STUDY PROTOCOL

Social Behavioral Template

A multi-level intervention to increase access and use of the patient portal

Protocol Number

2000031753

Protocol Version

September 6, 2023

5

Clinical Trials Registration Number NCT05180721

Confidentiality Statement:

Synopsis

Purpose

Patient portals provide secure online access to medical records with the capability of messaging providers, filling prescriptions, viewing educational materials, and accessing clinic services. There is considerable evidence documenting disparities in patient portal use. Adults who are elderly, Black, Latinx, and those with low socioeconomic status (SES) and low health literacy are less likely to use patient portals as an adjunct to clinical care (Anthony et al. 2018; Grossman et al, 2019). Concern has been raised that this well-intentioned solution for patient-centered care may actually worsen health inequities unless portal use among the underserved is actively increased (Grossman et al, 2019; Veinot et al. 2018).

Therefore, the purpose of the study is to develop and evaluate a multi-level intervention aimed at increasing access and use of patient portals for diabetes management (MAP) in community health centers (CHCs). There are 2 phases in this study, developing and optimizing the intervention in Phase 1 using qualitative methods. In Phase 2, we will conduct a pilot study at two CHCs to evaluate the effect of the intervention on patient portal use, patient engagement with care, and clinical outcomes in adults with type 2 diabetes.

We are currently seeking IRB approval for Phase 1 as the intervention protocol will be finalized during this stage. Once that phase is complete, we will then submit an amendment for IRB approval for Phase 2 of the study. We have completed Phase 1 of the study.

We are now seeking IRB approval for Phase 2.

Anthony DL, Campos-Castillo C, Lim PS. Who Isn't Using Patient Portals And Why? Evidence And Implications From A National Sample Of US Adults. *Health Aff (Millwood)*. Dec 2018;37(12):1948-1954.
Grossman LV, Masterson Creber RM, Benda NC, Wright D, Vawdrey DK, Ancker JS. Interventions to increase patient portal use in vulnerable populations: a systematic review. *J Am Med Inform Assoc*. Aug 1 2019;26(8-9):855-870.
Veinot TC, Mitchell H, Ancker JS. Good intentions are not enough: how informatics interventions can worsen inequality. *J Am Med Inform Assoc*. Aug 1 2018;25(8):1080-1088.

Objectives

Aim 1. Optimize components of the *MAP* intervention for adults with T2D who access healthcare at CHCs. To accomplish this aim, we will conduct interviews/focus groups with adults with T2D and health care providers (n=24) from two CHCs to inform details of intervention design and to identify perceived barriers and facilitators to the delivery of the intervention. We will use these qualitative findings to finalize the *MAP* protocol.

Aim 2. Determine the effect size of *MAP* on the primary outcomes of portal use (number of logins) and A1C, among adults with T2D (n=30) who access healthcare at two CHCs. Secondary outcomes include: a) patient engagement with care (clinic appointments, referrals, ER visits, hospitalizations, use of community resources for social determinants of health); b) T2D clinical management (EMR data of A1C, blood pressure, lipid profile, BMI); c) T2D self-management (medication, blood glucose monitoring, healthy eating, physical activity); d) psychosocial outcomes (diabetes self-efficacy, autonomy support, and diabetes distress); e) technology outcomes (digital literacy, acceptance/use/confidence); and f) satisfaction. Using a within subjects, pre-post design we will pilot *MAP* in 30 adults with T2D who are not currently using the patient portal. Data will be collected at baseline, 3, and 6

months. We will also rigorously evaluate the feasibility of *MAP* using an established framework (acceptability, demand, implementation, adaptation, and integration).

Study Population

Adults with type 2 diabetes (T2D) of diverse race/ethnicity who access healthcare at community health centers (CHCs) will participate in the study. There are significant racial and ethnic disparities in the prevalence, morbidity, and mortality of T2D. Despite medical advances and increased access to medical care, these disparities persist. Racial/ethnic minorities are more likely to have poor glycemic control (Kiek et al, 2006), to develop diabetes-related complications (Osborn et al. 2013) and 1.5-2.3 times more likely to die from diabetes than whites (Spanakis et al. 2013). Further, minorities have been particularly affected by COVID-19, with increased risk for infection, morbidity, hospitalization, and mortality (Yancy 2020) Preexisting conditions, including and especially diabetes, increase risk for poor COVID-19 outcomes (Richardson et al. 2020). Thus, innovative approaches are urgently needed to address health inequities in T2D.

Increased patient portal use has the potential to increase engagement with care and improve diabetes health outcomes. Yet, despite increased access and popularity of patient portal use in the US, disparities in portal use continue. To date, no interventions on portal adoption have targeted adults with T2D of diverse race/ethnicity with limited resources, who have unique structural and social barriers to portal access, use, and diabetes self-management.

We will target adults with T2D who access health care at CHCs because CHCs play a critical role in addressing health inequities in T2D, providing care to over 27 million people in the US. The aim of CHCs is to provide affordable, high quality, comprehensive primary care to medically underserved populations, regardless of insurance status or ability to pay for care. Most CHC patients (92%) live in poverty or near-poverty as defined by the Federal Poverty Level; are disproportionately from racial/ethnic minority groups (total 63%:32% Hispanic, 22% Black, 9% other minorities); and have high rates of chronic conditions compared to the general population.

Kirk JK, D'Agostino RB, Jr., Bell RA, et al. Disparities in HbA1c levels between African-American and non-Hispanic white adults with diabetes: a meta-analysis. *Diabetes Care*. Sep 2006;29(9):2130-6.
Osborn CY, de Groot M, Wagner JA. Racial and ethnic disparities in diabetes complications in the northeastern United States: the role of socioeconomic status. *J Natl Med Assoc*. Spring 2013;105(1):51-8.
Spanakis EK, Golden SH. Race/ethnic difference in diabetes and diabetic complications. *Curr Diab Rep*. Dec 2013;13(6):814-23.
18. Yancy CW. COVID-19 and African Americans. *JAMA*. 2020;323(19):1891-1892.
19. Yan UY YY, Wang F, Ren H, Zhang S, Shi X, Yu X, Dong K. Clinical characteristics and outcomes of patients with severe covid-19 with diabetes. *BMC Open Diabetes Research & Care*. 2020;8:e001343.
20. Richardson S, Hirsch JS, Narasimhan M, et al. Presenting Characteristics, Comorbidities, and Outcomes Among 5700 Patients Hospitalized With COVID-19 in the New York City Area. *Jama*. May 26 2020;323(20):2052-2059.

Number of Participants

For Phase 1 of the study, we will enroll 24 participants. We will enroll 10 adults with T2D who access healthcare at a CHC in CT, 10 health care providers at CHCs (physicians, nurses, social workers), and 4 community health workers (CHW) who provide services at CHCs in CT.

For Phase 2 of the study, we will enroll 30 participants (15 from each of our clinical sites)

Study Design

In Phase 1 we will use a qualitative descriptive design, convening interviews/focus groups with stakeholders to guide the development of *MAP*. During this phase we will finalize the intervention protocol and develop promotional and training materials.

In Phase 2, we will evaluate the preliminary efficacy and feasibility of *MAP* using a pre-post design.

Study Duration

The study will last for two years. We anticipate completing Phase 1 in the first year. Participants of Phase 1 of the study will participate in one focus group or interview that will last about 1.5 hours.

We have completed Phase 1 of the study. We anticipate completing Phase 2 in the second year of the study. Participants of Phase 2 of the study will participate in a multi-level intervention that will last for 6 months.

Outcome Variables

In Phase 1, there are no outcome variables.

In Phase 2, our primary outcomes include portal use (e.g., number of logins) and glycosylated hemoglobin (A1C) measured with a fingerstick of blood and analyzed with the A1CNow+ system. Secondary outcomes include: patient portal engagement (number of clinic appointments, use of community resources, medication refills, ER visits, and hospitalizations during the previous 3 months). Other secondary outcomes include T2D clinical management (EMR data of A1C, blood pressure, lipid profile, BMI), self-management (medication, blood glucose monitoring, healthy eating, physical activity), psychosocial outcomes (diabetes self-efficacy, autonomy support, diabetes distress) technology acceptance/use/confidence, and satisfaction.

We will also collect data on the intervention implementation which will be assessed by data on the sequence and timing of sessions, # of rescheduled/reminders for sessions, and how the portal was used by patients, CHWs, nurses, and providers. Implementation will also be measured via treatment fidelity. Lastly, we will use field notes and meeting notes from training and communication with interventionists to determine barriers and facilitators to program implementation.

