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Protocol for the Diabetes, Distress, and Disparities (3-D) Study: An explanatory sequential mixed-methods design

(Running title: Protocol for the Diabetes, Distress, and Disparities Study)

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ABSTRACT

Introduction: Psychosocial factors impact diabetes outcomes, yet healthcare systems remain inadequately equipped to address these needs. Research centering the experiences of people with diabetes (PWD) can inform program implementation, policies, and partnerships to address psychosocial care needs. The goals of the Diabetes, Distress, and Disparities (3D) Study are to quantify the psychosocial care needs of PWD in a large academic medical center, generate insights regarding how psychosocial factors shape diabetes outcomes, and identify modifiable determinants of psychosocial care.

Methods and analysis: The 3D Study is recruiting adults with type 1 (T1D), type 2 (T2D), latent autoimmune diabetes in adults (LADA), and gestational diabetes (GD) from the Caswell Diabetes Registry at Michigan Medicine. The 3D Study uses an explanatory sequential mixed-methods design with two phases. Phase 1 (P1: target n=500, began July 2023) consists of an online survey to quantify prevalence and examine correlates of a wide range of psychosocial factors (e.g., diabetes-related distress, depression, stigma). This survey was refined through consultation with PWD. Phase 2 (P2) involves semi-structured telephone interviews with n=50 P1 respondents, recruited using maximum variation sampling informed by demographic characteristics and responses to psychosocial survey measures. P2 will explore a subset of factors (e.g., patient-provider communication, social support, barriers/promoters to care). To date, n=423 (4% response rate) have completed P1. In March 2024 we identified a target sample of P1 respondents (n=65) for recruitment into P2. All data collection is expected to be completed by August 2024. Analysis will involve quantitative linear and logistic regression to understand correlates of psychosocial outcomes from P1, and qualitative content analysis to clarify potential points of intervention from P2.

Ethics and dissemination: This study is approved by the University of Michigan Institutional Review Board (HUM00223735). Protocol materials are available at https://osf.io/yfz6b/.

Keywords: diabetes, mental health, epidemiology, public health, cross-sectional studies

List of abbreviations:

PWD = people with diabetes
3D = Diabetes, Distress and Disparities Study
T1D = type 1 diabetes
T2D = type 2 diabetes
LADA = latent autoimmune diabetes in adults
GD = gestational diabetes
INTERPRET-DD = The International Prevalence and Treatment of Diabetes and Depression Study
DAWN = The Diabetes Attitudes, Wishes and Needs Studies
ADA = the American Diabetes Association
SDOH = social determinants of health
CDI = Caswell Diabetes Institute
MICHR = Michigan Institute for Clinical and Health Research
DOCTR = University of Michigan Data Office for Clinical and Translational Research
PHI = Protected Health Information
HIPAA = Health Insurance Portability and Accountability Act
HRS = Health and Retirement Study
GAD-7 = Generalized Anxiety Disorder 7-Item
PHQ-9 = Patient Health Questionnaire 9-Item
OSF = Open Science Framework
P1 = Phase 1
P2 = Phase 2
PEERRS = Program for the Education and Evaluation of Responsible Research and Scholarship
OpenICPSR = Open Inter-University Consortium for Political and Social Research
NIMH = National Institute of Mental Health
OBSSR = Office of Behavioral and Social Science Research
RaDaR = Rigorous And Accelerated Data Reduction
PAID-11 = Problem Areas in Diabetes 11-Item

STRENGTHS AND LIMITATIONS

- The study team worked with people with diabetes (PWD) to refine the survey instrument to help ensure that the content of the survey reflects the issues and experiences that matter most to PWD.
- The low response rate to the Phase 1 survey, despite several efforts to augment uptake, has required modifications to the overall recruitment goal and analytic plans.
- The study interviews only PWD, but the perspectives of their families and healthcare workers are also important to consider in proposing actions to address gaps in psychosocial care.
- The study sample is reflective of the patient population seen at Michigan Medicine and reflects the demographics in Washtenaw County, but is not representative of the larger US population.

KEY MESSAGES

- Psychosocial aspects of diabetes care include addressing mental health conditions, diabetes-related distress, financial strain, and stigma.
- Psychosocial aspects of diabetes care are under-recognized by healthcare providers, and even when they are identified, providers often do not have the resources necessary to adequately address patient needs.
- The 3D Study of Diabetes, Distress and Disparities is a sequential mixed-methods study designed to identify modifiable gaps in addressing psychosocial aspects of diabetes care for adults with type 1, type 2 and gestational diabetes.
- Preliminary findings indicate 17% of participants have elevated depressive symptoms, 8% have elevated anxiety symptoms, and 26% have elevated diabetes-related distress.
- Addressing psychosocial aspects of diabetes can improve overall well-being of persons with diabetes and is consistent with calls for person-centered diabetes care.

INTRODUCTION

Mental health and diabetes outcomes are linked in a variety of ways that have implications both for promoting mental health, diabetes self-management, preventing complications, and supporting the overall well-being of people with diabetes (PWD)[1]. For example, the incidence and prevalence of type 2 diabetes (T2D) is approximately twice as high among people with a history of mental illness (e.g., schizophrenia, bipolar disorder, severe depression) compared to those without[2], and certain psychiatric medications further increase risk of obesity and T2D[3]. Mental health also impacts outcomes in type 1 diabetes (T1D). In adolescents with T1D, depression has been associated with increased risk of severe hypoglycemic and hyperglycemic events, and depressive symptoms often increase after such events[4 5]. In addition, up to half of PWD experience diabetes-related distress, which is associated with poor self-management[6 7]. Finally, while the evidence base is smaller, studies indicate that gestational diabetes (GD) and mental health, including prenatal and post-partum depression, are linked in important ways[8]. Despite the growing body of evidence indicating a bi-directional relationship between depression and related mental disorders with diabetes clinical outcomes[9], substantial gaps remain in the ability of healthcare systems to meet these psychosocial care needs[10].

Building on prior studies of psychosocial needs of people with diabetes

Two landmark international efforts laid the groundwork for our current understanding of the psychosocial care needs of PWD. The International Prevalence and Treatment of Diabetes and Depression (INTERPRET-DD) Study (n=2,783 adults with T2D ages 18 to 65) examined the prevalence and predictors of mental health conditions among adults with T2D seen in specialty clinics in 14 countries (not including the US). Overall, this study found that ~11% of adults with T2D had current major depression, yet less than 30% had been identified by a clinician, with large variability in detection across countries[11]. The Diabetes Attitudes, Wishes

and Needs (DAWN) Studies were two large surveys that sought to quantify psychosocial aspects of diabetes, globally and in the US, from the perspective of both patients and providers[12 13]. DAWN 1 consisted of a sample of PWD (n=5,104, including T1D and T2D) and generalist healthcare providers (n=3,827 physicians/nurses) drawn from 13 countries (including the US); this study found that 40% of PWD had poor well-being, yet only 10% had received care for their psychosocial needs[14]. DAWN 2 (n=17 countries (including the US) and n=8,596 PWD) found that 15% of PWD had probable depression, and 40% had significant diabetes-related distress, yet only 25% said they had been asked by their healthcare team how diabetes impacted their life[13].

