Assessment and Intervention for Diabetes Distress in Primary Care Using Clinical and Technological Interventions: Protocol for a Pilot Study

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Table of Contents

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Abstract

Background: Background

In the United States, diabetes is the eighth leading cause of death [1], with an estimated 38 million people living with diabetes [1]. This chronic condition requires consistent care for effective management to help avoid poor health outcomes [2]. In fact, it is estimated that people with diabetes (PWD) spend over 8,000 hours per year managing their diabetes outside of medical settings [3]. Diabetes distress is the disruptive and demanding emotional response to these daily demands of living with diabetes [4]. This emotional burden associated with diabetes is pervasive, with one in four people experiencing severe diabetes distress [4]. DD is associated with negative impacts on engagement in self-care and self-management behaviors, medication adherence, and exacerbation of mental health conditions [5].

Accordingly, the American Diabetes Association (ADA) recommends that diabetes care be delivered by an interdisciplinary team with a person-centered approach [6], and that it include regular screening for and monitoring of DD in routine diabetes care for PWD with treatment for DD to be provided by practitioners with specific training to address DD [5]. Additionally, a recent white paper by the National Committee for Quality Assurance (NCQA) suggested having a variety of pathways to tailor DD treatment for individuals who screen positive for DD by involving relevant healthcare professionals and care modalities [7]. Yet, in everyday clinical settings DD is infrequently identified and only a small number of PWD are asked how diabetes affects their life by their healthcare professionals [8]. As primary care is where most people receive their diabetes care, it is a crucial setting within which to assess and address DD [9,10]. However, there remains a lack of consistent screening for DD within primary care, which likely contributes to the emotional burden of diabetes going undetected and untreated [4,11]. Thus, even though DD is highly prevalent and there exist well-validated measures to assess for DD, there is a significant knowledge gap in best practices for implementing DD screening and treatment interventions systematically in primary care.

Clinical decision support systems (CDSS) have proven effective for prompting providers to deliver recommended care [12]. In general, CDSS improve healthcare delivery through the utilization of technology to enhance clinical-decision making, sometimes even using data and observations that are normally unobtainable by providers alone [13]. Clinical decision support technology leverages electronic health records, medical knowledge databases, and algorithms to provide patient-specific recommendations, thus enabling providers to make more informed decisions [14]. Benefits can include a reduction in medical errors, enhanced patient safety, improved decision-making, and scalability [14]. The recent integration of AI into healthcare technology has led to the classification of CDSS as either knowledge-based systems using traditional technology frameworks, or non-knowledge-based systems to indicate the utilization of AI to transform data into information for the user [15]. Recent reviews of studies that focus on the implementation of non-knowledge-based CDSS in diabetes care have demonstrated significant improvements in patients'

blood glucose, blood pressure, and lipid profiles in 71%, 67%, and 38% of the studies, respectively [15]. While CDSS can promote diabetes care by facilitating patient self-management, it is hoped that further emerging technology will allow for more efficient and effective management for many people living with diabetes [15].

Objective: Objective & Aims

The primary objective of this study is to assess the feasibility and accessibility of using interactive health information technology integrated into primary care workflows to improve screening and treatment for diabetes distress. This project will examine the technical and operational feasibility, patient and provider experience, and behavioral health outcomes of a new technology-supported workflow to conduct screening for diabetes distress and provide follow-up treatment by a multidisciplinary team in a primary care setting.

The aims of this pilot study are to (1) Design and implement individualized technology-supported DD workflows, (2) Evaluate the acceptability and integration of technology-based workflows to provide treatment for DD, and (3) Evaluate the change in DD (baseline, 3 months, and 6 months) in patients receiving screening and personalized treatment for it. Symptoms of anxiety and depression will also be evaluated.

Methods: Methods

Study Design

We propose a pilot clinical trial to be conducted at a suburban multi-disciplinary family medicine practice in an academic medical setting. The study is designed to provide feasibility and acceptability data for the development of DD-based screening and treatment using technology and clinical intervention.

Participants

Up to 30 adult English and/or Spanish-speaking patient participants with a diagnosis of type 1 diabetes or type 2 diabetes who receive their diabetes care from two primary care physicians at the primary care practice will be enrolled in the study. Clinic staff engaged in the new workflows for diabetes distress will also be invited to participate in surveys and interviews about their experience with the technology-supported intervention following completion of the study.

Inclusion Criteria: Age at time of consent 18-89 years; diagnosed with type 1 or type 2 diabetes; patient at the primary care clinic; able to understand English or Spanish; willing and able to sign the Informed Consent Form (ICF); willing to be contacted by the study team through the patient portal, phone, or text to complete study measures; ability to reliably send and receive text messages.

Exclusion Criteria: Participation in another study that might interfere with participation in this study; unable to follow the study procedures for the duration of the study or is deemed unacceptable to participate in the study per PI judgment; participant or participant’s immediate family member is an employee of the healthcare chatbot company providing services for the study; planning to move in the next 6 months; planning to change primary care practices in the next 6 months.

