The My Diabetes Care Patient Portal Intervention for Mobile Devices: A Usability Study

NCT04894916

Protocol and Statistical Analysis Plan

May 22, 2021

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1.0 Background

Diabetes is a leading cause of cardiovascular disease, renal failure, vision loss and non-traumatic lower limb amputations. Diabetes self-management can prevent or delay diabetes-related complications, yet patients struggle to consistently engage in recommended self-care behaviors. Patients with diabetes may lack the understanding and motivation necessary to successfully manage their disease. Among patients with diabetes, studies have found that higher patient activation (i.e., knowledge, skills and confidence to manage their own health and care) is associated with healthy eating, blood sugars monitoring, eye exams and immunizations. Many of these findings were reported in diverse and disadvantaged populations.

Patient portals offer a vehicle for interventions aimed at increasing patient activation, improving understanding, and promoting self-management, while overcoming the limitations of costly and difficult to scale face-to-face programs. We recently applied user-centered design sprint methodology and key strategies for patient engagement to develop a multi-faceted patient portal intervention, My Diabetes Care (MDC), designed to help patients better understand their diabetes health data as well as support self-management. MDC was embedded within an established patient portal, My Health at Vanderbilt (MHAV), on Epic's MyChart platform and best viewed on desktop devices. MDC uses infographics to visualize and summarize patients' diabetes health data, incorporates motivational strategies (e.g., social comparisons), and provides literacy-level appropriate educational resources. MDC is grounded in a well-established Chronic Care Model (CCM) adapted for eHealth (i.e., healthcare practices supported by electronic processes and communication). By leveraging elements within the Model's five domains (self-management support, delivery system design, decision support, clinical information systems, and eHealth education), MDC has the potential to create more informed and activated patients leading to improved outcomes.

In a prior longitudinal study of the MDC, participants, including those with limited HL, highly rated its usability, anticipated continued use, and reported that it improved their understanding of their personal diabetes health data. In addition, participants' patient activation scores significantly increased over the study period. When asked to identify enhancement that would increase their satisfaction with MDC participants indicated a desire use MDC on mobile devices. Moreover, most patient portal users now access the portal via mobile devices. Thus, we designed and assessed task-based usability of a mobile-friendly version of MDC. We found the final prototype of MDC Mobile (MDC-m) was very satisfying for participants to use.

2.0 Rationale and Specific Aims

To assess usage patterns, user experience, and to uncover errors in functionality prior to larger interventional trials, we will conduct a longitudinal usability study MDC-m. The study will utilize questionnaires to quantify participants' perceptions and responses to the MDC-m and semi-structured interviews to comprehensively assess users' experience, barriers to use, and reasons for non-use or discontinued use. Combining qualitative and quantitative assessments of usability identifies more usability concerns than quantitative (e.g., questionnaires) assessments alone. Each participant will have access to the MDC-m for 1 month from the time of enrollment. This duration allows sufficient time for participants to become familiar with MDC-m and determine if and how to use MDC-m in the management of their diabetes.

In the current study, we aim to: (1) assess the feasibility of the intervention and (2) the usability of the MDC-m over time among a diverse group of patients with type 2 diabetes mellitus (T2DM).

3.0 Inclusion/Exclusion Criteria

Participants will be eligible for the study if they have T2DM, currently taking at least one medication for diabetes, are able to speak and read in English, are age 21 or over, have reliable access to a smartphone or tablet with internet access and have a MHAV account.

We will exclude patients living in long term care facilities, patients with known cognitive deficits, patients with severe visual or hearing impairment, patients with unintelligible speech (e.g., dysarthria), and patients currently participating in other diabetes related studies.

4.0 Enrollment/Randomization

Participants will be able to complete an electronic consent form and enroll online via Research Electronic Data Capture (REDCap™) version 5.0.8.

5.0 Study Procedures

Setting. The Vanderbilt Adult Primary Care (VAPC) clinics are located throughout the greater Nashville, TN area. An EHR (Epic Systems Corp.) stores all clinical data and patients receive access to their clinical data via an integrated and highly-adopted patient web portal, My Health at Vanderbilt (MHAV), that is accessible on desktops and via a native mobile app for iOS and Android mobile operating systems.

Participants and Recruitment. Potential participants will be identified automatically using VUMC's *Subject Locator* to query the EHR for patients with upcoming clinic appointments who meet the discrete inclusion and exclusion criteria. In addition, VUMC population health and quality improvement initiatives have created a report that identifies established patients with diabetes who receive care at the primary care clinics participating in the study. These patients are the target population for study (i.e., Vanderbilt primary care patients with diabetes) and as such these patients are potentially eligible to participate in the study. With permission of the clinic director, potentially eligible patients, will be mailed a recruitment letter describing the study and providing contact information for IRB approved study personnel. If after a receiving the letter, a patient is interested in the study, the patient may contact study personnel to learn more and consider participating in the study. The recruitment letter will include a QR code and URL link to the eligibility screener in Research Electronic Data Capture (REDCap). Participants whose REDCap screener indicates they are eligible can advance to the REDCap ICD. Participants will complete an electronic consent form and enroll online via REDCap. Our target enrollment is 65 participants. In accordance with best practices and to reflect a range of patient experience with diabetes and groups with distinct usability needs, we will aim to recruit a study sample with at least 25% representation of each of the following characteristics: (a) limited health literacy and (b) age 65 or over. Some participants may have one or more of these characteristics.

