Using Peer Support to Aid in Prevention and Treatment in Prediabetes (UPSTART)

Study Protocol

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Principal Investigators: Michele Heisler and Julie Schmittdiel

A. SIGNIFICANCE

The Challenge of Preventing Diabetes. In the US almost 30 million people have type 2 diabetes mellitus (T2DM), with projected prevalence by 2050 of 1 in 5 adults.[1-3] T2DM results in high morbidity, mortality, and annual costs of $306 billion.[4] The high prevalence of diabetes is due in large part to obesity, consumption of calorie-dense foods, and sedentary behaviors.[3] 86 million US adults—1 in 3—have prediabetes, defined as a fasting plasma glucose of 100-125 mg/dL, 2-hour plasma glucose of 149-199 mg/dL, or hemoglobin A1c (A1c) of 5.7%-6.4%.[2,3,5] Annual incidence of T2DM is 5-10% in adults with prediabetes compared with 1% per year in the general population.[6,7] Yet, only 1 in 13 adults with prediabetes are aware of their risk,[8] and fewer are taking steps to avoid diabetes. There is an urgent need to develop and evaluate effective and scalable interventions to prevent or delay the onset of diabetes, enhance its early detection, and increase uptake of lifestyle and pharmacological diabetes prevention interventions. Identifying persons at high risk for developing diabetes, linking them to and supporting their engagement in structured diet and physical activity promotion programs that reduce incidence of diabetes by 50% could prevent 8.6 million new cases of T2DM over the next decade.[9]

Low-income and Racial/Ethnic Minorities Experience Disproportionate Risk. The need to prevent T2DM is especially pressing for socioeconomically disadvantaged and for racial and ethnic minority populations. T2DM is up to two times as prevalent in US adults with low incomes and education levels compared to higher-SES adults.[10,11] African Americans, Asian Americans, and Latinos are 30-70% more likely to have T2DM than non-Latino whites.[12] Low-income and Latino and African American adults on average have more risk factors for diabetes, including higher rates of overweight, obesity, and being sedentary, than non-Latino, higher-SES whites.[13] Asian American and Latinos develop T2DM at lower body mass indices (BMI) than other racial/ethnic groups.[14] Among Latino adults, decreasing BMI by 1 unit is estimated to reduce the incidence of diabetes by 12%. And, after controlling for age and family history, prevention of weight gain from normal to overweight BMI categories would decrease the incidence of T2DM by 62% among Mexican Americans.[12,15-17]

Structured Lifestyle Interventions Can Prevent or Delay T2DM. Randomized controlled trials (RCTs) conducted in the US, China, Finland, Japan, and India documented 30-60% reductions in diabetes incidence in high-risk adults.[18-21] Several found an extended "legacy" effect.[22-26] In the US Diabetes Prevention Program (DPP), adults with impaired glucose tolerance who lost 5-7% of their body weight and achieved 150 minutes of moderate physical activity per week reduced their chance of getting T2DM by 16% per year (58% over 3 years).[19,27,28] Diabetes incidence was decreased by 16% for every kilogram of weight lost.[29] The DPP has been successfully adapted into group-based versions[30-33] in multiple settings including YMCA's,[34-36] churches,[37] and community health care centers.[38-41] It has also been adapted for delivery via automated telephone system,[42] television, DVD, and e-health platforms.[43-45] Culturally tailored DPP adaptations are effective among African American and Latino adults,[46-49] as are those delivered by different providers and technologies.[50-52] For example, DPP adaptations led by community health workers (CHWs) achieved weight loss of 6-7%.[34,40,53-56] Two systematic reviews concluded that programs achieving a mean weight loss at 1 year of just 2.5% confer a 60% reduction in development of diabetes at 6 years, with half of participants reverting to normoglycemia.[57,58]

Now a Wide Array of Evidence-Based Diabetes Prevention Programs and Increased Coverage. In 2012, the CDC's National DPP Initiative began to support scaling up community-based DPP programs.[59] In 2015, the US Preventive Services Task Force (USPSTF) recommended screening for abnormal blood glucose in overweight and obese adults aged 40 to 70 and referral to diabetes prevention interventions.[60] The Community Preventive Services Task Force in turn recommended that health care systems and community organizations offer such programs.[61] In 2016, Medicare joined many private insurers to reimburse CDC-recognized DPPs (including the Omada[62] online program) for the estimated 22 million beneficiaries with prediabetes.[63] If there is good uptake by Medicare beneficiaries, federal spending on diabetes treatment is estimated to decrease by $1.3 billion in the first decade, with even greater savings over the next decade.[63] Both of the health systems for our proposed study—Michigan Medicine (MM) and Kaiser Permanente Northern CA (KPNC)—are now themselves offering structured diabetes prevention programs and encouraging referrals to online and the many locally available community programs (see Appendix A).

The Problem of Poor Uptake of and Engagement in Diabetes Prevention Programs. Unfortunately, even when referred to programs, rates of uptake/participation (attending at least one session) and engagement (completing a sufficient number of sessions) of eligible adults are very low.[64] Adults with prediabetes must have knowledge of their elevated but modifiable risk for T2DM and of recommended behaviors and available

programs as well as motivation, self-efficacy, and support to engage in and sustain behaviors.[65-67] Low-income and racial and ethnic minorities in particular face multiple social and environmental barriers to participation in formal programs.[68] These include competing demands, time constraints, erratic work schedules, food insecurity, poor access to healthy foods, and limited opportunities for physical activity. Latino immigrants may face additional barriers related to acculturation and language.[68-70] Rates of uptake and engagement are thus disproportionately low. In trials of community-based diabetes prevention programs, participants on average attended only 40 to 60% of diabetes prevention sessions.[35,49,71] Yet, active engagement is critically important. One review found that change in weight was similar whether the intervention was delivered by health professionals or lay workers,[72] but there was a dose-response association between number of sessions attended and amount of weight loss—with a 1% greater weight loss for every four sessions attended.[72]

Rates of uptake of formal programs are even lower than rates of engagement. Studies of referral from primary care to free community-based lifestyle programs indicate that uptake may be about 30% for any participation and as low as 5% for participation at a level necessary to achieve targets.[8,45,65,73-75] A 2014 review of community-based US DPPs further lamented the lack of minority populations in the reviewed interventions and called for the identification of best practices under real life conditions to identify, recruit, enroll, and retain minority populations in community-based diabetes prevention programs. It is essential to identify the most effective recruitment methods to reach vulnerable populations at high risk for developing diabetes.[51]

Need for Effective, Scalable Primary-Care based Programs to Increase Uptake and Engagement. It is encouraging that there are now many diabetes prevention options as well as increased insurance coverage of them. There is nationwide momentum to increase access to the DPP and other programs, but the vast majority of at-risk individuals do not participate. This is thus an opportune time to develop and evaluate the implementation in real-life settings of effective, scalable approaches to connect adults with prediabetes to available programs and provide support to help them maintain engagement and sustain achieved gains. Most adults are screened for, diagnosed with, and referred to programs for prediabetes by their primary care providers (PCPs). Thus, primary care-based programs to support patient uptake and engagement in diabetes prevention programs and behaviors could reach large numbers of at-risk individuals and improve their health outcomes. To date, most initiatives focus solely on increasing health care provider identification and referral of patients to programs.[76,77] In light of the multiple barriers many low-income and ethnic and racial minority adults face to enrolling in and engaging in such programs, additional low-cost primary care-based approaches are necessary to link patients to and help them initiate and sustain engagement in health system, community-based, or e-health programs and/or in healthy behaviors that decrease risk of progression to diabetes.