Data Collection

Outcome Measures

Both qualitative and quantitative methods will be used to assess study outcomes at the patient level, practice level, and technology system level. Patient-level health outcomes include DD, depression, and anxiety measured at baseline, 3 months, and 6 months using the T1-DDAS or T2-DDAS, PHQ-8, and GAD-7. User experience with technology will be assessed through administration of the UMUX-lite at 3 months, the System Usability Scale at 3 months, and a technology use assessment at baseline and 3 months. In addition, qualitative data from interviews and responses to open-ended survey items will be collected from practice staff, primary care physicians, and patients to determine the acceptability and feasibility of implementing screening and technology-supported treatment for diabetes distress. Further, PCPs will complete the Diabetes Distress Provider Time Survey to track activities and time spent on workflow tasks. Acceptability with the eConsults will be evaluated by standard data collection protocols in the EHR. eConsult data will capture the sent requests from PCPs and responses given by specialists. AI chatbot performance data will be collected from the chatbot system and used to evaluate engagement with the AI chatbot according to the People at the Center for Mobile Application Design (PACMAD) framework [23]. Table 1 lists the measures to be collected for this study in detail.

Results: Results

Implementation Status
The principal investigator met with clinic leadership to describe the project and obtained buy-in from the team. Workflows were developed that outline study design and patient flow (see Figure 1). The principal investigator conducted a team training with the clinic where this study will take place as well as met with the primary care physicians that will be participating in this study to provide education and training on diabetes distress, an overview of validated measures for diabetes distress (e.g., T1-DDAS and T2-DDAS) and conversational tools that can be used to support people with diabetes and diabetes distress.
T1-DDAS and T2-DDAS scoring was incorporated in the EHR through an EHR build. Chatbot content specific to diabetes distress was developed with assistance from two leading diabetes psychologists with expertise in diabetes distress. The chatbot was field tested by the primary research team and patients with diabetes through a patient advisory committee and feedback was incorporated in refinements of the chatbot content.

Recruitment Status
Patient recruitment is anticipated to begin during late June-July 2024.

Research Status
IRB approval was obtained on March 15, 2024. We have signed contracts with RAs that will be performing the duties of providing outreach to eligible patients, obtaining informed consent from patient participants, administering screening tools at the 3 month post screening and 6 month post-screening timepoints. Additionally, RAs will ensure that data collection from patient screeners is complete and documented appropriately. Following 3 months post screening, research assistants will conduct the semi-structured interviews and administer the survey questions with both patients and clinical staff. At the 6 month study timepoint, the primary team will send the remaining screeners to patient participants. The primary research team has been meeting weekly since November 2023 to develop the research plan and discuss project tasks.

Technology Status
Licensing agreements and institutional risk assessment approval for the AI chatbot were obtained before patient recruitment. The AI chatbot was initially beta-tested by the primary research team and patients with diabetes to determine if messages could be delivered on a schedule and that the system could get replies back. The beta-test revealed that additional content related to suicidality and ‘hating having diabetes’ was needed, more training on the model to correctly match intents to the content library was needed, and that more of the intents had existing content in the chatbot library but that improving the link to these was still needed. Prior to study launch, the primary research team retested the chatbot system to ensure that the updates had been completed.
eConsults are an active clinical care option for PCPs at our institution, fully integrated into the EHR and in use by over 28 specialties [25]. As a result, they are a readily usable aspect of this study. For our study, specialists available by eConsults will include behavioral health, social work, care management, diabetes education, pharmacy, and endocrinology.
T1-DDAS and T2-DDAS were created and incorporated into the EHR as flowsheets. The PHQ-8 and GAD-7 are already embedded in the EHR. The results of the diabetes distress screeners will be able to be pulled into visit documentation, facilitating care coordination with eConsulted providers. Additionally, flowsheet data can be tracked over time and will be easily accessible for providers to review during and after patient visits.

Funding Status
Funding for this study was secured from the Peer Mentored Care Collaborative (PMCC) in January 2024.

Conclusions: Conclusions
Creating and disseminating workflows for screening and treating DD in primary care is an important component for delivering whole-person diabetes care. The use of an AI chatbot to deliver individualized treatment and support for DD and eConsults providing additional specialty support are expected to help increase support and treatment for DD without contributing to increased workload for primary care practices. This study is intended to help us to begin to understand how to implement diabetes distress screening and treatment in primary care settings in a scalable and real-world manner. Clinical Trial: N/A

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Abstract

Background: Diabetes distress (DD) is a common emotional response to living with diabetes. If not addressed, DD can have negative impacts on diabetes management, including progression to other mental health conditions such as depression and anxiety. Routine screening and treatment for DD is recommended, with primary care being an ideal setting given that the majority of people with diabetes receive their diabetes care from primary care providers. Research is needed to understand how to effectively and feasibly integrate DD screening and treatment into routine diabetes care.