Collectively, INTERPRET-DD and the DAWN studies demonstrated that psychological distress and depression are common concerns for PWD, both in the US and globally, and that there are substantial gaps in meeting these mental health care needs. Moreover, the American Diabetes Association (ADA) Mental Health Toolkit[15], Standards of Diabetes Care[16], and Position Statements by the ADA emphasize the importance of addressing mental, behavioral, and social aspects of health as central components of diabetes care[1]. However, even with these guiding documents, questions remain regarding the most *appropriate setting, frequency,* and *acceptability* of these assessments; such guidance is essential to closing the gaps in psychosocial care documented by these landmark studies[1]. In addition, the INTERPRET-DD and the DAWN studies spanned multiple types of healthcare and payer systems, but were limited in their ability to identify actionable steps that specific providers or care organizations could take to address the psychosocial care needs identified. Finally, while INTERPRET-DD and DAWN provided a broad understanding of the psychosocial care needs of PWD internationally, they did not fully assess the unique opportunities (and challenges) of the US context. As a result, while these landmark studies demonstrated the scope of the mental health challenges PWD are experiencing around the globe, they could only provide limited insight as to how US healthcare systems should change to address those challenges.

Considering social determinants of diabetes care

Increasingly, healthcare systems are seeking to address, or at the very least *assess*, social determinants of health (SDOH). The concept of SDOH encompasses factors outside the clinical setting, such as socioeconomic status, neighborhood characteristics, housing, access to grocery stores and greenspace, food insecurity, social integration and support, and experiences of stigma and discrimination[17]. Leaders in the field emphasize that policy and programmatic efforts must address these "upstream" factors to engage in equitable diabetes care[18 20]. These social determinants not only contribute to disparities in healthcare access, but also play a profound role in shaping the mental health experiences of individuals managing diabetes. For example, diabetes-related distress is higher among adolescents with lower socioeconomic status[21], and food insecurity is associated with elevated depressive symptoms among adults with T2D[22]. A growing body of evidence indicates that addressing SDOH is an essential component of person-centered diabetes care, with positive impacts on both self-management and mental health outcomes for PWD[23 24]. However, many questions remain as to how social factors shape mental health outcomes for PWD, and healthcare systems and providers can best address these complex relationships.

Current study

To address these gaps in how to address psychosocial aspects of diabetes care, the Caswell Diabetes Institute (CDI) at the University of Michigan recently launched the Diabetes, Distress, and Disparities (3D) Study of Self-Management and Mental Health. This paper describes the rationale, study design, sampling approach, data collection procedures, and preliminary findings from the 3D Study. The overarching goals of the 3D Study are to quantify the psychosocial care needs of PWD in a large academic medical center, generate insights

regarding how psychosocial factors shape diabetes outcomes, and identify approaches for addressing gaps in psychosocial care in an equitable manner.

METHODS

Study design and eligibility criteria

Overview of study design (**Figure 1**). The 3D Study uses an explanatory, sequential mixed methods design, wherein the quantitative (Phase 1, P1) and qualitative (Phase 2, P2) components are directly linked in two ways: (1) the responses to P1 inform the sampling frame for P2, and (2) the responses to the psychosocial measures included in the P1 survey inform the content of the semi-structured interview used in P2. These two phases have distinct but intersecting goals. The quantitative survey addresses a broad range of psychological, social, behavioral, and environmental factors and is designed to generate a comprehensive understanding of the breadth of psychosocial care needs of PWD. In contrast, the semi-structured qualitative interviews of P2 are designed to probe select topics in greater depth, and to examine processes and relationships that can inform suggestions for improving person-centered diabetes care. Finally, the *sequential* nature of the design facilitates the integration of qualitative and quantitative information across the phases, through both the purposeful sampling (i.e., based on the responses to P1) and content of the P2 qualitative interview guide.

Study eligibility criteria. The 3D Study is recruiting adults with T1D, T2D, latent autoimmune diabetes of the adult (LADA, type 1.5), or past or current GD from the CDI Repository. The CDI Repository consists of individuals (both alive and deceased) with a diabetes diagnosis identified on their problem list and/or a Michigan Medicine visit diagnosis (limited to office visit, virtual visit, or hospital encounter types). The ICD-9 and ICD-10 codes used to include individuals in the registry are ICD-9: 249, 250, and 775.1 and ICD-10: E08, E09, E10, E11, E13, O24, and P70.2. Conditional on being in the registry, the 3D Study inclusion criteria are (1) being at least 18 years old, and (2) having at least three clinical encounters (i.e.,

office visits, virtual visits, hospital admissions, or emergency department visits) in the last two years (4/1/2021 through 3/31/2023) by any department at Michigan Medicine.

Patient and public involvement

Feedback from PWD and other stakeholders was incorporated into our study design and data collection instruments. First, the team met twice with the CDI Diabetes Patient and Family Advisory Board, including piloting the P1 survey instrument; this resulted in shortening of the length of the survey instrument and expansion of the response options to some questions. Second, due to the lack of racial diversity of the CDI Advisory Board, we conducted two focus groups of PWD through the Michigan Institute for Clinical and Health Research (MICHR) Community Engagement Studio. Third, we consulted with investigators from the INTERPRET-DD and DAWN studies, including reviewing their data collection protocols. Finally, we consulted with the University of Michigan Department of Family Medicine Qualitative and Mixed Methods Learning Lab (QMMLL: https://www.mixedmethods.org/) during the study design phase, which resulted in revisions to the design of P2 from virtual focus groups to semi-structured one-on-one telephone interviews.

Data Collection

Fieldwork procedures for Phase 1

The top half of **Figure 2** shows recruitment through March 7, 2024. For this phase, potentially eligible individuals are contacted via email by the University of Michigan Data Office for Clinical and Translational Research (DOCTR). DOCTR serves as a broker who securely handles protected health information (PHI), which is not shared with the research team unless a person consents to be in the study. The CDI provided DOCTR with ~62,000 adults and their diabetes type data, which was then limited to those with email information (~58,000 individuals). This sample was then split into T1D/LADA, T2D, or GD, and emails were sent out in batches of 500: T1D and T1.5/LADA=150, T2D=300, and GD=50. Individuals receive an initial email

inviting them to participate, then two follow-up emails, and a final reminder email that their unique survey link is going to expire in one month. The data of each email is recorded and tracked, as are intermediate steps (e.g., clicking on the email link, even if the person chooses to not participate).

Phase 1 fieldwork began July 2023, with an expected response rate of 20% and an initial recruitment goal of 2,500 individuals. This sample size was chosen to ensure that correlates of the psychosocial outcomes could be examined both *across* and *within* each of the four diabetes types. However, as shown in **Figure 2**, the current response rate (~4%) is substantially lower than this expectation, although it is in line with other web surveys[25]. Therefore, the expected sample for the P1 survey has now been revised to 500 individuals, with the majority having T1D or T2D (each type will have an n~200) based on recruitment to date. With this smaller sample size we will have sufficient power to detect small to moderate effect sizes when comparing *across* the T1D and T2D groups (e.g., we have 80% power to detect Cohen's d=0.3). We will have sufficient power to detect moderate to large effect sizes *within* each diabetes group (e.g., we have 80% power to detect Cohen's d=0.4 *within* the T1D or T2D group). However, the study will no longer have sufficiently large samples of the LADA or GD types to conduct quantitative examinations within these groups. Phase 1 fieldwork is expected to conclude by June 30, 2024.

Phase 1 data collection instrument

The online survey is being conducted using Qualtrics, which is HIPAA-compliant. The functionality of Qualtrics means that the survey can be completed using a computer or tablet/cell phone. Items included in the survey were derived from existing health surveys (e.g., INTERPRET-DD, DAWN, and the Health and Retirement Study (HRS) Diabetes Study)[26] to enhance comparability with these prior studies. The P1 survey takes approximately 40 minutes to complete and consists of 11 core domains that are asked of all participants, regardless of diabetes type, which is then followed by a set of questions that are relevant to their specific type

of diabetes (e.g., diabulimia for T1D, weight blame for T2D). The primary psychosocial outcomes assessed by the P1 survey include: mental health (depressive symptoms, anxiety symptoms, diabetes-related distress), stigma/discrimination, behavioral health, and social relationships. The primary diabetes clinical and healthcare outcomes assessed in the survey include: glycemic control, complications, medications (including costs), and technology (e.g., continuous glucose monitors, insulin pumps). The primary independent variables and correlates of these outcomes that are assessed in the survey include social and demographic characteristics, healthcare utilization, and diabetes history. Details of the survey content is provided in **Table 1** and the data collection instrument is available at https://osf.io/yfz6b/.

