12] In the Atlanta, GA area, South Asian subgroups experience high rates of limited English proficiency (LEP) and social disadvantages, including limited access to health insurance, transportation, and limited household income. Combined 5-year estimates from the 2015 ACS found that in the Atlanta, GA area, among individuals age 18-64 speaking a language other than English at home, 45% of Bangladeshis and 75% of Nepalese speak English less than very well. Further, among adults age 18-64, 49% of Bangladeshis and 36% of Pakistanis reported having no health insurance.[13, 14] Community health worker (CHW) approaches have demonstrated efficacy in delivering culturally relevant programs for diabetes control in African American and Latino populations.[15] Our previous work in New York City (NYC) has demonstrated the acceptability and efficacy of a CHW-led diabetes management intervention among Bangladeshis,[16, 17] as well as improvements in HTN control among South Asian groups through culturally tailored CHW interventions implemented in community and clinical settings.[18] Additionally, we have found meaningful reductions in BP among participants with comorbid diabetes and HTN using combined data from their studies.[19] Scaling such programs remains a challenge without appropriate attention to factors that impact replication across diverse geographic contexts and settings, adaptation of programs to the diversity across South Asian communities, and consideration of adoption and sustainability for community-clinical linkage models. Moreover, with challenges related to the COVID-19 pandemic, evaluating, and understanding how best to meet the needs of vulnerable

populations is necessary, especially through the utilization of telehealth. Thus, a critical need exists to tailor, translate, and disseminate evidence based CHW interventions to maximize impact in ameliorating comorbid CVD disparities.

To address these needs, we designed the DREAM Initiative (Diabetes Research Education, and Action for Minorities) Atlanta, a 6-month, CHW-led, randomized controlled trial (RCT) designed to improve BP control among South Asian Americans in Atlanta, GA. The aims of the DREAM Initiative include to: 1) build an infrastructure to support training and mentoring of CHWs in Atlanta in the delivery of the DREAM program for the Atlanta context; 2) test the effectiveness of a BP control and diabetes management program compared to usual care for South Asians; and 3) use mixed methods in order to delineate factors influencing the reach, appropriateness, fidelity, adoption, and maintenance of the intervention. The main purpose of this paper is to describe the study protocol and present baseline characteristics of the DREAM Initiative study in Atlanta, GA. The outcomes for aims 2 and 3 will be included in future publications.

Methods:

Study Team and partners:

This study created a new collaboration between Emory School of Medicine and NYU Grossman School of Medicine. Building on the successful DREAM initiative based in NYC, this study capitalized on the NYC-based expertise to build capacity among partners in Atlanta.[20, 21] The DREAM ATL team consisted of the site principal investigator (PI), a project coordinator, and three CHWs. The NYC team consisted of the overall PI, project coordinator, program manager, data manager, CHW supervisor, and three NYC-based CHWs who serve as mentors for the Atlanta-based team. The team also included community advisory boards based in NYC and in Atlanta that informed the development and adaptation of the intervention.

Study design

DREAM ATL consisted of 3 phases: 1) Research training, technical assistance, and capacity-building to community and clinical sites in ATL to inform the implementation of a culturally tailored, evidenced-based CHW program; 2) Implementation of a CHW-led intervention compared to usual care among South Asian individuals with comorbid diabetes and uncontrolled HTN in Atlanta, utilizing a wait-list control design; and 3) Dissemination of study findings. The full project period took place over 24 months. Phase 1 took place from months 1-6, in which there were capacity-building activities, CHW hiring and training, and program adaptation to the Atlanta context. Phase 2 took place from months 7-18 and included the RCT implementation. Finally, Phase 3 took place from months 19-24 and included dissemination efforts.