Objectives: This study aims to (1) Design and implement individualized technology-supported DD workflows, (2) Evaluate the acceptability and integration of technology-based workflows to provide treatment for DD, and (3) Evaluate the change in DD (baseline, 3 months, and 6 months) in patients receiving screening and personalized treatment. Additional outcomes include evaluating changes in symptoms of depression and anxiety.

Methods: Thirty English and Spanish-speaking primary care patients with either type 1 or type 2 diabetes will receive screening for DD during clinical visits and subsequent support from an artificially intelligent (AI) healthcare chatbot with interactive tailored messaging. Patients with moderate DD will be referred through electronic consultation (eConsult) to specialty providers (including behavioral health) if needed. Patients with severe DD will be referred through eConsult for behavioral health care in addition to other specialty providers if needed. Health outcomes will be measured through validated screening measures for DD symptoms, depression, and anxiety. Technological outcomes will be measured through surveys assessing user experience with technology and system usability, and by system performance data. Qualitative data on acceptability and satisfaction with the clinical workflows and technological interventions will be collected through interviews with patients and clinical providers.

Results: Workflows for screening and treating DD have been approved and clinical staff have received training on the process. Electronic surveys for screening measure collection have been created. Data from visit screeners will be entered into the electronic medical record during the medical appointment. Messaging content for the AI chatbot has been developed and its delivery beta tested with the research team. Recruitment will begin in July 2024.

Conclusions: This study is expected to demonstrate the feasibility and acceptability of integrating individualized workflows for DD into primary care. Improving clinical and technological interventions for addressing diabetes distress in primary care can provide alternative care options for busy primary care providers.

Keywords: diabetes distress; primary care; healthcare chatbot; artificial intelligence; eConsult

Introduction

Background

In the United States, diabetes is the eighth leading cause of death [1], with an estimated 38 million people living with diabetes [1]. This chronic condition requires consistent care for effective management to help avoid poor health outcomes [2]. In fact, it is estimated that people with diabetes (PWD) spend over 8,000 hours per year managing their diabetes outside of medical settings [3]. Diabetes distress is the disruptive and demanding emotional response to these daily demands of living with diabetes [4]. This emotional burden associated with diabetes is pervasive, with one in four people experiencing severe diabetes distress [4]. DD is associated with negative impacts on engagement in self-care and self-management behaviors, medication adherence, and exacerbation of mental health conditions [5].

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Objective & Aims

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Intervention Implementation Process

Pre-Implementation

The principal investigator conducted a practice-level training session for clinical team members. The training included an orientation to DD, person-first language, a review of the DD screeners, and a brief introduction on how to support patients experiencing DD. This training was informed by

expertise from clinical experts on DD.

Implementation

Patients will complete informed consent to participate in the research study. After being consented, they will attend a scheduled diabetes-specific visit with their primary care physician (PCP). The workflow for the diabetes-specific visit is presented in Figure 1. At clinic check-in, front desk staff or a medical assistant (MA) will provide the patient with the appropriate assessment to complete based on their diagnosis, either the Type 1 Diabetes Distress Assessment System (T1-DDAS) [16] or the Type 2 Diabetes Distress Assessment System (T2-DDAS) [17]. Clinic staff will also provide the patient with the Patient Health Questionnaire (PHQ-9) [18] to assess for symptoms of depression and the Generalized Anxiety Disorder-7 (GAD-7) [19] to assess for symptoms of anxiety. The PHQ-9 and GAD-7 questionnaires are already part of the rooming process and thus not an addition to the established workflow. During the visit rooming process, the MA will enter the results of the screeners (e.g., PHQ-9, GAD-7, T1-DDAS or T2-DDAS) into the flowsheets in the electronic health record (EHR).

If there is a negative screen on the T1-DDAS or T2-DDAS, the MA will communicate this to the PCP. The PCP will then provide validation and encouragement based on the skills they learned in the team training. The patient and provider will then collaboratively determine which aspect(s) of DD the patient would like to start to receive information and/or guidance on from the artificially intelligent (AI) chatbot. Even though the patient is not currently experiencing DD, it is hypothesized that receiving coping skills and other information from the chatbot will help mitigate future distress. The PCP will send these identified areas through the EHR to the research team so they can send a push notification from the AI chatbot to the patient's cell phone in these specific areas.

