Novel Interventions to Increase Uptake of Diabetes Self-Management Support Training within Primary Care

PROmoting Diabetes Education and Management Through Peer Support and Team Referral

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PROMPT

Novel Interventions to Increase Uptake of Diabetes Self-Management Support Training within Primary Care

STUDY PROTOCOL

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STUDY SYNOPSIS

Study Description

Living with diabetes can be challenging, however Diabetes Self-Management Education and Support (DSMES) is well known to help persons with diabetes (PWD) learn to cope with the uncertainties of life with diabetes. Unfortunately, DSMES is underutilized in the current health care setting. This is a multifactorial problem with the two largest issues being providers not referring patients and patients not attending the DSMES programs. These programs and the health care workers who support them have the potential to modify the disease course for many PWD, including potentially modifying long term morbidity and mortality. We are proposing a feasibility study to evaluate the impact of best practice advisories (BPAs) delivered to the health care provider and the diabetes care and education (DCE) specialists via the electronic health record when a PWD is identified as qualifying for DSMES. We will determine if the BPAs influence the time to referral for DSMES as well as the factors that predict whether a patient is referred to DSMES. We also propose to assess the impact of a peer support on motivating PWD to attend DSMES and make healthier lifestyle choices. We hypothesize that if PWD are able to connect with a peer who is also living with diabetes, they may be more likely to attend DSMES. Finally, we will assess qualitatively how the health care providers felt about the use of the BPA reminders, explore how the PWD felt about the utility of the peer supporters, and the overall relevance of the diabetes education they received. From these lessons learned we will collaborate with our stakeholders to design a large, pragmatic randomized trial designed to increase the uptake of DSMES, a vital piece of the diabetes puzzle.

Objectives

Aim 1 Evaluate the relative impact of BPAs on DSMES services among providers at 6 primary care clinics.
Aim 2 Conduct a 6-month pilot of DSMES among 90 PWD randomized to one of two groups: usual care or peer support.
Aim 3 Engage stakeholders in designing a future large scale DSMES services trial

Endpoints

Aim 1 *Primary Outcome:* Odds of referral for DSMES services; *Secondary Outcome:* Time from index patient visit to referral to DSMES services
Aim 2 *Primary Outcome*: Odds of attending 1 DSMES class; *Secondary Outcomes:* Time to get to DSMES class, Number of PWD who attended at least 2 DSMES classes, Number of PWD who complete entire DSMES class including 3-month follow-up, Change in A1c from baseline to end of DSMES class, Change in A1c from baseline to 6 months, Change in Diabetes Distress from baseline to end of DSMES class, Change in Diabetes Self-Efficacy from baseline to end of DSMES class
Aim 3 Themes from Qualitative Interviews with Patients, Providers and Peer Supporters

Study Population

Aim 1: Six primary care practices from within the state of North Carolina. The providers will be a mix of genders, and ages. Providers will be a convenience sample based upon the six practices that are identified to be a part of this study.
Aim 2: 90 adult patients with type 2 diabetes from one of the six practices identified in Aim 1.
Aim 3: Providers, patients, from Aims 1 and 2 as well as peer supporters for the qualitative interviews planned in Aim 3.

Stage

This is a pilot, planning grant from which the data will be used to design and implement a larger trial designed to promote utilization of DSMES classes amongst patients with type 2 diabetes.

Description of Sites/Facilities Enrolling Participants

Six primary care practices from the University of North Carolina Physician Network Practices.

Description of Study Intervention

Aim 1: Four UNCPN practices receive a suite of tools intended to increase the rate of referral to DSMES classes for patients with type 2 diabetes. In these four practices, the assigned DCE specialist will have access to a list of eligible patients who have upcoming appointments with their primary care providers. When an eligible patient presents for an

appointment in one of the four intervention clinics, a best practice advisory (BPA) will fire within the EHR and encourage the provider to place a referral for DSMES classes. In the two practices that are the standard of care practices, the lists of eligible patients for the DCE specialists will be generated but hidden from the providers.

Aim 2: Ninety patients with type 2 diabetes who meet criteria for referral for DSMES classes will be enrolled and randomized in a 1:1 fashion to receive either DSMES class plus the addition of a peer supporter or just standard DSMES without peer support. DSMES classes will be offered both virtually and in person. Patients will be allowed to choose their preferred format after discussion with their DCE.

Aim 3: No intervention is included in Aim 3. Aim 3 is a qualitative assessment of the interventions.

Study Duration

Providers will be involved in the intervention for the entirety of the study. Patients will be involved from the point of referral to DSMES class to the 3 month follow up after the conclusion of DSMES class (up to 12 months after the consent date depending on DSME class availability).

1 - STATEMENT OF COMPLIANCE

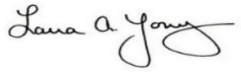
1.1 STATEMENT

The trial will be conducted in accordance with International Council on Harmonization Good Clinical Practice (ICH GCP), applicable United States (US) Code of Federal Regulations (CFR), and the NIDDK Terms and Conditions of Award. The Principal Investigators will assure that no deviation from, or changes to the protocol will take place without prior agreement from the funding agency and documented approval from the Institutional Review Board (IRB), except where necessary to eliminate an immediate hazard(s) to the trial participants. All personnel involved in the conduct of this study have completed Human Subjects Protection and ICH GCP Training.

The protocol, informed consent form(s), recruitment materials, and all participant materials have been or will be submitted to the IRB for review and approval. All changes to the consent form(s) will be IRB approved; a determination will be made regarding whether a new consent needs to be obtained from participants who provided consent, using a previously approved consent form.

1.2 INVESTIGATOR'S SIGNATURE

Co-Principal Investigator:

Signed:		Date:	1/03/2023
	Name: Laura A. Young, MD, PhD		
	Title: Associate Professor of Medicine		

Co-Principal Investigator:

Signed:		Date:	1/03/2023
	Name: Katrina E. Donahue, MD, MPH		
	Title: Professor of Family Medicine		

2 - INTRODUCTION

2.1 Study Rationale

Living with diabetes can be challenging, however Diabetes Self-Management Education and Support (DSMES) is well known to help persons with diabetes (PWD) learn to cope with the uncertainties of life with diabetes. Unfortunately, DSMES is underutilized in the current health care setting. This is a multifactorial problem with the two largest issues being providers not referring patients and patients not attending the DSMES programs. These programs and the health care workers who support them have the potential to modify the disease course for many PWD, including potentially modifying long term morbidity and mortality.

We propose a feasibility study to evaluate the impact of best practice advisories (BPAs) delivered to the health care provider and the diabetes care and education specialists via the electronic health record when a PWD is identified as qualifying for DSMES. We will determine if the BPAs influence the time to referral for DSMES as well as the factors that predict whether a patient is referred to DSMES. We also propose to assess the impact of a peer support on motivating PWD to attend DSMES and make healthier lifestyle choices. We hypothesize that if PWD are able to connect with a peer who is also living with diabetes, they may be more likely to attend DSMES. Finally, we will assess qualitatively how the health care providers felt about the use of the BPA reminders, explore how the PWD felt about the utility of the peer supporters, and the overall relevance of the diabetes education they received. From these lessons learned we will collaborate with our stakeholders to design a large, pragmatic randomized trial designed to increase the uptake of DSMES, a vital piece of the diabetes puzzle.

2.2 Background

The Global and Individual Burden of Diabetes. Close to 10% of the US population currently has diabetes, and this already staggering prevalence is expected to rise to 13% by the end of this decade and to 17% by 2060.[1] Diabetes is a condition in which the pancreas does not produce enough insulin (Type 1) or the body cannot properly utilize the insulin being produced (Type 2). Among persons with diabetes (PWD), 90-95% have Type 2, a largely preventable but generally chronic condition.[2] Diabetes is a major cause of blindness, kidney failure, heart attacks, stroke, limb amputations, and premature mortality, along with impacts of quality of life and the ability to work. Treatment includes diet modification, exercise, blood glucose monitoring, medication, foot/skin care, sleep hygiene, medication use and regular screenings—a regimen that can be overwhelming to anyone, let alone persons who are ill. Indeed, the average PWD is expected to engage in 4 hours of diabetes self-care daily. More so than many chronic conditions, diabetes outcomes hinge on successful self-management, but clinical targets are not being met. From a cross-sectional, nationally representative sample of PWD in the US, data shows that only 64% were meeting A1c targets. When a composite goal, which included A1c, cholesterol, blood pressure and other non-glycemic targets was assessed, only 25% of PWD were meeting their targets.[3] National and global success in minimizing and preventing the devastating negative effects of diabetes therefore hinge, in large degree, on assisting patients to properly manage their condition.

Diabetes Self-Management Education and Support Classes. Diabetes Self-Management Education and Support (DSMES) classes are a structured approach to help PWD learn to complete and manage the many self-care practices needed to successfully live with diabetes. DSMES provides a broad approach, addressing clinical, educational, psychosocial, and behavioral topics, and can be delivered in a variety of formats, including group classes or one on one sessions.[4] Taught by Diabetes Care and Education (DCE) specialists, they cover issues such as avoiding longer-term complications, developing personal action plans, and dietary information and meal planning. PWD who receive DSMES experience advances in many areas of their diabetes care. Improvements in glycemic control are notable, with A1c improvements of 0.45-0.57%,[5-8] and these A1c improvements are additive to pharmacotherapy and lifestyle therapy.[5-9] DSMES completion also reduces the onset and/or worsening of diabetes-related complications and results in lower all-cause mortality.[10-12] PWD who complete DSMES training demonstrate improved self-efficacy, higher quality of life, and reduced diabetes distress,[13-17] have better coping skills and are able to engage in healthy lifestyle behaviors more effectively.[15,16] However, despite the observed benefits of DSMES, only a small minority of PWD actually receive DSMES. Within the first year of diagnosis, the Center for Disease Control and Prevention reported that 6.8% of PWD who had private insurance participated in DSMES.[18] Only 5% of Medicare enrollees receive DSMES within the first year of diagnosis.[19] Similarly low rates of DSMES participation were reported for PWD who had diabetes for over a year, but met other criteria for DSMES referral.[20] *Given the critical importance of self-management to diabetes success and the*

demonstrated value of DSMES class completion on diabetes outcomes, efforts to increase DSMES use have great potential to slow the global epidemic, reducing the burden of this disease on individuals, families, and the economy.

Barriers to DSMES Use. Patients are referred to DSMES by a health care provider, and typically their primary care provider. Referrals are the main avenue through which patients learn that DSMES exists and is an option for them. Once referred, patients are generally responsible for contacting the class provider and for attending and completing the program of classes. Barriers to DSMES participation therefore occur at the level of the: a) healthcare system and health care provider, and b) patient.[4]

a. Healthcare system and provider barriers to DSMES referral. Heath care provider barriers include lack of awareness of DSMES services, limitations on who can make the referral, unclear referral processes, and unconscious or implicit bias (i.e. providers may assume their patients will be unwilling or unable to engage in DSMES).[21-24] It has been shown that physicians are overall positive about DSMES that are delivered by trained DCE specialists. However, there was some reported concern about losing patients who are sent to DSMES. In fact, 11% of patients from this same study reported changing health care providers as a result of DSMES.[22] Additionally, providers reported that while they do want their patients to have DSMES, they are sometimes concerned about the information that is provided and in fact do not agree with the information their patients are given.[22]

Such bias has been found to be a significant contributor to racial/ethnic healthcare inequality.[25] Healthcare system barriers to DSMES referral include lack of awareness on the part of administration, limited Diabetes Care and Education (DCE) specialists to refer to, limited resources for marketing, and low reimbursement rates.[26] Attempts within the UNC Health Care System to improve DSMES access are instructive with regard to both of these barrier categories. A dedicated DCE specialist was embedded within the primary care practices in the network, but referral rates for DSMES remained low. In a data pull among 53,347 patients with type 2 diabetes in the UNC Heath Care System over an 18-month time period 2019 to 2020, nearly three quarters received some type of referral, but only 20% received a referral for DSMES. And although Black and Hispanic populations have higher rates of diabetes, over half of the referrals were for White PWD. These findings are similar to others, in which older patients, non-whites, and males are least likely to be referred for DSMES. Thus, simply placing a DCE specialist into a practice does not sufficiently improve referral rates. DCE specialists currently rely on providers to send in referrals to connect patients with DSMES classes, but DCE specialists have expertise in understanding which patients are at key inflection points in their respective care and disease status, thus where patients may benefit from engaging in DSMES classes. Our team, along with our collaborating DCE specialists, expect that by including DCE specialists in the Best Practice Advisory (BPA) processes, an action that has not been previously operationalized within EHRs, greater numbers of patients will be referred to and thus involved in self-management activities.

b. Patient-level barriers affecting DSMES use. Once a referral for DSMES has been placed, multiple patient barriers can intervene to lower rates of uptake. A valuable way for understanding patient-level barriers is through the lens of Social Determinants of Health (SDOH). SDOH are the conditions within the environments in which people are live, work, recreate, and age that affect their overall health and quality of life. SDOH encompasses things like safe housing and neighborhoods, transportation, education, job opportunities, income, access to healthy food and clean air and water, access to health care (including insurance), and equality (levels of racism and discrimination). Insurance coverage is especially relevant to DSMES because, while most policies do cover some diabetes education and even DSMES, they can be associated with costly co-payments born by the PWD. In addition to their many self-care activities, PWD are leading busy lives, working, caring for children and aging parents, etc. In this setting, even seemingly small issue like not having ready childcare or a reliable car or other means of transportation can become major barriers to DSMES participation. For working PWD, finding a convenient time to attend DSMES can be a challenge since most classes are offered during the workday.[23] Finally, comorbid mental health (e.g., depression, anxiety) or other chronic conditions can make attending DSMES classes difficult. Additionally, it has been shown that PWD who are of lower socioeconomic status, less educated and with clinically greater disease severity are less likely to attend DSMES.[27,28]

For PWD who manage to attend a class or two, these same SDOH barriers can lower retention and completion rates. In a large practice survey from the American Association of Diabetes Educators (AADE), only 23% of participants completed 75% or more of the program.[20] The authors suggest that low completion arises from a variety of factors, including perceptions that the program did not meet needs due to cultural or educational factors, lack of understanding or knowledge of the benefit of DSMES, and the referring provider insufficiently emphasizing the importance of program completion. A handful of RCTs have identified methods for increasing attendance and completion rates, including

telehealth formats, coaching programs, discussion groups, online resources, and more intensive programs. One intervention provided free parking and bus tokens to patients referred to DSMES as an attempt to improve attendance. Over the course of the quality improvement intervention, the team discovered that the no show rate only modestly changed from 22% to 19%.[29] A telemedicine approach for rural PWD demonstrated retention rates of over 80%.[30] They attribute this to labor intensive efforts to stay connected to the patient through numerous reminder phone calls and mailings. It is notable that many of these interventions only show modest improvements in attendance rates or require significant resources to deploy on a large health care system scale, thus limiting their pragmatic use in today's health care system.