Phase 1: Training, technical assistance, and program adaptation—During Phase 1, CHWs were hired in Atlanta via job postings through Emory University, recruitment through Atlanta South Asian Health Alliance, and word of mouth from NYC-based CHWs. Once hired and onboarded, the study team adapted the intervention materials and data

collection tools for the Atlanta context through a community-engaged process, including input and review from community partners through the Atlanta South Asian Health Alliance. Simultaneously, Atlanta CHWs and NYC CHWs participated in learning exchanges, first in-person and then virtually. Training of Atlanta CHWs was led by NYC CHWs and consisted of an initial in-person, three-day training in January of 2020. Day 1 provided training in CHW core competencies; topics included: history of CHWs, health and public health, strength-based perspectives, compassionate communication, adult learning and popular education techniques, and behavior change strategies. Day 2 included training on the study design, recruitment strategies and role play / practice; consenting, enrollment, and baseline data collection; and demonstrations of curriculum content and physical activity exercises by NYU CHWs. Day 3 included a site visit to an Atlanta recruitment site and discussion of local context; presentation of best practices in participant engagement, including case examples; review of protocols for home visits and 1-on-1 goal setting; strategies to address common challenges, with case examples; and discussion of CHW wellness (see Table 1 for details).

Following the three-day in-person training, CHWs participated in weekly virtual technical assistance meetings to discuss challenges, share tips, and discuss other needs of the teams. Atlanta CHWs practiced delivering the curriculum content for each group session and received feedback from the NYU program team and CHWs on the following measures: fidelity to session content, clarity/accuracy of explanation of key content for each session, and timing/spacing of presentation. In addition, the Atlanta-based project coordinator and site PI received directed mentorship and technical assistance from the NYC-based team to support intervention implementation, evaluation, and manuscript and grant writing. Finally, the Atlanta CHWs received four one-hour trainings from a behavioral health team on motivational interviewing techniques.

Phase 2: CHW-led Randomized Controlled Trial (RCT)

Participant Recruitment: Recruitment occurred in 2 rounds, and each round of recruitment lasted two months. The first round of recruitment took place July of 2020, and the second round of recruitment took place January of 2021. South Asians were recruited from three clinical sites in ATL, as well as through community-based referrals. 1) The Emory Family Medicine Clinic is in North ATL and serves approximately 1,200 unique South Asian patients annually; 2) Grady Clinic at Brookhaven is a safety net county clinic that sees a high volume of low-income South Asians (approximately 6,000 per year); and 3) The Shifa Free Clinic is a free community-based clinic coordinated by the Islamic Circle of North America, Atlanta branch, to serve uninsured and under-insured South Asians in GA. On average, the Shifa clinic sees 200 unique South Asian patients per month. Both Emory Family Medicine Clinic and Grady Clinic utilize EHR systems, which were used to generate lists of eligible patients for the intervention. Each of the sites expressed interest and commitment to participating in the study. At the time of the study implementation, the Shifa Clinic was transitioning to an EHR system, so patient recruitment was conducted through physician referral and medical chart review. Potential participants were recruited through a clinic EHR list and sent a letter inviting participation in the study. Participants were also enrolled through virtually conducted community-based recruitment, with the

CHWs referring participants through their community networks and through advertisements of the study on social media, community organizations, community events and religious organizations.

After initial recruitment, CHWs followed up with phone calls, during which they explained the study and the elements of informed consent. A screening form was completed to verify eligibility. Inclusion criteria included: 1) South Asian ethnicity; 2) between the ages of 21 and 85 years; 3) diabetes diagnosis; 4) HTN diagnosis or 5) an uncontrolled BP reading in the last six months or at screening. Exclusion criteria included 1) pregnant at time of screening; 2) Type 1 diabetes or diabetes secondary to other conditions; and 3) inability to perform unsupervised physical activity (determined by self-report on the screening form). CHWs called potential participants a maximum of three times over a two-week period at varying times of the day to invite them into the study. Once participant eligibility was verified, individuals were required to sign and electronically send a consent form via text or email to officially enroll into the study. A baseline survey assessing demographics and current lifestyle behaviors was then completed by the CHW over the phone with the participant.

Following enrollment and completion of the baseline survey, all individuals completed the first session of the five-session intervention, after which individuals were randomized. Stratified randomization, using CHW, age (55 and >55), and gender. For instance, randomization occurred within each grouping (e.g., CHW1, age>55 and female), to balance the treatment and control groups by gender and age for analysis purposes, and by CHW for caseload. In order to minimize intervention contamination amongst control group participants, family members were enrolled into the same group by randomizing older women first and placing their family members into the same group. Control participants received usual care with their primary care providers and were not contacted during the intervention period, and education sessions were offered at a later date after the study as a point of service and not as part of the research.