B. INNOVATION

Peer Support is an Innovative and Effective Approach to Improve Health Behaviors and Outcomes. One promising and highly scalable approach to motivate and support adults at risk for diabetes would be to pair them with a fellow patient with prediabetes who has completed a diabetes prevention program and is working to sustain their own healthy behaviors. There is a large and growing body of evidence on the feasibility, wide acceptability, and effectiveness of peer support for diabetes self-management and other areas of prevention and chronic disease management in diverse settings and populations.[78-81] "Peer support" is "support from a person who has experiential knowledge of a specific behavior or stressor and similar characteristics as the target population."[82] In our and others' prior RCTs of mutual peer support and of volunteer peer health coach models, peer support compared to other approaches including nurse care management led to improved health behaviors—such as diet, exercise, medication adherence—and clinical outcomes such as blood glucose control and weight loss.[53,83-89] 82.6% of 46 peer support interventions examined in a systematic review found significant benefits from peer support compared to a comparison group (52.2%) or from baseline (30.4%).[90] Within diabetes, a 2016 meta-analysis of 17 studies demonstrated significant benefits of peer support with an average decline in A1c of 0.5%, a clinically meaningful improvement.[91] Peer support among patients with prediabetes is an innovative approach that could extend these benefits to encourage uptake and sustain engagement in formal programs and healthy behaviors to prevent diabetes.

Why and for Whom Peer Support Could Be Especially Effective. A key reason peer support can be an effective complement to formal health care is the nonhierarchical, reciprocal relationship created between peers with shared characteristics, challenges, and experiences.[92,93] In addition, peer supporters often have more time and are more accessible to patients than health care providers.[94] Information and support from peers who share a common ethnic and socio-economic background may be particularly effective among racial

and ethnic minorities and/or low-income individuals who face access barriers to health care and less trust in health care providers.[95,96] Peer support is intrinsically culturally sensitive and tailored, as there is far less social distance between peers than between patients and health care professionals. Peer supporters who themselves report higher level of distress managing a condition[89,97] and who are more 'autonomy-supportive'[86] are more effective in helping their partners achieve clinical goals. Participants who have lower levels of health literacy, lower social support, and higher levels of distress about managing their condition benefit most from peer support interventions.[98] Moreover, peers who take on the helper role often gain competence and motivation in the target behaviors as much as those helped.[99] Peer supporters can gain a greater sense of purpose through volunteering to help another that in turn can motivate them to improve their own health behaviors.[100-102]

Reasons Some Peer Support Programs Fail. Three key lessons from unsuccessful prior peer support interventions must guide the development of new interventions. First, proactive outreach by peers through phone, text message, and/or email outreach is essential—unsuccessful interventions have relied on face-to-face sessions with no outreach to participants.[80,103,104] Second, effective initial and booster training and fidelity assessments as well as ongoing support of peer coaches are vital.[103] In Leahey et al.'s RCT, the peer coaches in one arm had been poorly trained and were highly directive ("non-autonomy-supportive") leading to little weight loss among their assigned participants.[86] That and other studies reinforce a third lesson: the importance of participants feeling that they share important characteristics and experiences with their supporters. Rather than serving as inspiring role models, peer supporters who have never struggled with the behaviors an intervention is seeking to improve are less effective than supporters who themselves have also overcome challenges.[86,97,105] Innovative peer support programs for diabetes prevention that address these concerns have the potential to harness the value of peer support for reducing diabetes risk and improving healthy lifestyles.

Promise of Implementing Primary Care-based Peer Support Program for Prediabetes. This evidence supports the promise of a well-designed peer support program that pairs adults with prediabetes with a trained peer volunteer from the same primary care center and community. This approach could be a cost-effective strategy to increase uptake and engagement in prevention programs and to improve health behaviors if individuals are not able to participate at all or regularly in formal programs. To date, there have been no pragmatic clinical studies in real-life routine practice comparing this strategy with health care provider identification and referral alone. In addition to evaluating effectiveness of such an intervention, rigorous process evaluations are essential to inform broader dissemination and implementation. Such an evaluation is especially timely in our two study health systems as there is strong stakeholder support for adopting and scaling up such a program if found effective. For example, the University of Michigan Health System (MM) Patient and Family-centered Care (PFCC) Program has established infrastructure and staffing for a health system-wide volunteer peer support program. They have recruited, trained, and supervise over 70 volunteer patient peers working with other patients undergoing transplants and with burns and spinal cord injuries. They are now extending programs to patients with cystic fibrosis, HIV and for caregivers. PFCC leadership has expressed their commitment to assume all recruitment, training, and supervisory functions for this program if found effective (see support letter). Similarly, the Kaiser Permanente Northern California (KPNC) leadership for prediabetes population care has expressed strong interest in adding this program to their menu of system-wide programs to support behavior change if our study demonstrates its effectiveness (see letter of support).

C. APPROACH

Overview. The proposed UPSTART (Using Peer Support to Aid pRevenTion of Diabetes) intervention seeks to address the need to test in routine primary care evidence-based approaches to increase uptake, engagement, and maintenance of healthy behaviors necessary to decrease progression to diabetes among primary care patients with prediabetes, especially low-income and racial and ethnic minority adults with prediabetes. Our design will be an effectiveness-implementation hybrid design type 1: We will test effects of the intervention on outcomes while observing and gathering information on implementation.[106] We will conduct a parallel, two-armed, randomized controlled pragmatic clinical trial[107] including adults with prediabetes at two primary care centers in two different health systems: KPNC and MM. The study primary care centers serve large numbers of low-income and racially and ethnically diverse patients. The trial will evaluate whether adding a 12-month predominantly telephone-based volunteer peer support program (UPSTART) to health care provider counseling and referral to diabetes prevention programs leads to greater uptake and engagement in formal diabetes prevention programs as well as improvements in A1c, weight loss, and waist circumference than health care provider counseling and referral alone (Aim 1). We will also compare differences in reported

physical activity, diet, and enrollment and engagement in diabetes prevention programs; potential mediators of autonomous motivation, behavior-specific self-efficacy, and perceived support; and moderators of health literacy, activation, and reported barriers to participation in diabetes prevention activities (Aim 2). To assist in both health systems' efforts to create a menu of program options for patients, we will examine patient characteristics associated with participation and engagement in the intervention. To enhance adoption of the intervention by the two study health systems and dissemination to other health systems if effective, we will evaluate costs and use an integrated RE-AIM[108] and Consolidated Framework for Implementation Research (CFIR)[109,110] framework to evaluate processes of intervention implementation in the two primary care settings (Aim 3). The study duration will be 5 years, to allow for peer supporter and patient recruitment, completion of the 12-month program, and assessment of outcomes at 6 months and at 12 months.

We will use mixed methods—i.e., the collection, analysis, and combining of both quantitative and qualitative data—to investigate elements important for implementation and dissemination.[111] Specifically, we will use an "embedded" mixed methods design involving collecting qualitative data during the intervention to better understand the mechanisms influencing implementation and outcomes.[112] We will gather data on how peer supporters, primary care clinic staff, and patients experience the intervention and how the experiences of participants together with the trial's results suggest we should modify the intervention. Using this approach, we aim to ensure that the intervention has the greatest possible likelihood of adoption in both MM and KPNC health systems should we find it has positive effects on processes and outcomes of care.