Previous Research. The majority of DSMES trials have focused on innovative ways to deliver DM education, with relatively few addressing how to increase the uptake of DM education in routine primary care practices. Among the relatively small number of studies addressing uptake, few are pragmatic trials assessing provider and patient barriers to DSMES within real world settings. One pragmatic trial randomized practices to refer patients to DSMES delivered in a traditional hospital-based setting vs a primary care medical home office setting. The authors proposed that referrals and retention within the context of a medical home office setting might be higher because they are within a known environment. They found modestly higher referral (18.4% vs 13.4%; P < .0001) and attendance (34.9% vs 26.1%; P = .02) rates for the medical home compared to those in the traditional hospital setting.31 Conducted within in a single federally qualified health center, a second pragmatic trial found that provider reminders might be a useful tool for increasing DSMES referral rates. By embedding a DSMES algorithm in the electronic health record and conducting provider training on its use, they increased the rate of e-referrals from 0% to 31%.32 Though this study was small and did not examine completion rates, it suggests that automated systems for alerting providers about the need for DSMES referral could yield significant benefits with regard to referrals.

Best Practice Alerts as a Potential Intervention to Increase DSMES Referrals. Best Practice Alerts (BPAs) are clinical decision support tools intended to enhance the receipt of evidence-based care. Embedded in electronic health record systems, they identify patient populations who may benefit from specific medical or other services, procedures, referrals, and/or treatments and send notifications to their providers. They guide clinical teams to act at the point of care by educating providers as to why an action is needed and then immediately directing providers to place orders in the electronic health record to move patients forward with appropriate treatments and treatment recommendations. An advantage of BPA's is that the systematic reminders can mitigate the impact of implicit racial and other bias among providers,33 and thus may be one component of the larger mission to achieve health equity. BPA's also help close provider knowledge gaps, particularly when the guidelines/care processes in question are not intimately linked to the provider's field of specialty and help overcome time constraints by speeding high quality patient care.33 While BPAs are successful in a variety of clinical situations,33-43 some studies have shown limited benefit. However, these studies have their own limitations, including retrospective designs34,36,43,44 and the lack of designs intended to rigorously test for a specific impact of the BPA's themselves.40,42 Thus, while BPAs appear promising, more research is needed to definitively determine the success of BPA approaches in prompting positive behavior change, especially in regard to DSMES referrals.35,44

Then too, not all BPAs are created the same. The effectiveness of BPA's may be enhanced by administrative approaches that automate immediate referrals to evidenced based care resources,40 include processes where primary care providers can co-manage patients with other healthcare professionals45 (such as certified DCE specialists, incentivize providers for referring patients to receive evidenced based care,40 and to adopt physician and organizational quality metrics that capture appropriate referral rates to DSME classes.46 Additionally, BPA workflows need to be thoroughly tested by development teams prior to activation to reduce unanticipated errors38,44 and minimize the number of BPA's triggered for any given patient. Too many alerts can lead to fatigue, cognitive overload, and desensitization.41 Research also supports the creation of BPA's for primary care settings that engage providers in "System 1" human thinking processes, which are rapid, more intuitive, and require less conscious deliberation compared to "System 2" processes that are slower and require more cognitive effort.47 Busy physicians perform real-world decisions using System 1 thinking via a knowledge base that efficiently uses cognitive effort and do so almost automatically.47 Experts in BPA design also recommend "one click" options and the use of obvious color changes (from yellow to green) when BPA's have been attended to and do not require further attention.47

A final important design feature for referral-related BPAs is that they occur during key inflection points in the care and disease status of each patient. In the case of DSMES, key timepoints are when physicians most in need of guidance to

improve patient care and when patients might be the most open to such guidance. Leading organizations have identified four critical timepoints for DSMES to take place: 1) at diagnosis, 2) annually and/or when not meeting treatment targets, 3) when complicating factors develop, and 4) when transitions in life and care occur.4 Some of these leading organizations include the American Diabetes Association, the Association of Diabetes Care and Education Specialists, the Academy of Nutrition and Dietetics, and the American Association of Family Physicians. Not only are these critical times important moments in the lives of PWD when they may need additional guidance to ensure successful daily management of their diabetes, but they are also milestones in chronic disease management that health care providers and BPA's can relatively easily identify. But while BPAs appear to be a promising, pragmatic approach for increasing referral rates, they do not address the second half of the equation: patient level barriers impacting participation and completion. For this, we assert that a more personal approach is needed, such as peer support.

Peer Support. Peer support has a long history of helping patients with chronic disease receive and provide social support both for emotional and medical reasons. Peer support is defined as "support from a person who has experiential knowledge of a specific behavior or stressor and similar characteristics as the target population."48 Peer support has been delivered in a variety of ways, including professional-led group visits with peer exchange, peer-led face to face self-management programs, peer coaching, support groups, and community health workers.49 These interventions have been delivered in person, via telephone and virtual via the internet. It has been proposed that the unique contribution of peer support is the nonhierarchical, reciprocal relationship created through sharing similar life experiences and coping strategies.48,50 Peer supporters are typically volunteers or nonprofessional staff, making this type of intervention less resource intensive compared to other interventions and a particularly interesting model to add to existing interventions that are underutilized, such as DSMES. Peer supporters even tend to live in the same communities as the patients they will support, a fact that helps in decreasing cultural and other communication and trust barriers. As an intervention, peer support has been shown to be particularly potent in the field of diabetes, being linked to improved diabetes self-care behaviors,48,50 improved mental health and reduced problematic health behaviors.48,50-55 Given the volunteer nature of the model, however, training of peer supporters should be conducted via an established peer support program.

2.3 Risk/Benefit Assessment

2.3.1 Known Potential Risks

Potential risks associated with participation in this study are generally of a psychological nature. Patient participants may experience embarrassment by personally disclosing that they have diabetes. Additionally, there is a potential for a breach of confidentiality.

2.3.2 Known Potential Benefits

This study will contribute to generalizable knowledge by trying to improve diabetes care within primary care settings by increasing the referral rates of patients to DSMES and helping address barriers that prevent patients from fully engaging in the diabetes education experience. Once a referral has been made for DSMES, PWD may benefit from the support of a trained peer (also coping with diabetes) to help them make the decision to attend, encourage them to continue the course to completion, and help them problem solve barriers that arise.

2.3.3 Assessment of Potential Risks and Benefits

To minimize potential risks, study staff and data collectors will be trained in the importance of protecting the confidentiality of all study participants. Data will be stored in locked filing cabinets or on password-protected secure servers. It is possible people feel some embarrassment when answering survey questions or discussing their issues with their peer supporter or other classmates. Survey question data will be protected and participants are not required to answer any particular questions. Also, peer supporters undergo training around confidentiality and privacy. At the beginning of each class participants are reminded that the personal information discussed during the education classes should remain confidential.

3 - OBJECTIVES AND ENDPOINTS

3.1 Objectives and Endpoints

Objectives

Aim 1. Evaluate the relative impact of BPAs on DSMES services among providers at 6 primary care clinics.
Aim 2. Conduct a 6-month pilot of DSMES among 90 PWD randomized to one of two groups: usual care or peer support.
Aim 3. Engage stakeholders in designing a future large scale DSMES services trial

Endpoints

Aim 1

Primary Outcome: Odds of receipt of referral for DSMES services within 30 days of index PCP visit
Secondary Outcome: Time from index patient visit to referral order placed for DSMES services – Initially planned, but was not done as referrals were made at the patient visit.

Aim 2

Primary Outcome: Odds of attending 1 DSMES class within 6 months of date of informed consent documentation.
Secondary Outcomes:

- Time to get to DSMES class
- Number of PWD who attended at least 2 DSMES classes
- Number of PWD who completed the entire DSMES class including 3-month follow-up
- Change in A1c from baseline to end of DSME class
- Change in A1c from baseline to 6 months
- Change in Diabetes Distress from baseline to end of DSME class (3-month follow-up)
- Change in Diabetes Empowerment from baseline to end of DSME class (3-month follow-up)

Aim 3

Themes from Qualitative Interviews with Patients, Providers and Peer Supporters

4 - STUDY DESIGN

4.1 Overall Design

Aim 1: We will evaluate the impact of Best Practice Advisories (BPAs) + Diabetes Care and Education (DCE) Specialist engagement on DSMES service referral patterns among providers at 6 primary care clinics, see Figure 1. Four practices will receive BPAs that are sent to the providers when a patient meets criteria for referral for DSMES class. The DCE Specialists in these practices will also have access to a report that is updated weekly that will identify all patients with upcoming appointments that meet criteria for referral for DSMES class.

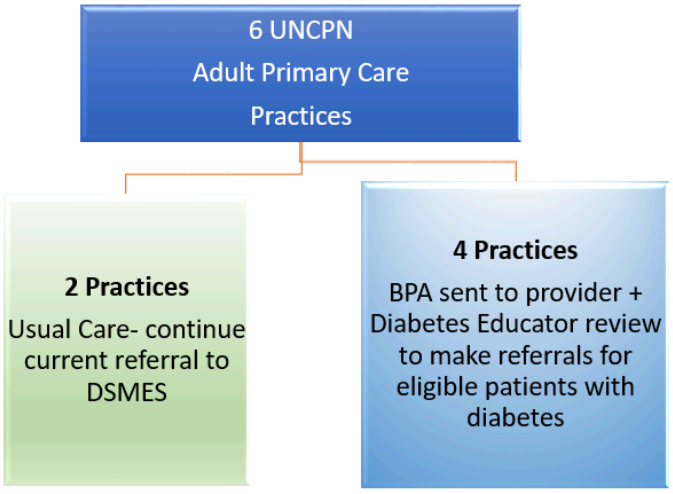


Figure 1 PROMPT Practice Randomization

Aim 2: Across all six practices, patients who have been referred for DSMES class will be recruited to participate in an enhanced experience that will include engagement with a peer supporter during their participation in the DSMES class. We will recruit 90 participants and 45 will be randomized to receive peer support and 45 will receive routine care.

Aim 3: We will complete structured, qualitative interviews with health care providers, patients and peer supporters who participated in the study to generate a more holistic view of the intervention impact.

4.2 Scientific Rationale for Study Design

This study design will allow us to assess:

- If an automated suite of tools designed to increase referrals to DSMES classes results in higher number of referrals for DSMES compared to those practices who do not receive the suite of tools in their practice.
- If using a peer supporter can help increase patient engagement and attendance to DSMES classes.
- The design allows us to independently assess the impact of each intervention and determine if they work best individually or in concert with each other. If one intervention is not effective, we would still be able to assess the impact of the other intervention. This design will allow us to design the most beneficial intervention for a larger, pragmatic, multi-institution intervention.

4.3 Justification for Intervention

DSMES is beneficial for PWD. Unfortunately, referral rates are quite low. Additionally, attendance by PWD is also quite low. This intervention is designed to increase both the referral rates to DSMES and attendance to DSMES by PWD. We are addressing two large issues that have been identified as gaps in care/management for PWD.

4.4 End-of-Study Definition

Aim 1: Providers are considered to have completed the study if they have referred patients who may benefit from additional diabetes self-management education to a diabetes educator and/or directly referred patients to DSME classes
Aim 2: A participant is considered to have completed the study if he or she has completed the baseline assessment with the DCE Specialist and at least 1 DSMES class.
Aim 3: Major themes have been identified from the qualitative interviews.

5 - STUDY POPULATION

5.1 Inclusion Criteria

- Provider participants: Primary care providers employed at the participating practices
- Patient participants: Adult, English-speaking patients diagnosed with type 2 diabetes who are referred to DSMES class from a provider at one of the study practices.
- Peer supporters

5.2 Exclusion Criteria

- Non-English Speaking
- Not willing to work with a peer coach
- Planning to relocate out of area in the next 6 months

5.3 Lifestyle Considerations

Patients who are attending DSMES classes will be taught about healthy lifestyle choices that are recommended for PWD. They have a choice to adopt these recommendations. They may also be assigned a peer supporter. While it is encouraged that they engage and communicate with the peer supporter throughout their time in the study, this too is a choice for participants.

5.4 Screen Failures – AIM 2

Screen failures are defined as participants who consent to participate in this study but are not subsequently randomized to a treatment arm. We anticipate a very low screen fail rate given the few inclusion/exclusion criteria.

5.5 Strategies for Recruitment and Retention

Practices: Six primary care practices within the UNC Physicians Network (UNCPN) will be recruited. Based upon the strong relationship we have built with the UNCPN over the past decade, we will work with the UNCPN leadership team to identify practices most likely to be interested in participation. We will ensure a diverse group of practices, including a mix of rural and urban locations. Upon identification of the potential practices, our seasoned practice facilitator will arrange lunch and learn sessions within the potential practices, where they will present the project and discuss the

requirements of participating. Practices will have the opportunity to discuss participation amongst their team members, and we will follow up with them within a week to determine their interest in enrolling.

Patients: Patients who have been referred for DSMES classes will be consented and randomized to peer support or usual care. PWD who are randomized to the peer support group will have standard DSMES classes and as well as support via a peer supporter. The no peer support group will receive standard DSMES class only. After a referral for DSMES class has been placed, our research team will contact them to discuss our pilot trial. Multiple recruitment approaches will be used including phone call direct referral from health care providers and informational flyers provided to DCE's who can hand flyers to potential participants. Patients will be compensated for filling out surveys at baseline and 3 months ($15 per survey). Twenty enrolled patient participants will be offered $50 if they choose to participate in a semi-structured qualitative interview (Aim 3).

6 - STUDY INTERVENTION

6.1 Study Intervention Description

AIM 1: Practice Level Implementing the BPA (months 1-18)

Six primary care practices within the UNC Physicians Network (UNCPN) will be recruited. Eligible patients:

- Must be aged 18 years and older
- Must speak and understand English
- Must have a diabetes diagnosis and either
    - Last a1c in the past 12 months greater than 8.5% or
    - New dx of T2DM within the last 12 months code: E11.x
- Must not have participated in DSMES within the last 12 months
- Must not be a prisoner or inmate
- Can qualify if they have had a Hospitalization (defined by having an admission summary) in last 3 months or within the past 12 months they have had:
    - new dx of Neuropathy (peripheral, or ED codes): E11.40
    - new dx of MI-- I2-I25
    - new dx of Stroke- I60 - I69
    - new dx of nephropathy (CKD, microalbuminuria) N18.x
    - new dx of Foot ulcer
    - new dx of retinopathy
    - new dx of peripheral vascular disease Y83.5, E878.5, 890-887.99

Upon identification of the potential practices, our practice facilitator will arrange lunch and learn sessions within the potential practices, where they will present the project and discuss the requirements of participating. Practices will have the opportunity to discuss participation amongst their team members, and we will follow up with them within a week to determine their interest in enrolling.