CHW Intervention: Individuals randomized to the treatment group received four additional group educational sessions (a total of five sessions). Group sessions occurred monthly, and each session was scheduled at least three times a month to accommodate the varying schedules of working individuals and at-home caretakers. Thus, participants had multiple opportunities to attend each group session. The intervention occurred in two separate rounds over the study period, allowing each CHW to manage no more than 25 participants at a time. Each session was conducted in Bengali or English and involved a discussion of different content areas related to management of comorbid diabetes and HTN. Educational sessions included examples tailored for South Asians, keeping specific cultural and religious practices in mind such as culturally-tailored foods, gender-specific exercises, and situations specific to the Bangladeshi community. For example, diet and exercise education included examples that were specific to South Asian culture and food, such as tailoring the plate method to the South Asian diet and home-based exercises for women.[16] Educational sessions were guided by the Health Belief Model and Social Support Theory (see Table 2 for session information).[22, 23]

After each session, CHWs followed up with participants during a one-on-one phone call, in which goal setting activities were discussed using motivational interviewing techniques. Goal setting activities included lowering BP, lowering HbA1c, lowering weight, and maintaining a healthy weight. Short-term action plans (to be followed by participants for two weeks) included eating a healthy diet, being physically active, quitting/reducing smoking, and managing stress. CHWs also provided referrals to social services, community-based resource needs, and specialty care (such as Medicaid services, food pantries, and domestic violence support).

Covid-19 adaptations: The COVID-19 pandemic lockdown order took place in March of 2020 in Atlanta. At that time, the CHWs were receiving training and capacity building for the DREAM Initiative. The project was initially designed to hold educational sessions in-person at the clinic and community sites; due to the pandemic, the entire curriculum was modified to be delivered virtually, reflecting similar modifications made in the NYC-based DREAM Initiative upon which the Atlanta intervention was adapted.[20] Additional trainings were developed to train the team on delivering the modified intervention via virtual group and individual education sessions, and the project coordinator assisted with the necessary technical training required. Techniques to best present to an audience online were also practiced during the capacity-building in preparation to implement a virtual study. With a study population consisting of older individuals, the CHWs also needed skills to teach their participants how to connect to the meetings, send documents electronically, and to use their patient portals. This process has been described in detail elsewhere.[24]

By July of 2020, the CHWs were prepared to start recruitment. CHWs recruited patients directly through the EHR at two clinical sites, participant and CHW network referrals, and virtual community events. Virtual sessions took place, and all survey data collection was done remotely. Weight scales and electronic BP cuffs were mailed to each participant, and biometric screening data was collected virtually with assistance from participants after receiving training from the CHW team. All modifications are summarized in Table 3.

Data collection and outcome measures: Table 4 summarizes all study measures. Surveys were collected from all participants at baseline and 6-months. Baseline surveys were conducted by a CHW or bilingual study team member following consent and before the participant attended Session 1. The 6-month surveys were conducted over zoom by study staff after completing Session 5 and receiving the final follow-up phone call through the CHW coaching component of the intervention. Survey measures were developed based on their 1) brevity; 2) presence of domains with face validity for Asian American or low literacy communities; and 3) valid psychometric properties, thus enhancing scientific rigor. Survey measures included questions about self-efficacy and medication adherence. Each participant was mailed an Alcedo Blood Pressure Monitor and Etekcity Digital Body weight scale at the start of the study. Baseline Glycated hemoglobin (HbA1c), weight, and BP data were collected via chart review and patient report. Their BP value and weight were recorded in the baseline survey by the CHW at baseline if they did not have an EHR value. The BP data was recorded twice more during the intervention period at each one-on-one call with the CHW. . The end of study HbA1c, weight, and BP data were collected via

patient report or point of care testing with a study team member when needed. Focus groups and key informant interviews were done after the 6-month intervention to describe the implementation process. The primary study outcome is BP control, defined as <130/80 mmHg, and secondary outcomes include HbA1c, weight, and body mass index (BMI).

Patient-engagement measures: Contact with eligible treatment group participants were collected in REDCap[25, 26] or on paper-based Case Report Forms, including phone contact attempts, patients' intervention status (declined, enrolled, not reached, etc.), completion of intervention activities (such as health education sessions and one-on-one phone calls), and completion of data collection, referrals, and intervention activities across sites and CHWs. To keep track of each participant's progress in meeting their health goals, CHWs also made use of action plans and provided individualized counseling during phone calls. Finally, small incentives (i.e., $10 grocery store gift cards) were provided at each session to encourage ongoing attendance and upon completion of the endpoint survey.