Preliminary Studies. The proposed intervention builds on the prior work of Michele Heisler, MD, MPA (MPI) and Julie Schmittdiel, PhD (MPI), as well as that of the multi-disciplinary team of co-investigators Caroline Richardson MD, Jeff Kullgren MD, Alyce Adams PhD, Richard Grant MD, Monique Hedderson, PhD, Romain Neugebeauer, PhD, and Laura Damschroder, MA. Drs. Heisler and Schmittdiel have led multi-site RCTs and implementation studies. Dr. Heisler's evaluations of different peer support models to improve health behaviors and outcomes provide a strong foundation for the proposed intervention. Dr. Schmittdiel's research on strategies to improve the performance of health care systems has included studies of natural experiments such as the Natural Experiments in Diabetes Translation (NEXT-D) study, which provided pilot data for the proposed study. Drs. Heisler and Schmittdiel have a strong track record of collaboration together. For example, they co-led the five-site cluster randomized pragmatic trial funded by NIDDK and VA of the AIM intervention.[113-116]

On the MM team, Dr. Richardson is the former Medical Director of the Ypsilanti Health Center, the proposed MM study site. The proposed study draws on lessons from her federally funded intervention and implementation studies of technology-mediated health behavior change programs for diet, exercise and weight loss[117-119] and of the VA DPP Clinical Demonstration Project.[120,121] Dr. Kullgren's RCTs testing behavioral economic strategies to promote weight loss,[122,123] physical activity,[124] and treatment adherence[125] have informed the proposed intervention, as has a mixed-methods study he and Dr. Heisler recently completed examining engagement in behaviors to prevent diabetes among newly diagnosed adults with prediabetes.[126] On the KPNC team, Dr. Hedderson contributes expertise and insights from her two RCTs evaluating diabetes prevention programs for at-risk pregnant women, one at the individual and one at the health system level.[127-131] Our proposed recruitment and intervention strategies have been informed by Dr. Adams's disparities-focused research. In multiple studies she has identified modifiable determinants of poor clinical outcomes among racial and ethnic minority adults with chronic conditions.[132-134] She has then designed and evaluated health system and policy level strategies to address these.[132-138] Dr. Grant's prior work and current RCTs testing strategies to prepare adults with multiple conditions to negotiate priorities with their PCPs at clinic visits have informed the proposed intervention's communication approaches.[139] Dr. Neugebauer has provided biostatistical expertise for Dr. Schmittdiel's pragmatic trials and evaluations of health plan experiments to reduce diabetes risk.[140,141] His research on the most reliable, robust, and precise causal inferences in RCTs have guided our statistical approaches. Finally, our assessment of implementation will be guided by Laura Damschroder's extensive prior work and expertise in mixed methods. She was the lead developer of the Consolidated Framework for Implementation Research (CFIR),[109] which has been cited by >500 published articles.[110] As we propose to do, she used the RE-AIM and CFIR frameworks to evaluate the VA DPP[120] and the large-scale VA weight management program MOVE!,[121] using CFIR to systemically assess contextual factors that influenced RE-AIM domains.[120]

Lessons from Our Prior RCTs of Peer Support Interventions. The proposed pragmatic clinical trial has been informed by Dr. Heisler's prior RCTs testing different peer models to help improve health behaviors and outcomes. One of her pragmatic clinical trials among adults with poorly controlled diabetes in two VA health

systems compared a reciprocal peer support model (P2P)—in which two participants were paired together and both gave to and received help from each other—with nurse care management (NCM).[142] In that study, PCP participants had clinically and statistically significantly greater improvements in A1c and key patient-centered outcomes after the 6-month intervention than those in the NCM arm. The P2P program was especially effective among participants with low health literacy, low social support, and high diabetes distress.[98,143] Based on that trial's success, we are now using RE-AIM and CFIR to evaluate the implementation of P2P in conjunction with shared medical appointments for adults with poorly controlled diabetes in five VA health systems.[144] In two of our RCTs of reciprocal peer support among previously hospitalized heart failure patients[145,146] and among adults with intractable depression,[147] however, the peer support arm did no better than enhanced usual care. Lessons from these two null trials have informed the current application. For example, because engagement was very low in both populations, we concluded that for very ill individuals and for those grappling with depression in which activation is low, models in which trained peers reach out to participants would be more effective than mutual peer support models requiring both to reach out to each other.[81,146,147]

We have also gained invaluable lessons from our prior RCTs testing volunteer peer supporter models among low-income Latino and African American adults with poorly controlled diabetes receiving care at urban primary care centers. In two RCTs, participants in the peer coach arm maintained gains from a diabetes self-management program 12 months after the end of the program significantly better than usual care,[148-150] and in another trial equally well as an arm that received support from salaried CHWs.[151] Based on our earlier successful RCT in which we developed and tested whether an interactive, tailored e-health tool would enhance self-management support from CHWs for Latino and African American low-income adults with diabetes,[152,153] we are now comparing peer coaching alone, peer coaching facilitated by an interactive, tailored e-health tool, and usual care for predominantly African American adults with poorly controlled diabetes.[154] From these peer coach trials, we have tested and refined a plethora of training and fidelity assessment resources that will be adapted for our proposed study. These include training curricula and manuals for initial training to peer supporters in Motivational Interviewing-based, autonomy supportive communication skills[148,155] (see Appendix A), in-depth peer supporter fidelity assessment check lists (Appendix B) and procedures, and protocols for monthly booster sessions. Our experiences have reinforced the critical importance of regular support sessions to allow exchange, reinforcement, and booster training for volunteer peer supporters.

Needs Assessment among Latino and African American Adults with Prediabetes. In early 2016, we conducted interviews with 20 low-income African American and Spanish-speaking Latino adults with prediabetes who receive primary care from the Ypsilanti Health Center, one of the proposed study sites. We assessed barriers and facilitators of participation in structured behavior change programs and elicited their preferences for assistance in finding and engaging in diabetes prevention programs and/or activities. Interviewees liked the idea of participating in formal healthy behavior programs that would help them 'get healthy' and lose weight. Yet, they cited numerous barriers to regular participation in formal programs. These included time limitations, limited availability due to long hours, multiple jobs and/or changing work schedules, lack of childcare, and lack of transportation. Interviewees overwhelmingly agreed that additional support from somebody they trusted and who could reach out to them by phone, email, and/or text would be invaluable. Interviewees said they would prefer that such additional support come from a peer rather than a clinician or expert. They felt it would be helpful to have support from a peer to help them eat healthier and exercise more because it would be 'moral support' that would help motivate them to know someone was checking in on them who understood their barriers and difficulties. Almost all preferred receiving telephone calls approximately once a week while they were trying to initiate healthier behaviors. Most noted also appreciating email and/or texts but not as a substitute for calls. Most said an initial face-to-face meeting with their peer supporter would be ideal but beyond that trying to meet face-to-face would be too difficult. Characteristics they would like the supporter to have were confidence, ability to motivate, and understanding of the difficulties adults with pre-diabetes face as they had achieved something similar themselves (lost weight or increased physical activity).

> *"It's that I don't have time, I have to work, and I work a lot, even on Sundays. This is what impedes me from joining because I am tired and it's exhausting to get up and go to something like that. One wants to join but they are tired from working so much."*

Recognition and Treatment of Prediabetes in Primary Care Visits. Despite the efficacy of formal diabetes prevention programs in reducing diabetes risk, as noted above, too few at-risk adults are benefiting from these. One barrier to wider adoption of lifestyle interventions and metformin may be a lack of strong evidence-

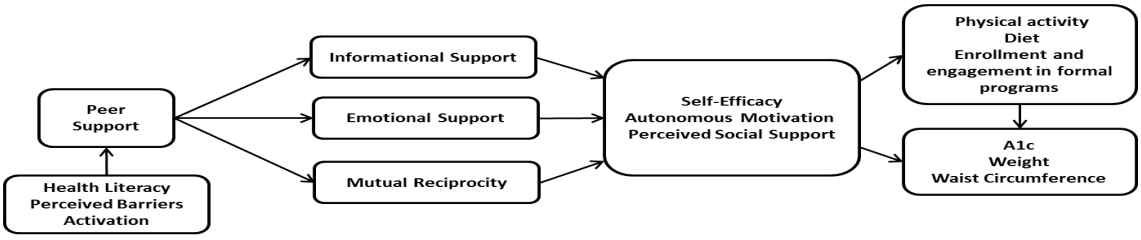
based guidelines for PCPs on appropriate care paths for prediabetes.[156-158] Dr. Schmittdiel and colleagues examined PCPs' recognition of and treatment for prediabetes from 2006 to 2011. Within KPNC <18% of patients with a blood sugar level indicating prediabetes were re-tested for FPG or A1c levels within six months, and <1% were prescribed metformin.[159] These findings suggest that outreach beyond the traditional office visit, using methods such as those we propose, could be a useful strategy to improve prediabetes care.