Once identified, we will randomize practices into two groups. Two practices will receive usual care. (Group1), in which providers make referrals to DSMES services without the aid of enhanced EMR functions that identify PWD that are eligible for DSME referral. The research team will be able to understand which patients meet DSME referral criteria, but in the usual care practices, this information will not be provided to the health care providers. Providers (primary care and diabetes educators) in the four remaining practices (Group 2) will receive a BPA (Figure 2a) that will alert them that the patient is eligible for DSMES referral and include a option to place an order for referral to DSME classes. The BPA will include options for providers to choose regarding why a DSME order was not placed. Figure 2b lists the amount of time before the provider will see the BPA again. This information was provided to the providers in a tip sheet.

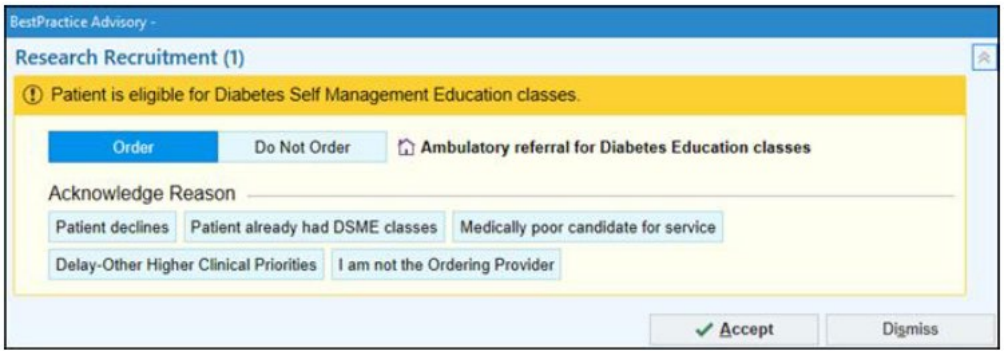


Figure 2a: Screen capture of the BPA from provider "tip sheet"

Acknowledge Reason	Supression Duration	Applies to
Patient declines	6 Months	All encounters and all users
Patient already had DSME classes*	6 Months	All encounters and all users
Medically poor candidate for service (i.e.: Patient has cancer, chemotherapy, etc.)	Will not fire again	All encounters and all users
Delay – Other Higher Clinical Priorities	3 Months	All encounters and all users
I am not the Ordering Provider	Will not fire again	For only this user and only this current encounter

Figure 2b: BPA behavior for each reason for declining the BPA

Aim 1: Implementing the Standing Order (Months 13-18)

While not part of the original research plan, during collaborative meetings between the research team and clinicians providing DSME services during the first 12 months it was suggested that we design the BPA functionality to also allow clinical staff to also see the BPA so they could place the order during rooming. This is a similar process to how "standing orders" work to for services such as yearly influenza vaccine administration and other standard prevention services. The provider would then see the DSMES order rather than the BPA and could choose to sign the order or dismiss it.

To implement this change the team leadership engaged the health care system's Standing Order Committee with the proposed change for the subset of clinics randomized to receive the BPA. Once permission was granted the BPA was updated and was operationalized in the thirteenth month of the study.

AIM 2: Patient Level

Patients who have been referred for DSMES classes will be consented and randomized to peer support or usual care. PWD who are randomized to the peer support group will have standard DSMES classes and as well as support via a peer supporter. The no peer support group will receive standard DSMES class only. After a referral for DSMES class has been placed, our research team will contact them to discuss our pilot trial. Once a patient has provided consent, they will be randomized to usual care or peer support. All referred patients, regardless of study group, will be scheduled for an initial one-on-one assessment by the DCE specialist embedded within the primary care practice. During the assessment, the DCE specialist may identify unmet social needs/social determinants of health and refer internally to the practice's care management staff. Via chart review, we will collect noted which unmet social needs are identified at the initial DCE visit as an exploratory exercise to guide our understanding of current practices related to SDOH assessments. Patients in both study arms will have access to the standard DSMES group classes while some may choose to continue with individual level instruction with their DCE. Patients will be compensated for filling out surveys at baseline and 3 months ($15 per survey). Following the initial assessment by the DCE specialist the participant will complete the five DSMES class series associated with their primary care practice. These classes may be offered in person or virtually.

6.2 Fidelity

6.2.1 Interventionist Training and Tracking

The peer supporters will receive a 2-day training session hosted by the Peers for Progress Training Team. Curriculum topics were: (1) Diabetes education, (2) What is Peer Support, (3) Communication Skills Training, (4) Communication Skills Practice, (5) How to handle likely challenges that will arise, (6) how to support patients, (7) Documentation and data collection (8) Background on the health system where study practices sit. This will prepare them to serve as effective Peer Supporters within the program. Supporters will meet with the study team regularly to compare notes, evaluate their role as peer supporters, discuss challenging situations and any other issues that may arise.

6.3 Measures to Minimize Bias: Randomization and Blinding

At the practice level, a stratified random sampling strategy is implemented using two insurance measures (% of patients covered by Medicaid and separately, the % covered by Medicare) as the strata variables. Four practices are randomly selected into the intervention group (Group 2) to receive BPA alert and two practices into the control group (Group 1) of no BPA alert. This randomization strategy was performed to ensure that the two groups resemble each other on these primary factors (i.e., insurance measures). At the patient level, the simple random sampling method will be applied to randomize the patients. Each individual of the total eligible 90 patients have an equal probability of being randomly selected to either the peer coaching (intervention) or no peer (control) coaching group.

6.4 Study Intervention

Aim 1: Practice Level

We will track how the providers respond to the BPA alert. We will also track how many patients qualify for referral and are actually referred to the DCE specialist by practice. We will track how providers engage with the BPA choices. We will calculate the number and percentages of people who are initially considered eligible for DSME referral from our CDW-H data pulls, that attend visits with their primary care providers where a BPA should fire, and then how many people are referred to and then attend at least one DSME class after their DCE visit.

Aim 2: Patient Level

Attendance at all DSMES education sessions will be monitored and recorded by study staff by chart review. and The study team will also review the following REDCap data entered by peer supporters: (1) number of peer support interactions, (2) who initiated contact, (3) the type of contact (phone call, text, email, etc.), (4) duration of contact, (5) support provided to patient, and (6) any relevant notes related to DSMES classes.

7 – AIM 2 STUDY INTERVENTION/ AND PARTICIPANT DISCONTINUATION/WITHDRAWAL

7.1 Choosing to not to participate in the peer support intervention.

If a study participant is dissatisfied with their initially randomized peer supporter, they will be offered to work with another peer supporter. If participants ultimately do not want to engage or continue to work with any of the peer supporters, they will be encouraged to remain in the study and attend all data collection phone calls.

7.2 Participant Withdrawal from the Study

Participants are free to withdraw from participation in the study at any time upon request. If a participant withdraws from the study entirely, we will report the date and reason for withdrawal. Subjects who sign the informed consent form and are randomized but do not receive the study intervention may be replaced. Subjects who sign the informed consent form, and are randomized and receive the study intervention, and subsequently withdraw, or are discontinued from the study, will not be replaced.

An investigator may discontinue a participant from the study for the following reasons:

- Lost-to-follow up; unable to contact subject (see Section 7.3, Lost to Follow-Up)
- Any event or medical condition or situation occurs such that continued collection of follow-up study data would not be in the best interest of the participant or might require an additional treatment that could confound the interpretation of the study
- The participant meets an exclusion criterion (either newly identified study exclusion category or not previously recognized exclusion criterion) that precludes further study participation

7.3 Lost to Follow-up

A participant will be considered lost to follow-up if he or she fails to return for DSMES class or scheduled study visits and study staff are unable to contact the participant after ***at least*** 3 attempts, on different days of the week and time of day.

The following actions will be taken if a participant fails to return to the DSMES classes or the end-of-study visit:

- If the participant has been randomized to the peer support intervention group the peer supporter will make at least 3 attempts to contact the participant.
- The peer supporter will attempt to contact the participant, reschedule the missed contact, counsel the participant on the importance of maintaining the assigned visit schedule and ascertain if the participant wishes to and/or should continue in the study.
- Before a participant is deemed lost to follow-up, the investigator or designee will make every effort to regain contact with the participant (where possible, 3 telephone calls and, if necessary, a letter to the participant's last known mailing address). These contact attempts will be documented in the participant's study file.
- Should the participant continue to be unreachable, he or she will be considered to have withdrawn from the study with a primary reason of lost to follow-up.

8 – STUDY ASSESSMENTS AND PROCEDURES

8.1 Endpoints and Other Non-Safety Assessments

Table 1 outlines the primary outcome for Aim 1. We will collect data via the Electronic Medical Record (EMR) from the Carolina Data Warehouse for Health (CDW-H). The primary outcome will be the odds of referral for DSMES, which is defined as when an order for DSME classes was placed by a primary care provider within 30 days of a patient being seen by a primary care provider in their office setting. Initiall we planned a secondary outcomee to collect data on the number of days from the patient visit to the referral placed. Once data collection began we discovered the clinic workflows were such that referrals were placed the same day of the visit, or not at all. We will also examine demographics and how they do or do not predict who is referred for DSMES.

Table 1. Primary and secondary outcomes for Aim 1

	Outcome	**Source**	**Timing**
Aim 1- Evaluate the relative impact of BPAs on DSMES service referral rates	**Primary:** Odds of referral for DSMES	EHR data	Within 30 days of patient seen in office by PCP

Table 2 outlines primary and secondary outcomes for Aim 2. The primary outcome is the odds of attending 1 DSMES class. We anticipate attendance opportunities will be within 6 months of referral. We will also examine the time from study consent date to attendance of the first DSMES class attendance to serve as a measure of exposure to the peer coaching intervention or to a usual care experience. DSME Class attendance will be captured in the EMR via use of billing codes (G0108 – individual educational session vs. G0109 Group DSME class). Other secondary outcomes include A1C (within 3 months prior to the DSMES initial visit) and all A1C's at least 3 months apart (+/- one month) for up to 6 months after enrollment. These data will be collected by chart review.

Diabetes Distress scale and the Diabetes Self efficacy scales[56-58] will be collected by the research assistant at the baseline study data collection visit and at the 3-month study data collection visit.

Table 2. Primary and secondary outcomes for Aim 2

	Outcome	**Source**	**Timing**
Aim 2 – Assess the impact of peer support on PWD attendance and completion rate of DSMES services.	**Primary:** Odds of attending 1 DSMES class	EHR data/chart review	Starting with date of study consent to date of first group or individual DSME class
	Secondary: Time to get to initial DSMES class	EHR data/chart review	Number of days from informed consent to first group or individual DSME class, where entire process starting with

			study consent date is within a 6-month time interval
	Secondary: Number of PWD who attended at least 2 DSMES classes	EHR data/chart review	Number of days from patient consent to date of second DSMES class where entire process starting with study consent date is within a 9-month time interval
	Secondary: Number of PWD who completed the entire DSMES class including 3-month follow-up.	EHR data/chart review	Number of days from patient visits to attending all classes and follow up within a 12-month time frame.
	Secondary: Change in A1c from baseline to end of DSME class	EHR data/chart review	Baseline A1c can be any A1C (point of care or lab results) within 3 months before the index DCE visit to any subsequent A1C's that are at least 3 months since the index A1C. Accept 4-week window for for 3-month A1c (after the index A1C).
	Secondary: Change in A1c from baseline to 6 months	EHR data	Baseline A1c can be any A1C (point of care or lab results) within 3 months before the index DCE visit to any subsequent A1c's that are at least 6 months since the index A1C. Accept 4-week window for for 6-month A1c (after the index A1C).
	Secondary: Change in Diabetes Distress from baseline to end of DSME class	Diabetes Distress Survey[56-57]	Baseline research data collection visits and 3-month (+/- 4 weeks) data collection visits
	Secondary: Change in Diabetes Self-Efficacy from baseline to end of DSME class	Diabetes Self Efficacy Survey[56]	Baseline and 3-month research data collection visits and 3-month (+/- 4 weeks) data collection visits

8.2 Safety Assessments

Diabetes Self-Management Education and Support (DSMES) has the potential to significantly improve diabetes outcomes, but only to the degree that physician and patient barriers can be overcome. The proposed practice-based intervention will likely do more good than harm given the focus to increase referrals and attendance to DSMES classes for persons with diabetes (PWD). In addition, the sample size is small and not a phase III or multi-site RCT. Therefore, we do not intent do have a data and safety monitoring board for this study. However, we will have a data safety monitoring plan in place. First, we will obtain UNC Institutional Review Board approval prior to recruiting or enrolling any subjects. Second, in year 1 of the project, we will engage our faculty biostatistician (Dr. Ping) to serve as a data monitor to assess study conduct, fidelity to the intervention and study design, and data quality throughout the course of the study. Third, patients will have the contact information of the PI, Project Manager, and practice facilitator should issues related to enrollment and participation occurs. Fourth, the PI will also have regular meetings with the research team to discuss recruitment, enrollment, and data management.

The PIs will also be responsible for monitoring the data, assuring protocol compliance, and conducting the safety reviews. During the review process, the PIs in conjunction with the data monitor, will evaluate whether the study should

continue unchanged, require modification/amendment, or close to enrollment. Our data management team will generate and present an audit report at weekly team meetings. Each variable will be checked for out of range values, and where possible, for logical errors.

This protocol presents minimal risks to the subjects and Unanticipated Problems Involving Risks to Subjects or Others (UPIRSOs), including adverse events, are not anticipated. In the unlikely event that such events occur, Reportable Events (which are events that are serious or life-threatening and unanticipated (or anticipated but occurring with a greater frequency than expected and possibly, probably, or definitely related) or Unanticipated Problems Involving Risks to Subjects or Others that may require a temporary or permanent interruption of study activities will be reported immediately (if possible), followed by a written report within 5 calendar days of the PIs becoming aware of the event to the IRB and any appropriate funding and regulatory agencies. The PIs will apprise fellow investigators and study personnel of all UPIRSOs and adverse events that occur during the conduct of this research project through weekly study meetings. The protocol's research oversight bodies, funding and regulatory agencies, and regulatory and decision-making bodies will be informed of severe adverse events within 5 days of the event becoming known to the PI.