Fieldwork procedures for Phase 2

The bottom half of **Figure 2** shows selection of a subset of participants (~27%) who consented to be contacted for Phase 2. Selection criteria for interviewees were determined based on the results of the first stage of the study. We used maximum variation sampling[27] to capture the breadth of experiences represented in the survey, informed by responses to five features: (1) diabetes control (indicated by self-reported A1c), (2) symptoms of depression and anxiety (measured using standardized screening scales the PHQ-9 and GAD-7, respectively), (3) symptoms of diabetes distress (measured by the PAID-11), (4) history of mental health treatment, and (5) social factors such as experiences of discrimination and stigma. In addition, we considered demographic characteristics (e.g., age, race, sex, educational attainment and household income) in constructing the sample.

Eligibility for the second phase of the study is conditional on (1) completing the P1 survey, (2) providing contact information at the completion of the survey (this is the only way that the study team obtains identifiers; up to this point only DOCTR has contact information for participants), and (3) checking the box at the end of the survey stating that they are willing to be recontacted for P2. Using the features described above, in March 2024 we selected the

recruitment frame for Phase 2 (n=65 P1 respondents, in anticipation of a ~20% refusal rate); the goal sample size for Phase 2 is 50 participants. This sample size was chosen given the multiple psychosocial features used to inform the sampling frame, and the desire for adequate representation across race/ethnicity, age, diabetes type, and indicators of socioeconomic status in the qualitative component.

Recruitment for Phase 2 began in late March 2024 and is expected to conclude by August 30, 2024. Recruitment for this Phase involves the study team contacting selected participants via email and then telephone to assess interest. Batches of n=10 potential P2 respondents are released every 2-3 weeks to the research staff for recruitment to facilitate problem-solving and team debriefing each week. Once the interview is scheduled, research staff send a reminder email a few days before the interview. The informed consent process is audio-recorded, as well as the entire interview. Interviews will be later transcribed for analysis.

Phase 2 data collection instrument

Phase 2 consists of in-depth semi-structured qualitative interviews conducted by telephone or zoom. The data collection instrument was created by the study team, which includes a person with T1D and a clinical health psychologist that works with PWD and their families. The goal was to create an approximately hour-long semi-structured interview that addressed psychosocial factors that were (1) prevalent among the sample, based on the P1 survey responses and (2) could provide insight regarding gaps, barriers, and promoters to psychosocial health for PWD. The instrument was revised in an iterative process, considering order of questions, stems vs. probes, and length. The content of the interview is summarized in **Table 3** and all data collection materials are available at https://osf.io/yfz6b/.

All staff involved in the P2 fieldwork underwent training in qualitative interviewing by a team member (A.R.P.) with extensive experience in this method, including role-playing (i.e., simulated interviews) and piloting the instrument with multiple members of the study team.

Interviewer bias was reduced through the implementation of a standardized interview guide and the systematic training of interviewers.

Linkage with healthcare records

At the conclusion of data collection, the study team will work with DOCTR to link the survey data for P1 participants to their Michigan Medicine healthcare utilization records for the calendar years 2023 and 2024. DOCTR will conduct this linkage and then return a dataset to the 3D Study team that does not have any personal identifiers, but it will have an anonymous code that will allow us to link these healthcare records to the P1 survey responses. These data will be used to assess metrics of healthcare utilization, including referrals to social work/behavioral health, emergency department visits, hospitalizations, diabetes-related complications (e.g., hypoglycemic episodes, amputations) and other metrics of care quality.

Data analysis plans

Quantitative data analysis: We will use descriptive statistics (means, proportions) to quantify the prevalence of psychosocial outcomes, focusing on symptoms of depression, anxiety, diabetes-related distress, and diabetes-related stigma. We will use linear and logistic regression to examine the correlates of those psychosocial outcomes, accounting for age, sex, and race. We will examine variation in these relationships by diabetes type (T1D vs. T2D), duration of diabetes, glycemic control (indicated by hemoglobin A1c), and diabetes care regimen (e.g, oral medications, insulin). We will examine the relationship between indicators of SODH (e.g., educational, household income, self-reported financial strain) and psychosocial outcomes.

Table 2 provides an illustration of the types of descriptive statistics we will estimate from the P1 survey. The left-hand column shows the P1 sample (n=423 through March 7, 2024), and the right-hand column shows the subset of n=65 P1 respondents that have been selected for

recruitment into P2. Data collection for both phases is ongoing. Currently, 41% of P1 respondents have T2D, 49% have T1D (this group was over-sampled for by design), 3% have LADA and 7% have GM (current or past). Regarding psychosocial factors, 17% have elevated anxiety symptoms as indicated by the GAD-7, 8% have elevated depressive symptoms as indicated by the PHQ-9, and 26% have elevated diabetes-related distress as indicated by the PAID-11. While the average hemoglobin A1c is 7.1, which is in the acceptable range, 17% have an A1c ≥8%, indicating poor glycemic control.

Qualitative data analysis. We will use the Rigorous And Accelerated Data Reduction (RADaR)[28] technique for qualitative data analysis to identify prominent themes related to psychosocial aspects of diabetes care. RADaR is an iterative process for analyzing qualitative data in a manner that moves between individual and team-based activities. The analytic team will consist of 2-4 people, who will begin by listening to the audio recordings and reading the transcripts of the semi-structured interviews from P2, then will create a spreadsheet of all data elements, with text organized by interview questions. This table will then be reduced as appropriate for the specific research question being addressed (e.g., analyses examining barriers to care will focus on those probes and responses that address that topic). The team will then begin generating codes, individually and refined collectively, that they will apply to the transcripts; they will create a definition and codebook, which will be revised as needed using a process of debate and consensus. The team will then define and apply the (sub)codes and identify illustrative quotes. Given the maximum variation sampling approach used for P2, the team will examine whether and how themes varied as a function of the quantitative characteristics that informed this sampling frame.

Ethics, Data Availability, and Dissemination

The protocol for this study was approved by the University of Michigan Institutional Review Board (HUM00223735) and complies with the Health Insurance Portability and Accountability Act (HIPAA) standards. All participants provided informed consent, whether written (Phase 1) or oral (Phase 2). All participants signed a HIPAA waiver as part of P1 that permits researchers to work with DOCTR to link their survey data to their healthcare records (described above).

The 3D Study was pre-registered in the Open Science Framework (OSF) and all project and data collection materials are available at https://osf.io/yfz6b/. All data is kept on a password and two-factor protected server housed at the University of Michigan, in a folder that is only accessible by the project team. Only authorized research personnel (e.g., principal investigator, project coordinator, select research staff) have access to the identifying information on participants. All team members completed certification through the University of Michigan Program for the Education and Evaluation of Responsible Research and Scholarship (PEERRS).

Plans for data sharing were described as part of the informed consent process. De-identified data from P1 survey will be made available through OpenICPSR (https://www.openicpsr.org/openicpsr/) within 6 months of completing data collection. To protect confidentiality, de-identified data from P1 linked healthcare records and the P2 semi-structured interviews (recordings or transcripts) will not be publicly available, but will be available from the corresponding author on reasonable request.