Data Collection and Outcome Measures. Study participants will complete questionnaires electronically via email using REDCap at two time points: enrollment (T_0) and end of study (T_1). Participants will complete an enrollment questionnaire (T_0) including basic sociodemographic questions and validated measures of health literacy and eHealth literacy.

The primary outcome measures **(Table 1)** will be: (a) ease of use and satisfaction as assessed by the System Usability Scale at T_1, (b) system usage data of MDC-m at T_1, (c) user experience as assessed by end of study questionnaire and semi-structured interviews at T_1. In addition, we will assess pre/post change in the following secondary cognitive and behavioral outcomes (Table 1) to estimate effect size and standard deviations for power analyses necessary to plan subsequent randomized controlled trials.

Table 1. Outcome Measures

Primary Outcomes	Measures	Variable Type	How Collected	Time Point
Usability	System Usability Scale	Continuous	Questionnaire	T_1
System usage data	MDC-m visits Duration of MDC-m visits	Continuous and categorical	Self-report	T_1
User experience	Assess participants' perspectives on content, layout, acceptance, and particular features and functionality	Categorical, Qualitative	Questionnaire, Interviews	T_1
Secondary Cognitive/Behavioral Outcomes				
Diabetes knowledge	Short Diabetes Knowledge Instrument (SDKI)	Continuous	Questionnaire	T_0 and T_1
Diet adherence	Summary of Diabetes Self-Care Activities (SDSCA) – General Diet Subscale Summary of Diabetes Self-Care Activities (SDSCA) – Specific Diet Subscale	Continuous	Questionnaire	T_0 and T_1
Exercise adherence	SDSCA – Exercise Subscale	Continuous	Questionnaire	T_0 and T_1
Medication adherence	Adherence to Refills and Medications Scale	Continuous	Questionnaire	T_0 and T_1
Glucose self-monitoring adherence	SDSCA – Self-monitoring of Blood Glucose Subscale	Continuous	Questionnaire	T_0 and T_1
Medication adherence	Adherence to Refills and Medications Scale (ARMS)	Continuous	Questionnaire	T_0 and T_1
Diabetes self-efficacy	Perceived Diabetes Self-Management Scale (PDSMS)	Continuous	Questionnaire	T_0 and T_1
Diabetes distress	Problem Areas in Diabetes Scale (PAID)-5	Continuous	Questionnaire	T_0 and T_1
Knowledge of Diabetes Measures	Unique study specific items to assess participants' knowledge of measures of diabetes health status	Categorical	Questionnaire	T_0 and T_1
Diabetes Attitudes	Unique study specific items to assess participants' attitudes toward social and goal-based comparison information regarding their diabetes health status	Categorical	Questionnaire	T_0 and T_1

Diabetes Readiness for Change	Four items assessment resources to assess stage of change based on the Transtheoretical Model (TTM) of behavior change. It includes questions on physical activity, medication management, glucose self-monitoring, and diet.	Categorical	Questionnaire	T_0 and T_1

Based on pilot testing, we estimate time to completion for questionnaires to be 20 minutes at T_0 and 25 minutes at T_1. Participants will be compensated $40 for completing the enrollment questionnaire, $35 for completing the study end questionnaire, and $5 for first 10 minutes of MDC-m use during which participants will be encouraged to familiarize themselves with the full functionality of the MDC-m.

At the conclusion of their one month of MDC-m access, we will conduct one-on-one, semi-structured interviews with a subsample of at least 10 participants including at least two participants from each of the purposively sampled groups (i.e., participants with limited health literacy and age 65 or over). This methodology is most appropriate for in-depth assessment of patients' perceptions and reactions regarding a proposed intervention. Interviews are preferred over focus groups for understanding usability because focus groups can amplify bias and individual opinions. Interviews will take place by phone or via Zoom within two weeks of participants concluding their one month of MDC-m access and will last approximately 30-40 minutes. Participant MDC-m access will be available during the interview to allow participants to recall and/or reference particular concerns or perceptions of usability. A trained interviewer will use a semi-structured interview guide to facilitate the interview and elicit in-depth understanding of participants' perceptions and experiences with specific MDC-m functionality as well as barriers to use, and reasons for non-use or discontinued use. Additional participants will be enrolled until saturation is reached. Saturation will be defined as no new usability concerns raised in the preceding two interviews and typically occurs between 10 and 30 interviews. Participants will be compensated an additional $40 for the interview.

6.0 Statistical Analysis Plan

We will use descriptive statistics to characterize the study participants and survey data. We will use a one sample t-test to compare the mean SUS score at T1 to the threshold score of 71 indicative of "good" usability. To assess whether there was a significant improvement in the continuous secondary cognitive/behavioral outcomes from baseline to end of study (T0 to T1), we will perform two-sided paired t-tests on the pairwise differences. If any of the distributions of pairwise differences suggest asymmetry or nonnormality, the non-parametric Wilcoxon signed-rank test will be performed in lieu of paired t-tests. We will use the McNemar's test for to compare paired proportions. Our primary outcome will be System Usability Scale (SUS) score at the end of the study period (T1).