If there is a positive screen on the T1-DDAS or T2-DDAS, the MA will communicate the severity and source of DD to the PCP. On the T1-DDAS there are 10 Sources of distress including Financial Worries, Interpersonal Challenges, Management Difficulties, Shame, Hypoglycemia Concerns, Healthcare Quality, Lack of Diabetes Resources, Technology Challenges, Burden to Others, and Worries About Complications. The T2-DDAS indicates specific areas or Sources of distress that people with type 2 diabetes may experience. On the T2-DDAS there are 7 Sources of distress including Hypoglycemia, Long-term Health, Healthcare Provider, Interpersonal Issues, Shame/Stigma, Healthcare Access, and Management Demands. The research team has developed specific content areas for Sources of distress for both the T1-DDAS and T2-DDAS meant to provide targeted and individualized material to support the needs of patients delivered through the AI chatbot. The study design for levels of DD are the same for type 1 and type 2 diabetes. There are 3 levels of distress on the T1-DDAS and T2-DDAS: 1. Mild, 2. Moderate, 3. Severe. The levels and source of distress will guide clinical decision-making and intervention pathways that are selected. For each level of distress, the PCP will provide validation and support to patients based on skills they learned during the team-training. For mild levels of DD on the T1-DDAS or T2-DDAS, the PCP will discuss the top three sources of distress with the patient and the patient will then obtain a push notification on their cell phone from the AI chatbot on these specific areas. For moderate levels of diabetes distress on the T1-DDAS or T2-DDAS, the provider will discuss the main sources of distress with the patient and determine if an eConsult or referral might be indicated based on the needs of the patient in addition to the AI chatbot. An eConsult to the following specialists will be made available: endocrinology, clinical pharmacy, social work/care management, diabetes education, and behavioral health (BH). For severe levels of DD on the T1-DDAS or T2-DDAS, the PCP will discuss/provide a referral to behavioral health, collaboratively determine which areas of distress would be more relevant for the patient to receive from the AI chatbot and determine if an eConsult to any of the above stated specialties would be indicated. Integrating eConsults into the treatment process allows the PCP to ask a specific clinically oriented question about their patient and obtain an asynchronous response from the specialist. Thus, allowing for shared care decisions between the PCP and specialist

without having to refer the patient to an in person appointment and leading to a possible delay in care [20].

AI Chatbot Intervention

All patient participants, regardless of whether they have DD or the severity of the DD, will be enrolled to receive text messages from the AI chatbot. The AI chatbot will provide education on DD, normalization of DD, suggestions for solution-focused coping strategies, and information provision on patient resources and support. For patients not reporting symptoms of DD, chatbot messaging will be seen as a preventative measure to provide information and build awareness of DD should this arise in the future. For patients reporting DD, the AI chatbot will be seen as a resource to provide suggestions for coping strategies connecting to local support resources and/or psychoeducational material. Following a collaborative discussion with their PCP on the sources of DD that they would like to receive support on, they will obtain a push notification with the top 3 identified areas of distress. Following this initial conversation, the AI chatbot will deliver a 12-week curriculum on topics specifically related to DD and the sources of DD (for either the T1-DDAS or T2-DDAS). Development of the AI chatbot content was overseen and reviewed by DD expert consultants.

The technology will facilitate error free delivery of messages via text to user cell phones using an AI chatbot that deploys natural language processing (NLP) for highly precise communications. We will maximize chatbot precision so that users are more often sent a response from our system that matches the intent of their query. Specifically, we have developed and categorized anticipated “intents”—i.e., the specific topics we believe people want to learn or ask about DD and self-management, along with 25-50 variations on ways to ask each question. Question variations allow the system to have enough initial data to learn how to interpret user questions, tolerate misspellings, and recognize the underlying intent of each question. When the system cannot match a response to the question intent, it reverts to a fixed choice (called a “pick list”) of responses, e.g., “I think you are asking about one of these topics: (1) Cost of diabetes medicine, (2) Cost of treatment, (3) Where to find medications near me. Please type the number corresponding to the topic you wish to explore or try your question again.” We rely on data augmentation techniques to create and continuously update a robust library of questions and question variations that the system draws on to generate precise and consistent responses to user queries. We do this through “lemmatization” and “stemming”, both processes that group together the different inflected forms and stems of a word so they can be analyzed as a single item (e.g., runs, run and running are all forms of the word ‘run’ and thus ‘run’ is the lemma, or root, for all these words). After doing this pre-process work on our prototype dataset, we use Multinomial Naïve Bayes, Linear SVC and multi-class regression algorithms to anticipate prediction accuracy in correctly matching a response to a question.

eConsult Intervention

The eConsult system within the EHR provides a streamlined and timely consultative process that enhances communication between primary care providers and specialists regarding specific patient areas of distress. The PCP sends a focused question with relevant subjective and objective patient information to a specialist through the eConsult system. The specialist then reviews pertinent information from the EHR and responds to the PCP in a detailed fashion with recommendations regarding diagnosis, treatment, and follow-up plan.