Statistical analysis

Implementation evaluation—Informed by its applications in past research, the Reach, Effectiveness, Adoption, Implementation, Maintenance (RE-AIM) framework will be used to evaluate the CHW training and the implementation of the intervention through the completion of key informant interviews and surveys.[27–29] Atlanta DREAM also utilized the Consolidated Framework for Implementation Research (CFIR) framework to study program outcomes (summarized in Table 5), which were measured at baseline and at follow-up.[30]

Focus groups with participants and interviews with CHWs will be analyzed deductively through rapid qualitative analyses, initially conducted by one study team member, and then validated by two additional study team members. Rapid qualitative analysis has been shown to be an effective approach to obtain distinct themes and actionable suggestions from qualitative data in implementation research.[31, 32] The analysis will involve preparing a preliminary codebook with topics related to program experiences and design, learning and application of the intervention, recruitment and challenges of the intervention and feedback on telehealth sessions. Key themes will also be grouped according to the domains for the CFIR framework (i.e., intervention, outer setting, inner setting, process, and individuals involved). Together, these topics will be analyzed to help inform the experiences of participants and CHWs in the program.

Intervention evaluation—The primary outcome of interest is BP control (<130/80 mmHg) at 6-month follow-up. We will be comparing participants randomized to the treatment group to those randomized to the control group. Due to the binary outcome (whether BP is controlled or not), we will use logistic regression analysis. We will use a generalized estimated equation (GEE) model for repeated measures over time with a binomial distribution, while adjusting for study arm, time point, age, and sex. Odds ratios will be reported.

Secondary clinical outcomes of interest include changes in HbA1c, weight, and BMI at 6-month follow-up. For analyses of the secondary outcomes of interest, similar GEE models

will be used to estimate the intervention effect. We will use the appropriate model depending on whether the outcomes are continuous or binary. All analyses will be conducted using SAS.

Sample size calculation—We conservatively estimated a 20% difference in effect size (i.e., BP control) when comparing intervention and control group participants. Our power calculation was based on results from a previous study.[19] At six-month follow-up we conservatively estimated a 15% BP control rate for the control group and a 35% BP control rate for the treatment group. In our previous work, BP control rates at baseline varied; however, in the proposed study all participants will have a recently documented uncontrolled BP at baseline. Further, in our past work control group participants experienced almost no change in BP control at follow-up; here we conservatively estimate a 15% BP control rate at follow-up. Accrual of 162 participants, 81 randomized to each group, will provide greater than 80% power to detect this difference, using a 2-sided, 0.05-level test. These calculations assume a 10% loss to follow-up, compared to 15% in our NYC study.[21]

Ethics and data sharing: The study protocol and procedures were approved by a single IRB between Emory University and NYU Grossman School of Medicine. Written informed consent was obtained from all participants. The study was registered at clinicaltrials.gov as of February 10, 2020 (NCT04263311). This study will comply with the NIH Public Access Policy, the public will have access to the published results of this intervention.

Baseline Results:

Study recruitment began in July of 2020. A total of 403 individuals were contacted. Of these, 195, were screened and consented, and 190 completed the baseline survey and Session 1 and were randomized into the study. Between consent and randomization, two individuals were lost to follow-up, two were ineligible post-consent, and one passed away (see Figure 1). Baseline survey data was collected between July 7, 2020, and March 7, 2021. Table 6 presents the baseline characteristics and outcome measures of the DREAM Atlanta intervention. The study included 56.3% female participants and 43.7% male participants. The majority of participants (93.2%) were born in Bangladesh, and mean years lived in the US was 15.2 (SD=11.3). Approximately half of participants had a college degree, 45.8% spoke English not well or not at all, and 89.9% had some form of health insurance. English spoken fluency differed significantly by study group (53.6% of the intervention group spoke English not well or not at all compared to 37.6% of the control group). No other significant differences were seen at baseline.