Locations/Facilities

Our partner CHCs are located in Connecticut (CT), a small and densely populated state with some of the most prominent health disparities in the country. Fair Haven CHC is located in New Haven, CT and provides care to approximately 7,100 residents, 63% Hispanic, 20% Black, 15% white, with 1600 diagnosed with T2D. Norwalk CHC is located

in Norwalk CT and provides care to approximately 20,000 residents, 60% Hispanic, 15% Black, 25% white, with 3000 diagnosed with T2D.

Abbreviations

Abbreviation	Explanation
MAP	Multi-level intervention aimed at increasing access and use of patient portals for diabetes management
T2D	Type 2 diabetes
CHC	Community health center
A1C	Laboratory measurement of glycemic control completed approximately every 3 months

Glossary of Terms

Glossary	Explanation

Table of Contents

Protocol Revision History

Version Date	Summary of Substantial Changes
2	Change in process of informed consent to include consent via zoom or computer.
3	This version to seek approval for Phase 2 of the study.

1 Background

1.1 Background

Patient portals provide secure online access to medical records with the capability of messaging providers, filling prescriptions, viewing educational materials, and accessing clinic services. There is considerable evidence documenting disparities in patient portal use. Adults who are elderly, Black, Latinx, and those with low socioeconomic status (SES) and low health literacy are less likely to use patient portals as an adjunct to clinical care (Anthony et al, 2018; Grossman et al. 2019). Concern has been raised that this well-intentioned solution for patient-centered care may actually worsen health inequities unless portal use among the underserved is actively increased (Grossman et al., 2019; Veinot et al. 2018: Lorenc et al 2013).

Portal adoption interventions can successfully increase portal use. In a systematic review of interventions to increase portal use in vulnerable populations, 67% of studies (12/18) showed a significant increase in portal use, predictors of use, or reduced disparities. Free or low-cost internet access, technical training and assistance, and proactive outreach from the healthcare team through the portal have the strongest evidence for improving health equities in portal use and outcomes (Lorenc et al 2013). In the general population, patient portal use has been shown to increase patient engagement with office visits and decrease emergency room visits and hospitalizations (Reed et al., 2019). Patient portal use also increases patient knowledge, self-efficacy, decision-making, medication use, and preventive screening (Han et al, 2019). In adults with diabetes, greater portal use of secure messaging with providers led to improved glycemic control (A1C) compared to non-users (Dekvota et al, 2016: Chung et al. 2017; Harris et al, 2018; Kuo et al, 2016). Other trials have demonstrated significant reductions in A1C through diabetes self-management support and education via the portal (Tang et al, 2013; Ralston et al, 2009; Alturkistani et al, 2020). Thus, fostering communication with providers and diabetes self-management support are promising features of portals for adults with diabetes. However, to date there are no interventions promoting engagement in clinical care and diabetes self-management via patient portals in adults with type 2 diabetes (T2D) of diverse race/ethnicity who experience considerable health disparities.

The World Health Organization (WHO) *Social Determinants of Health Equity* provides a useful framework for reducing disparities in patient portal use. It posits that socioeconomic position produces health disparities through four intermediary factors - material circumstances, psychosocial factors, behavioral/biological factors, and the healthcare system. We will develop and evaluate a multi-level intervention aimed at increasing access and use of patient portals for diabetes management (*MAP*) in community health centers (CHCs). *MAP* will intervene on each intermediary factor of the WHO framework. Specifically, *MAP* will: 1) provide free access to tablets and internet (material circumstances); 2) deliver technology training and support (psychosocial factors); 3) assess social determinants of health and refer to community resources (material circumstances); and, 4) provide diabetes self-management support and referral to clinic services (behavioral/biological factors). *MAP* will be delivered by community health workers and nurses already embedded in CHCs' healthcare system. Intervention components will be tailored for low-literacy, low-numeracy adults and communications will be designed to increase participant's autonomy for portal use and diabetes self-management. We hypothesize that *MAP* will increase portal use and patient engagement with health care, improve diabetes self-management and psychosocial outcomes, and ultimately improve glycemic control.

Anthony DL, Campos-Castillo C, Lim PS. Who Isn't Using Patient Portals And Why? Evidence And Implications From A National Sample Of US Adults. *Health Aff (Millwood)*. Dec 2018;37(12):1948-1954.
Grossman LV, Masterson Creber RM, Benda NC, Wright D, Vawdrey DK, Ancker JS. Interventions to increase patient portal use in vulnerable populations: a systematic review. *J Am Med Inform Assoc*. Aug 1 2019;26(8-9).

Veinot TC, Mitchell H, Ancker JS. Good intentions are not enough: how informatics interventions can worsen inequality. *J Am Med Inform Assoc*. Aug 1 2018;25(8):1080-1084.
Lorenc T, Petticrew M, Welch V, Tugwell P. What types of interventions generate inequalities? Evidence from systematic reviews. *J Epidemiol Community Health*. Feb 2013;67(2):190-3.
Reed ME, Huang J, Brand RJ, et al. Patients with complex chronic conditions: Health care use and clinical events associated with access to a patient portal. *PLoS One*. 2019;14(6):e0217636.
Han HR, Gleason KT, Sun CA, et al. Using Patient Portals to Improve Patient Outcomes: Systematic Review. *JMIR Hum Factors*. Dec 19 2019;6(4):e15038.
Devkota B, Salas J, Sayavong S, Scherrer JF. Use of an Online Patient Portal and Glucose Control in Primary Care Patients with Diabetes. *Popul Health Manag*. Apr 2016;19(2):125-31.
Chung S, Panattoni L, Chi J, Palaniappan L. Can Secure Patient-Provider Messaging Improve Diabetes Care? *Diabetes Care*. Oct 2017;40(10):1342-1348.
Harris SM, Joyce H, Miller A, Connor C, Amiel SA, Mulnier H. The attitude of healthcare professionals plays an important role in the uptake of diabetes self-management education: analysis of the Barriers to Uptake of Type 1 Diabetes Education (BUD1E) study survey. *Diabet Med*. Jun 8 2018.
Kuo A, Dang S. Secure Messaging in Electronic Health Records and Its Impact on Diabetes Clinical Outcomes: A Systematic Review. *Telemed J E Health*. Sep 2016;22(9):769-77.
Tang PC, Overhage JM, Chan AS, et al. Online disease management of diabetes: engaging and motivating patients online with enhanced resources-diabetes (EMPOWER-D), a randomized controlled trial. *J Am Med Inform Assoc*. May 1 2013;20(3):526-34.
Ralston JD, Hirsch IB, Hoath J, Mullen M, Cheadle A, Goldberg HI. Web-based collaborative care for type 2 diabetes: a pilot randomized trial. *Diabetes Care*. Feb 2009;32(2):234-9.
Alturkistani A, Qavi A, Anyanwu PE, Greenfield G, Greaves F, Costelloe C. Patient Portal Functionalities and Patient Outcomes Among Patients With Diabetes: Systematic Review. *J Med Internet Res*. Sep 22 2020;22(9):e18976.

1.2 Prior Experience (if applicable)

N/A

2 Rationale/Significance

2.1 Rationale and Study Significance

There are significant racial and ethnic disparities in the prevalence, morbidity, and mortality of T2D. Despite medical advances and increased access to medical care, these disparities persist.

Increased patient portal use has the potential to increase engagement with care and improve diabetes health outcomes. Yet, despite increased access and popularity of patient portal use in the US, disparities in portal use continue. More than 100 studies have demonstrated substantial disparities in portal use (Grossman et al, 2019). In a systematic review of patient portal interventions for adults of diverse race/ethnicity and limited resources, technical training was the most effective strategy in improving patient portal logins, use of features, and secure messaging (Grossman et al. 2019). Interventions promoting patient portal use, such as accessing medical records and secure messaging with provider, improve knowledge, self-efficacy, and medication adherence in adults with chronic illnesses[6] and glycemic control in adults with diabetes (Tang et al, 2013: Alturkistani et al, 2020; Harris et al, 2013). To date, no interventions on portal adoption have targeted adults with T2D of diverse race/ethnicity with limited resources, who have unique structural and social barriers to portal access, use, and diabetes self-management.