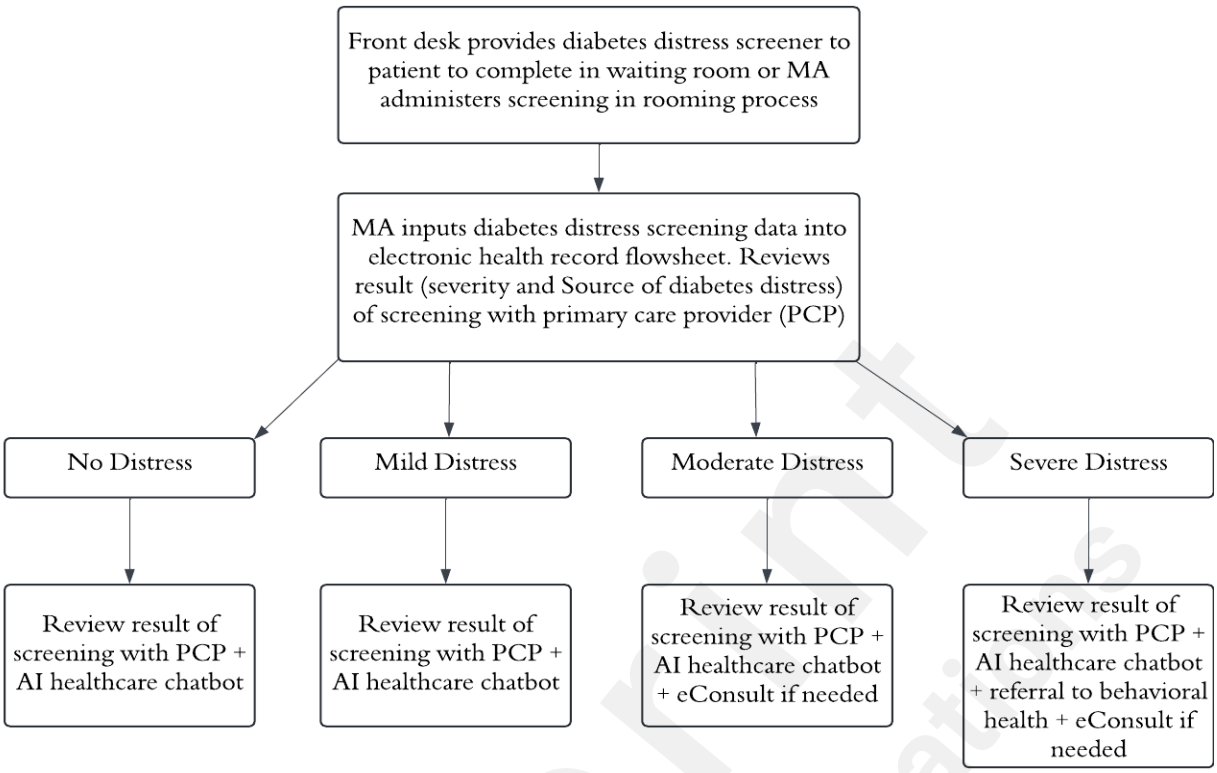
Following the collaborative conversation with the PCP in the diabetes-specific visit, an eConsult with different specialties (indicated above) will be placed through the electronic health record. eConsults will be used to assist with clinical decision-making and obtaining specialized knowledge and support from various healthcare professionals based on the specific source of diabetes distress. If the patient requires additional support, the eConsult system will allow for a conversion to an in-person or telemedicine visit with the needed specialty.

Post Study Intervention

Post-study timepoint 1 (3 months following initial screening**):** the research assistant (RA) will send patients a link to complete the screening measures through the patient portal. The screening measures completed at 3 months post screening will assess for diabetes distress, symptoms of depression and anxiety, and technology use (see Table 1). Outside the clinical setting, the PHQ-8 will be administered instead of the PHQ-9. The technology measures include the Usability Metric for User Experience-lite (UMUX-lite) [21], System Usability Scale (SUS) [22], Technology Use Assessment, AI Chatbot System Performance Metrics, eConsult System Performance Metrics. Qualitative data will be collected at 3 months post-screening. The RA will call each patient to conduct a semi-structured interview and ask survey questions if patients have not completed surveys electronically within 1 week. The qualitative interview will include questions about participating in screening for diabetes distress, experience with the AI healthcare chatbot, and being referred to specialty providers through eConsults. Further, the RA will obtain qualitative data through semi-structured interviews and survey questions with 6 clinical staff and both primary care providers who participated in the study. The questions for healthcare staff/providers will assess their time spent and experience implementing workflows that screen for diabetes distress and offer treatment options through provider support, AI healthcare chatbot, and eConsults.

Post-study timepoint 2 (6 months following initial clinic visit): the RA will send patients a link to complete the screening measures through the patient portal at the 6 month timepoint. The screening measures completed at the 6 month timepoint are included in Table 1. If patients do not complete the surveys electronically within 1 week, the RA will call to follow up and administer surveys via phone.

Figure 1. Primary care diabetes distress screening and treatment workflow



Methods

Study Design

We propose a pilot clinical trial to be conducted at a suburban multi-disciplinary family medicine practice in an academic medical setting. The study is designed to provide feasibility and acceptability data for the development of DD-based screening and treatment using technology and clinical intervention.

Participants

Up to 30 adult English and/or Spanish-speaking patient participants with a diagnosis of type 1 diabetes or type 2 diabetes who receive their diabetes care from two primary care physicians at the primary care practice will be enrolled in the study. Clinic staff engaged in the new workflows for diabetes distress will also be invited to participate in surveys and interviews about their experience with the technology-supported intervention following completion of the study.