KPNC Regional Strategies for Population-Based Prediabetes Care. In response to the need for strategies to address prediabetes outside of office visits, in 2015 KPNC introduced the Prediabetes Online Tool. This web-based tool accessible through the KPNC patient portal offers health education information on prediabetes and direct links to KPNC programs. The main health-plan based program to help KPNC members improve healthy lifestyles that is linked to the Prediabetes Online Tool is the Motivational-Interviewing (MI)-based Telephonic Wellness Coaching Center (WCC). MI is a highly effective collaborative, person-centered form of guiding to elicit and strengthen motivation for behavioral change.[160,161] A typical coaching engagement consists of one initial session and up to six follow up contacts, but participants determine the number of sessions based on their individual need and interest. Studies led by Dr. Schmittdiel demonstrated that participation in WCC sessions is associated with improved patient satisfaction, smoking cessation, and clinically meaningful weight loss.[162-164] Participants lost more than 9 pounds on average in the 12 months after starting the program.[164] This confirmed that programs to help patient with prediabetes connect to the WCC along with other local DPP programs could be a highly successful strategy for decreasing diabetes risk in the prediabetes population.

Increasing Health Care Engagement for Prediabetes Patients. Despite the effectiveness of elements of the prediabetes population management strategy found in our previous studies, Dr. Schmittdiel and colleagues have shown that current levels of engagement among KPNC members with prediabetes are sub-optimal. In 2013, her team conducted a randomized encouragement trial that reached out to prediabetes patients outlining the risks of high blood sugar and encouraging enrollment in the WCC.[165] Patients were randomized to receive outreach via letter, interactive voice response (IVR) telephone message, secure email message, or no outreach. While email messages were the most effective mode of outreach, only 3% of the patients in this arm made and kept a WCC appointment. Most strikingly, over the 6-month period *none* of the prediabetes patients (0%) in the arm who received no proactive outreach enrolled in the program. This study underscores the need for new and innovative strategies, such as the peer-support program outlined in our current proposal.

The Intervention

Conceptual Framework of Intervention Design. The below figure illustrates the proposed causal pathways through which we hypothesize that the peer support intervention will improve health behaviors and outcomes.

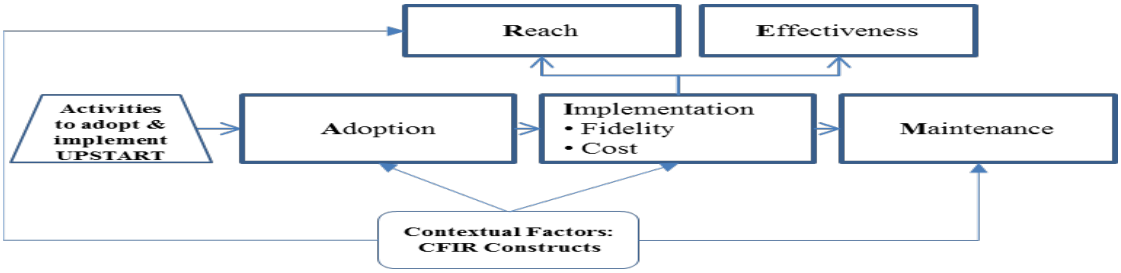


Self-Determination Theory (SDT) and Social Comparison Theory (SCT) provide the theoretical foundations for the intervention and for the Motivational Interviewing-based training the peer supporters will receive.[166] SDT provides a conceptual framework for understanding human behavior across a continuum of motivation and suggests that cultivating autonomy, relatedness to others and competence ("self-efficacy") is required for sustained behavioral change. Higher levels of autonomous motivation (i.e., when people perceive that reasons for a behavior are chosen, emanate from oneself and correspond to values and goals that are important to oneself) in contrast to controlled motivation (when people act because they feel pressured or compelled to do so) are associated with engagement in and maintenance of healthy behaviors.[166-168]

The UPSTART intervention[167,169] is designed for peers to interact and provide support in a way that is autonomy supportive with the goal of enhancing autonomous motivation and self-efficacy for healthy behaviors. Motivational Interviewing (MI)-based approaches are congruent with SDT and aim to enhance autonomous motivation.[170] To the extent that peer support facilitates satisfaction of participants' needs for autonomy, competence, and relatedness, while also providing informational and emotional support, it may provide an effective means to increase participants' uptake, engagement, and maintenance of diabetes prevention activities. Findings from Social Comparison Theory (SCT) show that lateral comparisons with

"similar" targets (e.g., peers trained to be autonomy supportive who themselves have prediabetes and struggle with similar problems as their matched participant) may promote greater motivation and health behavior change than upward comparisons with individuals with whom one does not identify and/or whose success seems unattainable so comparisons with whom can induce frustration and hinder performance.[171-173] The key SDT and SCT constructs of the importance of generating a feeling of "relatedness" with the peer supporter, thereby enhancing social support, trust, mutual reciprocity, and competence/self-efficacy have been shown to be correlated with healthy behaviors among Latino and other low-income and racial/ethnic minority adults.[174,175]

Conceptual Framework of Implementation Assessment. Two theoretical program change frameworks will guide our mixed methods, multi-dimensional evaluation of implementation of UPSTART. The first is the RE-AIM framework[108] that will be used to assess external validity and prospects for maintenance of UPSTART in the two study health centers and for dissemination throughout the two health systems. RE-AIM consists of five domains: 1) reach to targeted population; 2) effectiveness; 3) adoption; 4) implementation consistency, costs, and adaptations; and 5) maintenance of program benefits.[108,176] The second is the CFIR to assess barriers and facilitators that may affect adoption, implementation, and/or maintenance.[109,177] The CFIR comprises 39 constructs across 5 domains culled from published implementation frameworks and models[178-180] to systematically assess contextual factors that may influence program implementation: 1) intervention characteristics; 2) outer setting (e.g., external policies and incentives); 3) inner setting (e.g., leadership engagement); 4) individual characteristics; and 5) process by which implementation is accomplished.[109,177] The adjacent figure shows the framework that integrates RE-AIM and CFIR to guide our process evaluation.



Study Sites. *KPNC Oakland Medical Center (OMC)*: KPNC's OMC provides primary and specialty care to >210,000 predominantly non-white members: 28% are African-American, 25% Latino, and 16% Asian. Approximately 37% of adults in Oakland are overweight, with higher rates among African Americans and Latinos. OMC has on-site lab, pharmacy, nutrition, and health education services. *MM Ypsilanti Health Center (YHC) and East Ann Arbor Health and Geriatric Center*: YHC provides primary care to >10,000 patients 18 years and older. Approximately 50% are Medicaid enrollees, 40% are African-American, 10% are Latino, and 5% are Asian. Over 30% of YHC patients have ICD-10 codes of obesity. Ypsilanti had a median household income of $32,000 in 2014, compared to the national household median of $53,000.[181] Nearly 60% of county adult residents are overweight or obese.[182] YHC has on-site lab, pharmacy, nutrition, and health education services including a DPP program.

Peer Supporter Selection, Training, and Fidelity Assessment. If recruited peer supporters participate only for 12 months, we will recruit 75 peer supporters. Based on our and others' prior interventions,[53,83-85,87-89,149,150,183] we anticipate that many peer supporters will choose to participate longer than 12 months so we will need to recruit fewer new supporters. Study participants who complete the initial 6 months of the intervention and are interested in becoming peer supporters will also be actively recruited—and about 20% of peer supporters in our interventions have been participants who became supporters after completing the program. In our discussions with YHC and OMC PCPs, most identified 2-5 of their patients they would recommend to be peer supporters. To recruit the initial cohort, we will first contact patients recommended by PCPs and from lists of patients who completed MM and KPNC diabetes prevention programs. Peer supporters may be eligible if they meet the following inclusion criteria: are aged 18 years and older and:

1. have completed a formal diabetes prevention program in the past 36 months, **or**
2. have completed the first six months of the intervention arm of the UPSTART program.