CHCs play a critical role in addressing health inequities in T2D, providing care to over 27 million people in the US (National Association of Community Health Centers, 2020). The aim of CHCs is to provide affordable, high quality, comprehensive primary care to medically underserved populations, regardless of insurance status or ability to pay for care. Most CHC patients (92%) live in poverty or near-poverty as defined by the Federal Poverty Level; are disproportionately from racial/ethnic minority groups (total 63%:32% Hispanic, 22% Black, 9% other minorities); and have high rates of chronic conditions compared to the general population. In 2018, 21% of adults seen at CHCs had T2D compared to 11% in the general population. Our goal, therefore, is to determine the effect of a multi-level intervention to increase patient portal use among adults with T2D who access healthcare at CHCs by providing tablets, home internet, and technology support, as well as personalized care to improve engagement with health care and diabetes self-management.

Social determinants of health are important considerations in developing interventions for adults with T2D who access care at CHCs. The Social Determinants of Health Equity framework (Soar & Irwin, 2010), developed by the WHO, posits that socioeconomic and political context contribute to one's socioeconomic position, with populations stratified based on education, occupation, and income (**Figure 1**). These structural determinants of health operate through intermediary and social determinants of health to shape health outcomes. Intermediary and social determinants include material circumstances (e.g., access to tablets/internet, food security), behavioral and/or biological factors (e.g., taking medications), psychosocial factors (e.g., technology literacy), and the health care system (access to care). By situating our program in CHCs, where the

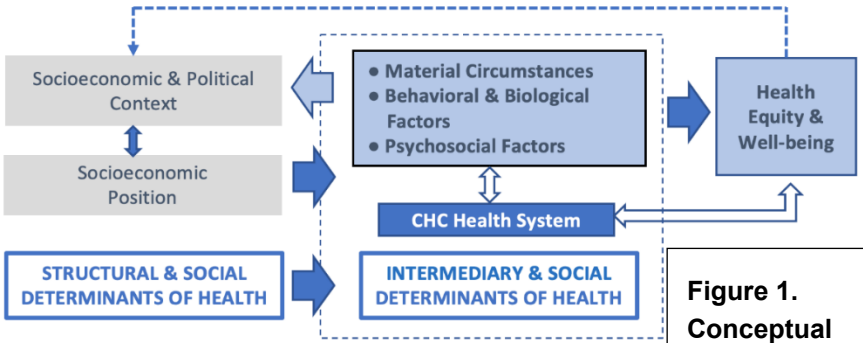


Figure 1. Conceptual Framework

underserved access health care, and by addressing intermediary determinants of health in a multi-level intervention, we are highly likely to improve outcomes for adults with T2D from communities experiencing disparities.

The proposed study addresses several gaps in the literature. First, the theory-guided intervention addresses health disparities by using a multi-level approach that addresses intermediary determinants of health. The intervention will be delivered by staff who are imbedded in the existing clinical operations of the CHCs, thus increasing the potential for scale up to other CHCs (over 1400 nationwide). In addition, we propose integrating diabetes self-management support into the portal adoption intervention and thus expect not only increased portal use but also improved diabetes self-management and glycemic control

Grossman LV, Masterson Creber RM, Benda NC, Wright D, Vawdrey DK, Ancker JS. Interventions to increase patient portal use in vulnerable populations: a systematic review. *J Am Med Inform Assoc*. Aug 1 2019;26(8-9):855-870.

Tang PC, Overhage JM, Chan AS, et al. Online disease management of diabetes: engaging and motivating patients online with enhanced resources-diabetes (EMPOWER-D), a randomized controlled trial. *J Am Med Inform Assoc*. May 1 2013;20(3):526-34.

Alturkistani A, Qavi A, Anyanwu PE, Greenfield G, Greaves F, Costelloe C. Patient Portal Functionalities and Patient Outcomes Among Patients With Diabetes: Systematic Review. *J Med Internet Res*. Sep 22 2020;22(9):e18976.

Harris LT, Koepsell TD, Haneuse SJ, Martin DP, Ralston JD. Glycemic control associated with secure patient-provider messaging within a shared electronic medical record: a longitudinal analysis. *Diabetes Care*. Sep 2013;36(9):2726-33

National Association of Community Health Centers. The number of patients continues to grow at community health centers. https://www.nachc.org/the-number-of-patients-continues-to-grow-at-community-health-centers/. 2017. Accessed October 1, 2020.

Solar O & Irwin A. *A conceptual framework for action on the social determinants of health. Social Determinants of Health Discussion Paper.* World Health Organization. 2010. https://www.who.int/sdhconference/resources/ConceptualframeworkforactiononSDH_eng.pdf

2.2 Risks

For Phase 1 of this study, there are minimal risks. We will collect personal health information from adults with T2D regarding their age, gender, race/ethnicity, type of insurance, duration of T2D, and self-report of most recent A1C (measurement of glycemic control). We will collect information from health care providers and community health workers on age, gender, race/ethnicity, type of healthcare provider and years providing care in a CHC. There is a risk of loss of confidentiality. The study will be conducted in accordance with HIPAA regulations. All study staff will receive certified IRB training and will sign a confidentiality agreement. Strict safeguards will be in place to ensure the confidentiality of the data. Confidentiality will be protected through coding mechanisms. Each study subject will be given a unique study identification number that will be used on all study forms and data files. Each participant's identifying data will be separated from the study data. The code linking a participant to their code number will be maintained in a separate file on a secure server at Yale (eg. Secure Box). All identifying information will be destroyed at the earliest possible time following completion of the study. Results from this investigation will be reported in aggregate, with no potential for individual patients to be identified.

For Phase 2 of this study, there are minimal risks. We will collect personal health information from adults with T2D that includes demographic, clinical, behavioral, and psychosocial data. There is a risk of loss of confidentiality. All practices completed in Phase 1 to decrease this risk will be followed in Phase 2. All participants will participate in an intervention that includes education and support on how to log in and use the patient portal and nurse coaching on diabetes self-management via the patient portal. There is a slight risk of hypoglycemia if diabetes self-management is improved; however, all participants will be receiving the nurse coaching by a nurse from the clinic in which they receive medical care and all patients will be

continue to be followed by their primary care provider for the duration of the study. Nurses will assess for depressive symptoms at their initial session with participants using the PHQ-2. Participants will be informed of a positive screen and advised to contact their primary care provider or behavioral health professional. Primary care providers will also be informed of a positive screen. Nurses will be in communication with primary care providers for any concerns regarding the health status of study participants and all participants will be advised that communications with the nurse on the patient portal are for non-urgent medical concerns. Both patient portals specify that communication with providers is for non-urgent medical questions.

2.3 Anticipated Benefits

There is no direct benefit to study participants in Phase 1. Participants may feel like they are contributing to knowledge on diabetes self-management in adults with T2D.

In Phase 2, there is no direct benefit to study participants. Participants will receive a tablet and an approximately 6 month data plan (until study completion). They will be able to keep the tablet at the end of the study. Participants may learn how to better manage their diabetes, enjoy communicating with their nurse about their diabetes and may feel like they are contributing to knowledge on diabetes self-management in adults with T2D. Some pariticipants may improve their glycemic control.

3 Study Purpose and Objectives

3.1 Purpose

The purpose of the study is to develop and evaluate a multi-level intervention aimed at increasing access and use of patient portals for diabetes management (MAP) in community health centers (CHCs). There are 2 phases in this study, developing and optimizing the intervention in Phase 1 using qualitative methods. In Phase 2, we will conduct a pilot study at two CHCs to evaluate the effect of the intervention on patient portal use, patient engagement with care, and clinical outcomes in adults with type 2 diabetes.
We are seeking IRB approval for Phase 1 and will submit an amendment for IRB approval prior to the implementation of Phase 2.
We are now seeking approval for Phase 2 of the study.

3.2 Hypothesis

In Phase 1, there is no hypothesis.

Phase 2 is a pilot study and we do not have specified hypotheses. Participants who complete the intervention may improve their engagement with care and clinical, psychosocial and technology outcomes compared to baseline.