We will engage our faculty biostatistician (Dr. Ping) to serve as a data monitor to assess study conduct, fidelity to the intervention and study design, and data quality throughout the course of the study. The PI, project coordinator, and the data monitor will be responsible for monitoring the data, assuring protocol compliance, and conducting the safety reviews monthly, which must be conducted at a minimum of every 6 months (including when reapproval of the protocol is sought). During the review process, the PI and data monitor will evaluate whether the study should continue unchanged, require modification/amendment, or close to enrollment. Either the PI, the IRB or the data monitor will have the authority to stop or suspend the study or require modifications.

9 - STATISTICAL CONSIDERATIONS

9.1 Sample Size Determination

AIM 1: Practice Level We generated the prevalence of type 2 diabetes in this population using the Informatics for Integrating Biology and the Bedside (i2b2) instance and data from 45,928 unique patients with type 2 diabetes aged 18 and over seen between 7/1/2019 and 12/31/2020 at UNCPN. Using a denominator of 247,707 total adult patients seen in one of 67 primary care practices during this time interval, the prevalence is 18.5%. With an estimated patient panel of 2300 patients per provider FTE and 18% of patients in primary care practices with diabetes, we estimate that 375 patient encounters per practice over 18 months will be eligible for referral to DSMES services. These estimates yield 750 patient encounters for the no BPA control group and 1500 encounters for the BPA intervention group (total N = 125 encounters over 18 months x 18 providers = 2250 encounters).

Aim 2: Patient Level In a binary logistic regression model assuming alpha = .05, 80% power, and N=90, the minimum detectable effect size is odd ratio (OR) = 3.72, which is considered a medium-large effect. In a linear regression model assuming 4 predictors, critical? = .05, 80% power, and N=90, the minimum detectable effect size is f2 (OR) = .09, which is considered a small-medium effect.

Aim 3: Qualitative Assessment

N/A

9.2 Statistical Analyses

9.2.1 General Approach

Aim 1: Practice Level At the end of the 18-month intervention period and at 12 months as an interim analysis, we will conduct a multilevel logistic regression model with patient data (Level 1) nested within provider (Level 2). We will use a binary logit function and maximum likelihood estimation to predict odds of provider referring an eligible patient to DSMES services after a patient encounter. We will test both unadjusted and adjusted models for intervention condition controlling patient gender, age, race, and health insurance status (Level 1). The same predictor variables specified for the binary logistic regression will be tested in the hazard model. Model diagnostics, including comparative model fit statistics for the logistic regression (e.g., -2LL, AIC and BIC) and those for the proportional hazard assumption for the hazard model (Kaplan-Meier curves, Schoenfeld residuals), will be used to evaluate the models. Solutions to non-optimal model specification, such as model re-specification (e.g., stratified cox model for hazard model), will be identified using a combination of model specifics, theoretical considerations, and best practices.

Aim 2: Patient Level We will randomize 90 PWD who have be referred to DSMES to either Peer Support (n=45) or No Peer support (n=45). We will compute descriptive statistics for all variables (means/SDs and proportions), including the outcomes of the percentage of patients receiving A1c and the percent completing surveys at 3 and 6 months. In the case of unadjusted models, we will use chi-square difference testing to compare conditions for binary outcomes (attending =1 DSMES class, DSMES class completion) and independent samples t-tests for continuous outcomes (difference between baseline and 3 months for A1c, diabetes distress, and self-efficacy).

Aim 3: Qualitative Assessment Patient semi-structured interviews, provider focus group sessions, and peer coaching semi-structured interviews will be audio recorded with permission and transcribed verbatim removing personal identifiers. Codebooks will be developed consisting of a priori codes derived from the interview and focus discussion guides as well as any additional concepts that emerge during the analysis. Transcripts will be independently coded by at least two researchers experienced in qualitative research, and differences will be reconciled with discussion and consensus. The qualitative data software analysis program ATLAS.ti will be used to facilitate analyses. Original codes will be combined into categories connecting them with codes in terms of conditions that give rise to them, properties that are common to them, strategies that guide them, and consequences they share. Summary themes among participants will be identified. Finally, representative quotations will be chosen to illustrate research findings.

9.2.2 Analysis of the Primary Endpoint(s)

Aim 1: Practice level

The primary outcome of aim 1 is odds of referral to DSMES class within 30 days of a visit with PCP. The data will come from the Electronic Medical Record (EMR).

9.2.3 Analysis of the Secondary Endpoint(s)

Aim 2: Partcipant level

Examine the time from referral to DSMES class attendance. Class attendance will be captured in the EMR. Other secondary outcomes include a1c (prior to referral, at the end of 3-month class and at 6 months (+ or – 2 months); these data will be collected in the EMR. Survey data from the DES and DDS as well as demographics will be captured in Redcap by a research assistant at baseline and three months.

10 - SUPPORTING DOCUMENTATION AND OPERATIONAL CONSIDERATIONS

10.1 Regulatory, Ethical, and Study Oversight Considerations

10.1.1 Informed Consent Process

Research team personnel will obtain consent only. All efforts will be made to ensure that a potential participant understands that participation is voluntary. All staff will be trained in proper informed consent techniques. At the enrollment visit, the consent forms will be read to the patient before they are asked to sign. Only UNC project staff will obtain consent and will follow procedures that minimize coercion or undue influence.

10.1.1.1 Consent/Assent and Other Informational Documents Provided to Participants

See Appendix for consent and HIPAA forms.

10.1.1.2 Consent Procedures and Documentation

Written consent and HIPAA waiver must be obtained from all eligible patients who agree to enroll in the study. Research personnel will review the consent and waiver forms with each potential patient participant. The potential participant will be given the opportunity to read or have read the forms or have them read aloud to them. The research team member will review each section of the consent form with the patient to ensure they understand what they are agreeing to. If the patient agrees to participate, they will be asked to sign the consent and will be offered to keep a copy of the consent form to take with them. Signed consent and HIPAA forms will be stored in the designated locked filing cabinet in the project office.

10.1.2 Study Discontinuation and Closure

As the study reaches completion, the study PI's will oversee the staff actively work with data collectors and the practice sites to resolve any outstanding queries with the goal of data closure and documentation.

10.1.3 Confidentiality and Privacy

Data collectors will be trained in the importance of protecting the confidentiality. Data will be stored in locked filing cabinets or on password-protected secure servers. It is possible people feel some embarrassment when answering survey questions or discussing their issues with their peer supporter. Survey question data will be protected and participants are not required to answer any particular questions. Additionally, peer supporters will undergo training around confidentiality and privacy.

10.1.4 Key Roles and Study Governance

Role	Name
Co-PI (Contact)	Katrina Donahue MD, MPH
Co-PI	Laura Young, MD, PhD
Co-Investigator	Jacqueline Halladay, MD, MPH
Biostatistician	Ping Chen, PhD
Co-Investigator—Qualitative Analysis	Maihan Vu DrPH
Project Manager	Erica Richman, PhD, MSW
Study Coordinator	Kathleen Mottus, PhD
Practice Facilitator	Jennifer Rees, RN, CPF
Stakeholder	Ginger Calhoun, MS, RD, LDN, CDCES - UNC Health Alliance
Stakeholder	Sue Kirkman, MD - UNC Endocrinology
Stakeholder	Evan Richardson, RN, MSN, CNM - MAHEC
Stakeholder	Lynne Fiscus, MD, MPH - President & CEO of UNCPN
Stakeholder	Sachin Gupta, MD - Chief Med Officer UNCPN
Stakeholder	Joanne Rinker, MS, RDN, BC-ADM, CDCES, LDN, FADCES
Stakeholder	Quirina Vallejos, MPH – UNC Lineberger
Stakeholder	Rayhaan Adams, MSW, LCSW – Aledade, Director, Attribution & Wellness
Stakeholder	Ed Fisher, PhD - Peers for Progress, UNC
Stakeholder	Kathryn Higdon, MSN, RN - UNC Health Alliance
Stakeholder	Ginger Poulton, MD - MAHEC
Stakeholder	April Reese, MPH - Natl Assoc of Chronic Disease Directors

Governance: Drs. Donahue and Dr. Young will provide oversight of the entire Program and development and implementation of all policies, procedures and processes. In these roles, Dr. Donahue and Dr. Young will be responsible for convening, leading and synthesizing stakeholder input. They will both ensure that the Specific Aims are carried out fully. They will jointly ensure that systems are in place to guarantee institutional compliance with US laws, DHHS and NIH policies including human research, data and facilities. Specifically, Dr. Donahue will lead the team, providing oversight of all study personnel. She will guide all aspects of data analysis, data interpretation and dissemination of findings. Dr. Young will oversee all clinical aspects of the program, including managing protocol adherence, interpretation and analysis of clinical information that will be part of the data collection process. Dr. Donahue will be responsible for the overall coordination of the team's work, including the strategy for building and sustaining relationships with community practices targeted for recruitment of potential participants. Dr. Donahue will serve as the contact PI throughout the life of the grant and will assume fiscal and administrative management including maintaining communication between PIs and among all team members through weekly meetings, emails, and conference calls as needed. She will also be responsible for communication with NIH and submission of annual reports. Publication authorship will be based on the relative contributions of the PIs and key personnel. Drs. Young and Donahue have a longstanding collaboration and have demonstrated the strength of their approach as a multi-PI team in their most recently completed PCORI project.

Conflict Resolution: No disputes are anticipated but were they to arise we would convene a vote of the full study team. Should the need arise to involve a neutral party, Dr. Mark Holmes, Director of the Cecil G. Sheps Center for Health Services Research, will hear both sides of the argument and make a third party decision.

10.1.5 Quality Assurance and Quality Control

For Quality Assurance and control, the Peers for Progress trainers will conduct 15-minute huddles with study peer supporters every two to four weeks. During these meetings, a member of the team with clinical experience will help address any medical questions or issues that arise. The research team will also conduct bi-monthly reviews of peer supporter data recorded in REDCap Database to look for inconsistencies, unexpected data points, repetitive and identical responses, lack of data collection, etc.

10.1.6 Data Handling and Record Keeping

Information about study subjects will be kept confidential and managed according to the requirements of the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Those regulations require a signed subject authorization informing the subject of the following:

- What protected health information (PHI) will be collected from subjects in this study
- Who will have access to that information and why
- Who will use or disclose that information
- The rights of a research subject to revoke their authorization for use of their PHI

Data collectors will be trained in the importance of protecting the confidentiality. Primary data, which contains identifiers, will be audio recordings and will be kept in locked storage cabinets and separate from consent forms. All audiotapes will be erased or destroyed at the end of the study. Data for analysis and reporting purposes will be stripped of all unique identifiers. Reports will not provide practice-specific or individual-specific identifiers.

10.1.7 Protocol Deviations

10.1.8 Publication and Data Sharing Policy

At the end of the study, the research team plans to prepare a de-identified limited-access dataset suitable for sharing with other researchers. A researcher wishing to use the dataset will be required to obtain approval from UNC using an agreement form which clearly specifies the intended analyses as well as assurances that UNC policies and HIPAA regulations will be followed. De-identified quantitative data that are released will be accompanied by a codebook including variable names, labels, and means/frequencies. Qualitative summary reports will include documentation regarding the representativeness of the data and other potential limitations for use. Interview guides, survey instruments, sampling plans, and other data collection instruments that are not included in publications will also be made available. Survey instruments and guides developed by our project will be made available to qualified individuals upon request. In all cases, we stipulate appropriate (and inappropriate, when necessary) use of research, training, and intervention materials.

Publication Policy Scope: This Policy for Authorship applies to scholarly work including abstracts, posters, manuscripts and books or other products intended for internal or external dissemination that include information such as data or descriptions of processes from work conducted as part of PROMPT study. Publications and other dissemination products are an important part of academic productivity and promotion and the process for determining authorship and content of such publications and other dissemination products needs to adhere to accepted ethical and integrity standards. The purpose of this policy is to provide such standards to guide authors while preparing and submitting scholarly publications or other dissemination products.

Authorship Defined: An “author” is someone who has made substantive intellectual contributions to published work. Authorship credit should be based on 1) substantial contributions to conception and design, acquisition of data, or analysis and interpretation of data; 2) drafting the article or reviewing/revising it critically for important intellectual content; and 3) final approval of the version to be published. Authors listed on a publication should meet conditions 1, 2, and 3. Meeting all three conditions means that an author is prepared to assume public responsibility for the content of the scholarly work

Order of Authors: The sequencing of authors is a joint decision or agreement of those who meet the conditions of being an author. The joint decision/agreement needs to be made at the earliest point in developing the scholarly product. When the idea of the scholarly product is conceived the criteria of authorship should be discussed and individuals can state their commitment to meeting those criteria. The exact listing order of the authors will be discussed by the group. Eligible authors will decide on the person who will coordinate the efforts of the writing team as lead

author (most typically the first or senior author). If during the conduct of the work, one or more of the committed individuals is unable to meet the conditions for authorship, the lead person for the project is responsible for re-visiting the decision/agreement of authorship and revising the order of authors with the agreement of the eligible group.