Findings from the 3D Study will be disseminated to research audiences at scientific conferences (e.g., meetings of the Psychosocial Aspects of Diabetes, American Psychosomatic Society) and peer-reviewed publications. Results will be disseminated to leaders at Michigan Medicine through CDI. Finally, results and their implications will be disseminated to PWD and

their families through partnerships with the CDI Patient Advisory Board, advocacy organizations (e.g., local chapters of the American Diabetes Association), and lay media outlets (e.g., Psychology Today, The Conversation).

CONCLUSION

It is established that psychosocial factors are a critical component of person-centered health care. However, these factors are under-recognized by healthcare providers, and even when they are identified, are often inadequately addressed. Preliminary data from the 3D Study demonstrates substantial psychological distress among adults with diabetes, consistent with prior studies. The sequential, explanatory mixed-methods design of the 3D study aims to identify modifiable gaps in addressing psychosocial aspects of diabetes care in a large academic healthcare system. When completed, the 3D Study will integrate qualitative interviews, quantitative survey measures, and clinical healthcare records to generate a comprehensive understanding of the psychosocial care needs of PWD. This knowledge will be shared with advocates and various stakeholders throughout the healthcare system, with the goal of informing the implementation of programs, policies and partnerships to improve psychosocial care outcomes for PWD.

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AUTHOR CONTRIBUTIONS

B. Mezuk: Conceptualization, Methodology, Writing -Review & Editing, Supervision, and Funding acquisition

A. Rodríguez-Putnam: Investigation, Methodology, Writing - Review & Editing, Supervision, Data Curation

B. Flores: Data Curation, Investigation, Methodology, Writing - Original Draft

E Spring: Writing - Review & Editing, Methodology, Investigation

A. Miller: Writing - Review & Editing, Methodology

R. Messina: Methodology, Writing - Review & Editing, Supervision

A. Ewen: Methodology, Writing - Review & Editing

C. Zhong: Data Curation, Formal Analysis, Software

C. Devries: Conceptualization, Methodology, Investigation, Writing - Original Draft, Writing - Review & Editing, Supervision, Data Curation, Formal Analysis, and Software

P. Choudhary: Data Curation, Writing - Original Draft

COMPETING INTERESTS

The authors declare that they have no competing interests to report.

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Table 1: Domains and source of items measured in the quantitative survey (Phase One) of the 3-D Study

Section of survey [number of questions]	Measurements and descriptions	Source of items and Name of instruments (if applicable)
Diabetes History and Other Health Conditions [8 questions]	Overall health, A1c, age of diabetes diagnosis, type of medication taken for diabetes, when last A1c test was, how well-controlled diabetes is for 6 months, and other comorbid health conditions.	HRS, DAWN-2
Diabetes Complications [6 questions]	Chronic pain, diabetes complications, diabetic amputations, and diabetic eye disease or laser eye surgery from diabetes.	HRS
Medications and Testing [8 questions]	Insulin usage, ITAs, checking blood sugar, monthly out-of-pocket costs, and cost barriers	HRS
Technology [9 questions]	Continuous glucose monitors, insulin pumps, technology access barriers, public visibility of diabetes, and technology hyper-awareness.	HRS

Social Determinants of Health [8 questions]	Employment status, educational attainment, type of health insurance, household income, financial issues, and history of homelessness.	HRS: PLQ, DAWN 2
Behavioral Health and Mental Healthcare [38 questions]	Exercise, sleep, alcohol and tobacco use, feelings at diabetes diagnosis (and if there was offered support), mental healthcare received in the past year, severe mental illness diagnosis, mood stabilizer/antipsychotic/anticonvulsant usage, traumas, and history of suicidal thoughts and attempts.	GSA, NHANES, BRFSS, NSDUH, HRS: PLQ, BRFSS: ACE
Mental Health [18 questions]	Adapted American Diabetes Association Toolkit	PHQ-9, GAD-7, PAID-11, and HFS-II W.
Stigma and Discrimination [16 questions]	Discrimination, employment discrimination, social isolation/stigma, internal stigma, negative/incorrect assumptions, healthcare professional negative/incorrect assumptions, intersectional experiences of discrimination/stigma other than diabetes.	DAWN 2, GDMQ-36, HRS, ITAS, HFS-II W, T1-DDS
Healthcare Use and Experiences [14 questions]	Emergency room visits, diabetes education/nutrition education class, provider satisfaction, main diabetes provider, length of time seen, and COVID-19 concerns.	HRS, DAWN 2

Social Relations [13 questions]	Social network, social support, and diabetes impact.	HRS: PLQ, HRS, DAWN 2
Demographics [6 questions]	Race/ethnicity, gender, marital status, and sexual orientation.	NSDUH, BRFSS
Diabetes Type Specific Questions [45 questions]	type 1/1.5 (LADA)- Technology, Powerlessness, Negative Social Perceptions, Physician Distress, Friends/Family Distress, Hypoglycemia Distress, Management Distress, and Eating Distress [16 questions]	T1-DDS, DEPS-R
	T2D- Impact of diabetes on health and quality of life (QoL), care and support, self-management, involvement/role of family members, diabetes beliefs and attitudes. [11 questions]	DAWN 2, HRS
	Gestational diabetes- concerns about high-risk pregnancy, perceived constraints, GDM complications, support, and medication and treatment. [12 questions]	GDMQ-36, DAWN 2, HRS

*Acronyms for the name of surveys and instruments: HRS, Health and Retirement Study; DAWN 2, Diabetes Attitudes, Wishes and Needs second study; PLQ, Personal Lifestyle Questionnaire; GSA, Global Sleep Assessment; NHANES, National Health and Nutrition Examination Survey; BRFSS-ACE, Behavioral Risk Factor Health Surveillance System Adverse Childhood Experience Module; NSDUH, National Survey on Drug Use and Health; ADA, American Diabetes Association Toolkit; PHQ-9, Patient Health Questionnaire-9; GAD-7, Generalized Anxiety Disorder-7; PAID-11, Problem Areas in Diabetes-11; HFS-II W, Hypoglycemia Fear Survey-II; T1-DDS, Type-1 Diabetes Distress Scale; GDMQ-36, Quality of life questionnaire for women with gestational diabetes mellitus; ITAS, Insulin Treatment Appraisal Scale.

Table 2. Descriptive characteristics of Phase 1 Survey Respondents and anticipated Phase 2 Interview Sample of the 3-D Study

	Phase 1 Survey completed through 3/7/2024 N=423	Target sample for Phase 2 N= 65
Demographic characteristics		
Age mean (range)	54.67 (19-92)	48 (19-75)
Race N (%)		
Asian	15 (3.55%)	5 (7.79%)
Black	47 (11.11%)	11 (16.92%)
Latino	12 (2.84%)	5 (7.69%)
Native American	6 (1.42%)	2 (3.08%)
White	330 (78.01%)	39 (60.0%)
Not disclosed	13 (3.07%)	3 (4.62%)
Gender N (%)		
Woman	254 (60.05%)	40 (61.54%)
Man	162 (38.30%)	24 (36.92%)
Transgender and other	7 (1.66%)	1 (1.54%)
Household Income N (%)		
<25k	56 (13.24%)	13 (20%)
25-49k	68 (16.08%)	7 (10.77%)
50-74k	67 (15.84%)	7 (10.77%)