3.3 Objectives

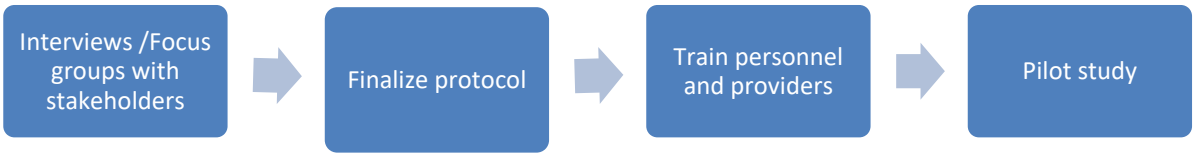
The primary objective of Phase 1 is to optimize components of the *MAP* intervention for adults with T2D who access healthcare at CHCs. To accomplish this aim, we will conduct interviews/focus groups with adults with T2D and health care providers (n=24) from two CHCs to inform details of intervention design and to identify perceived barriers and facilitators to the delivery of the intervention. We will use these qualitative findings to finalize the *MAP* protocol.
The primary objective of Phase 2 is to determine the effect size of *MAP* on the primary outcomes of portal use (number of logins) and A1C, among adults with T2D (n=30) who access healthcare at two CHCs. Secondary outcomes include: a) patient engagement with care (clinic appointments, referrals, ER visits, hospitalizations, use of community resources for social determinants of health); b) T2D clinical management (EMR data of A1C, blood pressure, lipid profile, BMI); c) T2D self-management (medication, blood glucose monitoring, healthy eating, physical activity); d) psychosocial outcomes (diabetes self-efficacy, autonomy support, and diabetes distress); e) technology outcomes (digital literacy, acceptance/use/confidence); and f) satisfaction. Using a within subjects, pre-post design we will pilot *MAP* in 30 adults with T2D who are not currently using the patient portal. Data will be collected at baseline, 3, and 6 months. We will also rigorously evaluate the feasibility of *MAP* using an established framework (acceptability, demand, implementation, adaptation, and integration).

4 Study Design

We will use mixed-methods to develop and evaluate *MAP* for adults with T2D. This project will be conducted in two phases. In Phase 1 we will use a qualitative descriptive design, convening interviews/focus groups with stakeholders to guide the development of *MAP*. During this phase we will finalize the intervention protocol and develop promotional and training materials. In Phase 2 we will train personnel in intervention delivery (one community health worker [CHW] and one nurse at each CHC) and inform other health care providers at the clinics (e.g., physicians, pharmacists) about *MAP*. We will then implement *MAP* and evaluate the preliminary efficacy and feasibility of *MAP* using a pre-post design. IRB approval will be obtained prior to start-up of Phase 2.

In Phase 2, we will use a pre-post design, collecting data from participants at baseline, 3 and 6 months. We will evaluate change over time in participants.

Study Design:



APPROVED BY THE YALE UNIVERSITY IRB 9/18/2023

4.1 Study Duration

The entire study will last for 2 years.

Phase 1 will be conducted in the first year. Participants will participate in one interview or focus group that will last approximately 1.5 hours.

Phase 2 will be conducted in the second year of the study. Participants will participate in a 6-month intervention.

4.2 Outcome Variables/Endpoints

In Phase 1, there are no outcome variables/endpoints.

4.2.1 Primary Outcome Variables/Endpoints

In Phase 1, this is not applicable.

In Phase 2, the primary outcomes are patient portal use (number of logins over past 3 months) and glycosylated hemoglobin (A1C).

4.2.2 Secondary and Exploratory Outcome Variables/Endpoints (if applicable)

In Phase 1, this is not applicable.

In Phase 2, secondary outcomes include: a) patient engagement with care (clinic appointments, referrals, ER visits, hospitalizations, use of community resources for social determinants of health); b) T2D clinical management (EMR data of A1C, blood pressure, lipid profile, BMI); c) T2D self-management (medication, blood glucose monitoring, healthy eating, physical activity); d) psychosocial outcomes (diabetes self-efficacy, autonomy support, and diabetes distress); e) technology outcomes (digital literacy, acceptance/use/confidence); and f) satisfaction.

We will also collect data on the intervention implementation which will be assessed by data on the sequence and timing of sessions, # of rescheduled/reminders for sessions, and how the portal was used by patients, CHWs, nurses, and providers. Implementation will also be measured via treatment fidelity. Lastly, we will use data from all field notes of trainings and meetings with interventionists to determine barriers and facilitators to implementation.

5 Study Participants

5.1 Study Population

Phase 1: Participants withT2D diagnosed with T2D for at least 6 months aged 18 years or older, of diverse race/ethnicity, who access healthcare at CHCs. We will seek variability with respect to age, gender, race/ethnicity, and duration of T2D. Participants will be recruited from an outpatient setting – CHCs.

We will also recruit healthy health care providers who provide care for adults with T2D at CHCs.

Phase 2: Participants withT2D diagnosed with T2D for at least 6 months aged 18 years or older, of diverse race/ethnicity, who access healthcare at CHCs. We will seek variability with respect to age, sex, race/ethnicity, and duration of T2D. Participants will be recruited from outpatient settings – Fair Haven and Norwalk CHCs. These are the same CHCs we worked with in Phase 1.

5.2 Number of Participants

For Phase 1, we will recruit health care providers (n=5), CHWs, (n=2), and adults with T2D (n=5), at each clinical site (total sample: 10 providers, 4 CHWs, and 10 adults with T2D).

For Phase 2, we will recruit 30 adults with T2D (n=15 from each clinic).

5.3 Eligibility Criteria

Phase 1 eligibility criteria for adults with T2D

In order to be eligible for inclusion in the study, an individual must meet all of the following criteria:

Established patient of one of the partner CHCs;
Age ≥18 years;
Diagnosed with T2D ≥ 6 months;
Able to read in English or Spanish.

Any individual who meets any of the following criteria will be excluded from participation in this study:

Cognitive impairment (≥3 errors on the Six Item Screener for cognitive impairment in clinical research [SIS]) (Callahan et al. 2002) as they will have difficulty in completing the study requirements

Gestational diabetes

Diagnosis of type 1 diabetes

Callahan CM, Unverzagt FW, Hui SL, Perkins AJ, Hendrie HC. Six-item screener to identify cognitive impairment among potential subjects for clinical research. *Med Care*. Sep 2002;40(9):771-81.

Phase 1 eligibility criteria for health care providers

In order to be eligible for inclusion in the study, an individual must meet all of the following criteria:

Health care provider or community health worker at one of our partner CHC

Provides care/services for adults with T2D

Any individual who meets any of the following criteria will be excluded from participation in this study:

None

Vulnerable/special populations that will be included are: economically or educationally disadvantaged populations and elderly populations (who do not demonstrate cognitive impairment. These groups have health disparities with respect to patient portal use and are important to include in the research to be able to address their needs and improve health equity and health outcomes.

Phase 2: Inclusion criteria are: established patient of one of the partner CHCs; age 18 years or older; diagnosed with T2D >6 months; most recent A1C >7.5%; no current use of patient portal, no intention of moving/changing clinic within 6 months; and able to read in English or Spanish. Exclusion criteria include: cognitive impairment and gestational diabetes. Participants who participated in Phase 1 will be eligible to participate in Phase 2.

Vulnerable/special populations that will be included are: economically or educationally disadvantaged populations and elderly populations (who do not demonstrate cognitive impairment). These groups have health disparities with respect to patient portal use and are important to include in the research to be able to address their needs and improve health equity and health outcomes.

5.4 Recruitment Procedures

Phase 1:

We will use convenience and purposive sampling through flyers at clinics, in-person recruitment by research assistants (RAs), social media advertisements at clinics, and recommendations from clinic leadership and participants.

For providers, we will use convenience and purposive sampling to achieve variation in type of provider (e.g. MD or NP), age, gender, and race/ethnicity. For CHWs, we will seek diversity in years at CHC, gender, and race/ethnicity. For adults with T2D, we will also use convenience and purposive sampling to achieve variation in use of portals (never users, occasional users, frequent users) as well as variation in age, gender, race/ethnicity, and duration of T2D.

Interested participants will be invited to contact the research team to obtain more information about the study. At the first contact, a trained research assistant will determine eligibility using an established script. If eligible and interested, the research assistant will inform the person about the study procedures and schedule an appointment for the informed consent. If not eligible or interested, the participant will be thanked for their time.

Ideally, we will conduct focus groups in-person if safe to do so, or via Zoom. If an eligible and interested participant can not make the focus group interview time, we will schedule an individual interview in-person (if safe to do so) or via zoom, depending on participant preference. Providers will not complete interviews during work hours. Interviews will be scheduled at lunch, in the evening, or other times that the employee is not working at the clinic.

Phase 2: We will use convenience and purposive sampling through flyers at clinics, in-person recruitment by clinic personnel, social media advertisements at clinics, and recommendations from clinic leadership and participants.

Recruits who express an interest in the study will be invited to contact a language-concordant member of the research team to obtain more information about the study. At this contact, an IRB-approved trained consentor will determine eligibility using an established script. If eligible and interested, the research assistant will inform the recruit about the study procedures and schedule an appointment for the informed consent. If not eligible or interested, the recruit will be thanked for their time. If eligible and interested, the recruit will move on to the consent procedure.