REFERENCES

1. Lin J, Thompson TJ, Cheng YJ, et al. Projection of the future diabetes burden in the United States through 2060. *Popul Health Metr.* 2018;16(1):9.
2. American Diabetes A. 2. Classification and Diagnosis of Diabetes: Standards of Medical Care in Diabetes-2021. *Diabetes Care.* 2021;44(Suppl 1):S15-S33.
3. Kazemian P, Shebl FM, McCann N, Walensky RP, Wexler DJ. Evaluation of the Cascade of Diabetes Care in the United States, 2005-2016. *JAMA Intern Med.* 2019;179(10):1376-1385.
4. Powers MA, Bardsley JK, Cypress M, et al. Diabetes Self-management Education and Support in Adults With Type 2 Diabetes: A Consensus Report of the American Diabetes Association, the Association of Diabetes Care & Education Specialists, the Academy of Nutrition and Dietetics, the American Academy of Family Physicians, the American Academy of PAs, the American Association of Nurse Practitioners, and the American Pharmacists Association. *Diabetes Care.* 2020;43(7):1636-1649.
5. Tshiananga JK, Kocher S, Weber C, Erny-Albrecht K, Berndt K, Neeser K. The effect of nurse-led diabetes self-management education on glycosylated hemoglobin and cardiovascular risk factors: a meta-analysis. *Diabetes Educ.* 2012;38(1):108-123.
6. Steinsbekk A, Rygg LO, Lisulo M, Rise MB, Fretheim A. Group based diabetes self-management education compared to routine treatment for people with type 2 diabetes mellitus. A systematic review with meta-analysis. *BMC Health Serv Res.* 2012;12:213.
7. Deakin T, McShane CE, Cade JE, Williams RD. Group based training for self-management strategies in people with type 2 diabetes mellitus. *Cochrane Database Syst Rev.* 2005(2):CD003417.
8. Chrvala CA, Sherr D, Lipman RD. Diabetes self-management education for adults with type 2 diabetes mellitus: A systematic review of the effect on glycemic control. *Patient Educ Couns.* 2016;99(6):926-943.
9. Powers MA. 2016 Health Care & Education Presidential Address: If DSME Were a Pill, Would You Prescribe It? *Diabetes Care.* 2016;39(12):2101-2107.
10. Diabetes C, Complications Trial Research G, Nathan DM, et al. The effect of intensive treatment of diabetes on the development and progression of long-term complications in insulin-dependent diabetes mellitus. *N Engl J Med.* 1993;329(14):977-986.
11. Stratton IM, Adler AI, Neil HA, et al. Association of glycaemia with macrovascular and microvascular complications of type 2 diabetes (UKPDS 35): prospective observational study. *BMJ.* 2000;321(7258):405-412.
12. He X, Li J, Wang B, et al. Diabetes self-management education reduces risk of all-cause mortality in type 2 diabetes patients: a systematic review and meta-analysis. *Endocrine.* 2017;55(3):712-731.
13. Cochran J, Conn VS. Meta-analysis of quality of life outcomes following diabetes self-management training. *Diabetes Educ.* 2008;34(5):815-823.
14. Toobert DJ, Glasgow RE, Strycker LA, et al. Biologic and quality-of-life outcomes from the Mediterranean Lifestyle Program: a randomized clinical trial. *Diabetes Care.* 2003;26(8):2288-2293.
15. Toobert DJ, Strycker LA, King DK, Barrera M, Jr., Osuna D, Glasgow RE. Long-term outcomes from a multiple-risk-factor diabetes trial for Latinas: inverted exclamation markViva Bien! *Transl Behav Med.* 2011;1(3):416-426.
16. Tang TS, Funnell MM, Oh M. Lasting effects of a 2-year diabetes self-management support intervention: outcomes at 1-year follow-up. *Prev Chronic Dis.* 2012;9:E109.
17. Thorpe CT, Fahey LE, Johnson H, Deshpande M, Thorpe JM, Fisher EB. Facilitating healthy coping in patients with diabetes: a systematic review. *Diabetes Educ.* 2013;39(1):33-52.
18. Li R, Shrestha SS, Lipman R, et al. Diabetes self-management education and training among privately insured persons with newly diagnosed diabetes--United States, 2011-2012. *MMWR Morb Mortal Wkly Rep.* 2014;63(46):1045-1049.
19. Strawbridge LM, Lloyd JT, Meadow A, Riley GF, Howell BL. Use of Medicare's Diabetes Self-Management Training Benefit. *Health Educ Behav.* 2015;42(4):530-538.

20. Rinker J, Dickinson JK, Litchman ML, et al. The 2017 Diabetes Educator and the Diabetes Self-Management Education National Practice Survey. *Diabetes Educ.* 2018;44(3):260-268.
21. Centers for Disease Control and Prevention. Diabetes Self-Management Education and Support (DSMES) Toolkit [Internet], 2018. Accessed 3 September 2019. Available from https://www.cdc.gov/diabetes/dsmes-toolkit/index.html.
22. Peyrot M, Rubin RR, Funnell MM, Siminerio LM. Access to diabetes self-management education: results of national surveys of patients, educators, and physicians. *Diabetes Educ.* 2009;35(2):246-248, 252-246, 258-263.
23. Lawal M, Woodman A, Fanghanel J, Ohl M. Barriers to attendance at diabetes education centres: perceptions of education providers. *J Diabetes Nurs.* 2017;21:61-66.
24. Azam LS, Jackson TA, Knudson PE, Meurer JR, Tarima SS. Use of secondary clinical data for research related to diabetes self-management education. *Res Social Adm Pharm.* 2017;13:494-502.
25. Chapman EN, Kaatz A, Carnes M. Physicians and implicit bias: how doctors may unwittingly perpetuate health care disparities. *J Gen Intern Med.* 2013;28(11):1504-1510.
26. Carey ME, Agarwal S, Horne R, Davies M, Slevin M, Coates V. Exploring organizational support for the provision of structured self-management education for people with Type 2 diabetes: findings from a qualitative study. *Diabet Med.* 2019;36(6):761-770.
27. Harris S, Mulnier H, Amiel S. The Barriers to Uptake of Diabetes Education study (abstract). *Lancet.* 2017;389:S44.
28. Ross S, Benavides-Vaello S, Schumann L, Haberman M. Issues that impact type-2 diabetes self-management in rural communities. *J Am Assoc Nurse Pract.* 2015;27(11):653-660.
29. Morrison B. Increasing Attendance at Scheduled Appointments for Group Classes at a Diabetes Education Center. *Clin Diabetes.* 2019;37(4):379-381.
30. Davis RM, Hitch AD, Salaam MM, Herman WH, Zimmer-Galler IE, Mayer-Davis EJ. TeleHealth improves diabetes self-management in an underserved community: diabetes TeleCare. *Diabetes Care.* 2010;33(8):1712-1717.
31. Krall JS, Kanter JE, Ruppert KM, Arena VC, Solano FX, Siminerio LM. Effect of a Primary Care-Based Diabetes Education Model on Provider Referrals and Patient Participation. *Sci Diabetes Self Manag Care.* 2021;47(1):74-84.
32. James TL. Improving Referrals to Diabetes Self-Management Education in Medically Underserved Adults. *Diabetes Spectr.* 2021;34(1):20-26.
33. Lee J, Szeto L, Pasupula DK, et al. Cluster Randomized Trial Examining the Impact of Automated Best Practice Alert on Rates of Implantable Defibrillator Therapy. *Circulation Cardiovascular quality and outcomes.* 2019;12(6):e005024.
34. Reed HL, Van Schooneveld TC, Reha CG, Bergman SJ. Use of a best practice alert linking Clostridioides difficile infection test results to a severity-based treatment order set. *Infection control and hospital epidemiology.* 2019;40(4):467-469.
35. Fitzpatrick SL, Dickins K, Avery E, et al. Effect of an obesity best practice alert on physician documentation and referral practices. *Transl Behav Med.* 2017;7(4):881-890.
36. McDanel DL, Azar AE, Dowden AM, et al. Screening for Beta-Lactam Allergy in Joint Arthroplasty Patients to Improve Surgical Prophylaxis Practice. *The Journal of arthroplasty.* 2017;32(9S):S101-S108.
37. Hye RJ, Smith AE, Wong GH, Vansomphone SS, Scott RD, Kanter MH. Leveraging the electronic medical record to implement an abdominal aortic aneurysm screening program. *Journal of vascular surgery.* 2014;59(6):1535-1542.
38. Barnes GD, Spranger E, Sippola E, et al. Assessment of a Best Practice Alert and Referral Process for Preprocedure Antithrombotic Medication Management for Patients Undergoing Gastrointestinal Endoscopic Procedures. *JAMA network open.* 2020;3(2):e1920548.
39. Ota T, Patel RJ, Delate T. Effectiveness of Best Practice Alerts for Potentially Inappropriate Medication Orders in Older Adults in the Ambulatory Setting. *The Permanente journal.* 2020;24.
40. Delitto A, Patterson CG, Stevans JM, et al. Stratified care to prevent chronic low back pain in high-risk patients: The TARGET trial. A multi-site pragmatic cluster randomized trial. *EClinicalMedicine.* 2021;34:100795.

41. Ancker JS, Edwards A, Nosal S, Hauser D, Mauer E, Kaushal R. Effects of workload, work complexity, and repeated alerts on alert fatigue in a clinical decision support system. *BMC medical informatics and decision making.* 2017;17(1):36.
42. DeSilva MB, Kodet A, Walker PF. A Best Practice Alert for Identifying Hepatitis B?Infected Patients. *The American Journal of Tropical Medicine and Hygiene.* 2020;103(2):884-886.
43. Bedoya AD, Clement ME, Phelan M, Steorts RC, O'Brien C, Goldstein BA. Minimal Impact of Implemented Early Warning Score and Best Practice Alert for Patient Deterioration. *Critical care medicine.* 2019;47(1):49-55.
44. Swedlund M, Norton D, Birstler J, Chen G, Cruz L, Hanrahan L. Effectiveness of a Best Practice Alerts at Improving Hypertension Control. *American journal of hypertension.* 2019;32(1):70-76.
45. Alsayed Hassan D, Curtis A, Kerver J, Vangsnes E. Diabetes Self-Management Education and Support: Referral and Attendance at a Patient-Centered Medical Home. *Journal of primary care & community health.* 2020;11:2150132720967232.
46. Mehta S, Mocarski M, Wisniewski T, Gillespie K, Narayan KMV, Lang K. Primary care physicians' utilization of type 2 diabetes screening guidelines and referrals to behavioral interventions: a survey-linked retrospective study. *BMJ open diabetes research & care.* 2017;5(1):e000406.
47. Zazove P, McKee M, Schleicher L, et al. To act or not to act: responses to electronic health record prompts by family medicine clinicians. *J Am Med Inform Assoc.* 2017;24(2):275-280.
48. Dennis CL. Peer support within a health care context: a concept analysis. *Int J Nurs Stud.* 2003;40(3):321-332.
49. Heisler M. Overview of Peer Support Models to Improve Diabetes Self-Management and Clinical Outcomes. *Diabetes Spectrum.* 2007;20(4):214-221.
50. Malchodi CS, Oncken C, Dornelas EA, Caramanica L, Gregonis E, Curry SL. The effects of peer counseling on smoking cessation and reduction. *Obstet Gynecol.* 2003;101(3):504-510.
51. Winzelberg AJ, Classen C, Alpers GW, et al. Evaluation of an internet support group for women with primary breast cancer. *Cancer.* 2003;97(5):1164-1173.
52. Joseph DH, Griffin M, Hall RF, Sullivan ED. Peer coaching: an intervention for individuals struggling with diabetes. *Diabetes Educ.* 2001;27(5):703-710.
53. Wilson W, Pratt C. The impact of diabetes education and peer support upon weight and glycemic control of elderly persons with noninsulin dependent diabetes mellitus (NIDDM). *Am J Public Health.* 1987;77(5):634-635.
54. Keyserling TC, Ammerman AS, Samuel-Hodge CD, et al. A diabetes management program for African American women with type 2 diabetes. *Diabetes Educ.* 2000;26(5):796-805.
55. Keyserling TC, Samuel-Hodge CD, Ammerman AS, et al. A randomized trial of an intervention to improve self-care behaviors of African-American women with type 2 diabetes: impact on physical activity. *Diabetes Care.* 2002;25(9):1576-1583.
56. Anderson RM, Funnell MM, Fitzgerald JT, Marrero DG. The Diabetes Empowerment Scale: a measure of psychosocial self-efficacy. *Diabetes Care.* 2000;23(6):739-743.
57. Fisher L, Glasgow RE, Mullan JT, Skaff MM, Polonsky WH. Development of a brief diabetes distress screening instrument. *Ann Fam Med.* 2008;6(3):246-252.
58. Polonsky WH, Fisher L, Earles J, et al. Assessing psychosocial distress in diabetes: development of the diabetes distress scale. *Diabetes care.* 2005;28(3):626-631.

Appendix: Forms and Guides

1. Consent and HIPPA forms
- **1.1 Adult Consent**
- **1.2 HIPAA**
- **1.3 Patient Verbal Consent for Interview**
- **1.4 Peer Supporter Verbal Consent for Interview**
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2. Interview Guides
- **2.1 Diabetes Self-Management Education and Support Classes (DSMES) Patient Interview Guide**
- **2.2 Diabetes Self-Management Education and Support Classes (DSMES) Peer Supporters Interview Guide**
- **2.3 Diabetes Self-Management Education and Support Classes (DSMES) Provider and StaffInterview Guide**

3. REDCap – Peer Support Tracking

4. REDCap – Participant Baseline Data

5. REDCap – Participant Follow up

1. Consent and HIPPA forms
1.1 Adult Consent
University of North Carolina at Chapel Hill
Consent to Participate in a Research Study
Adult Participants

Consent Form Version Date: 6/1/22
IRB Study # 22-0357
Title of Study: Novel Interventions to Increase Uptake of Diabetes Self-Management Support Training within Primary Care
Principal Investigator: Katrina Donahue
Principal Investigator Department: Family Medicine
Principal Investigator Phone number: (984) 974-4652
Principal Investigator Email Address: katrina_donahue@med.unc.edu
Funding Source and/or Sponsor: National Institutes of Health (NIH); National Institutes of Health (NIH)

Study Contact Telephone Number: (919) 966-0599; (919) 843-4401; (919) 966-7737
Study Contact Email: kmottus@email.unc.edu; jennifer_rees@med.unc.edu; elr@email.unc.edu

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CONCISE SUMMARY

The purpose of this study is to see if adding a peer support person to the care time makes a person referred to Diabetes Education classes more likely to attend, and more likely to complete the classes. The peer support person will be someone that has diabetes and has completed the classes and is trained to support people like you.

Participants in this study will be randomized to get the usual support from their provider and care team or be contacted by the peer support person. Participants will answer survey questions at the beginning of the study and 3 months later. Data about your diabetes and class attendance will be obtained from your medical records. All participation will end after the 3-month survey.

There is a potential risk that others may find out you are in this study.

If you are interested in learning more about this study, please continue to read below.

What are some general things you should know about research studies?
You are being asked to take part in a research study. To join the study is voluntary.

You may choose not to participate, or you may withdraw your consent to be in the study, for any reason, without penalty.

Research studies are designed to obtain new knowledge. This new information may help people in the future. You may not receive any direct benefit from being in the research study. There also may be risks to being in research studies. Details about this study are discussed below. It is important that you understand this information so that you can make an informed choice about being in this research study.

You will be given a copy of this consent form. You should ask the researchers named above, or staff members who may assist them, any questions you have about this study at any time.

What is the purpose of this study?
The purpose of this study is to see if adding a peer support person to the care time makes a person referred to Diabetes

Education classes more likely to attend, and more likely to complete the classes. Diabetes Education has been shown to be effective at improving outcomes for patients with diabetes. Referral to Diabetes Education and attendance at Diabetes Education Classes has been historically low.

The practice you are seen at is participating in one part of the study to improve rates of referral to the Diabetes Education Classes. People who are referred to the classes from those practices are eligible for the study.

People who enroll in the study will be randomized to get a peer support person or receive the usual support from their practice care team. The peer support person will be a patient with diabetes who completed the Diabetes Education Classes and received training in how to best support people like you. You will fill out Surveys at the start of the study and 3 months later.