Inclusion Criteria: Age at time of consent 18-89 years; diagnosed with type 1 or type 2 diabetes; patient at the primary care clinic; able to understand English or Spanish; willing and able to sign the Informed Consent Form (ICF); willing to be contacted by the study team through the patient portal, phone, or text to complete study measures; ability to reliably send and receive text messages.

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Data Collection

Outcome Measures

Both qualitative and quantitative methods will be used to assess study outcomes at the patient level, practice level, and technology system level. Patient-level health outcomes include DD, depression, and anxiety measured at baseline, 3 months, and 6 months using the T1-DDAS or T2-DDAS, PHQ-8, and GAD-7. User experience with technology will be assessed through administration of the UMUX-lite at 3 months, the System Usability Scale at 3 months, and a technology use assessment at baseline and 3 months. In addition, qualitative data from interviews and responses to open-ended survey items will be collected from practice staff, primary care physicians, and patients to determine the acceptability and feasibility of implementing screening and technology-supported treatment for diabetes distress. Further, PCPs will complete the Diabetes Distress Provider Time Survey to track activities and time spent on workflow tasks. Acceptability with the eConsults will be evaluated by standard data collection protocols in the EHR. eConsult data will capture the sent requests from PCPs and responses given by specialists. AI chatbot performance data will be collected from the chatbot system and used to evaluate engagement with the AI chatbot according to the People at the Center for Mobile Application Design (PACMAD) framework [23]. Table 1 lists the measures to be collected for this study in detail.

Table 1. Diabetes distress pilot study measures

Measure	Description	Collection Timepoints
Type 1-Diabetes Distress Assessment System (T1-DDAS)	30 items; 5-point Likert scale. Assesses the emotional impact of living with Type 1 Diabetes. Determines the severity and Source of DD. The Source(s) of DD indicates which aspect(s) of living with type 1 diabetes are creating challenges.	- Baseline (at initial clinic visit) - 3 month post screening - 6 month post screening
Type 2-Diabetes Distress Assessment System (T2-DDAS)	29 items; 5-point Likert scale. Assesses the emotional impact of living with Type 2 Diabetes. Determines the severity and Source of DD. The Source(s) of DD indicates which aspect(s) of living with type 2 diabetes are creating challenges.	- Baseline (at initial clinic visit) - 3 month post screening - 6 month post screening
Patient Health Questionnaire-8 (PHQ-8)	8 items; 4-point Likert scale. Brief screener assessing symptoms of depression.	- Baseline (at initial clinic visit) - 3 month post screening - 6 month post screening
Generalized Anxiety Disorder-7 (GAD-7)	7 items; 4-point Likert scale. Brief screener assessing symptoms of anxiety.	- Baseline (at initial clinic visit) - 3 month post screening

		- 6 month post screening
Usability Metric for User Experience-lite (UMUX-lite)	2 items; 7-point Likert scale. Brief measure assessing participant's experience of technology (i.e., AI chatbot).	- 3 month post screening
System Usability Scale (SUS)	10 items; 5-point Likert scale. Brief measure assessing the usability of the technology (i.e., AI chatbot).	- 3 month post screening
Technology Use Assessment	12 item survey assessing user's comfort with and routine use of technology in daily life.	- Baseline (at initial clinic visit) - 3 month post screening
Practice Demographics	Clinic data (i.e., number of patients with diabetes, clinical staff and roles).	- Baseline
AI Chatbot System Performance Metrics	Engagement and operational metrics recording during the period of system use.	- 3 month post screening
eConsult System Performance Metrics	Operational metrics recorded during system use from study-specific standardized templates, including number of patients receiving eConsults, which specialists were eConsulted, what were the consult questions, time to response by the specialist, and did the patient follow up with the specialist if referred.	- 3 month post screening - 6 month post screening
Patient Demographics	Includes age, race/ethnicity, gender, sexual orientation, healthcare insurance type, and co-morbid medical diagnoses if applicable.	- Baseline
Qualitative Data - Clinical Staff	Semi-structured interview and survey questions. Questions assessing experience implementing new workflows and screening patients for diabetes distress from clinical staff.	- 3 month post screening
Qualitative Data - Patients	Semi-structured interview and survey questions. Questions assessing participants' experience of being screened for diabetes distress, using an AI chatbot, and being referred to targeted providers	- 3 month post screening

	using eConsults.	
Diabetes Distress Provider Time Survey	Survey form tracking the types of tasks and amount of time spent on tasks related to workflow	- PCP completes following each participant encounter

Data Analysis

Quantitative Data Analysis

The study team will use standard statistical packages (e.g., R) to conduct data analysis. Descriptive statistics (means, SD, frequency distributions, proportions) will be used to summarize baseline patient characteristics, clinical and behavioral outcomes, and other quantitative outcome measures and responses to closed-ended survey items. As a feasibility study, it is not powered for inferential analyses or power analyses, but the results are expected to inform future work. Based on results from similar studies, a 60% threshold will be used to determine technical and operational feasibility and user acceptability, i.e., 60% of participants remain engaged with the technology solutions throughout the duration of the study, and 60% of participants report positive experiences and satisfaction levels with the program overall [24].