5.5 Consent/Assent Procedures/HIPAA Authorization

Phase 1:

- Consent forms describing in detail the study intervention, study procedures, and risks are sent electronically or given to the participant and written, electronic, or audio-recorded verbal documentation of informed consent is required prior to starting procedures/administering study intervention.
- Consent forms will be Institutional Review Board (IRB)-approved. A trained research assistant will explain the research study to the participant and answer any questions that may arise. This conversation will take place in a private room.
- Participants will have the opportunity to carefully review the written consent form and ask questions prior to signing. The participants should have the opportunity to discuss the study with their family or surrogates or think about it prior to agreeing to participate.
- Participants must be informed that participation is voluntary and that they may withdraw from the study at any time, without prejudice. A copy of the informed consent document will be given to the participants for their records.
- A verbal explanation will be provided in terms suited to the participant's comprehension of the purposes, procedures, and potential risks of the study and of their rights as research participants.
- Prior to the focus group or interview with patient participants, informed consent will be obtained by a trained research assistant. Participants will be asked if they prefer

to read the informed consent or have the informed consent document read to them. If done via Zoom, participants will be asked if they want to read the informed consent document that was sent to them electronically prior to the Zoom meeting or if they would prefer to have the research assistant share the informed consent document on the screen. The research assistant will paraphrase key sections, answer any questions, assure understanding by asking participants to state their understanding of the study procedures, and obtain written, electronic, or audio-recorded verbal informed consent based on patient preference. If patients prefer to complete the informed consent process remotely, we will send a copy of the informed consent via or mail or electronically. We will then send the patient participant a link to a secure Zoom meeting. At this Zoom meeting, the research assistant will follow the aforementioned procedure to obtain informed consent. We will provide patients with the option to audio record the review of the last paragraph of the informed consent and ask patients to state if they consent to the study or to send them a link to an electronic survey in Qualtrics that they can read the last paragraph of the informed consent with options to ‘agree’ or ‘not agree’ to participation.

For interviews with healthcare providers that are conducted in person or over Zoom, we will provide them with a copy of the informed consent document via email prior to the interview and obtain verbal consent prior to the actual interview.

Phase 2:

- Consent forms (English or Spanish) describing in detail the study intervention, study procedures, and risks will be sent electronically to the recruit or handed to them on paper. The choice of in-person or electronic will be determined by recruit preference. Written, electronic, or audio-recorded verbal documentation of informed consent will be obtained prior to starting procedures/administering study intervention.
- Consent forms will be Institutional Review Board (IRB)-approved. A trained and IRB-approved RA (fluent in Spanish for Spanish speaking recruits) will explain the research study to the recruit and answer any questions that may arise. This conversation will take place in a private room/setting.
- Recruits will have the opportunity to carefully review the written consent form and ask questions prior to signing. They will have the opportunity to discuss the study with their family or surrogates or think about it prior to agreeing to participate.
- Recruits will be informed that participation is voluntary and that they may withdraw from the study at any time, without prejudice. A copy of the informed consent document will be given to the participants for their records.
- A verbal explanation will be provided in terms suited to the participant's comprehension of the purposes, procedures, and potential risks of the study and of their rights as research participants.

- Prior to baseline data collection, informed consent will be obtained by a trained RA. Recruits will be asked if they prefer to read the informed consent or have the informed consent document read/paraphrased. If done via Zoom, participants will be asked if they want to read the informed consent document that was sent to them electronically prior to the Zoom meeting or if they would prefer to have the RA share the informed consent document on the screen. The RA will paraphrase key sections, answer any questions, assure understanding by asking participants if they have any questions, and obtain written, electronic (Qualtrics), or audio-recorded verbal informed consent based on patient preference.

6 Study Methods/Procedures

6.1 Study Procedures

Phase I:

Interested participants will be screened by a trained research assistant using a script. If not eligible or interested, people will be thanked for their time.

If eligible and interested, we will obtain informed consent as previously described. We will also collect data via focus groups, scheduling individual interviews if logistical challenges arise. There will be different semi-structured interview/focus group guides for clinic personnel and patients. Focus groups will be composed of the same subject group – all providers or all patients. Interviews/focus groups with stakeholders will be conducted by the PIs or their designee and a bilingual RA. Participants of focus groups/interviews will be asked to talk about their experiences with patient portals. Specifically, participants will be asked to describe barriers and facilitators to patient portal use for engagement in diabetes care, technology needs, and feedback on the proposed content and procedures of *MAP.*

Providers and CHWs will complete a demographic survey on age, sex, race/ethnicity, type of provider, years in practice, and years at CHC. Adults with T2D will be asked to provide data on age, sex, race/ethnicity, type of insurance, duration of T2D, most recent A1C, and years receiving care at CHC. If adults with T2D cannot recall their most recent A1C, we will ask them to contact their health care provider and provide this information to us at a later date. All interviews/focus groups will be scheduled at convenient times for participants, via ZOOM or in-person if it is safe to do so. If focus groups are conducted via ZOOM, participants will be asked to change their name to a pseudonym prior to entry into the focus group. Interview/focus groups will be conducted in Spanish as needed. Interviews/focus groups will be audiotaped, transcribed verbatim, and Spanish transcripts translated to English. No videos will be recorded for ZOOM interviews.

Phase 2:

For recruitment, flyers will be posted at the clinic and clinicians will be encouraged to refer eligible participants. Information about the study will also be posted on clinic social media channels. Interested recruits will be screened by a language concordant trained RA using a script. If not eligible or interested, people will be thanked for their time.

If eligible and interested, a trained RA will enroll participants from the CHCs. The RA will obtain written informed consent and collect data (in English or Spanish depending on preference). We will use REDCap™, an NIH-supported, FDA-compliant electronic data capture application for data collection and storage. RAs will enter data at the time of data collection into the database via tablets. Trained RAs or nurses will obtain point-of-care A1C values with a fingerstick of blood, following all protocols for safety.

All participants who enroll in the study will receive standard T2D care at their CHC and the *MAP* intervention. The MAP intervention consists of 4 components:

1. Supplies/Needs: Provision of tablet, provision of an approximately 6-month data plan (until study completion), and referral for community resources such as food or housing assistance. Participants will keep the tablet after they finish the study. Tablets will be set to the appropriate language (English or Spanish per participants preference).

2. Technology Training: In-person training and ongoing support on how to use the patient portal with their tablet by trained community health workers (CHW) or nurse from the respective clinics. The CHW or nurse will give participants their tablet with data plan. They will meet 1:1 with participants in person or by telehealth. Sessions will cover: 1) how to use the tablet; 2) how to use the portal; 3) social determinants needs assessment; and 4) connection to community resources. The number, duration, and spacing of sessions will be determined by clinical need and participant availability, but it is anticipated that participants will have 4-6 individual sessions of approximately 30 minutes each over the course of the first month of the intervention. Sessions will be conducted face-to-face in the clinic or over secure telemedicine through MyChart/Healow. During the first or second session, the interventionist will conduct a screening for the social determinants of health (eg, housing, food, utilities). According to existing clinic protocol, participants with any such needs will be given referrals to community resources and assistance with accessing them such as completing an application for subsidized housing or obtaining groceries from a food bank.
   Attendance will be recorded and CHWs will complete a fidelity checklist after each session. The CHWs will remind participants about sessions. Once technology competence has been established through a teach-back method, participants will be connected with the nurse at each site. Interventionists will remain available after these sessions are concluded, in case participants have additional needs/questions regarding material needs and/or tablet/portal use. Participants will be given the contact information for the interventionist and encouraged to contact them with any questions.
   See Appendix X for details of this component of the intervention.
3. Diabetes Support: Diabetes self-management support will be provided by a nurse via the patient portal. The nurse will have an initial in person or telehealth session with participants to assess their diabetes self-management challenges and successes. Nurses will assess for depressive symptoms at their initial session with participants using the PHQ-2 (an established depressive symptom screener for primary care). Participants will be informed of a positive screen and advised to contact their primary care provider or behavioral health professional. Primary care providers will also be informed of a positive screen. At this meeting the nurse and participant will co-create a diabetes self-management plan aligned with their treatment plan prescribed by the participants' primary care provider. The nurse will work with each patient to individualize diabetes behavioral targets, considering the following priorities: use of the portal, attendance at appointments, uploading of blood glucose data to the portal, medication refills and adherence, and lifestyle and emotional factors. After this initial session, the nurse will proactively contact participants via the portal approximately 2 times/week or as clinically indicated for 3 months to check-in, provide diabetes education, provide motivational support, and/or answer any participant questions about their diabetes. After 3 months, the nurse will check-in with participants one time per week. See Appendix X for details of the intervention.
4. Text Messages: CHWs and nurses may also send text message reminders to participants for appointments or to check/use patient portal.