We will get information about your attendance in classes and results of your A1c that your care team orders from your medical records. We will determine the proportion of participants that attend classes and how many they attend as well as changes in their A1c. We get information from your medical records for 6 months after you enroll

You are being asked to be in the study because you are from one of our study practices and your provider or care team has referred you to Diabetes Education Classes.

Are there any reasons you should not be in this study?
You should not be in this study if you are not eligible to enroll in the Diabetes Education Classes, cannot speak English, or you are moving in the next 6 months.

How many people will take part in this study?
Approximately 90 people seen in UNC-PN clinics will take part in this study.

How long will your part in this study last?
Your active participation in this study will last 3 months and will follow your medical records for a total of 6 months.

What will happen if you take part in the study?

- Consent. You will be asked review and sign this consent for and to sign a separate form ("HIPAA Authorization") to allow researchers to review your medical records.
- Once you have consented to be in the study you will be randomized to additional peer support or usual support given by your practice. This means you will be assigned to one of the two group by chance, like flipping a coin.
- At that time, you will fill out surveys about your experience as a person living with diabetes. You may choose not to answer a question for any reason
- If you are assigned to peer support, you will be contacted by your peer supporter
- You will decide if you will attend the Diabetes Education Classes and how many you will attend, and when
- At 3 months you will fill out surveys about your experience as a person living with diabetes. You may choose not to answer any question for any reason.
- We will follow your medical records for a total of 6 months.

What are the possible benefits from being in this study?

Research is designed to benefit society by gaining new knowledge. There is little chance you will benefit from being in this research study.

What are the possible risks or discomforts involved from being in this study?
You may feel uncomfortable answering some of the questions about diabetes that you are asked.

Someone could learn you are helping with this study. We will store all the information about this study in a secure office at the Sheps Center in Chapel Hill NC 27599. All study data will be stored with a number rather than your personal information. Even with these precautions there could be a risk of a breach of confidentiality.

There may be uncommon or previously unknown risks. You should report any problems to the researcher.

What if we learn about new findings or information during the study?
You will be given any new information gained during the course of the study that might affect your willingness to continue your participation.

How will information about you be protected?
Your personal information will be stored in a database on a secure server at the Sheps Center at UNC-Chapel Hill. Only individuals who need to see your identifying information will have access to the database. All study data will be coded with your study number.

Participants will not be identified in any report or publication about this study. We may use de-identified data and/or specimens from this study in future research without additional consent.

Although every effort will be made to keep research records private, there may be times when federal or state law requires the disclosure of such records, including personal information. This is very unlikely, but if disclosure is ever required, UNC-Chapel Hill will take steps allowable by law to protect the privacy of personal information. In some cases, your information in this research study could be reviewed by representatives of the University, research sponsors, or government agencies (for example, the FDA) for purposes such as quality control or safety.\

What is a Certificate of Confidentiality?
This research is covered by a Certificate of Confidentiality. With this Certificate, the researchers may not disclose or use information, documents or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings in the United States, for example, if there is a court subpoena, unless you have consented for this use.

The Certificate cannot be used to refuse a request for information from personnel of a federal or state agency that is sponsoring the study for auditing or evaluation purposes or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

The Certificate of Confidentiality will not be used to prevent disclosure as required by federal, state, or local law, such as mandatory reporting requirements for child abuse or neglect, disabled adult abuse or neglect, communicable diseases, injuries caused by suspected criminal violence, cancer diagnosis or benign brain or central nervous system tumors or other mandatory reporting requirement under applicable law. The Certificate of Confidentiality will not be used if disclosure is for other scientific research, as allowed by federal regulations protecting research subjects or for any purpose you have consented to in this informed consent document.

You should understand that a Certificate of Confidentiality does not prevent you from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

What will happen if you are injured by this research?

All research involves a chance that something bad might happen to you. If you are hurt, become sick, or develop a reaction from something that was done as part of this study, the researcher will help you get medical care, but the University of North Carolina at Chapel Hill has not set aside funds to pay you for any such injuries, illnesses or reactions, or for the related medical care. Any costs for medical expenses will be billed to you or your insurance company. You may be responsible for any co-payments and your insurance may not cover the costs of study related injuries.

If you think you have been injured from taking part in this study, call the Principal Investigator at the phone number provided on this consent form. They will let you know what you should do.

By signing this form, you do not give up your right to seek payment or other rights if you are harmed as a result of being in this study.

What if you want to stop before your part in the study is complete?

You can withdraw from this study at any time, without penalty. The investigators also have the right to stop your participation at any time. This could be because you have had an unexpected reaction, or have failed to follow instructions, or because the entire study has been stopped.

If you withdraw or are withdrawn from this study all data collected up until the point of withdrawal will be retained, however no additional information will be collected unless you provide additional written permission for further data collection at the time of your withdrawal

Will you receive anything for being in this study?

You will be receiving $30 for taking part in this study. $15 after each completed survey. Any payment provided for participation in this study may be subject to applicable tax withholding obligations

Will it cost you anything to be in this study?

If you enroll in this study, you will have costs which include:

- Costs associated with your usual care including attendance at the Diabetes Education Classes.
- Phone minutes or text message costs associated with communicating with your Peer Supporter.

Who is sponsoring this study?

This research is funded by the National Institutes of Health. This means that the research team is being paid by the sponsor for doing the study. The researchers do not, however, have a direct financial interest with the sponsor or in the final results of the study.

What if you have questions about this study?

You have the right to ask, and have answered, any questions you may have about this research. If you have questions about the study (including payments), complaints, concerns, or if a research-related injury occurs, you should contact the researchers listed on the first page of this form.

A description of this clinical trial will be available on www.clinicaltrials.gov, as required by U.S. Law. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

What if you have questions about your rights as a research participant?

All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If

you have questions or concerns about your rights as a research subject, or if you would like to obtain information or offer input, you may contact the Institutional Review Board at 919-966-3113 or by email to IRB_subjects@unc.edu.

Participant's Agreement:

I have read the information provided above. I have asked all the questions I have at this time. I voluntarily agree to participate in this research study.

_____
Signature of Research Participant

_____
Date

_____
Printed Name of Research Participant

_____
Signature of Research Team Member Obtaining Consent

_____
Date

_____
Printed Name of Research Team Member Obtaining Consent

_____
Signature of Witness if applicable; e.g. literacy issues, visually impaired, physically unable to sign, witness/interpreter for non-English speaking participants using the short form)

_____
Date

_____
Printed Name of Witness

1.2 HIPAA

University of North Carolina at Chapel Hill

HIPAA Authorization for Use and Disclosure of Health Information for Research Purposes

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IRB Study # 22-0357

Title of Study: Novel Interventions to Increase Uptake of Diabetes Self-Management Support Training within Primary Care

Principal Investigator: Katrina Donahue
Mailing Address for UNC-Chapel Hill Department: Aycock Family Medicine Bldg , 590 Manning Drive, Campus Box 7595, Chapel Hill, NC 27599

This is a permission called a "HIPAA authorization." It is required by the "Health Insurance Portability and Accountability Act of 1996" (known as "HIPAA") in order for us to get information from your medical records or health insurance records to use in this research study.

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1. If you sign this HIPAA authorization form, you are giving your permission for the following people or groups to give the researchers certain information about you (described below):

Any health care providers or health care professionals or health plans that have provided health services, treatment, or payment for you such as physicians, clinics, hospitals, home health agencies, diagnostics centers, laboratories, treatment or surgical centers, including but not limited to the UNC Health Care System.

2. If you sign this form, this is the health information about you that the people or groups listed in #1 may give to the researchers to use in this research study:

Any information in your medical records that relates to your participation in this research. These records might include information about mental health, drug or alcohol use, HIV/AIDS or other communicable diseases, or genetic testing. Other information includes: A1c, Attendence at Diabetes Education Classes.

3. The HIPAA protections that apply to your medical records will not apply to your information when it is in the research study records. Your information in the research study records may also be shared with, used by or seen by collaborating researchers, the sponsor of the research study, the sponsor's representatives, and certain employees of the University of North Carolina at Chapel Hill or other affiliated entities conducting the research, or government agencies (like the FDA) if needed to oversee the research study. HIPAA rules do not usually apply to those people or groups. If any of these people or groups reviews your research record, they may also need to review portions of your original medical record relevant to the situation. The informed consent document describes the procedures in this research study that will be used to protect your personal information. You can also ask the researchers any questions about what they will do with your personal information and how they will protect your personal information in this research study.

If study participant payments are described in the consent form, payments may be paid through a partner financial institution or its vendor. By participating in this Study, you authorize the disclosure of limited protected health information to a financial institution or its vendor to facilitate such payments or for tax reporting purposes.

4. If this research study creates medical information about you that will go into your medical record, you may not be

able to see the research study information in your medical record until the entire research study is over.

5. If you want to participate in this research study, you must sign this HIPAA authorization form to allow the people or groups listed in #1on this form to give access to the information about you that is listed in #2. If you do not want to sign this HIPAA authorization form, you cannot participate in this research study. However, not signing the authorization form will not change your right to treatment, payment, enrollment or eligibility for medical services outside of this research study.

6. This HIPAA authorization will stop 6 months after your study start date.

7. You have the right to stop this HIPAA authorization at any time. You must do that in writing. You may give your written stop of this HIPAA authorization directly to Principal Investigator or researcher or you may mail it to the department mailing address listed at the top of this form, or you may give it to one of the researchers in this study and tell the researcher to send it to any person or group the researcher has given a copy of this HIPAA authorization. Stopping this HIPAA authorization will not stop information sharing that has already happened.

8. You will be given a copy of this signed HIPAA authorization.

_____

Signature of Research Subject

_____

Date

_____

Print Name of Research Subject

For Personal Representative of the Research Participant (if applicable)

Print Name of Personal Representative: _____
Please explain your authority to act on behalf of this Research Subject:

_____

I am giving this permission by signing this HIPAA Authorization on behalf of the Research Participant.

_____

Signature of Personal Representative

_____

Date

1.3 Patient Verbal Consent for Interview

IRB Study #22-0357

Hello, my name is _____. I am from the University of North Carolina at Chapel Hill, and we are conducting research to understand your thoughts and experiences with DSMES classes.

You are being asked to participate in an interview, a researcher from our team will call you and ask you a series of questions about the study you've been in. Your participation is completely voluntary. You may skip any questions that you do not want to answer. If you decide not to take part in the interview or to skip some of the questions, it will not affect your relationship with your healthcare provider in any way, and you are free to stop the interview at any time.

This interview should take 45 minutes. The researcher will be in a private space during the interview, and she will work around your schedule to ensure you are also able to have privacy.

The interview will be audio recorded so it can be transcribed and qualitatively analyzed. We understand if you do not want to be recorded but if this is the case, you will not be able to participate. All recordings will be stored on a server that can only be accessed by people on the research team. All recordings will be destroyed after the study ends.

Any information you provide, including your name will be kept confidential. We will not identify you or use any information that would make it possible for anyone to identify you in any study reports. We will ask you for your email address so that we can compensate you for your time; we will compensate you $50 for your participation. No identifying information will be stored with your interview data. This research is very low risk but there is always a risk of a breach of confidentiality. If this happens, you could experience some embarrassment or feel uncomfortable in some way. Please know that we will immediately report the breach to the research ethics authority at UNC to ensure we handle it appropriately and that it doesn't happen again. To avoid a breath, research assistants and all study staff will be carefully trained by the investigators.

We anticipate minimal risks to your participation and will make every effort to keep your responses confidential; however, there is a risk of a breach of confidentiality in any research that stores data. We will not record your name with your responses and all publications will be present data in aggregate form, never identifying individuals or their place of work.

All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject you may contact, anonymously if you wish, the Institutional Review Board at 919-966-3113 or by email to IRB_subjects@unc.edu.

Do you have any questions?
Do you agree to participate in the interview?

1. Peer Supporter Verbal Consent for Interview

IRB Study #22-0357

Hello, my name is _____. I am from the University of North Carolina at Chapel Hill, and we are conducting research to understand your thoughts and experiences with the study and interacting with the DSMES patients. The insights and information we learn from you will help us improve this study design and enhance future clinical trials to best meet the needs of patients, providers and staff, and peer supporters.

You are being asked to participate in an interview, a researcher from our team will call you and ask you a series of questions about the study you've been in. Your participation is completely voluntary. You may skip any questions that you do not want to answer. If you decide not to take part in the interview or to skip some of the questions, it will not affect your relationship with us or to your practice in any way, and you are free to stop the interview at any time.

This interview should take about 45 minutes. The researcher will be in a private space during the interview, and she will work around your schedule to ensure you are also able to have privacy.

The interview will be audio recorded so it can be transcribed and qualitatively analyzed. We understand if you do not want to be recorded but if this is the case, you will not be able to participate. All recordings will be stored on a server that can only be accessed by people on the research team. All recordings will be destroyed after the study ends.

Any information you provide, including your name will be kept confidential. We will not identify you or use any information that would make it possible for anyone to identify you in any study reports. No identifying information will be stored with your interview data. This research is very low risk but there is always a risk of a breach of confidentiality. If this happens, you could experience some embarrassment or feel uncomfortable in some way. Please know that we will immediately report the breach to the research ethics authority at UNC to ensure we handle it appropriately and that it doesn't happen again. To avoid a breath, research assistants and all study staff will be carefully trained by the investigators.

We anticipate minimal risks to your participation and will make every effort to keep your responses confidential; however, there is a risk of a breach of confidentiality in any research that stores data. We will not record your name with your responses and all publications will be present data in aggregate form, never identifying individuals.

All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject you may contact, anonymously if you wish, the Institutional Review Board at 919-966-3113 or by email to IRB_subjects@unc.edu.

Do you have any questions?
Do you agree to participate in the interview?

1.5 Provider Verbal Consent for Focus Group

IRB Study #22-0357
Hello, my name is _____. I am from the University of North Carolina at Chapel Hill, and we are conducting research to understand your thoughts and experiences with our study. The insights and information we learn from you will help us improve this study design and enhance future clinical trials to best meet the needs of patients, providers and staff, and peer supporters.

You are being asked to participate in a focus group that should take 30-45 minutes. I'll as the group a series of questions related to how you've experienced this study with the idea that you and others feel comfortable responding. Your participation is completely voluntary. You may choose not to answer any questions for any reason.

If you decide not to take part in the interview or to skip some of the questions, it will not affect your job in any way, and you are free to stop the interview at any time.