Qualitative Data Analysis

This study's acceptance is determined by patient and health care provider user experience through interviews, clinical team member feedback, and responses to user experience surveys. An overall positive rating on tailored survey items or positive themes identified from qualitative data represents acceptability for this study. The program will be deemed acceptable among participants overall if 60% or more of participants report positive ratings and themes. Qualitative analysis of open-ended survey data and interview data will be conducted using rapid thematic and content analysis to assess user experience by identifying and exploring common topics and themes that emerge from participants' responses.

Ethical Considerations

Approval and Study Consent

This study has been approved by the Colorado Multiple Institutional Review Board (COMIRB) as protocol #24-0186. The principal investigator and primary care providers will assemble a patient list from the Diabetes Registry in the EHR and send this to the research assistant (RA). The RA will outreach to potential participants via the patient portal in the electronic medical record, by email, and/or by phone using scripted language to invite patients to participate. As part of enrollment, the patient will opt-in to receive text messages from the AI chatbot. If a patient declines to participate, this will be documented for evaluation purposes and so that the same patient is not re-approached in association with a future scheduled clinic visit. If the patient expresses interest in participating, the research team will complete informed consent and study enrollment prior to a future clinic visit. As part of the consent process, patients will agree to a chart audit by the research assistant within four weeks of their initial visit to ensure all initial measures are completed.

Safety and Potential Risks

The procedures utilized in the proposed research study pose no greater than minimal risks to patients and practices involved in the study. The AI chatbot is a non-generative system meaning that it does

not independently develop content. The primary clinical team has generated the content and reviewed by expert consultants on diabetes distress. Patients could experience worsening of their symptoms of diabetes distress as a result of interacting with the AI chatbot and discussing the emotional and psychological aspects of diabetes with their medical provider. However, we do not expect that these are likely risks for patients participating in the study. If these concerns arise through review of messages and chatbot interactions or as reported by patients, the principal investigator will review and refer as appropriate to other health care providers for follow-up. The clinic where this study will take place has fully staffed behavioral health providers integrated into the practice who will be available to discuss any concerns that providers and patients may experience.

Compensation

Patient participants will receive a small financial incentive at two separate time points. They will receive two $25 gift cards (totaling $50). The first $25 gift card will be given after enrollment in the study and completing the first set of surveys. The second $25 gift card will be given after completing the 3-month post-screening questionnaires. Providers will receive no direct financial incentive. The primary care clinic where this study will take place will receive a financial incentive for participating and attending the team training.

Results

Implementation Status

The principal investigator met with clinic leadership to describe the project and obtained buy-in from the team. Workflows were developed that outline study design and patient flow (see Figure 1). The principal investigator conducted a team training with the clinic where this study will take place as well as met with the primary care physicians that will be participating in this study to provide education and training on diabetes distress, an overview of validated measures for diabetes distress (e.g., T1-DDAS and T2-DDAS) and conversational tools that can be used to support people with diabetes and diabetes distress.

T1-DDAS and T2-DDAS scoring was incorporated in the EHR through an EHR build. Chatbot content specific to diabetes distress was developed with assistance from two leading diabetes psychologists with expertise in diabetes distress. The chatbot was field tested by the primary research team and patients with diabetes through a patient advisory committee and feedback was incorporated in refinements of the chatbot content.

Recruitment Status

Patient recruitment is anticipated to begin during late June-July 2024.

Research Status

IRB approval was obtained on March 15, 2024. We have signed contracts with RAs that will be performing the duties of providing outreach to eligible patients, obtaining informed consent from patient participants, administering screening tools at the 3 month post screening and 6 month post-screening timepoints. Additionally, RAs will ensure that data collection from patient screeners is complete and documented appropriately. Following 3 months post screening, research assistants will conduct the semi-structured interviews and administer the survey questions with both patients and clinical staff. At the 6 month study timepoint, the primary team will send the remaining screeners to patient participants. The primary research team has been meeting weekly since November 2023 to develop the research plan and discuss project tasks.

Technology Status

Licensing agreements and institutional risk assessment approval for the AI chatbot were obtained before patient recruitment. The AI chatbot was initially beta-tested by the primary research team and

patients with diabetes to determine if messages could be delivered on a schedule and that the system could get replies back. The beta-test revealed that additional content related to suicidality and 'hating having diabetes' was needed, more training on the model to correctly match intents to the content library was needed, and that more of the intents had existing content in the chatbot library but that improving the link to these was still needed. Prior to study launch, the primary research team retested the chatbot system to ensure that the updates had been completed.

eConsults are an active clinical care option for PCPs at our institution, fully integrated into the EHR and in use by over 28 specialties [25]. As a result, they are a readily usable aspect of this study. For our study, specialists available by eConsults will include behavioral health, social work, care management, diabetes education, pharmacy, and endocrinology.