MAP will follow guidelines for health care for low-literacy and low-numeracy patients with diabetes (For example, keeping sessions brief, presenting information in small chunks, use of pictures when possible). In addition, all contacts between the nurse or CHW and participant will be guided by principles of autonomy support. Autonomy support refers to a patient's perception that their healthcare provider recognizes the person's personal agency,

encourages self-efficacy, and supports their self-care choices. Autonomy support is in contrast to simply providing information and is also in contrast to provider attempts to control or coerce patient behavior which can actually hinder engagement in health behaviors.

Interventionist Training

CHWs and nurses from each CHC will receive training on the *MAP* protocol that will entail self-study, small group class sessions, and live practice. Training is anticipated to require the equivalent of approximately 2 days for CHWs and nurses, with homework and practice between training sessions. Training will cover: orientation to research and goals of the study; human subjects protection; protocol and documentation; and, team roles, responsibilities, and supervision. Training will also cover details of the intervention content through materials made for this study. CHWs and nurses will be taught specific strategies for working with low-literacy/low-numeracy individuals.

Training will also teach CHWs and nurses how to provide autonomy support to participants. Research shows that autonomy support can be learned and practiced.[48-51] Through scripts, role-play, and illustrative case examples, they will be trained to use specific techniques such as acknowledging the participant perspective, identifying participant goals, emphasizing participant responsibility, and providing encouragement. The co-PIs will observe role plays and complete treatment fidelity checklists; CHWs and nurses will be allowed to deliver the intervention to participants only after the PIs judge that their skill level is sufficient. Drs. Wagner and Whittemore have extensive experience training CHWs and nurses in delivery of behavioral interventions. After the formal training, the PIs, the study nurse and CHW will meet approximately weekly during the first four weeks of intervention delivery and bi-weekly thereafter or as indicated by the PIs. Clinics will be compensated for the salary of the nurse and CHW for training, delivering the intervention, and completing study tasks.

Follow-up data will be collected at 3 and 6 months. At each data collection session, an appointment for the next data collection session will be scheduled. Participants will be sent a text message, email message, phone call, or calendar reminder (based on preference) for data collection appointments (3, 2, and 1 day prior). To maximize retention, we will explain all study procedures in the informed consent process, provide escalating incentives for study assessments, and collect data on alternate contact persons. Our research team has ample experience with longitudinal research demonstrating successful retention with hard to reach populations including Latinx adults with T2D. Study participants will received compensation for data collection (Baseline $40.00, 3-month $40.00, 6-month $60.00)

6.1.1 Data Collection

Phase 1: Data for interviews/focus groups will be conducted using a semi-structured interview guide. Participants – healthcare providers/community health workers and adults with T2D – will participate in one interview or focus group which will last approximately 1 hour and a half. Interview data will provide information on perceived barriers, facilitators, and needs of stakeholders on patient portal use/non-use. Our stakeholders are providers who will be communicating with patients via the patient portal and adults with T2D who will be using the patient portal to learn more about their diabetes and communicate their needs to their provider. Data will be collected via audio-recordings and recordings will be transcribed verbatim. Data will be coded and summarized per established and rigorous procedures. All data will be stored with a participant ID only. The code linking a participant

to their code number will be maintained in a separate file on a secure server at Yale (eg. Secure Box). No identifying data will be included in transcripts (eg. if a name is used that information will not be transcribed).

Phase 2: Participant data for this phase will consist of self-report data by participants (demographic and medical history data, study questionnaires), laboratory data (fingerstick glycosylated hemoglobin A1C), electronic medical record data (e.g. body mass index, recent laboratory data), and patient portal data (e.g., number of logins, number of messages sent/received, content of messages sent/received) (see Table 1). All questionnaires have demonstrated adequate reliability and validity.

Data will also be obtained on program implementation, fidelity, and barriers/facilitators to implementation from meeting field notes.

All data will be stored with a participant ID only. The code linking a participant to their code number will be maintained in a separate file from the data files on a secure computer from Yale. No identifying data from field notes will be recorded.

Table 1: Data Collection	
Sociodemographics	16 items (sex, age, primary language, etc.); Self-rated health (1 item); Charlson comorbidity index (19 items);
Outcome	Measurement
Primary:	
Patient Portal Use	Patient portal data: Number of logins Features used (prescription requested, checked lab, appointment requested) Number of messages sent/received Content of messages Number of blood glucose uploads Number of nurse education materials sent
Glycoslyated Hemoglobin (A1C)	A1C now point of care with fingerstick of blood
Secondary:	
Engagement with care	Clinic appointments Referrals ER visits Hospitalizations Use of community resources
T2D clinical management	EMR data: dates of service, A1C, blood pressure, lipid profile, height, weight, BMI
T2D self-management	Self-rated health (1 item); Medication adherence, blood glucose monitoring, healthy eating, physical activity (24 items)
Psychosocial outcomes	Diabetes self-efficacy (8 items) Autonomy support (health care climate) (7 items) Diabetes distress (20 items)
Technology acceptance/use	Digital health literacy (3 items) Technology acceptance (8 items) Technology use (6 items) Technology confidence (4 items) Tablet use (3 items)

	Barriers/Facilitators (13 items)
Satisfaction	Satisfaction with program (4 items) Satisfaction with health care provider (3 items)
Use of community resources	1 items

6.2 Method of Assignment/Randomization (if applicable)

Phase 1: Not applicable

Phase 2: Not applicable

6.3 Adverse Events Definition and Reporting

Phase I: Not applicable

Adverse event means any untoward medical occurrence associated with the use of an intervention in humans, whether or not considered intervention-related.

An adverse event (AE) or suspected adverse reaction is considered "serious" if, in the view of either the investigator or sponsor, it results in any of the following outcomes: death, a life-threatening adverse event, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions, or a congenital anomaly/birth defect.
For Phase 1, we will be interviewing participants and there is no intervention.
For Phase 2, risk of the study is considered minimal and adverse events are defined in Table 2:

Adverse event	Any untoward or unfavorable medical occurrence in a human subject, including any abnormal abnormal sign (for example, abnormal physical exam or laboratory finding), symptom, or disease, temporally associated with the subject's participation in the research, whether or not considered related to the subject's participation in the research
Serious adverse event	Any adverse event that: 1. results in death; 2. is life-threatening (places the subject at immediate risk of death from the event as it occurred); 3. results in inpatient hospitalization or prolongation of existing hospitalization; (e.g., hospitalization for asthma or hypoglycemia) 4. results in a persistent or significant disability/incapacity; 5. results in a congenital anomaly/birth defect; or 6. based upon appropriate medical judgment, may jeopardize the subject's health and may require medical or surgical intervention to prevent one of the other outcomes listed in this definition (e.g., allergic bronchospasm requiring intensive treatment in the emergency room or at home, convulsions that

	do not result in inpatient hospitalization, or the development of drug dependency or drug abuse).
Unanticipated problems	Any incident, experience, or outcome that meets **all** of the following criteria: 1. unexpected (in terms of nature, severity, or frequency) given (a) the research procedures that are described in the IRB-approved research protocol and informed consent document; and (b) the characteristics of the subject population being studied; 2. related or possibly related to participation in the research (reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and 3. suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

The research team will meet with RNs at least every 2 weeks during study implementation. The RNs, CHW, and/or research team will report adverse events or unanticipated problems that they identify during the intervention implementation at research meetings. The PIs will solicit more information about the event if needed and will determine if it's serious orunanticipated, using the definitions identified in the table above. Serious adverse events, deaths or unanticipated problems involving risk to subjects encountered during the study will be reported by phone as soon as identified to the Institutional Review Board at Yale. In addition, the PI will follow-up immediately to elicit as much information as possible about the event. The PI is responsible for complying with all regulations concerning the reporting of serious adverse events. The decision to terminate participation for a study participant due to an adverse experience rests with the investigator who is responsible until the study is completed or adverse events are stable or resolved. In making termination decisions, the PI may carry out discussions with Co-Investigators, consultants, or other personnel. If the IRB determines that the adverse event was attributable to the intervention, the PI will notify the NIH grant administrator within 72 hours of receipt of the IRB decision.