The discussion will be audio recorded so it can be transcribed and qualitatively analyzed. We understand if you do not want to be recorded but if this is the case, you will not be able to participate. All recordings will be stored on a server that can only be accessed by people on the research team. All recordings will be destroyed after the study ends.

Any information you provide, including your name will be kept confidential. We will not identify you or use any information that would make it possible for anyone to identify you in any study reports. No identifying information will be stored with your interview data. This research is very low risk but there is always a risk of a breach of confidentiality. If this happens, you could experience some embarrassment or feel uncomfortable in some way. Please know that we will immediately report the breach to the research ethics authority at UNC to ensure we handle it appropriately and that it doesn't happen again. To avoid a breath, research assistants and all study staff will be carefully trained by the investigators.

We anticipate minimal risks to your participation and will make every effort to keep your responses confidential; however, there is a risk of a breach of confidentiality in any research that stores data. We will not record your name with your responses and all publications will be present data in aggregate form, never identifying individuals or their place of work.

All research on human volunteers is reviewed by a committee that works to protect your rights and welfare. If you have questions or concerns about your rights as a research subject you may contact, anonymously if you wish, the Institutional Review Board at 919-966-3113 or by email to IRB_subjects@unc.edu.

Do you have any questions?
Do you agree to participate in the interview?

2. Interview Guides
2.1 Diabetes Self-Management Education and Support Classes (DSMES) Patient Interview Guide

Participant Sample:

20 patients selected purposefully from among all participating Aim 2 intervention practices who completed all the DSMES class (N=10), and those that attended at least one class, but did not complete all the class (N=10).

Methodology:

Individual interviews will be approximately 45 minutes in length. Interview format will be based on patient preference and can include in-person, telephone, and video call.

Procedures:

1. Interviewer will greet participant and provide an explanation of the purpose of the interview:

   Thank you for talking to me. My name is _____ and the purpose of this discussion is for me to listen to your thoughts and experiences with DSMES classes. The insights and information we learn from you will help us improve this study design and enhance future large-scale clinical trials to best meet the needs of patients, providers and staff, and peer supporters. You should feel free to make any sort of comments – positive or negative – about what we are talking about today. There are no right or wrong answers. All you share today is confidential and we will only share your de-identified information in a summarized form. Your participation is voluntary and can choose not to answer any question you do not want to answer.

2. Interviewer will review each of the key sections of the consent form/information sheet. Important points to note:

   - Purpose of the study and what participants are being asked to do
   - Length of participation – 45 minutes
   - Risks, benefits, and compensation
   - Protection of privacy
   - Be sure to note that discussions will be recorded. If participants do not wish to be recorded, they will be unable to join this study.
   - Who to call with questions

   Just a reminder, your participation is voluntary, and you may choose to stop participating in the discussion at any time. As a thank you for your time, you will receive (incentive). Do you have any questions before the begin?

3. Interviewer will confirm participant agrees to participate in the interview and to be recorded.

   We will start the recorders now.

Patient Interview Questions

1. **For this project, there were a total of four classes offered. It looks like you participated in (___#__) classes. Tell me about your experiences with those classes. What is your overall impression of the DSMES classes?**

    a. What do you remember most about the classes?

    b. What was most helpful about the classes?

    c. What was least helpful about the classes?

    d. If you could change one thing about the classes, what would it be?

2. **To what extent did the DSMES classes meet your needs? Thinking about your diabetes care needs, how relevant was the:**

    a. Content and information you received

    b. Delivery of the information

    c. Language, vocabulary, terminology

    d. Structure and format of the classes

3. **Some people wonder if DSME classes as they are currently offered could be improved so that more people might attend them. If you could design the classes, how might they look? Tell me your thoughts about:**

    a. Content: focus on costs of foods, discuss other ways to manage diabetes, have opportunities to discuss "home remedies" that you have heard about, have content more relevant to people from diverse backgrounds (race, age, employment type, gender, religious affiliations)

    b. Format: Face to face vs. virtual/online vs. a mix of both

    c. Structure: More group discussions vs. less

    d. Class location: Have classes at a grocery store or other location (church, park, community center)

    e. Testimonies: Have patients share more about what works for them

4. **What role or impact did the peer supporter have on your participation of the DSMES classes? This can be a positive or negative impact.**

    Prompt: Encourage attendance?
    Complete DSMES classes?

5. **Thinking specifically about the DSMES classes, what are some of the things that made it easier for you to attend?**

    a. What were the challenges or things that made it difficult for you to attend?

    b. Thinking about other patients, what might potential challenges be for them to participate in a DSMES class?

6. **In what ways could this project better support you in your diabetes care?**

7. **Based on our discussion today, what can we do to help patients be successful in their diabetes self-management?**

Is there anything else you would like to add before we end our discussion?

Thank you!

We will now turn off the recorders.

2.2 Diabetes Self-Management Education and Support Classes (DSMES) Peer Supporters Interview Guide

Participant Sample:

Study Peer Supporters

Methodology:

Individual interviews approximately 45 minutes in length. Interview format will be based on patient preference and can include in-person, telephone, and video call.

Procedures:

4. Interviewer will greet participant and provide an explanation of the purpose of the interview:

   Thank you for talking to me. My name is _____ and the purpose of this discussion is for me to listen to your thoughts and experiences with DSMES classes. The insights and information we learn from you will help us improve this study design and enhance future large-scale clinical trials to best meet the needs of patients, providers and staff, and peer supporters. You should feel free to make any sort of comments – positive or negative – about what we are talking about today. There are no right or wrong answers. All you share today is confidential and we will only share your de-identified information in a summarized form. Your participation is voluntary and can choose not to answer any question you do not want to answer.

5. Interviewer will review each of the key sections of the consent form/information sheet. Important points to note:

   - Purpose of the study and what participants are being asked to do
   - Length of participation – 45 minutes
   - Risks, benefits, and compensation
   - Protection of privacy
   - Be sure to note that discussions will be recorded. If participants do not wish to be recorded, they will be unable to join this study.
   - Who to call with questions

   Just a reminder, your participation is voluntary, and you may choose to stop participating in the discussion at any time. Do you have any questions before the begin?

6. Interviewer will confirm participant agrees to participate in the interview and to be recorded.

   We will start the recorders now.

Peer Supporters Interview Questions

1. Before we started the project, you attended a two-day training led by ____. What is your overall impression of the training?

    a. How prepared were you to work with participants following the training you received?

    b. What was most helpful about the training?

    c. What was least helpful about the training?

    d. If you could change one thing about the training, what would it be?

2. What considerations should be made when matching peer supporters to participants?

3. What were the key challenges and barriers to providing peer support that arose?

    a. You mentioned ___ as an issue. How did you handle that?

4. In what ways could this project better support you as a peer supporter?

    a. What additional supports could you use?

5. Based on our discussion today, what can we do to help patients be successful in their diabetes self-management?

6. Is there anything else you would like to add before we end our discussion?

Thank you!

We will now turn off the recorders.

2.3 Diabetes Self-Management Education and Support Classes (DSMES) Provider and Staff Focus Group Guide

Participant Sample:

Four focus groups will be held, with one from each of the 4 participating UNCPN Aim 2 intervention practices. Focus groups will include 5 to 10 physicians, DCE specialists and staff.

Methodology:

Focus group discussions lasting approximately 30-45 minutes in length.

Procedures:

7. Interviewer will greet participant and provide an explanation of the purpose of the discussion:

   Thank you for talking to me. My name is _____ and the purpose of this discussion is for me to listen to your thoughts and experiences with our study. The insights and information we learn from you will help us improve this study design and enhance future large-scale clinical trials to best meet the needs of patients, providers and staff, and peer supporters. You should feel free to make any sort of comments – positive or negative – about what we are talking about today. There are no right or wrong answers. All you share today is confidential and we will only share your de-identified information in a summarized form. Your participation is voluntary and can choose not to answer any question you do not want to answer.

8. Interviewer will review each of the key sections of the consent form/information sheet. Important points to note:

   - Purpose of the study and what participants are being asked to do
   - Length of participation – 30-45 minutes
   - Risks, benefits
   - Protection of privacy
   - Be sure to note that discussions will be recorded. If participants do not wish to be recorded, they will be unable to join this study.
   - Who to call with questions

   Just a reminder, your participation is voluntary, and you may choose to stop participating in the discussion at any time. Do you have any questions before the begin?

9. Interviewer will confirm participants agree to participate in the discussion and to be recorded.

   We will start the recorders now.

Provider and Staff Focus Group Discussion Guide

1. To start, tell me your overall impressions of our study.

    a. From your perspective, how well did this study seem to fit with what you are currently doing to help your patients with diabetes?

    b. What stands out as a strength of this study?

    c. What do you see as a weakness or limitation of this study?

I would like to shift gears and talk about some specific parts of this study.

2. First, think about the **BPA reminders** which looked like this (Show Visual). How useful were the best BPA reminders for DSMES referral for your patients?

    a. What, if anything, could we do to make them more useful?

3. Next, let's talk about the **referral recommendations**. How appropriate was the referral recommendations during the critical diabetes time points in care?

4. Another key part of our project were **peer supporters** to help patients with their diabetes care. What, if anything, did you hear about the peer supporters?

    If Yes: Please share what you know or have heard about the peer supporters.

5. In what ways could this project better support you as a provider and staff?

    a. What additional supports (e.g., time, money, training, education) could you use?

6. Based on our discussion today, what can we do to help patients be successful in their diabetes self-management?

7. Is there anything else you would like to add before we end our discussion?

Thank you!
We will now turn off the recorders.

Peer Support Tracking

Please complete the survey below.

Thank you!

Patient Name	_____
Patient Study Id	_____
Peer Coach	_____
Who Intitiated the Contact	◯ Peer Coach ◯ Participant
Type of Contact	◯ Phone Call ◯ Text ◯ Email ◯ Video Call
Duration of Contact	◯ Less than 5 minutes ◯ 5 to 9:59 minutes ◯ 10 to 14:59 minutes ◯ over 15 minutes
Number of text exchanges	_____
Number of email exchanges	_____
Support Provided	☐ Encouraged DSMES Class attendence ☐ Emotional Support ☐ Encouragment or motivational support ☐ Problem solving ☐ Other
Describe Other	_____
Notes: (significant barriers, comments about DSMES classes,)	_____

PROMPT Baseline

Please complete the survey below.

Thank you!

Interviewer ID

_____

Screening ID (S11001, etc)

_____

Baseline Date

_____

Attitudes Toward Diabetes - DES:

I am going to read you some statements about diabetes. Each statement finishes the sentence "In general, I believe that..." The response categories are: Strongly Disagree, Somewhat Disagree, Neutral, Somewhat Agree, and Strongly Agree. It is important that you answer every statement; however you can choose not to answer any question.

In general, I believe that I:...know what part(s) of taking care of my diabetes that I am dissatisfied with.

- ◯ Strongly Disagree
- ◯ Somewhat Disagree
- ◯ Neutral
- ◯ Somewhat Agree
- ◯ Strongly Agree
- ◯ Prefer not to answer

In general, I believe that I:...am able to turn my diabetes goals into a workable plan.

- ◯ Strongly Disagree
- ◯ Somewhat Disagree
- ◯ Neutral
- ◯ Somewhat Agree
- ◯ Strongly Agree
- ◯ Prefer not to answer

In general, I believe that I:...can try out different ways of overcoming barriers to my diabetes goals.

- ◯ Strongly Disagree
- ◯ Somewhat Disagree
- ◯ Neutral
- ◯ Somewhat Agree
- ◯ Strongly Agree
- ◯ Prefer not to answer

In general, I believe that I:...can find ways to feel better about having diabetes.

- ◯ Strongly Disagree
- ◯ Somewhat Disagree
- ◯ Neutral
- ◯ Somewhat Agree
- ◯ Strongly Agree
- ◯ Prefer not to answer

In general, I believe that I:...know the positive ways I cope with diabetes-related stress.

- ◯ Strongly Disagree
- ◯ Somewhat Disagree
- ◯ Neutral
- ◯ Somewhat Agree
- ◯ Strongly Agree
- ◯ Prefer not to answer

In general, I believe that I:...can ask for support for having and caring for my diabetes when I need it.

- ◯ Strongly Disagree
- ◯ Somewhat Disagree
- ◯ Neutral
- ◯ Somewhat Agree
- ◯ Strongly Agree
- ◯ Prefer not to answer

In general, I believe that I:...know what helps me stay motivated to care for my diabetes.

- ◯ Strongly Disagree
- ◯ Somewhat Disagree
- ◯ Neutral
- ◯ Somewhat Agree
- ◯ Strongly Agree
- ◯ Prefer not to answer

In general, I believe that I:...know enough about myself as a person to make diabetes care choices that are right for me.

- ◯ Strongly Disagree
- ◯ Somewhat Disagree
- ◯ Neutral
- ◯ Somewhat Agree
- ◯ Strongly Agree
- ◯ Prefer not to answer

DDS:
DIRECTIONS: Living with diabetes can sometimes be tough. There may be many problems and hassles concerning diabetes and they can vary greatly in severity. Problems may range from minor hassles to major life difficulties. Listed below are 17 potential problem areas that people with diabetes may experience. Consider the degree to which each of the 17 items may have distressed or bothered you DURING THE PAST MONTH and circle the appropriate number.

Please note that we are asking you to indicate the degree to which each item may be bothering you in your life, NOT whether the item is merely true for you. If you feel that a particular item is not a bother or a problem for you, you would circle "1". If it is very bothersome to you, you might circle "6".