Peer supporters may also be eligible if they are aged 18 or older and meet inclusion criteria that demonstrate improvements in BMI or A1c, through electronic medical record review, who:

3. Had an HbA1c in the prediabetes range (5.7-6.4 %) in the prior 36 months, with most recent (in past 12 months) measurement being either: less than 5.7% or 0.4% A1c points less than prior A1c; **or**
4. had a BMI score of >=25 or >=23 in Asian Americans in the past 36 months and have achieved at least a 2% decrease in body weight in the last 12 months.

We will exclude peer supporters if they have had a diagnosis of a serious psychiatric disorder (bi-polar, dementia, schizophrenia, or personality disorder) in the past 24 months; substance abuse in the last 12 months; prior diagnosis of diabetes or taking a diabetes anti-hyperglycemic medication; any of the following concerns that would make it difficult to volunteer as a coach at this time: too depressed or worried about other matters; active cancer treatment; dialysis; other life-threatening illness; or have taken weight loss drugs, underwent gastric bypass, or have participated in a medicated meal plan in the past 12 months.
In our prior and current peer coach interventions,[154] this two-stage approach has been successful, and we have developed effective recruitment, screening, and enrollment procedures.

We will hold periodic ~3-4-hour initial trainings for new peer supporters over the study period. In addition, peer supporters will receive: 1) routine, structured check-ins that will include monthly peer support group meetings (teleconference or phone) to allow exchange; 2) back-up support: offering peer supporters contact information for staff who they can call; and 3) continuing education and booster training at the monthly group meetings to enrich their skill sets and knowledge. The initial training and booster sessions are adapted from peer and CHW trainings we have used successfully in prior interventions. The initial training will focus on key Motivational Interviewing (MI)-based communication skills and include role-playing activities. Peer supporters will also practice placing calls using the Interactive Voice Response (IVR)-supported telephone platform. A focus will be learning to help their partners create action plans and following up on how they are doing on their action plans (which will be the focus of the at-least weekly phone calls during the intervention's first six months and monthly calls during the final six months). Peer supporters will be asked to reflect on their own troubles initiating and sustaining healthy behaviors and then discuss how they might work with others to help them overcome these challenges. They will also review information on evidence-based weight loss and physical activity targets to reduce risk of diabetes and on all available diabetes prevention programs in which patients in their health system can enroll. Finally, they will become familiar with the printed educational and local program curricular materials participants will receive.

To assess fidelity, team members trained in MI will observe a random sample of kickoff sessions and IVR-facilitated telephone calls of each peer supporter, complete a fidelity check list and provide feedback to peer supporters. The IVR telephone platform peer supporters will use to contact participants will enable us to evaluate frequency and duration of contacts by each peer supporter-participant dyad to evaluate intervention engagement and dose. We will use these results to refine written training materials to be included in a "Train the Trainer" manual for a translation "toolkit" at the end of the grant period. Each supporter will be assigned 2 participants for a 12-month period, with the option of coaching more if they are interested and participants are available. Although their role as volunteers will be emphasized, to cover any expenses they will receive a stipend for the initial training and different stipend amounts based on number of contacts per month documented by the IVR system with each of their assigned participants. We will assess how participation as coaches affects their own changes in some of the study measures. Thus, peer mentors will undergo informed consent and receive incentives to complete same baseline, 6-, and 12-month surveys as the participants they will be supporting.

Patient Selection, Recruitment and Randomization. We will use a population-based approach to identify potentially eligible patients via KPNC and UM databases. Eligibility criteria will include: 18 years or older; no prior diagnosis of diabetes or use of anti-hyperglycemic drug use; BMI >=25 m2/kg or >=23 if Asian;[14] and 1 A1c of 5.7%-6.4% in the prior 3 months. We will exclude patients if they have had a diagnosis of a serious psychiatric disorder (bi-polar, dementia, schizophrenia, or personality disorder) in the past 24 months, substance abuse in the last 12 months, are pregnant or planning pregnancy, or have any of the following concerns that make it unimportant to them to work on decreasing their chances of developing diabetes right now: too depressed or worried about other matters; active cancer treatment; dialysis; other life-threatening illness.

A letter or email will be sent to eligible patients with a follow up call to provide more information about the study and further screen for eligibility.

- Pre-COVID: Eligible and interested patients will be scheduled for an enrollment visit at the clinic to complete in-person informed consent with a staff member, complete a baseline survey, get weighed and have their waist circumference measured, and have blood drawn at the lab for an A1c test.
- During COVID: Eligible and interested patients will be scheduled to complete most of the informed consent process over the phone followed by online consent signing or signing and

returning mailed hard copies. Baseline assessments: survey completed by phone or online, followed by a short visit at the clinic to get weighed and have blood drawn at the lab for an A1c text. The measure of waist circumference was dropped.

All participants will receive information on available local and online diabetes prevention programs and other local resources for healthy living. Participants will then be randomized to one of two arms. Randomization will be stratified by A1c and Latino ethnicity to allow for sub-analyses. Variable block sizes will preclude prediction of treatment assignments. Randomization lists will be established separately for each clinic site. After baseline assessment and receiving informational resources, participants will learn their study group assignment.

Peer Support Arm. Participants randomized to peer support will be matched with a peer supporter of the same gender, race/ethnicity, and approximate age, as possible. Matching on shared characteristics has been found to lead to better peer relationships in prior studies. Peer supporters will receive information on times their partner(s) have indicated they are best contacted.

- Pre-COVID: The dyads will meet for their kick-off session in person at the study site.
- During COVID: The dyads will meet for their kick-off session via phone or videoconference

In the kick-off session, they will get to know one another and review together information on available diabetes prevention programs and discuss options that might best meet participants' needs and preferences. They will also review provided educational materials and define together the participants' behavior change goals and specific steps to take to meet goals over the next week ("action plan").[185] The supporter will be instructed to make at least one contact (call or text exchange) to each peer partner each week for the intervention's first six months and at least once a month during the final six months. In our prior interventions, some dyads spoke and/or met more frequently. If the supporter does not make an initial contact using the study platform within the first 10 days, a team member will call to offer support.

In the at-least weekly contacts, the peer supporters will check in on how the participant is doing, ask about their action plans, offer encouragement, help their partners brainstorm about solutions to barriers they have been facing meeting their action steps, or set a new or different action step or goal. For participants enrolled in formal diabetes prevention programs, they will discuss areas covered in that week's session and targeted behaviors/goals for that week. For those participants enrolled in a structured program yet unable to attend program session/s (which we recognize for many participants may be often), the peer coach will help them review covered topics they missed and provide support for them to maintain their efforts until they can resume attending sessions. Peer supporters will be encouraged to use the toll-free IVR exchange system line to make contacts. We have used this system in prior peer support interventions,[142] and it is an efficient way for coaches to contact their matched peer participant without exchanging personal telephone numbers. If the participant does not want to continue receiving coaching, they can call the study's toll free number to be removed from the system. Research staff will monitor the contacts via a password-protected Internet web site. Through the automatic IVR monitoring system, we will be able to identify when contacts occurred, who made the contact, and how long participants talked. All these process data will be stored in a format accessible for statistical analysis as part of our process evaluation. Though often after an initial period in our prior interventions, participants and peer coaches have exchanged phone numbers (often bypassing the IVR system), peer coaches who complete 3-4 contacts each month to a peer participant via the IVR system receive increased stipend amounts and thus will have an incentive to use the IVR system.

Enhanced Usual Care. As described above, the enrollment session will include provision of informational and educational materials.