6.4 Reaction Management

Phase 1: Not applicable

Phase 2: All participants will be receiving care at a community health center. Participants will be referred to appropriated help, resources, or clinical care as needed.

6.5 Withdrawal Procedures

Phase 1: Not applicable

Phase 2: Participants will be informed that their participation in the study is voluntary and they are free to withdraw at any time and withdrawal from the study will not affect their relationships with anyone at the clinic. Participants who withdraw from the study will keep the the tablet provided from the study.

Withdrawal of enrolled participants who develop any of the exclusionary or potentially exclusionary criteria (e.g., pregnancy) will be assessed on a case by case basis depending on the severity and whether there are any potential risks to following the study protocol. The decision to withdraw a participant from the study will be ultimately made by the co-PIs. Data and/or sample collection will be discontinued depending on the severity of the condition. Should a participant develop an exclusionary condition, he or she will be given the opportunity to continue. He or she will also be given the opportunity to opt out from data collection even when the co-PIs had considered appropriate to continue collecting data.

6.6 Locations/Facilities

Phase 1: Interviews/focus groups, if able to be scheduled in-person, will be conducted at the CHC in a private room. Our clinic locations are Fair Haven Community Health Center in New Haven and Norwalk Community Health Center in Norwalk, CT. Interviews/focus groups may also be conducted by phone or ZOOM. We will provide participants access to ZOOM and instructions how to use it, if they are not familiar with this platform.

Phase 2: Data collection will be collected from participants in-person at the clinic or private location preferred by participants or via telehealth for study questionnaires. A1C data will be collected at the clinic or private location preferred by participants. Electronic health record and patient portal data will be collected by trained clinic personnel at each clinical site.

7 Statistical Design

7.1 Sample Size Considerations

Phase 1: Not applicable

Phase 2: Since this is a pilot study to provide preliminary data for a future large study, we conducted a power analysis to show an effect size on A1C using a feasible sample size of 30 participants. We chose the more conservative approach to power on A1C vs. portal logins as we anticipate a smaller effect size on A1C. In our recent study with low-income Latinx adults, we obtained a standard deviation of 1.2 and a sample correlation of 0.57 in repeatedly measured A1C over 6 months. The estimated standard deviation of changed A1C will be 0.72 and the sample size of 30 will produce a standard error of 0.13. Therefore, the proposed sample size of 30 could estimate a change of A1C over time with a margin of ±0.27% A1C for 95% confidence interval.

7.2 Planned Analyses

Phase I analysis:

The sample of participants in the interviews/focus groups will be described using frequency distributions and appropriate summary statistics (SAS version 9.4). Content analysis will be used to analyze qualitative data from each type of stakeholder along with field notes and interviewer observations (Hsieh, 2005) Rigor for this process includes: (a) transcribing taped interviews; (b) checking transcripts against tapes for accuracy; (c) developing coding categories by two members of the research team; (d) assigning codes of text with appropriate checks; (e) reviewing coded data to identify themes across participants; and (f) a team approach to data analysis. At research team meetings we will assess researcher bias, coding saturation, and interpretative congruence. Results will be used to finalize the intervention protocol for implementation in Phase 2

Hsieh HF, Shannon SE. Three approaches to qualitative content analysis. *Qual Health Res*. Nov 2005;15(9):1277-88.

Phase 2 Analysis: Data will be collected in the form of questionnaires online on the secure REDCap system. A1C data, electronic medical record data and patient portal data will entered into REDCap or Excel and meged into one database. All data that are downloaded from REDCap or Excel will be onto a Yale server, which has several secure firewall systems.. Descriptive analyses will be performed to assess demographic and clinical characteristics of the sample. Feasibility data will be summarized. Distributions of outcome variables will be examined for central tendency and dispersion. We will estimate the Cohen's D effect size of *MAP* on A1C and will examine the intervention effect over 6 months using generalized linear mixed model (GLMM) with random intercept, which will incorporate the correlation within repeatedly measured A1C. The slope of time will represent the average change of A1C over 6 months. The GLMM will include all participants with data at baseline and at least one of post-intervention value and will handle missing data using maximum likelihood approach. To confirm findings with missing data, we will rerun the GLMM with multiple imputations which will be produced by assuming multivariate normal distribution of repeatedly measured A1C. Number of logins and the repeatedly measured secondary outcomes will be analyzed with the same approach using the GLMM. Residuals will be assessed for normality assumption and

variables will be transformed with an appropriate form when the normality assumption does not hold. Count data such as portal use, clinic appointments, ER visits, and hospitalizations will be modeled using Poisson or Negative Binomial regression model. For exceeding zero count (i.e. a high proportion of no appointment, ER visit, hospitalization), zero-inflated regression models will be employed. We will also estimate the effects of portal use (frequency, type) and feasibility factors (e.g., acceptability, attendance, fidelity) on A1c at 6 months after controlling for baseline A1c using generalized linear model (GLM). For future research with a large sample size, we will obtain an effect size (partial eta square) of each factor from GLM. Qualitative data will be analyzed using the aforementioned content analysis approach.

7.2.1 Secondary Objective Analyses (if applicable)

Phase 1: Not applicable

Phase 2: See above analysis plan for primary and secondary outcomes.

7.2.2 Analysis of Subject Characteristics (if applicable)

Phase 1: Not applicable

Phase 2: Descriptive analyses will be performed to describe demographic and clinical characteristics of the sample.

7.2.3 Interim Analysis (if applicable)

Phase 1: Not applicable

Phase 2: Not applicable

7.3 Data Relevance

Phase 1: Qualitative data collected from our stakeholders – healthcare providers/community health workers of CHCs and adults with T2D who access care at CHCs – will provide information on the barriers, facilitators, and needs related to an intervention to increase patient portal use for diabetes care. This will allow us to complete our study aim which is to optimize components of the *MAP* intervention for adults with T2D who access healthcare at CHCs. We will use these qualitative findings to finalize the *MAP* protocol.

Phase 2: Data collected from participants, the electronic medical record, and patient portal will provide important information on whether the provision of material resources (tablet and data plan), technology assistance, and nursing education and support increases use of the patient portal and engagement with diabetes care. Adults with T2D who access clinical care at community health centers often do not have consistent engagement with clinical care, particularly through the patient portals. Use of patient portals has been shown to improve health care outcomes; thus, the data in this study will help us understand if our approach has the potential to improve health outcomes in this population.

7.4 Data Coding

Phase 1: We will used established content analysis procedures to code the data. Initially we will develop coding categories by two members of the research team. Next we will assign codes to text in our transcripts with appropriate checks (having the 2 coders independently

code the first 2 transcripts and check codes for agreement and resolve discrepancies). If the 2 coders cannot resolve discrepancies, these will be discussed with the Co-PIs. Once all data are coded, we will review coded data to identify themes across participants. During this process, we will use a team approach to data analysis to enhance rigor. At research team meetings we will assess researcher bias, coding saturation, and interpretative congruence.

Phase 2: Quantitative data will be coded based on a pre-determined system (either by assigning a number to specific characteristic or by following questionnaire scoring guidelines). De-identified data from REDCap will be downloaded into our statistical software for data analysis. For open-ended questions on Technology Barriers and Facilitators, we will use a content analysis method to code participant responses into categories in order to describe the most common barriers and facilitators.

7.5 Data Analysis Tools

Phase 1: We will use SAS or EXCEL to describe the sample. We will use NIVIVO, a qualitative data analysis software to analyze interview data.

Phase 2: We will use SAS or EXCEL to describe the sample.

7.6 Data Monitoring

Phase 1: Not applicable

Phase 2: The co-PIs (Whittemore and Wagner) are responsible for monitoring individual events and determining whether the study protocol needs modification to minimize risk.

The research team will have at least monthly meetings to review individual cases and ensure close monitoring of participants. If the team considers it appropriate, with a signed release of information from the participant, we will give any relevant information regarding the participant's health to their medical care providers.

7.7 Handling of Missing Data

Phase 1: Not applicable

Phase 2: To confirm findings with missing data, we will rerun the GLMM with multiple imputations which will be produced by assuming multivariate normal distribution of repeatedly measured A1C. Number of logins and the repeatedly measured secondary outcomes will be analyzed with the same approach using the GLMM.

8 Data/Specimen Handling and Record Keeping

8.1 Subject Data Confidentiality

Phase 1 and Phase 2: Participant confidentiality and privacy is strictly held in confidence by the participating investigators, their staff, and the sponsor(s)/funding agency. Therefore, the study protocol, documentation, data, and all other information generated will be held in strict confidence. Participants of focus groups will be informed not to divulge information they would not want repeated outside the focus group.