75k-99k	74 (17.49%)	13 (20%)
100k-149k	69 (16.31%)	8 (12.30%)
150-249k	53 (12.53%)	10 (16.92%)
>250k	27 (6.38%)	4 (6.15%)
Unknown and other	9 (2.13%)	2 (3.06%)
Educational Attainment N (%)		
≦ High school/GED	79 (18.67%)	12 (18.45%)
Trade, vocational program, or certificate	28 (6.62%)	6 (9.23%)
Associate	36 (8.51%)	9 (13.85%)
Bachelor	124 (29.31%)	11 (16.92%)
Master	110 (26.00%)	19 (29.23%)
Doctorate (PhD, MD, JD, etc)	46 (10.87%)	7 (10.77%)
Diabetes characteristics		
Diagnosis		
Type 2	172 (40.66%)	26 (40.0%)
Type 1	206 (48.70%)	31 (47.69%)
Type 1.5 (LADA)	14 (3.31%)	3 (4.62%)
Gestational (Current and Past)	31 (7.33%)	5 (7.68%)
Age of Diagnosis	32 (0-82)	30 (2-72)
Amount of years with diabetes	21 (0-67)	18 (1-53)
A1c	7.07 (3.4-14)	7.35(4.7-12.9)

Good Control (<=6.4) N (%)	124 (33.3%)	35 (53.85%)
Poor Control (>=8.0) N (%)	65 (17.4%)	30 (46.15%)
Depression, anxiety, and diabetes-related distress		
PHQ-9 Score	7.67 (0-25)	9.84 (0-24)
Elevated depressive symptoms (PHQ-9≥15)	71 (16.8%)	20 (31.25%)
GAD-7 Score	5.51 (0-21)	7.63 (0-20)
Elevated anxiety symptoms (GAD-7≥15) N (%)	33(7.9%)	9 (13.85%)
PAID-11 Score	11.85 (0-41)	17.23 (0-41)
Elevated diabetes distress (PAID-11≥18)	118(26.0%)	29 (45.31%)

*Values are mean (range) for continuous variables and N (%) for categorical variables.

**PHQ-9, Patient Health Questionnaire-9 (0-27, ≥ 15 indicate elevated depressive symptoms).

***GAD-7, Generalized Anxiety Disorder-7 (0-21, ≥ 15 indicate elevated anxiety symptoms).

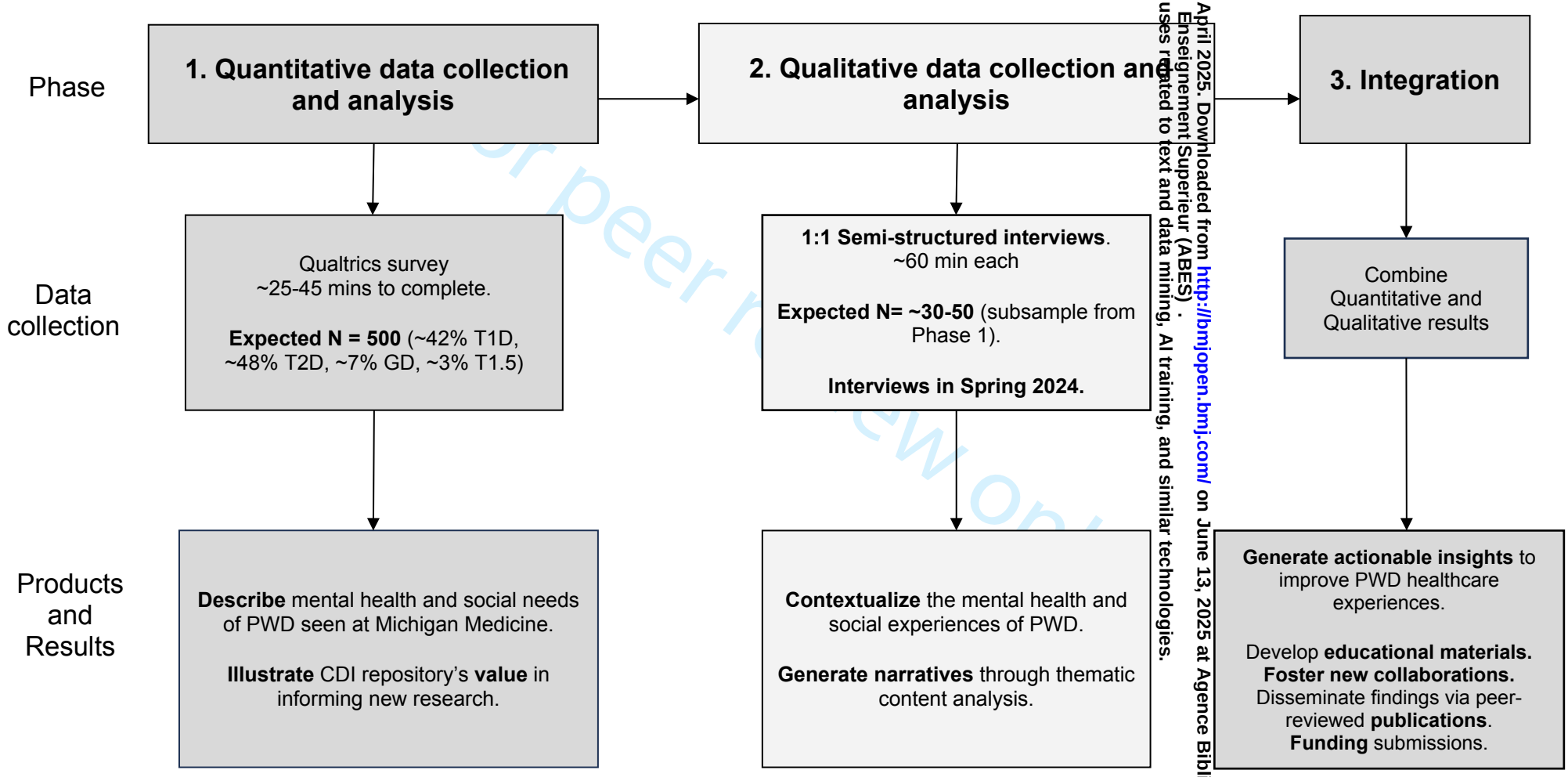
****PAID-11, Problem Areas in Diabetes-11 (0-44, ≥ 18 indicate elevated diabetes distress).

Table 3: Domains and Questions Included in the Interview Guide (Phase Two) of the 3-D Study

Domains of Interview Instrument	Questions
1. Diabetes Management & Patient-Provider Relationship	a. What helps you stay engaged with managing your diabetes? b. Can you tell me something that is important to you when it comes to your diabetes that isn't likely to show up in your medical record: that is, something that matters to you but isn't a blood test, diagnosis, or medication? c. How do your interactions with your doctors make you feel about your ability to manage your diabetes well?
2. Comorbidities and Other Health Conditions	a. Do you have any other conditions besides diabetes? b. How do you prioritize taking care of your diabetes with your other health conditions, whether in terms of taking medications as prescribed, following treatment recommendations, or other aspects of care?
3. Mental Health	a. How does the day-to-day experience of managing your diabetes - for example, checking your blood sugar, thinking about carbohydrates in food, or thinking about insulin or medication doses - impact your overall mental health? b. Are there specific aspects of having diabetes that become more challenging for you during times when you feel distressed, sad, or anxious? c. Has there ever been a time when you felt you had to make a "trade-off" between your diabetes and your mental health? [Can you tell me a little bit more about that?] d. What types of behaviors, activities, or strategies have you found to be beneficial to both your diabetes and your mental health?