T1-DDAS and T2-DDAS were created and incorporated into the EHR as flowsheets. The PHQ-8 and GAD-7 are already embedded in the EHR. The results of the diabetes distress screeners will be able to be pulled into visit documentation, facilitating care coordination with eConsulted providers. Additionally, flowsheet data can be tracked over time and will be easily accessible for providers to review during and after patient visits.

Funding Status
Funding for this study was secured from the Peer Mentored Care Collaborative (PMCC) in January 2024.

Discussion

Expected Findings

This pilot study is expected to demonstrate the acceptability and feasibility of implementing screening and treatment for DD in a primary care clinic. Through this study, workflows will be developed and implemented to screen for DD at a diabetes-specific visit. Following screening for DD, patients will engage in a clinical conversation with their PCP about the results of the screening measure. A tiered approach will be used to determine the type of intervention that is suggested to the patient. All patients (regardless of DD screening result) will receive access to the AI chatbot. Patients might also receive an eConsult to another healthcare specialist (e.g., social work, clinical pharmacy, care management, behavioral health, endocrinology, diabetes educator) to support the specific Source of DD. If levels of DD are in the high range, patients may also receive a referral to a behavioral health provider.

We anticipate that the use of technological interventions such as the AI chatbot and eConsults will be experienced positively by participants. It is expected that participants will view the AI chatbot as beneficial to their diabetes care and will find it easy to use. The semi-structured interviews will specifically request feedback on participant experience using the AI chatbot. The use of eConsults will allow PCPs to increase collaborative communication among the interdisciplinary team and provide participants with additional specialty services if needed. Having increased coordination among their primary care team will likely be seen as beneficial and helpful to participants.

This study is expected to increase provider and staff awareness and knowledge of screening for and intervening with diabetes distress through team and provider training. The training will provide opportunities for learning important psychological and emotional aspects of patients with diabetes that often go overlooked in clinical care. Clinical conversations focusing on the emotional side of living with diabetes are expected to be a new experience for patients in this study. While this might be a new type of clinical interaction, obtaining validation, normalization, reassurance, and empathy from their medical provider will likely be seen as a helpful and rewarding experience. Living with diabetes is a challenging undertaking that under the best of situations requires nuanced

interventions from providers and constant attention and monitoring on behalf of patients and their caregivers. Having a supportive environment to discuss challenging lived experiences is intended to improve the emotional burden of diabetes.

Even though DD has become increasingly viewed as an important aspect of diabetes care, there remains limited data on treatment approaches. Current literature points to the importance of addressing DD but interventions specifically focused on DD are needed [26]. Most studies do not examine DD as a primary outcome but deliver interventions focused on managing diabetes more broadly [26, 27]. This study will provide interventions that are meant to target DD specifically. The primary research team intends to continue pursuing funding opportunities to conduct larger studies in diabetes distress assessment and treatment in primary care settings.

Diabetes distress significantly impacts clinical, behavioral, and psychosocial outcomes in people living with diabetes. The majority of PWD receive their diabetes care in primary care. However, screening and treating DD does not routinely occur in primary care settings. The use of several interventions, including supportive dialogue with PCPs, an AI chatbot, and eConsults, will assist in delivering individualized treatment and support for DD without contributing to increased workload for primary care practices. Learning how to provide screening and treatment for DD in primary care settings is crucial to improving the care of people living with diabetes.

Limitations and Challenges

Given the current state of rapid evolution for AI technologies and associated policies governing AI use in practice, obtaining institutional approval to utilize the AI chatbot technology as part of patient care required an extensive review process. While healthcare technology continues to be seen as a scalable and feasible form of care delivery, administrative barriers can make implementation and usage challenging. Overcoming some of these barriers will likely contribute to increased uptake with technology.

Primary care is a fast-paced setting that is often stretched for resources, staffing, and time. Further, primary care is a diverse setting with varied access and structures to care delivery. Consequently, it is unlikely that a single approach or method to care is appropriate in all primary care settings. With significant variability in primary care, interventions need to have adequate flexibility to have a chance to be incorporated successfully into this care environment. Feasibility studies offer an opportunity to determine if interventions can be flexibly disseminated into primary care in a scalable fashion.

Conclusions

Creating and disseminating workflows for screening and treating DD in primary care is an important component for delivering whole-person diabetes care. The use of an AI chatbot to deliver individualized treatment and support for DD and eConsults providing additional specialty support are expected to help increase support and treatment for DD without contributing to increased workload for primary care practices. This study is intended to help us to begin to understand how to implement diabetes distress screening and treatment in primary care settings in a scalable and real-world manner.

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Authors' Contributions

MK, TO, SLM conceptualized the study. EK and JFG were involved in dissemination of the project. DS and JFT supervised the project and provided feedback. AS assisted with a literature search and adding content to the manuscript. MK drafted the manuscript and designed the figure and table. All authors reviewed and approved the final version of the manuscript.

Conflicts of Interest

TO has received funding through the University of Colorado for work related to diabetes technology, but has no COI related to diabetes distress, e-consults, or the use of an AI chatbot.

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Supplementary Files

Figures

Primary care diabetes distress screening and treatment workflow.