All research activities will be conducted in as private a setting as possible.

Representatives of the Institutional Review Board (IRB), regulatory agencies or study sponsor/funding agency may inspect all documents and records required to be maintained by the investigator for the participants in this study. The study site will permit access to such records.

The study participant's contact information will be securely stored at each study site for internal use during the study. At the end of the study, all records will continue to be kept in a secure location for as long a period as dictated by the reviewing IRB, Institutional policies, regulatory, or sponsor/funding agency requirements.

Study participant research data, which is for purposes of statistical analysis and scientific reporting, will be transmitted to and stored on the Yale Server that is password protected with multiple firewalls. This will not include the participant's contact or identifying information. Rather, individual participants and their research data will be identified by a unique study identification number. The study data entry and study management systems used will be secured and password protected. At the end of the study, all study databases will be de-identified and archived in a secured file on the Yale server.

8.2 Data Quality Assurance

Phase 1: The Co-PIs have experience with conducting formative research to inform intervention development. We also have expertise in the collection and analysis of qualitative data. The Co-PIs will train all research team members who will be obtaining informed consent, collecting data, and coding data for this phase of the study. We will provide research assistants with the opportunity to practice obtaining informed consent and collecting data with semi-structured interviews. We will review the transcripts of the first 3 interviews for training purposes. We will also develop and maintain a study manual which will provide resources and documentation of all study procedures.

Phase 2: The Co-PIs have expertise in the conduct of intervention development and evaluation research, implementing interventions, monitoring the fidelity of the intervention delivery, and collecting data accurately and consistently .The Co-PIs will train all research

team members who will be obtaining informed consent and collecting data. We will provide research assistants with the opportunity to practice obtaining informed consent and will debrief at research meetings. We will also develop a manual of study operation procedures and forms that will be available to all study personnel.

We will create a manual for the study interventionists on assisting participants with technology and on the nursing education and support component of the intervention. All interventionists will be trained by the Co-PIs and will be asked to demonstrate competency in role-play situations prior to engaging with study participants. Study interventionists will meet with the co-PIs weekly for the first 4 weeks and bi-weekly thereafter to review how things are going with study implementation and to discuss successes and challenges. The PIs will also be available to study interventionists for any questions that arise in between meetings. Intervention fidelity will be assessed by study interventionists and will be reviewed by the PIs. Any difficulties with protocol implementation will be addressed with the interventionists.

8.3 Data or Specimen Storage/Security

Phase 1: Data will be stored in a secure, password protected file on the Yale server.

Phase 2: Data will be stored in a secure, password protected file on the Yale server.

8.4 Study Records

Phase 1: Study records include regulatory documents, the protocol, consent forms, subject demographic information, and interview data. The Yale PI will be responsible for maintaining the study documentation. Flies that need to be shared by research team members will be in s Secure Box folder on the Yale Server. Research team members include the Co-PIs, the study coordinator, and research assistants.

Phase 2: Study records include regulatory documents, the protocol, consent forms, subject demographic information, and participant data (study questionnaires, electronic medical data, patient portal data). The Yale PI will be responsible for maintaining the study documentation. Flies that need to be shared by research team members will be in s Secure Box folder on the Yale Server. Research team members include the Co-PIs, the study coordinator, and research assistants.

8.5 Access to Source

Phase 1: Not applicable.

Phase 2: Source data consists of data collected from the electronic medical record and from the patient portal. Select personnel at each clinic will collect this data, record or export datato a study record form, de-identify the data, and securely transfer it to the PIs.

8.6 Retention of Records

Phase 1: Audio files will be destroyed as soon as the transcript has been checked. Transcripts of interviews (de-identified) will be maintained for one year or upon completion of a published manuscript of the aggregate data.

Phase 2: All data will be de-identified using a code number for each participant. De-identified data will be kept until all study results have been analyzed and manuscripts published or as long as legally required, whichever is longer and then destroyed.

8.7 Data and Safety Monitoring Plan

Phase 1: Not applicable

Phase 2: There will not be a data and safety monitoring board for this feasibility and pilot study. All participants will continue to receive standard care at the clinic. The co-PIs will monitor for any adverse events and the overall risk of the study.

The co-PIs (Whittemore and Wagner) are responsible for monitoring individual events and determining whether the study protocol needs modification to minimize risk.

The research team will have at least monthly meetings to review individual cases and ensure close monitoring of participants. If the team considers it appropriate, with a signed release of information from the participant, we will give any relevant information regarding the participant's health to their medical care providers.

9 Study Considerations

9.1 Institutional Review Board (IRB) Review

Phase 1: The protocol will be submitted to the IRB for review and approval. Approval of the protocol must be obtained before initiating any research activity. Any change to the protocol will require an approved IRB amendment before implementation. The IRB will have final determination whether informed consent and HIPAA authorization are required.

Study closure will be submitted to the IRB after all research activities have been completed.

Other study events (e.g. data breaches, protocol deviations) will be submitted per Yale policies.

Phase 2: Same as above.

9.2 Research Personnel Training

All study staff will receive certified IRB training. They will also be trained in all study procedures including informed consent, data collection, data confidentiality, and data analysis as appropriate.

9.3 Study Monitoring

Phase 1 and Phase 2: The Yale PI will monitor the implementation of all study procedures, assuring adequate training and completion of study related tasks. She will role play the informed consent procedure prior to starting study recruitment. Weekly meetings will be held with all research personnel to discuss study related activities and compliance with protocol. All questions related to study implementation will be discussed at this meeting. Procedures will be reviewed and modified as needed, obtaining IRB amendments if indicated.

9.4 Unanticipated Problems and Protocol Deviations

Phase 1: A protocol deviation is any noncompliance with the protocol. The noncompliance may be either on the part of the participant, the investigator, or the study site staff. As a result of deviations, corrective actions are to be developed by the site and implemented promptly.

It is the responsibility of the site investigator to identify and report deviations within 7 working days of identification of the protocol deviation. All deviations must be addressed in study source documents, reported to the study sponsor, and the reviewing Institutional Review Board (IRB) per their policies.

Unanticipated problems involving risks to participants or others include, in general, any incident, experience, or outcome that meets all of the following criteria:

- Unexpected in terms of nature, severity, or frequency given (a) the research procedures that are described in the protocol-related documents, such as the Institutional Review Board (IRB)-approved research protocol and informed consent document; and (b) the characteristics of the participant population being studied;

- Related or possibly related to participation in the research ("possibly related" means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research); and
- Suggests that the research places participants or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

If the study team becomes aware of an unanticipated problem (e.g. data breach, protocol deviation), the event will be reported to the IRB by email.

The UP report will include the following information:

Protocol identifying information: protocol title and number, PI's name, and the IRB project number;

- A detailed description of the event, incident, experience, or outcome;
- An explanation of the basis for determining that the event, incident, experience, or outcome represents an UP;
- A description of any changes to the protocol or other corrective actions that have been taken or are proposed in response to the UP.

To satisfy the requirement for prompt reporting, UPs will be reported using the following timeline:

- UPs will be reported to the IRB within 24 hours of the investigator becoming aware of the event.

9.5 Study Discontinuation

Phase 1: We do not anticipate any circumstances under which the study may be discontinued.

Phase 2: We do not anticipate any circumstances under which the study may be discontinued.

9.6 Study Completion

Phase 1 and Phase 2: The study completion date will be approximately 2 years after funding is received. The IRB will be notified by completing the appropriate forms.

9.7 Conflict of Interest Management Plan

Phase 1 and Phase 2: The independence of this study from any actual or perceived influence, such as by the pharmaceutical industry, is critical. Therefore, any actual conflict of interest of persons who have a role in the design, conduct, analysis, publication, or any aspect of this trial will be disclosed and managed. Furthermore, persons who have a perceived conflict of interest will be required to have such conflicts managed in a way that is

appropriate to their participation in the trial. The study leadership in conjunction with the appropriate conflict of interest review committee has established policies and procedures for all study group members to disclose all conflicts of interest and will establish a mechanism for the management of all reported dualities of interest.

All investigators will follow the applicable conflict of interest policies.

9.8 Funding Source

NIH: National Institute on Minority Health and Health Disparities

9.9 Publication Plan

The Yale PI holds primary responsibility for publishing the study results. Results of this study will be published in a timely manner upon completion of the study.

10 Appendices

Appendix #	Title	Section	Topic
1	Data Collection		
2	Intervention Protocols		

11 List of Tables