Measures and Data Collection. We will collect multiple types of data for our mixed methods evaluations. At baseline, 6 months, and 12 months, participants will complete surveys, assessments of A1c, and weight (and height at baseline to calculate BMI). Each survey will take <30 minutes. Participants will receive $20 for each assessment. To assess program implementation and factors affecting each of the RE-AIM domains,[108,176] we will conduct semi-structured interviews with peer supporters, participants, and clinic staff and leadership at 6 and 12 months, complete fidelity assessments of peer supporter-participant interactions, observe peer supporter monthly sessions, and tabulate IVR data on frequency and duration of contacts. For example, to gain more in-depth understanding of factors associated with level of engagement and with outcomes, we will examine baseline survey data for key correlates of different levels of engagement based on IVR data on completed contacts and duration of calls. We will categorize patient-supporter dyads using these data into

different levels of intervention engagement and conduct semi-structured interviews with purposive samples of peer mentors and participants with low, medium, and high engagement. We will operationalize data collection of the CFIR as a codebook for qualitative analysis to understand how contextual factors influence RE-AIM domains.[120]

Variables in our intervention conceptual framework will be measured according to the table of measures, below.

Measures		
Measure	**Timeframe**	**Instrument**
Primary Outcome Measures		
Change in Glycosylated Hemoglobin A1c (HbA1c)	6 months	Clinical laboratories at both study health centers
Change in body weight	6 months	Digital Scale used in clinic
Secondary Outcome Measures		
Change in Glycosylated Hemoglobin A1c (HbA1c)	12 months	Clinical laboratories at both study health centers
Change in body weight	12 months	Digital Scale
Change in whether participant enrolled in a formal program to prevent diabetes	12 months	Individual item on survey: Enrollment in diabetes prevention program (Yes/No)
Change in number of sessions participant attended in a formal program to prevent diabetes	12 months	Individual item on survey: asks participant to report number of sessions attended
Change in frequency participant engages in moderate to vigorous physical activity	12 months	Individual item on survey: asks participant number of days in week, on average, participant engages in moderate to vigorous physical activity; from the Godin Leisure Time Exercise Questionnaire[206,207]
Change in duration participant engages in moderate to vigorous physical activity	12 months	Individual item on survey: asks participant number of minutes per week, on average, participant engages in moderate to vigorous physical activity; from the Godin Leisure Time Exercise Questionnaire[206,207]
Change in diet	12 months	Participants will self-report diet using a 10-item custom survey developed by the study team, adapted from the eating habits items in the Behavioral Risk Factor Surveillance System Survey Questionnaire[208]
Change in patient activation	12 months	The Patient Activation Measure (PAM-13)[209] is a 13-item scale that measures participant beliefs, perceived knowledge, and confidence for engaging in behaviors related participant's health condition. It has a 0-100 scale, where a low score indicates low activation (disengaged and overwhelmed) and a high score indicates high activation (patient considers self their own advocate).
Change in participant's perceived confidence in their ability to take steps to prevent diabetes	12 months	Williams Perceived Competence Scale[210,211] comprises 4 items measuring the participant's perception of their own ability to take steps to prevent diabetes
Change in participant's reasons for starting or continuing steps to prevent diabetes	12 months	The Treatment Self-Regulation Questionnaire (TSRQ)[210,212] consists of 11 items that measure participants' perceptions of how true various reasons to take steps to help prevent diabetes may be to the participants
Change in the participant's level of social support related to improving their own health behaviors	12 months	Adapted from the Diabetes Social Support Scale[213] and consisting of 12 items that ask the participant to indicate their level of agreement with statements regarding accessibility of others who could provide social support in attempts to prevent diabetes via healthy lifestyle changes.

Measures		
Measure	**Timeframe**	**Instrument**
The role a participant's peer supporter played in assisting them to set and reach their goals	6 months and 12 months	The Patient Assessment of Chronic Illness Care (PACIC)[214] consists of 5 items that ask the participant to state how often their peer supporter engaged in supportive behaviors regarding setting and achieving goals in order to make healthy lifestyle changes.
Participant's perceived autonomy support from their peer supporter	6 months and 12 months	The Health Care Climate Questionnaire (HCCQ, long form)[215] consists of 15 items that ask the participant to rank their agreement with statements that indicate degree of autonomy support
Moderators		
Depression screener	Baseline, 6, and 12 months	Two item version of the Patient Health Questionnaire (PHQ-2)[216]
Health Literacy	baseline	Single item from the Functional Health Literacy Screener[217] asking respondent to indicate their confidence in filling out health forms by themselves.
Neighborhood characteristics	baseline	8 items from the Measurement Properties of Neighborhood Scales [218] that assess local access to food and neighborhood characteristics that promote or prevent outdoor physical activity
Social Determinants of health	6 and 12 months	Adapted one item from the PRAPARE tool[219] identifying unmet needs and the study team developed three items to determine how needs were addressed, needs that the peer supporter helped with, and resources and services they learned about from being in the study.
Mediators		
Healthcare climate (autonomy-support of health care provider)	Baseline, 6, and 12 months	The Health Care Climate Questionnaire (HCCQ, short form)[215] consists of 5 items that ask the participant to rank their agreement with statements that indicate degree of autonomy support
Dyads' contacts, last 6 mo: method, frequency, frequency of texts*	6 and 12 months	3 items

Cost data collected will include time spent recruiting, training, and supervising the peer coaches as well as total costs of the reimbursements provided to peer coaches throughout the intervention period. Staff will keep logs of all time spent in these activities. Finally, we will include the time and costs of proactively identifying and recruiting participants and of providing the teleconferencing system for peers (although this system is being used largely for research purposes and is not usual in actual practice for peer mentoring programs.)

Sample Size. Based on our prior research and data from previous Diabetes Prevention studies, we made these assumptions for sample size estimation: (a) two-tailed test at an alpha level of 0.05; (b) power of .90; (c) a mean difference of 0.16% in change of HbA_{1C} at 12-months between groups with a standard deviation of 0.4%, and (d) a 10% attrition rate. In addition, we accounted for possible correlations between members of the peer-coach dyads (intraclass correlation, or rho) in the intervention group.[186,187] We conducted the power analysis using the methods of Cohen.[188] In our prior peer support interventions the within-pair intraclass correlation of 0.01 was not statistically different from zero, but we included this value in our assumptions.[87,142] We will stratify randomization by site and are using power calculation assumptions to detect site-specific effects. With these assumptions, 296 participants are required (148 in each arm). In addition, over half of our target patient population is African American or Latino. A sample size of 128 (64 per group) will give us over 80% power (alpha = 0.05, two-tail) to detect a mean difference of 0.2% in change of HbA_{1C} from baseline to 12 months between the intervention and control groups for the combined ethnic minority subgroups (mainly Latino and African American).[21] A recent meta-analysis examining reductions in A1c among racial/ethnic minority groups suggests this estimated effect size is conservative.[189] With this sample size, we will also be able to detect clinically significant differences in weight and in our other self-reported secondary outcomes.