Discussion:

South Asians have been shown to have a high risk of diabetes, and a high proportion suffer from comorbid HTN.[33, 34] There is a need to develop scalable and sustainable models to address the specific needs of high-risk vulnerable populations who may have specific barriers to care including limited English proficiency, limited income, and lack of transportation. Moreover, there may be specific regional barriers, such as limited access to high quality food and affordable healthcare experienced by for adults living in the .[35, 36]

This study protocol is the first discussion of an intervention specific to South Asians in the Southeast U.S. with comorbid HTN and DMII. [37] Future study findings will help to fill an important gap in the research for this subgroup and will potentially have implications for translating strategies to other minority subgroups, as well as additional South Asian subgroups in Atlanta. Additionally, we describe adaptations that were used for a telehealth intervention; these adaptations may be relevant to future studies aiming to provide telehealth services for minority subgroups.

Several limitations must be considered as well. First, several modifications were made to the initial protocol due to the COVID-19 pandemic, thus the fidelity to the original intervention design has been impacted. Namely, there was less integration of the CHWs into clinical settings than initially proposed. Second, there is potential study contamination due to the close-knit nature of South Asian communities.[38] We have attempted to reduce this bias by including likely family members by matching contact information when randomizing, but there may be contamination of non-family members that we are unable to control for. Third, there were unanticipated challenges in clinical outcomes data collection given the ongoing pandemic. We collected clinical outcomes using multiple methods, including data from EHR and patient report. HbA1c data was only collected for subset of participants using EHR data or a scheduled point of care HbA1c testing for participants who could not see their routine providers when it could be safely done. Finally, while the intervention was designed for South Asians, sessions were only offered in Bengali and English, limiting the intervention to Bengali or-English speaking South Asian individuals. Future studies should include additional South Asian languages such as Urdu and Hindi, to better represent the South Asian population in Atlanta.

To our knowledge, this is the first study to attempt to scale out and test the effectiveness of a CHW-led multi-level intervention to control HTN and diabetes among underserved South Asians in the southeastern U.S. The findings from this study have boarder implications on the scalability of these types of interventions that have broad applicability to other vulnerable communities in the U.S.

Acknowledgements:

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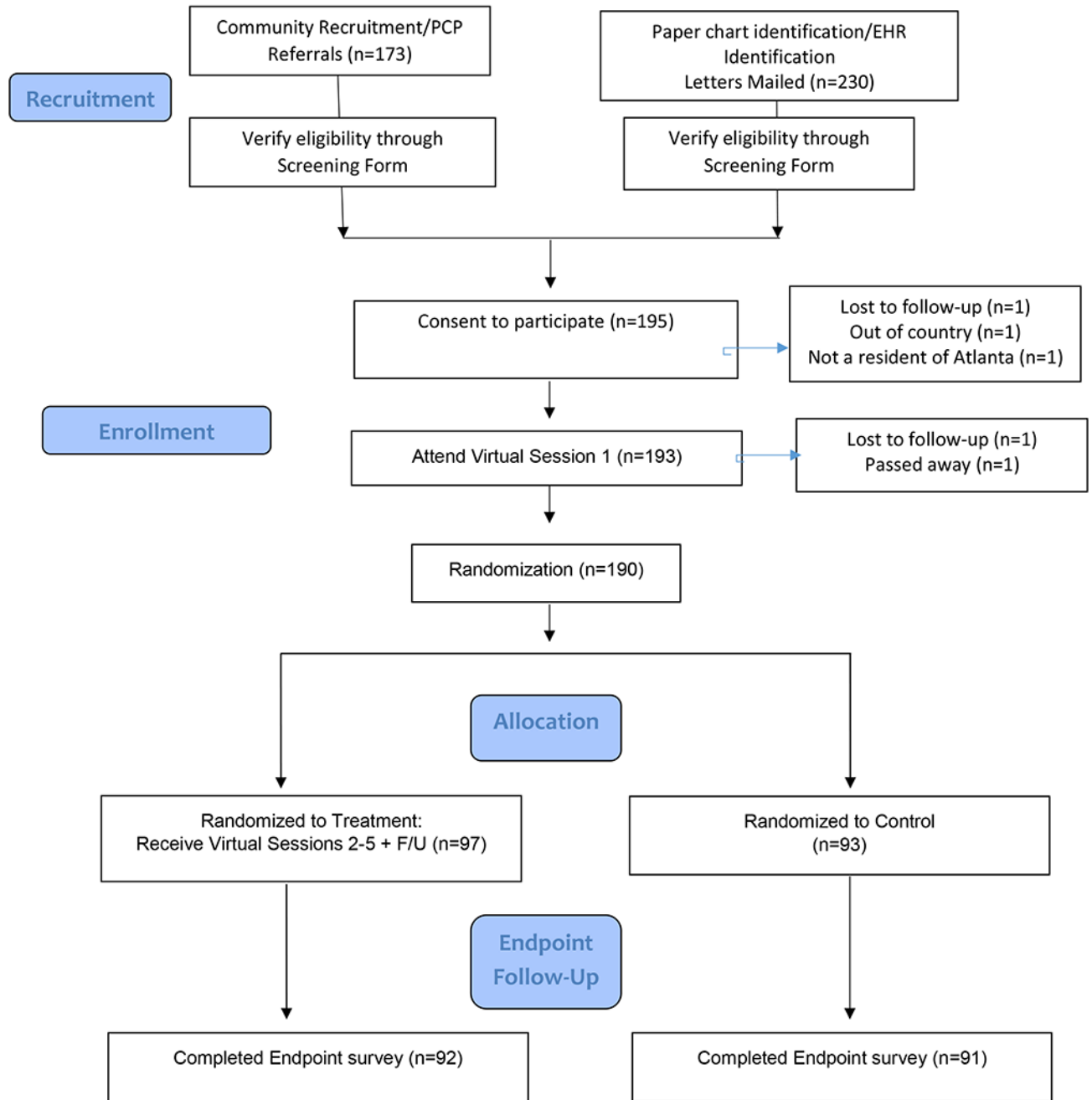
Figure 1:
Flow diagram for Recruitment, Screening, Enrollment, and Randomization