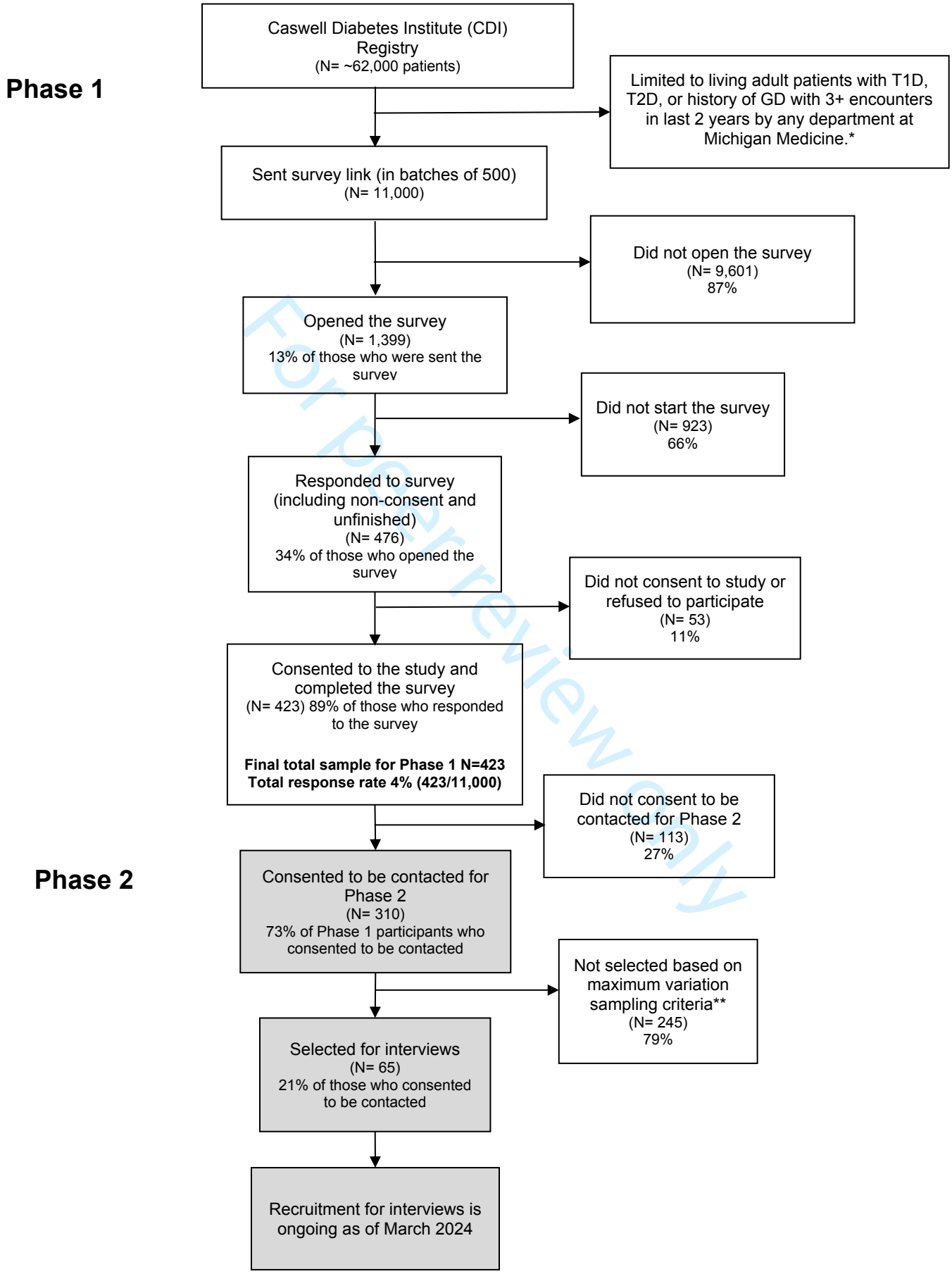
4. Stigma, Discrimination and Financial Strain	a. What are some of your thoughts, experiences, or feelings towards media representations of diabetes, particularly those that may be perceived as negative? b. How is diabetes viewed by the people you interact with the most? c. How have conversations with people with seemingly negative perceptions or misunderstanding about diabetes impacted you? d. How has the financial burden of taking care of your diabetes impacted you? e. Because of your diabetes, have you ever experienced poor treatment or negative attitudes from doctors or other medical staff? [Can you tell me more about that/those experiences?]
5. Family and Social Support	a. How has having diabetes affected your relationship with your family? b. What resources, people, or community supports have helped you adjust to living with diabetes? c. These last few questions are a little different than the ones previously. I'm going to read you four sentences that I'd like you to complete. i. The first sentence is: "When it comes to my diabetes, I wish my family and friends were MORE [fill in the blank]" ii. The second sentence is: "When it comes to my diabetes, I wish my family and friends were LESS [fill in the blank]" iii. The third sentence is: "When it comes to my diabetes, I wish my doctor was MORE [fill in the blank]" iv. The fourth sentence is: When it comes to my diabetes, I wish my doctor was LESS [fill in the blank]" d. Is there anything else you would like to share about your experiences with diabetes and mental health that we haven't discussed during this interview?

Figure 1. Study Design of the 3-D Study: An Explanatory Sequential Mixed Methods Design



*T1D, Type 1 Diabetes; T2D, Type 2 Diabetes; GD, Gestational Diabetes; PWD, people with diabetes; CDI, Caswell Diabetes Institute.

Figure 2. Flowchart of participant recruitment in the 3D Study (through March 7, 2024)



*T1D, Type 1 Diabetes; T2D, Type 2 Diabetes; GD, Gestational Diabetes.

**Participants selected for recruitment in Phase 2 (interviews) of the study were determined based on the results of the first stage of the study. We used maximum variation sampling to capture the breadth of experiences represented in the survey, informed by responses to five key features: (1) diabetes control (e.g., indicated by self-reported A1c), (2) symptoms of depression and anxiety (e.g., GAD-7, PHQ-9), (3) symptoms of diabetes distress (e.g., PAID-11), (4) history of mental health treatment, and (5) social factors such as experiences of discrimination and stigma. In addition, we considered demographic characteristics (e.g., age, race, sex, educational attainment and household income) in constructing the sample.

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Protocol for the Diabetes, Distress, and Disparities (3-D) Study: An explanatory sequential mixed-methods design

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Protocol for the Diabetes, Distress, and Disparities (3-D) Study: An explanatory sequential mixed-methods design

(Running title: Protocol for the Diabetes, Distress, and Disparities Study)

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ABSTRACT

Introduction: Psychosocial factors impact diabetes outcomes, yet healthcare systems remain inadequately equipped to address these needs. Research centering the experiences of people with diabetes (PWD) can inform program implementation, policies, and partnerships to address psychosocial care needs. The goals of the Diabetes, Distress, and Disparities (3D) Study are to quantify the psychosocial care needs of PWD in a large academic medical center, generate insights regarding how psychosocial factors shape diabetes outcomes, and identify modifiable determinants of psychosocial care.

Methods and analysis: The 3D Study is recruiting adults with type 1 (T1D), type 2 (T2D), latent autoimmune diabetes in adults (LADA), and gestational diabetes (GD) from the Caswell Diabetes Registry at Michigan Medicine. The 3D Study uses an explanatory sequential mixed-methods design with two phases. Phase 1 (P1: target n=500, began July 2023) consists of an online survey to quantify prevalence and examine correlates of a wide range of psychosocial factors (e.g., diabetes-related distress, depression, stigma). This survey was refined through consultation with PWD. Phase 2 (P2) involves semi-structured telephone interviews with n=40 P1 respondents, recruited using maximum variation sampling informed by demographic characteristics and responses to psychosocial survey measures. P2 will explore a subset of factors (e.g., patient-provider communication, social support, barriers/promoters to care). To date, n=573 (5% response rate) have completed P1. In March 2024 we identified a target sample of P1 respondents (n=65) for recruitment into P2. All data collection was completed by September 2024. Analysis will involve quantitative linear and logistic regression to understand correlates of psychosocial outcomes from P1, and qualitative content analysis to clarify potential points of intervention from P2.