Analysis Plans. Aim 1: Compare the effectiveness of the peer support program with enhanced usual care in decreasing A1c and weight. Our past experience in similar patient populations suggests that the primary outcome (change in A1c) will be close to normally distributed. To assess change in mean HbA1c, we will use a general linear mixed regression model: $Y_i = \beta_0 + \sum_{l=1}^{2} \beta_l X_{il} + \sum_{j=1}^{g} b_j Z_{ij} + \varepsilon_i$

where *i* represents the patient, *l* represents the intervention, *j* is the pair-group, β_l are parameters estimated from the data, X_{il} is the value of the l^{th} fixed effect (peer support versus usual care) for the i^{th} patient, b_j are parameters estimated from the data, Z_{ij} is the value of the j^{th} random effect (pairs) for the i^{th} patient, and ε_i is the residual error.[190] We need to account for the possibility that members of peer-peer partner pairs, because of their interactions with each other, might show a small positive intraclass correlation (ICC), a component of the variance attributable to the group. As recommended for group-randomized trials, the mixed model analyses will address potentially inflated type I errors that could occur if such clustering were not taken into account.[191] If patients drop out or request reassignment, they will be analyzed according to their initial pairing in an intent-to-treat analysis. After unadjusted changes in A1c are determined, further analyses using mixed-model ANCOVA will adjust for confounding effects of any variables that differed substantially between treatment arms. Both unadjusted and adjusted means with 95% confidence intervals will be reported for both arms. While the primary endpoint is the mean difference between baseline and 6-month A1c, analyses will be conducted to determine whether the intervention also affects the difference between baseline and 12-month A1c (i.e., the sustainability of any treatment effects) using a repeated-measures mixed model ANCOVA. We will follow these same methods in assessing changes in weight (continuous and % weight loss) and in waist circumference. We will conduct sensitivity analyses and use standard approaches to account for missing data.[192,193]

Aim 2: Identify patient characteristics associated with greater engagement in the peer support intervention and mediators and moderators of effectiveness. We will use multivariate modeling and path analyses.[194] Many of these outcomes will be measured using Likert scales. Thus, we will begin these analyses by developing contingency tables for ordered categorical data. We will then use generalized estimating equations (GEE) appropriate for modeling ordinal outcomes with correlated data.[190] We will use both quantitative and qualitative methods. We will compare patient characteristics and attitudes of participants and those not willing to participate in the study. Eligible refusers will be asked whether they would consent to a brief survey in which we will record information helpful in assessing the intervention's reach. We will model independent associations and pathways linking intervention exposure to outcomes using nested multivariate regression. Subsequent nested models will introduce potential mediators, and we will evaluate changes in the magnitude of the relationship between experimental condition and outcomes before and after the covariates are introduced. Analyses of potential moderators will use standard approaches to evaluate potential interactions between these covariates and patients' experimental condition.[194] Independent variables and moderators will be centered before testing interactions, so that multicollinearity between first order and higher-order terms will be minimized. Statistically significant interactions will be interpreted by plotting regression lines for high and low values of the moderator variable. Stata routines facilitate the plotting of these relationships.[195]

We will perform a thematic analysis of interview data using QSR NVivo, a qualitative data analysis package. Our overall approach to thematic analysis will be what Miller and Crabtree refer to as the "Editing Analysis Style," which contains both deductive and inductive elements.[196] Two investigators will independently read interview transcripts, break down responses into individual segments that express a single idea or theme and label these phrases with appropriate codes. An iterative process will be used to compare results until agreement is reached on the categories and criteria for inclusion.[197] We will examine in more depth factors contributing both to successful and unsuccessful peer mentor-partner matches and outcomes.

Aim 3: Evaluate program costs and barriers and facilitators to adoption, implementation, maintenance and spread using an integrated RE-AIM and CFIR framework. It is essential to collect and analyze information to determine the feasibility of (in terms of cost, effort, and interest) and most effective strategies to broadly disseminate and implement this intervention. We will examine costs from the perspective of the payer and create standard costs[198-204] to ensure that while the costs reported may be specific to the health plans and clinics studied; they approximate general charges a patient might be billed if these same services were purchased. All costs will be adjusted to current dollars using medical and pharmaceutical components of the Consumer Price Index. Our cost analysis will also estimate the costs of delivering the intervention itself, including costs associated with training, supporting, and incentivizing peer coaches, recruitment, IVR, and peer-to-peer communications.[205] Sensitivity analyses will be used to examine the impact of using different cost

estimates. We will provide stakeholders within KPNC and the Michigan Medicine clinics with all cost estimates but especially highlighting the costs of sustaining UPSTART over the long term.

The five domains of RE-AIM will be analyzed as follows: ***Reach:*** Calculate the enrollment rate of contacted eligible adults and compare characteristics of participants to non-participants. ***Effectiveness.*** Aims 1 and 2 will assess whether UPSTART is effective based on our primary and secondary outcome measures. We will also assess process measures such as differences in drop-out between groups or sub-groups. **Qualitative data analysis will explore participant, peer, and staff experiences with the program and key elements contributing to whether it was effective.**

Protocol for semi-structured, qualitative interviews with coaches and peers:

As enrolled participants complete their final, 12-month assessment, they are asked if they would be open to being contacted in the future about participating in an interview over the phone to describe their experiences in the study in their own words.

Those who indicate that they are open to being contacted will be contacted by study staff by e-mail or phone to schedule a one-hour time slot for the phone interview. No more than three attempts will be made to connect with each participant. Up to 65 participants (all consented and enrolled in the UPSTART study) will be interviewed; interviews will cease once thematic saturation has been reached. Staff will first explain the purpose of the interview, its length, the fact that they will be listened to by a note-taker (a study staff member) and audio recorded, and how the participant will receive a $20 gift card for participating. The audio recording is mandatory, so if someone does not want to be recorded, they can't participate in this phone interview. Staff will answer any questions, and if the participant is willing, the staff person will schedule a one-hour time block for the interview. The participant will be given the call-in number and code over the phone, via text, and/or via email, according to the participant's preference.

Shortly before the scheduled interview, staff will send the participant a reminder with the call-in information. Once the participant calls in, the interviewer will introduce herself and the note-taker, and then explain that she is going to describe the interview and officially ask for the participant's consent before starting the interview. Then, she will follow the consent script (uploaded in Section 10-1.1) to obtain verbal consent.

The study staff will document that the consent process took place and whether or not the subject verbally agreed to continue participating. If the subject declines participation, the interview will not be conducted, and nothing will be audio recorded. If the participant consents, then she will begin audio recording and start the interview. When audio recording begins, the system announces this to all on the call.

In order to capture responses to the interview questions, a study team member will be on the conference call to take notes during the interview. We will audio record the interview to check that the notes are complete and accurate. We will use a cloud-based conferencing service to conduct these interviews and to audio record (for example, Zoom). We will only use conferencing services where there is a Business Associate Agreement between the service and the University of Michigan, which means it complies with the Health Insurance Portability and Accountability Act of 1996 (also known as HIPAA) regulations. Also, recordings of the interviews will be encrypted and stored either in the secure conferencing service or on a secure, encrypted server. Once the research team compares the notes taken during the interview to the audio recording, the audio recording will be destroyed.

All participants who compete an interview will receive a $20 gift card in the mail, paid through the HSIP program. All participants submitted the information required by HSIP when they enrolled in the UPSTART study.

Interview recordings and notes will be labeled with a code to help protect confidentiality. In order to analyze the data collected, two separate study team members will review interview notes in order to develop a code book. This iterative process involves individual coding followed by meetings among the coders to come to agreement on a common list of codes. Once the codebook is established, the study staff will use the agreed-upon codes to code all interview notes. The study staff will use software such as NVivo to facilitate the coding and analysis of qualitative data. Analyses will be used to optimize the intervention for future use and identify key elements contributing to the intervention's effectiveness.

Protocol for semi-structured, qualitative interviews with key informants
In the final year of funding, we will conduct interviews with a selection of key informants who work at Michigan Medicine or the University of Michigan with the objective of judging prospects for sustained offering of UPSTART as part of usual care, identifying potential barriers to sustaining the program, and determining areas for modification.

We plan to conduct 10-20 interviews. Potential interviewees have been identified based on their role at MM; they are selected based on their likelihood of sharing information needed to meet our objective in the above paragraph. In addition, at the end of each interview, we will ask each interviewee if they would recommend others we should interview.

We plan to invite:

- the Medical Directors at the two sites where we offered the program, Ypsilanti Health Center and East Ann Arbor
- clinicians, social workers, and diabetes educators at these clinics
- 1-2 staff or leadership from the Office of the Patient Experience
- Leadership of Ambulatory Care Operations
- Leadership of Community Health Services
- Leadership the Office of Health Equity and Inclusion

The Principal Investigator will send an email invitation to each individual; attached to the email will be a 2-page infographic describing the study and a one-page list of topics we hope to cover in the interview.