1. Feeling that diabetes is taking up too much of my mental and physical energy every day

- ◯ Not a Problem
- ◯ A Slight Problem
- ◯ A Moderate Problem
- ◯ Somewhat Serious Problem
- ◯ A Serious Problem
- ◯ A Very Serious Problem
- ◯ Prefer not to answer

2. Feeling that my doctor doesn't know enough about diabetes and diabetes care.

- ◯ Not a Problem
- ◯ A Slight Problem
- ◯ A Moderate Problem
- ◯ Somewhat Serious Problem
- ◯ A Serious Problem
- ◯ A Very Serious Problem
- ◯ Prefer not to answer

3. Not feeling confident in my day-to-day ability to manage diabetes.

- ◯ Not a Problem
- ◯ A Slight Problem
- ◯ A Moderate Problem
- ◯ Somewhat Serious Problem
- ◯ A Serious Problem
- ◯ A Very Serious Problem
- ◯ Prefer not to answer

4. Feeling angry, scared and/or depressed when I think about living with diabetes.

- ◯ Not a Problem
- ◯ A Slight Problem
- ◯ A Moderate Problem
- ◯ Somewhat Serious Problem
- ◯ A Serious Problem
- ◯ A Very Serious Problem
- ◯ Prefer not to answer

5. Feeling that my doctor doesn't give me clear enough directions on how to manage my diabetes.

- ◯ Not a Problem
- ◯ A Slight Problem
- ◯ A Moderate Problem
- ◯ Somewhat Serious Problem
- ◯ A Serious Problem
- ◯ A Very Serious Problem
- ◯ Prefer not to answer

6. Feeling that I am not testing my blood sugars frequently enough.

- ◯ Not a Problem
- ◯ A Slight Problem
- ◯ A Moderate Problem
- ◯ Somewhat Serious Problem
- ◯ A Serious Problem
- ◯ A Very Serious Problem
- ◯ Prefer not to answer

7. Feeling that I will end up with serious long-term complications, no matter what I do.

- ◯ Not a Problem
- ◯ A Slight Problem
- ◯ A Moderate Problem
- ◯ Somewhat Serious Problem
- ◯ A Serious Problem
- ◯ A Very Serious Problem
- ◯ Prefer not to answer

8. Feeling that I am often failing with my diabetes routine.

- ◯ Not a Problem
- ◯ A Slight Problem
- ◯ A Moderate Problem
- ◯ Somewhat Serious Problem
- ◯ A Serious Problem
- ◯ A Very Serious Problem
- ◯ Prefer not to answer

9. Feeling that friends or family are not supportive enough of self-care efforts (e.g. planning activities that conflict with my schedule, encouraging me to eat the "wrong" foods).

- ◯ Not a Problem
- ◯ A Slight Problem
- ◯ A Moderate Problem
- ◯ Somewhat Serious Problem
- ◯ A Serious Problem
- ◯ A Very Serious Problem
- ◯ Prefer not to answer

10. Feeling that diabetes controls my life.

- ◯ Not a Problem
- ◯ A Slight Problem
- ◯ A Moderate Problem
- ◯ Somewhat Serious Problem
- ◯ A Serious Problem
- ◯ A Very Serious Problem
- ◯ Prefer not to answer

11. Feeling that my doctor doesn't take my concerns seriously enough.	◯ Not a Problem ◯ A Slight Problem ◯ A Moderate Problem ◯ Somewhat Serious Problem ◯ A Serious Problem ◯ A Very Serious Problem ◯ Prefer not to answer
12. Feeling that I am not sticking closely enough to a good meal plan.	◯ Not a Problem ◯ A Slight Problem ◯ A Moderate Problem ◯ Somewhat Serious Problem ◯ A Serious Problem ◯ A Very Serious Problem ◯ Prefer not to answer
13. Feeling that friends or family don't appreciate how difficult living with diabetes can be.	◯ Not a Problem ◯ A Slight Problem ◯ A Moderate Problem ◯ Somewhat Serious Problem ◯ A Serious Problem ◯ A Very Serious Problem ◯ Prefer not to answer
14. Feeling overwhelmed by the demands of living with diabetes.	◯ Not a Problem ◯ A Slight Problem ◯ A Moderate Problem ◯ Somewhat Serious Problem ◯ A Serious Problem ◯ A Very Serious Problem ◯ Prefer not to answer
15. Feeling that I don't have a doctor who I can see regularly enough about my diabetes.	◯ Not a Problem ◯ A Slight Problem ◯ A Moderate Problem ◯ Somewhat Serious Problem ◯ A Serious Problem ◯ A Very Serious Problem ◯ Prefer not to answer
16. Not feeling motivated to keep up my diabetes self management.	◯ Not a Problem ◯ A Slight Problem ◯ A Moderate Problem ◯ Somewhat Serious Problem ◯ A Serious Problem ◯ A Very Serious Problem ◯ Prefer not to answer
17. Feeling that friends or family don't give me the emotional support that I would like.	◯ Not a Problem ◯ A Slight Problem ◯ A Moderate Problem ◯ Somewhat Serious Problem ◯ A Serious Problem ◯ A Very Serious Problem ◯ Prefer not to answer

For this last section, I'd like to ask you a few questions about you.

Gender	◯ Male ◯ Female ◯ Non-binary ◯ Other ◯ Prefer not to say.
How old are you?	_____
Which race best describes you?	◯ White ◯ Black ◯ Asian/Pacific Islander/Native Hawaiian ◯ Native American ◯ Two or More ◯ Other/Unknown ◯ Prefer not to say
Which ethnicity best describes you?	◯ Not Latino or Hispanic ◯ Latino or Hispanic ◯ Prefer not to say
What level of education have you completed?	◯ Some High School ◯ High School ◯ Some College ◯ Bachelor's Degree ◯ Master's Degree ◯ Ph.D. or similar ◯ Technical/Trade School ◯ Prefer not to say
Are you Married, partnered, or living with someone?	◯ No ◯ Yes
Do you have friends, family, or other people who help you when you need it?	◯ No ◯ Yes ◯ Prefer not to say
If you have health insurance, which one(s) do you have?	◯ Commercial ◯ Medicaid ◯ Medicare ◯ Tricare ◯ Other ◯ I don't have health insurance. ◯ Prefer not to say
In terms of employment status, are you:	◯ Employed Full-Time ◯ Employed Part-Time ◯ Not Currently Employed (not retired) ◯ Retired (not working) ◯ Prefer not to say
We will now use a randomizer to find out if you will have the additional peer support person while you are taking the Diabetes Education classes.	
Randomization Result - Using the Excel sheet uncover the randomization to Peer Support or Control Enter 1 for Peer Support and 0 for Control	_____
Peer Supporter - If randomized to Peer Support record the number 1, 2, 3 here	_____

Assign Participant ID (P101, P102, etc)

_____

Make notes about sending gift card here. Email vs Mail, where to send.

_____

PROMPT Follow up

Please complete the survey below.

Thank you!

1) Interviewer ID

_____

2) Participant ID

_____

3) Follow up Date

_____

Attitudes Toward Diabetes - DES:

I am going to read you some statements about diabetes. Each statement finishes the sentence "In general, I believe that..." The response categories are: Strongly Disagree, Somewhat Disagree, Neutral, Somewhat Agree, and Strongly Agree. It is important that you answer every statement; however you can choose not to answer any question.

4) In general, I believe that I:...know what part(s) of taking care of my diabetes that I am dissatisfied with.

- ◯ Strongly Disagree
- ◯ Somewhat Disagree
- ◯ Neutral
- ◯ Somewhat Agree
- ◯ Strongly Agree
- ◯ Prefer not to answer

5) In general, I believe that I:...am able to turn my diabetes goals into a workable plan.

- ◯ Strongly Disagree
- ◯ Somewhat Disagree
- ◯ Neutral
- ◯ Somewhat Agree
- ◯ Strongly Agree
- ◯ Prefer not to answer

6) In general, I believe that I:...can try out different ways of overcoming barriers to my diabetes goals.

- ◯ Strongly Disagree
- ◯ Somewhat Disagree
- ◯ Neutral
- ◯ Somewhat Agree
- ◯ Strongly Agree
- ◯ Prefer not to answer

7) In general, I believe that I:...can find ways to feel better about having diabetes.

- ◯ Strongly Disagree
- ◯ Somewhat Disagree
- ◯ Neutral
- ◯ Somewhat Agree
- ◯ Strongly Agree
- ◯ Prefer not to answer

8) In general, I believe that I:...know the positive ways I cope with diabetes-related stress.

- ◯ Strongly Disagree
- ◯ Somewhat Disagree
- ◯ Neutral
- ◯ Somewhat Agree
- ◯ Strongly Agree
- ◯ Prefer not to answer

9) In general, I believe that I:...can ask for support for having and caring for my diabetes when I need it.

- ◯ Strongly Disagree
- ◯ Somewhat Disagree
- ◯ Neutral
- ◯ Somewhat Agree
- ◯ Strongly Agree
- ◯ Prefer not to answer

10) In general, I believe that I:...know what helps me stay motivated to care for my diabetes.

- ◯ Strongly Disagree
- ◯ Somewhat Disagree
- ◯ Neutral
- ◯ Somewhat Agree
- ◯ Strongly Agree
- ◯ Prefer not to answer

11) In general, I believe that I:...know enough about myself as a person to make diabetes care choices that are right for me.

- ◯ Strongly Disagree
- ◯ Somewhat Disagree
- ◯ Neutral
- ◯ Somewhat Agree
- ◯ Strongly Agree
- ◯ Prefer not to answer

DDS:
DIRECTIONS: Living with diabetes can sometimes be tough. There may be many problems and hassles concerning diabetes and they can vary greatly in severity. Problems may range from minor hassles to major life difficulties. Listed below are 17 potential problem areas that people with diabetes may experience. Consider the degree to which each of the 17 items may have distressed or bothered you DURING THE PAST MONTH and circle the appropriate number.

Please note that we are asking you to indicate the degree to which each item may be bothering you in your life, NOT whether the item is merely true for you. If you feel that a particular item is not a bother or a problem for you, you would circle "1". If it is very bothersome to you, you might circle "6".

12) 1. Feeling that diabetes is taking up too much of my mental and physical energy every day

- ◯ Not a Problem
- ◯ A Slight Problem
- ◯ A Moderate Problem
- ◯ Somewhat Serious Problem
- ◯ A Serious Problem
- ◯ A Very Serious Problem
- ◯ Prefer not to answer

13) 2. Feeling that my doctor doesn't know enough about diabetes and diabetes care.

- ◯ Not a Problem
- ◯ A Slight Problem
- ◯ A Moderate Problem
- ◯ Somewhat Serious Problem
- ◯ A Serious Problem
- ◯ A Very Serious Problem
- ◯ Prefer not to answer

14) 3. Not feeling confident in my day-to-day ability to manage diabetes.

- ◯ Not a Problem
- ◯ A Slight Problem
- ◯ A Moderate Problem
- ◯ Somewhat Serious Problem
- ◯ A Serious Problem
- ◯ A Very Serious Problem
- ◯ Prefer not to answer

15) 4. Feeling angry, scared and/or depressed when I think about living with diabetes.

- ◯ Not a Problem
- ◯ A Slight Problem
- ◯ A Moderate Problem
- ◯ Somewhat Serious Problem
- ◯ A Serious Problem
- ◯ A Very Serious Problem
- ◯ Prefer not to answer

16) 5. Feeling that my doctor doesn't give me clear enough directions on how to manage my diabetes.

- ◯ Not a Problem
- ◯ A Slight Problem
- ◯ A Moderate Problem
- ◯ Somewhat Serious Problem
- ◯ A Serious Problem
- ◯ A Very Serious Problem
- ◯ Prefer not to answer

17) 6. Feeling that I am not testing my blood sugars frequently enough.

- ◯ Not a Problem
- ◯ A Slight Problem
- ◯ A Moderate Problem
- ◯ Somewhat Serious Problem
- ◯ A Serious Problem
- ◯ A Very Serious Problem
- ◯ Prefer not to answer

18) 7. Feeling that I will end up with serious long-term complications, no matter what I do.

- ◯ Not a Problem
- ◯ A Slight Problem
- ◯ A Moderate Problem
- ◯ Somewhat Serious Problem
- ◯ A Serious Problem
- ◯ A Very Serious Problem
- ◯ Prefer not to answer

19) 8. Feeling that I am often failing with my diabetes routine.

- ◯ Not a Problem
- ◯ A Slight Problem
- ◯ A Moderate Problem
- ◯ Somewhat Serious Problem
- ◯ A Serious Problem
- ◯ A Very Serious Problem
- ◯ Prefer not to answer

20) 9. Feeling that friends or family are not supportive enough of self-care efforts (e.g. planning activities that conflict with my schedule, encouraging me to eat the "wrong" foods).

- ◯ Not a Problem
- ◯ A Slight Problem
- ◯ A Moderate Problem
- ◯ Somewhat Serious Problem
- ◯ A Serious Problem
- ◯ A Very Serious Problem
- ◯ Prefer not to answer

21) 10. Feeling that diabetes controls my life.

- ◯ Not a Problem
- ◯ A Slight Problem
- ◯ A Moderate Problem
- ◯ Somewhat Serious Problem
- ◯ A Serious Problem
- ◯ A Very Serious Problem
- ◯ Prefer not to answer

22) 11. Feeling that my doctor doesn't take my concerns seriously enough.

- ◯ Not a Problem
- ◯ A Slight Problem
- ◯ A Moderate Problem
- ◯ Somewhat Serious Problem
- ◯ A Serious Problem
- ◯ A Very Serious Problem
- ◯ Prefer not to answer

23) 12. Feeling that I am not sticking closely enough to a good meal plan.

- ◯ Not a Problem
- ◯ A Slight Problem
- ◯ A Moderate Problem
- ◯ Somewhat Serious Problem
- ◯ A Serious Problem
- ◯ A Very Serious Problem
- ◯ Prefer not to answer

24) 13. Feeling that friends or family don't appreciate how difficult living with diabetes can be.

- ◯ Not a Problem
- ◯ A Slight Problem
- ◯ A Moderate Problem
- ◯ Somewhat Serious Problem
- ◯ A Serious Problem
- ◯ A Very Serious Problem
- ◯ Prefer not to answer

25) 14. Feeling overwhelmed by the demands of living with diabetes.

- ◯ Not a Problem
- ◯ A Slight Problem
- ◯ A Moderate Problem
- ◯ Somewhat Serious Problem
- ◯ A Serious Problem
- ◯ A Very Serious Problem
- ◯ Prefer not to answer

26) 15. Feeling that I don't have a doctor who I can see regularly enough about my diabetes.

- ◯ Not a Problem
- ◯ A Slight Problem
- ◯ A Moderate Problem
- ◯ Somewhat Serious Problem
- ◯ A Serious Problem
- ◯ A Very Serious Problem
- ◯ Prefer not to answer

27) 16. Not feeling motivated to keep up my diabetes self management.

- ◯ Not a Problem
- ◯ A Slight Problem
- ◯ A Moderate Problem
- ◯ Somewhat Serious Problem
- ◯ A Serious Problem
- ◯ A Very Serious Problem
- ◯ Prefer not to answer

28) 17. Feeling that friends or family don't give me the emotional support that I would like.

- ◯ Not a Problem
- ◯ A Slight Problem
- ◯ A Moderate Problem
- ◯ Somewhat Serious Problem
- ◯ A Serious Problem
- ◯ A Very Serious Problem
- ◯ Prefer not to answer

29) Toward the end of the study we will be inviting participants to a focus group or interview to ask about your experiences with diabetes education classes. Would you like to be contacted about this opportunity.

- ◯ Yes
- ◯ No
- ◯ Prefer not to say

30) How would you like us to contact you?

_____

31) Record inforation about sending follow up gift card (Email vs mail) type, etc.

_____