Ethics and dissemination: This study is approved by the University of Michigan Institutional Review Board (HUM00223735). Protocol materials are available at https://osf.io/yfz6b/. Findings

from this study will be disseminated through peer-reviewed publications, presentations at conferences, and outreach to key stakeholders, including creating educational materials for patient advocacy groups and interprofessional practice.

Keywords: diabetes mellitus, mental health, epidemiology, public health, cross-sectional studies

List of abbreviations:

PWD = people with diabetes
3D = Diabetes, Distress and Disparities Study
T1D = type 1 diabetes
T2D = type 2 diabetes
LADA = latent autoimmune diabetes in adults
GD = gestational diabetes
INTERPRET-DD = The International Prevalence and Treatment of Diabetes and Depression Study
DAWN = The Diabetes Attitudes, Wishes and Needs Studies
ADA = the American Diabetes Association
SDOH = social determinants of health
CDI = Caswell Diabetes Institute
MICHR = Michigan Institute for Clinical and Health Research
DOCTR = University of Michigan Data Office for Clinical and Translational Research
PHI = Protected Health Information
HIPAA = Health Insurance Portability and Accountability Act
HRS = Health and Retirement Study
GAD-7 = Generalized Anxiety Disorder 7-Item
PHQ-9 = Patient Health Questionnaire 9-Item
OSF = Open Science Framework
P1 = Phase 1
P2 = Phase 2
PEERRS = Program for the Education and Evaluation of Responsible Research and Scholarship
OpenICPSR = Open Inter-University Consortium for Political and Social Research
NIMH = National Institute of Mental Health
OBSSR = Office of Behavioral and Social Science Research
RaDaR = Rigorous And Accelerated Data Reduction
PAID-11 = Problem Areas in Diabetes 11-Item

STRENGTHS AND LIMITATIONS

- The study team worked with people with diabetes (PWD) to refine the survey instrument to help ensure that the content of the survey reflects the issues and experiences that matter most to PWD.
- The low response rate to the Phase 1 survey, despite several efforts to augment uptake, has required modifications to the overall recruitment goal and analytic plans.
- The study interviews only PWD, but the perspectives of their families and healthcare workers are also important to consider in proposing actions to address gaps in psychosocial care.
- The study sample is reflective of the patient population seen at Michigan Medicine and reflects the demographics in Washtenaw County, but is not representative of the larger US population.

INTRODUCTION

Mental health and diabetes outcomes are linked in a variety of ways that have implications for promoting mental health, diabetes self-management, preventing complications, and supporting the overall well-being of people with diabetes (PWD)[1]. For example, the incidence and prevalence of type 2 diabetes (T2D) is approximately twice as high among people with a history of mental illness (e.g., schizophrenia, bipolar disorder, severe depression) compared to those without[2], and certain psychiatric medications further increase risk of obesity and T2D[3]. Mental health also impacts outcomes in type 1 diabetes (T1D). In adolescents with T1D, depression has been associated with increased risk of severe hypoglycemic and hyperglycemic events, and depressive symptoms often increase after such events[4,5]. While the evidence base is smaller, gestational diabetes (GD) and mental health, including prenatal and postpartum depression, are linked in important ways[6]. A history of GD is also a strong risk factor for developing T2D[7], suggesting that understanding the psychosocial experiences of individuals with GD could inform T2D prevention efforts. Finally, up to half of PWD experience diabetes-related distress, the emotional burden and stress specifically associated with managing diabetes[8], which is also associated with poor self-management[9,10]. In sum, despite the growing body of evidence indicating a bi-directional relationship between depression and related mental disorders with diabetes clinical outcomes[11], substantial gaps remain in the ability of healthcare systems to meet these psychosocial care needs[12].

Building on prior studies of psychosocial needs of people with diabetes

Two landmark international efforts laid the groundwork for our current understanding of the psychosocial care needs of PWD. The International Prevalence and Treatment of Diabetes and Depression (INTERPRET-DD) Study (n=2,783 adults with T2D ages 18 to 65) examined the prevalence and predictors of mental health conditions among adults with T2D seen in specialty clinics in 14 countries (not including the US). Overall, this study found that ~11% of

adults with T2D had current major depression, yet less than 30% had been identified by a clinician, with large variability in detection across countries[13]. The Diabetes Attitudes, Wishes and Needs (DAWN) Studies were two large surveys that sought to quantify psychosocial aspects of diabetes, globally and in the US, from the perspective of both patients and providers[14,15]. DAWN 1 consisted of a sample of PWD (n=5,104, including T1D and T2D) and generalist healthcare providers (n=3,827 physicians/nurses) drawn from 13 countries (including the US); this study found that 40% of PWD had poor well-being, yet only 10% had received care for their psychosocial needs[16]. DAWN 2 (n=17 countries (including the US) and n=8,596 PWD) was published in 2013 and provided a more detailed assessment of the psychosocial care needs of PWD. The study found that 15% of PWD had probable depression, and 40% had significant diabetes-related distress, yet only 25% said they had been asked by their healthcare team how diabetes impacted their life[15].

Collectively, INTERPRET-DD and the DAWN studies demonstrated that psychological distress and depression are common concerns for PWD, both in the US and globally, and that there are substantial gaps in meeting these mental health care needs. Moreover, the American Diabetes Association (ADA) Mental Health Toolkit[17], Standards of Diabetes Care[18], and Position Statements by the ADA emphasize the importance of addressing mental, behavioral, and social aspects of health as central components of diabetes care[1]. However, even with these guiding documents, questions remain regarding the most *appropriate setting, frequency,* and *acceptability* of these assessments; such guidance is essential to closing the gaps in psychosocial care documented by these landmark studies[1]. In addition, the INTERPRET-DD and the DAWN studies spanned multiple types of healthcare and payer systems, but were limited in their ability to identify actionable steps that specific providers or care organizations could take to address the psychosocial care needs identified. Finally, while INTERPRET-DD and DAWN provided a broad understanding of the psychosocial care needs of PWD internationally, they did not fully assess the unique opportunities (and challenges) of the US

context. As a result, while these landmark studies demonstrated the scope of the mental health challenges PWD are experiencing around the globe, they could only provide limited insight as to how US healthcare systems should change to address those challenges.

Considering social determinants of diabetes care

Increasingly, healthcare systems are seeking to address, or at the very least *assess*, social determinants of health (SDOH). The concept of SDOH encompasses factors outside the clinical setting, such as socioeconomic status, neighborhood characteristics, housing, access to grocery stores and greenspace, food insecurity, social integration and support, and experiences of stigma and discrimination[19]. Leaders in the field emphasize that policy and programmatic efforts must address these "upstream" factors to engage in equitable diabetes care[20-22]. These social determinants not only contribute to disparities in healthcare access, but also play a profound role in shaping the mental health experiences of individuals managing diabetes. For example, diabetes-related distress is higher among adolescents with lower socioeconomic status[23], and food insecurity is associated with elevated depressive symptoms among adults with T2D[24]. A growing body of evidence indicates that addressing SDOH is an essential component of person-centered diabetes care, with positive impacts on both self-management and mental health outcomes for PWD[25,26]. However, many questions remain as to how social factors shape mental health outcomes for PWD, and healthcare systems and providers can best address these complex relationships.