Table 1:

DREAM Atlanta CHW Learning Exchange Topics

Core Competencies
CHW Core Competencies (role, trust-building, communication, advocacy)
Referrals/Services, Institutional Trainings
Referrals / Services Mapping
Research Skills Trainings
Survey Administration
Study Protocol & Timeline
Study Tools & Protocols (Baseline, Follow-up, Action Plan, Progress Notes, Encounter Report, One-on-One Phone Calls etc.)
Taking Clinical Measurements (weight, height, blood pressure, etc.)
REDCap - CHW (Using REDCap, Data Entry)
REDCap- Supervisor (Reports for Project Management)
Programmatic Trainings
Study Curriculum / Presentation Skills Practice
Evaluation / Study Design (randomized control trial)
Recruitment, Best Practices
Goal-Setting Forms / Action Plan
Exercises Demonstrations
Best Practices for Optimizing Relationships with Providers
Virtual Group Session training

Table 2:

Intervention curriculum and key content objectives, DREAM Atlanta

ATL CHW Intervention Curriculum	Key Content Objectives
Session 1: Overview of Diabetes and Hypertension	Objectives- explain: 1. Type 2 Diabetes and the role of glucose and insulin on blood sugar. 2. How to check blood glucose 3. Diabetes symptoms and health problems associated with diabetes diagnosis 4. Correlation between diabetes and high blood pressure 5. Dangers of high blood pressure 6. Demonstrate how to measure and read blood pressure 7. Controlling blood pressure
Session 2: Nutrition	Objectives- explain: 1. How to build a health plate using the My Plate Method 2. What are fats, oils, and cholesterol 3. How to read and understand food and drink labels 4. Tips for healthy cooking and ordering out
Session 3: Physical Management	Objectives- explain: 1. Calories 2. BMI and healthy weight 3. Recommended exercise and tips to build activity into your day 4. Types of physical activity
Session 4: Stress Management	Objectives- explain: 1. Stress: bad stress and eustress (good) 2. Effects of stress on body, mood, and behavior choices 3. Healthy ways to cope with stress 4. Discuss 3 steps of mindfulness
Session 5: Diabetes and Hypertension Management	Objectives- explain: 1. Diabetes-related complications 2. High and low blood sugar symptoms 3. How to manage medications 4. Lower risk for heart disease 5. How to identify signs of Stroke and Heart attack; distinguishing between signs of Heart burn and heart attack

Table 3.