No more than three attempts will be made to connect with each potential interviewee. For those who are willing, the staff person will schedule a one-hour time block for the interview. The participant will be given the call-in number and code over the phone, via text, and/or via email, according to the individual's preference.

Shortly before the scheduled interview, staff will send a reminder with the call-in information. Once the interviewee calls in, the interviewer will introduce herself and the note-taker, and then explain that she is going to describe the interview and officially ask for the participant's consent before starting the interview. Then, she will follow the consent script (uploaded in Section 10-1.1) to obtain verbal consent.

The study staff will document that the consent process took place and whether or not the subject verbally agreed to continue participating. If the subject declines participation, the interview will not be conducted and nothing will be audio recorded. If the participant consents, then she will begin audio recording and start the interview. When audio recording begins, the system announces this to all on the call.

In order to capture responses to the interview questions, a study team member will be on the conference call to take notes during the interview. We will audio record the interview to check that the notes are complete and accurate. We will use the cloud-based conferencing service Zoom to conduct these interviews and to audio record because there is a Business Associate Agreement between Zoom and the University of Michigan, which means it complies with HIPAA regulations. Also, recordings of the interviews will be encrypted and stored either in the secure conferencing service or on a secure, encrypted server. Once the research team compares the notes taken during the interview to the audio recording, the audio recording will be destroyed.

Interview recordings and notes will be labeled with a code to help protect confidentiality. Analyses will be conducted in the same manner as described for the interviews with peers and coaches in the preceding section of this protocol.

Adoption. Two sites have agreed to participate but staff may differ in their openness to referring their patients to a peer support intervention if formally adopted. We will analyze staff attitudes toward the value of the program over the course of the study period. ***Implementation.*** We will analyze degree of fidelity as documented on the check lists of observed encounters. Interview data will be analyzed to assess CFIR constructs to explore barriers and facilitators to implementation. Any adaptations will be documented through project notes. Differences in implementation and in barriers/facilitators across the two study sites will also be documented. ***Maintenance.*** Individual-level maintenance of engagement is captured by our IVR data and by our measured outcomes. At the clinic level, qualitative data will be used to judge prospects for sustained offering of UPSTART as part of usual care, to identify potential barriers to sustaining the program, and determining areas for modification. As part of our process evaluation, we will seek opportunities to streamline the intervention through more efficient protocols. Field notes will be kept and analyzed to inform the next generation program. With this aim's findings, we will develop a tool kit of all training materials and protocols to guide dissemination efforts and to contribute to the field of implementation science.

Study Timeline: The timeline contains the study's activities for all years:

Study Activities	Year 1				Year 2				Year 3				Year 4				Year 5			
	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4
IRB and Administrative approvals																				
Staffing and clinical supports																				
Finalize program materials, surveys																				
Incorporate scripts and test IVR																				
Finalize training for Coaches																				
Recruit and train coaches																				
Enroll patients																				
Conduct Intervention																				
Collect 6-month data																				
Collect 12-month follow-up data																				
Analyze data																				
Qualitative and Cost Analyses																				
Report/Publications																				

Potential Problems and Solutions: We anticipate four key potential problems. First, our proactive identification process requires that patients have had a fasting glucose or A1c within the prior 12 months during our enrollment period of 24 months. Thus, vulnerable patients who fall out of clinical care for extended periods will not be captured. Such patients are often among the highest risk patients. Fortunately, both study sites have systems in place to proactively identify and reach out to patients who have not seen a PCP within two years. Such measures will help mitigate this problem. Second, although both sites are engaged in active efforts to screen for prediabetes and refer all patients with prediabetes to programs, we and clinical leaders at the two sites recognize that some potentially eligible patients we contact will not be aware that they have blood sugar levels in the prediabetes range. In fact, the clinical sites see our identification and outreach to such people who have fallen through the cracks as a support for their efforts and we will share all identification lists with the clinical staff. We will work with clinical leadership at both sites to ensure that they endorse the language in recruitment scripts and in the initial information session informing patients about prediabetes and measures they can take to prevent progression to diabetes. Third, as in our prior interventions, a very few patients who have blood glucose levels within 12 months before baseline in the prediabetes range will have levels in the

normal range when we check their A1c at baseline. Those of a slightly larger number will have progressed to levels consistent with diabetes (6.5% or greater). We will facilitate a nurse or PCP appointment with those who have progressed to diabetes. Those in the improved group will be invited to participate as a Peer Supporter. In both cases, we will give them information about the meaning of their A1c and provide educational materials and information on programs to improve health behaviors and/or for diabetes education. A fourth potential problem for this intervention targeting a lower-income, urban population is attrition. In our previous interventions with patients at federally qualified health centers, we have faced attrition of up to 20% over 12 months. However, in our and our colleagues' prior work at these two primary care centers, attrition rates have not exceeded 10%. Through our years of work with low-income, racial and ethnic minority populations, we have developed very effective strategies for recruitment and retention. Moreover, we will follow sound analytical approaches to address any missing data through intention to treat analyses that will aid in avoiding misleading interpretation of the data.

Expected Outcomes: The proposed study will provide rigorous evidence on the effectiveness of peer support to enhance uptake, engagement, and maintenance of behaviors to reduce risk of progression to diabetes. Findings from the study will provide invaluable information on required staff effort, costs, and key facilitators and barriers to implementing and sustaining this type of volunteer patient-led program. At the end of the study, along with preparing manuscripts for publication, we will create and disseminate a 'tool kit' with all recruitment, initial and booster training materials, fidelity assessments, recommended oversight procedures, among other materials to facilitate adoption and implementation of the program at other health centers and systems. We will also share the findings with multiple audiences, including research participants, health center and system leaders, policy makers, community leaders, and academic and public audiences. Finally, through the rigor and innovativeness of our proposed mixed methods assessment grounded in an integrated RE-AIM and CFIR framework, the proposed research will contribute both to translational and implementation science.

Future Directions: Perhaps the most important goal after the study's completion is to ensure that the program if found effective is fully adopted in both of the study sites and sustained over the longer term. Additionally, we will be positioned for broader dissemination and implementation throughout two large health systems. To help ensure this, in preparing this submission we have met with and secured the support of key stakeholders at both study health centers and systems, ensuring that these programs address their key priorities and incorporate metrics that matter to them in deciding whether to adopt the program. At the end of the study, there will be a cadre of trained and experienced peer supporters who can help train and support future peer supporters. Because this program relies on trained patient volunteers, the principal future need is limited staff effort to help recruit new peer supporters and provide them training and oversight/support. At MM, these functions would be assumed by the already existing health system-wide peer mentor program run by the MM's Patient- and Family-Centered Program that was established precisely to develop and oversee peer mentoring programs such as the one we propose to evaluate (see letter of support). At KPNC, the prediabetes population care leadership has also expressed strong interest in including support for this program among their other programs promoting healthy behaviors among KPNC members (see letter of support). One key reason KPNC and MM health system and health promotion leaders have strongly endorsed the proposed intervention (see letters of support) is that it is a low-cost, patient-led program that can provide flexible and frequent contact and support that many vulnerable patients need yet is beyond the scope of what health care providers can provide—and is thus an invaluable complement to formal health care.

At a broader policy level, through Dr. Heisler and Dr. Schmittdiel's leadership roles in their institutions' Centers for Diabetes Translational Research (CDTR), they will work to inform local, state, and national policy makers, such as CDC staff leading efforts to broadly disseminate different versions of the DPP, about key lessons gleaned from this study about how better to increase uptake of and engagement in diabetes prevention activities as well as to maintain achieved gains. Finally, we will build on knowledge gained through this study to continue developing and testing different peer support models that activate patients to improve their health and that contribute to creating more patient-centered health care systems. Well-designed peer support models such as the one we propose to evaluate hold promise to help stem the epidemic of diabetes and address widening disparities based on income and race/ethnicity in diabetes and its complications. Lessons from this study will also fruitfully inform the design of peer support models for patients who have other health conditions and who are working to improve other health behaviors.

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