Comparison of Adaptations from NYU DREAM to Atlanta DREAM

	NYU DREAM Program	Atlanta DREAM	Adaption (here describe the context of the modification and nature of the modification	Timing of Adaptation
Training of CHWs	• Core competency training • Motivational interviewing • Survey data collection and data entry • REDCap enhancing communication • Conflict resolution skills • Intervention topic-related training, including diabetes, hypertension, nutrition, and physical activity • CITI human subjects research training	• NYU DREAM trained and mentored Atlanta DREAM • Initial Atlanta CHW training was done in-person • Continued training was moved to virtual settings due to COVID-19 • Survey data collection and data entry • REDCap enhancing communication • Conflict resolution skills • Intervention topic-related training, including diabetes, hypertension, nutrition, and physical activity • CITI human subjects research training	• NYC DREAM oversaw the training and mentoring of ATL DREAM • Atlanta DREAM had an initial in-person training, which was led by NYU DREAM • Atlanta DREAM met NYU DREAM virtually every week to address any ongoing issues regarding implementation and/or participant recruitment	Pre- and during implementation
Content of the Program	• Five group sessions in total: Diabetes overview, education sessions on healthy eating, physical activity, diabetes management, and stress and family support • Two one-on-one in-person meetings to engage in goal-setting activities regarding health behaviors, medication adherence or other diabetes related issues	• Five group sessions in total: Diabetes and hypertension overview, education sessions on healthy eating, physical activity, diabetes and hypertension management, and stress and family support • Two one-one-on in-person meetings to engage in goal-setting activities regarding health behaviors, medication adherence or other diabetes related issues	• Addition of education sessions on hypertension and management of hypertension	Pre- and during implementation
Context of the Program	• Format: Five group-based health education sessions • Two one-on-one in-person meetings • Up to nine follow-up calls • Setting: In-person and virtual (Intervention delivery had to be modified and sessions were held virtually due to COVID-19) • Recruitment: 1 month recruitment period • Recruitment done in three waves, each consisting of two rounds of CHW intervention • PCPs are first recruited and participants are then screened for eligibility using EHR systems • CHWs also helped with recruitment of participants through their own referral system and connections in their community	• Format: Five group-based health education sessions • Two one-on-one virtual meetings • Up to seven follow-up calls • Setting: Virtual • Recruitment: 1 month recruitment period • EHR systems at Emory Family Medicine Clinic, Grady Clinic and Shifa Clinic was used to generate lists of eligible participants • CHWs also helped with recruitment of participants through their own referral system and connections in their community	• Both groups had the same number of group-based health education sessions and one-on-one meetings with participants	Pre- and during implementation
Evaluation of the Program	• Evaluation of the program was done using the RE-AIM framework through the completion of provider surveys before and after intervention, and through follow-up key informant interviews • Data related to primary and secondary outcomes are extracted from EHR systems at baseline, 6-month, 12 month and 18 month	• Evaluation of the program was done using the RE-AIM and CFIR frameworks through exploratory, secondary subgroup analyses (provider surveys and key informant interviews at baseline and at follow-up) • Data related to primary and secondary outcomes are collected six months following the index office visit	Inclusion of CFIR framework to evaluate study outcomes Study outcomes measured and compared twice for Atlanta study: at baseline and follow-up	Post-implementation

Table 4.

The schedule of enrolment, interventions, and assessments for the DREAM ATL Intervention

	STUDY PERIOD (July 2020-August 2021)								
	Screening	Enrolment	Post-allocation						Close-out
TIMEPOINT**	$-t_1$	0	M1	M2	M3	M5	M5	M6
ENROLLMENT:									
Eligibility screen	X								
Informed consent		X							
Allocation		X							
INTERVENTIONS:									
CHW Lifestyle Intervention									
Usual Care									
ASSESSMENTS:									
Main Outcome: Blood Pressure	X	X							X
Weight	X	X							X
HbA1c	X								X
BRFSS physical activity, physical health, mental health, nutrition, PHQ-2		X							X
Health Self-efficacy (previous interventions), Instrumental Support		X							X
Adherence to Refills and Medications Scale (ARMS)		X							X
BRFSS diabetes management		X							X
Health Information, Insurance,		X							X
Community and social service use			X	X	X	X	X		

Table 5:

Study Measures in context of the REAIM and CFIR Frameworks

CONSTRUCTS		MEASURES (Quantitative/ Qualitative)	DATA SOURCES	TIME FRAME
REACH: What % of the target population came into contact with the program? Were participants representative of the target population?				
Participants		• % patients with Type II diabetes with uncontrolled BP • % patients at risk who received CHW coaching • Representativeness of patients willing to participate in study, referred to CHW, who accept referral and who are reached	• EHR data • In-depth interviews with CHWs	• Baseline, 6 months • Year 2
EFFECTIVENESS: Did program achieve key targeted outcomes?				
Primary Outcome		• % achieved BP Control • Change in HbA1c, weight, BMI	• Patient data from EHR	• Baseline, 6 months
Secondary Outcomes		• Self-Efficacy, Medication Adherence, Referral to Social Services	• Patient data from EHR • Patient survey	• Baseline, 6 months
ADOPTION: Did the organization use the program?				
Adoption		• Utilization patterns	a) CHW interviews b) Utilization reports from Redcap	• Year 2
IMPLEMENTATION (CFIR constructs to systematically guide identifying barriers/facilitators to implementation): How closely did staff members follow the program (consistency of delivery)? How well did the staff adhere to intervention fidelity? Was the program delivered as intended? Was the program consistent and aligned with clinic sites' missions?				
CFIR	Intervention Characteristics/Fidelity	a) % of study staff attending trainings and orientations b) # CHW sessions/phone calls attended per patient and fidelity to the curriculum	a) Training log, trainee evaluations; Utilization reports from Redcap b) Fidelity checklist, session attendance records, CHW encounter logs c) Utilization records from Redcap; attendance logs, staff meeting minutes	a) Baseline; Post training; 6 months b) Monthly c) Bi-annually
	Characteristics of Individuals	• Attitudes, norms, self-efficacy, and intention [39, 40]	• CHW interview and participant focus groups	• Baseline, 6 months
	Inner Setting	• Barriers and facilitators to workflow and referral processes	• CHW interviews	• Year 2
	Outer Setting	• Perceived contextual barriers and facilitators	• CHW interviews	• Year 2
MAINTENANCE: Is the organization willing to sustain the program? Is the program able to become part of routine practice?				
Practice patterns		• Current clinic site patterns, barriers and facilitators	• In-depth interviews with CHWs	• Year 2
Organizational characteristics		• # patients, staff characteristics	• Baseline workflow analysis • Partner input into referral system	• Baseline

REAIM: Implementation Framework Reach, Effectiveness, Adoption, Implementation, Maintenance; CFIR: Consolidated Framework for Implementation Research; EHR: electronic health record; CHW: community health worker; HbA1C: glycated hemoglobin; BMI: Body Mass Index

Table 6.

DREAM Atlanta baseline characteristics and outcome measures by study group

	Overall (n=190)	Treatment (n=97)	Control (n=93)	p-value
		n (%) or mean±SD	n (%) or mean±SD	
Female	107 (56.3)	56 (57.7)	51 (54.8)	0.688
Age, y	56.0±11.7	56.2±12.4	55.7±11.0	0.756
Country of birth				0.606
Bangladesh	177 (93.2)	92 (94.8)	85 (91.4)	
India	7 (3.7)	3 (3.1)	4 (4.3)	
Pakistan	6 (3.2)	2 (2.1)	4 (4.3)	
Years in U.S., y	15.2±11.3	14.5±11.8	16.0±10.8	0.390
Education				0.056
<High school	30 (15.9)	18 (18.8)	12 (12.9)	
High school or GED/Some college	64 (33.9)	38 (39.5)	26 (72.0)	
College graduate	95 (50.2)	40 (41.7)	55 (59.1)	
Insured	169 (89.9)	83 (87.4)	86 (92.5)	0.246
Speaks English less than very well	153 (80.5)	81 (83.5)	72 (77.4)	0.298
Weight, lbs	156.3±24.9	156.2±23.0	156.4±26.8	0.943
BMI, km^2	27.1±4.3	27.5±4.4	26.6±4.2	0.147
SBP	139.2±4.3	139.3±17.0	139.0±16.1	0.912
DBP	84.7±9.5	84.9±9.5	84.5±9.5	0.782
HbA1c (n=53)	7.1±1.1	7.1±1.1	7.2±1.0	0.756