Current study

To bridge these gaps in how to address psychosocial aspects of diabetes care, the Caswell Diabetes Institute (CDI) at the University of Michigan recently launched the Diabetes, Distress, and Disparities (3D) Study of Self-Management and Mental Health. This paper describes the rationale, study design, sampling approach, data collection procedures, and

preliminary findings from the 3D Study. The objectives of the 3D Study are to: (1) quantify the psychosocial care needs of PWD in a large academic medical center, (2) generate insights into how psychosocial factors shape diabetes outcomes, and (3) identify equitable approaches to address gaps in psychosocial care.

METHODS

Study design and eligibility criteria

Overview of study design (**Figure 1**). The 3D Study uses an explanatory, sequential mixed methods design, wherein the quantitative (Phase 1) and qualitative (Phase 2) components are directly linked in two ways: (1) the responses to Phase 1 inform the sampling frame for Phase 2, and (2) the responses to the psychosocial measures included in the Phase 1 survey inform the content of the semi-structured interview guide used in Phase 2. These two phases have distinct but intersecting goals. The quantitative survey addresses a broad range of psychological, social, behavioral, and environmental factors and is designed to generate a comprehensive understanding of the breadth of psychosocial care needs of PWD. In contrast, the semi-structured qualitative interviews of Phase 2 are designed to probe select topics in greater depth, and to examine processes and relationships that can inform suggestions for improving person-centered diabetes care. Finally, the *sequential* nature of the design facilitates the integration of qualitative and quantitative information across the phases, through both the purposeful sampling (i.e., based on the responses to Phase 1) and content of the qualitative interview guide.

Study eligibility criteria. The 3D Study is recruiting adults with T1D, T2D, latent autoimmune diabetes of the adult (LADA, type 1.5), or past or current GD from the patient records at Michigan Medicine. While GD typically resolves after birth of the child, we included individuals with a history of GD in the sample both because of the established relationship

between GD and T2D risk, as well as to address the substantial knowledge gap regarding the potential long-term relationship between GD and mental health[27]

Michigan Medicine is a leading academic medical center that serves a diverse patient population, offering specialized diabetes care and conducting cutting-edge research on diabetes and related conditions. Each year, there are approximately 2.8 million all-cause outpatient visits, 46,000 all-cause hospital discharges, and 110,000 all-cause emergency department visits. Persons were eligible if they were aged 18 or older, have a diabetes diagnosis identified on their problem list, and have at least three clinical encounters (i.e., office visits, virtual visits, hospital admissions, or emergency department visits) in the last two years (4/1/2021 through 3/31/2023) by any department at Michigan Medicine. The ICD-9 and ICD-10 codes used to identify cases of diabetes care: ICD-9: 249 (secondary diabetes mellitus), 250 (diabetes mellitus), and 775.1 (neonatal diabetes mellitus) and ICD-10: E08 (diabetes mellitus due to underlying condition), E09 (drug or chemical-induced diabetes mellitus), E10 (type 1 diabetes mellitus), E11 (type 2 diabetes mellitus), E13 (other specified diabetes), O24 (diabetes mellitus during pregnancy, childbirth, and the puerperium), and P70.2 (neonatal diabetes mellitus).

Patient and public involvement

Feedback from PWD and other stakeholders was incorporated into our study design and data collection instruments. First, the team met twice with the CDI Diabetes Patient and Family Advisory Board, including piloting the Phase 1 survey instrument; which resulted in shortening of the length of the survey instrument and expansion of the response options to some questions. Second, due to the lack of racial diversity of the CDI Advisory Board, we conducted two focus groups of PWD through the Michigan Institute for Clinical and Health Research (MICHR) Community Engagement Studio. Third, we consulted with investigators from the INTERPRET-DD and DAWN studies, including reviewing their data collection protocols. While the 3D Study is not seeking to be a direct replication of INTERPRET-DD or DAWN, by aligning our measurement tools with those of these prior studies we reduce the risk that design

decisions underlying any disparate findings across these studies. Finally, we consulted with the University of Michigan Department of Family Medicine Qualitative and Mixed Methods Learning Lab (QMMLL: https://www.mixedmethods.org/) during study design development, which resulted in revisions to the design of Phase 2 from virtual focus groups to semi-structured one-on-one telephone interviews.

Data Collection

Fieldwork procedures for Phase 1

The top half of **Figure 2** shows Phase 1 participant recruitment in the 3D Study. For this phase, potentially eligible individuals are contacted via email by the University of Michigan Data Office for Clinical and Translational Research (DOCTR). DOCTR serves as a broker who securely handles protected health information (PHI), which is not shared with the research team unless a person consents to be in the study. The CDI provided DOCTR with ~62,000 adults and their diabetes type data, which was then limited to those with email information (~58,000 individuals). This sample was then split into T1D/LADA, T2D, or GD, and emails were sent out in batches of 500: T1D and T1.5/LADA=150, T2D=300, and GD=50. Individuals receive an initial email inviting them to participate (**online supplementary appendix A**), then two follow-up emails, and a final reminder email that their unique survey link is going to expire in one month. The subject line of the email was “Letter of Invitation to Participate in Research.” The content of the email itself was concise, consisting of two paragraphs that introduced the study, the project coordinator and the PI. To provide additional context, we also included an infographic with detailed information about the study. The data of each email is recorded and tracked, as are intermediate steps (e.g., clicking on the email link, even if the person chooses to not participate). As an incentive for completing the survey, participants could provide their contact information to enter into a raffle to win a $100 gift card; one winner was drawn for every 100 completed surveys. Because participants were anonymous to the research team unless they

provided their contact information in the survey, and due to budget constraints, we were not able to provide an incentive to all Phase 1 participants.

Phase 1 fieldwork began July 2023, with an expected response rate of 20% and an initial recruitment goal of 2,500 individuals. This sample size was chosen to ensure that correlates of the psychosocial outcomes could be examined both *across* and *within* each of the four diabetes types. However, as shown in **Figure 2**, the actual response rate (~5%) is substantially lower than this expectation, although other web surveys have reported similar response rates[28]. Therefore, the expected sample for the Phase 1 survey was revised to 500 individuals, with the majority having T1D or T2D (each type has an n~200). However, even with this smaller sample we will have sufficient power to detect small to moderate effect sizes when comparing *across* the T1D and T2D groups (e.g., we have 80% power to detect Cohen's d=0.3). We will have sufficient power to detect moderate to large effect sizes *within* each diabetes group (e.g., we have 80% power to detect Cohen's d=0.4 *within* the T1D or T2D group). However, the study will no longer have sufficiently large samples of the LADA or GD types to conduct quantitative examinations within these groups.

At the time of the initial submission of this protocol paper (April 2024), fieldwork for both Phases 1 and 2 were in progress. At the time of the first decision on this manuscript (December 2024) both phases of fieldwork had closed (recruitment for Phase 1 closed in August 2024; recruitment for Phase 2 began in March 2024 and concluded in September 2024). We have updated sample characteristics (e.g., Table 2) in this paper to reflect the final sample at the time of receiving the first revision request.

Phase 1 data collection instrument

The online survey was conducted using Qualtrics, which is HIPAA-compliant. The functionality of Qualtrics means that the survey can be completed using a computer or tablet/cell phone. Items included in the survey were derived from existing health surveys (e.g.,

INTERPRET-DD, DAWN, and the Health and Retirement Study (HRS) Diabetes Study)[29] to enhance comparability with these prior studies. The Phase 1 survey takes approximately 40 minutes to complete and consists of 11 core domains that are asked of all participants, regardless of diabetes type, which is then followed by a set of questions that are relevant to their specific type of diabetes (e.g., diabulimia for T1D, weight blame for T2D). The primary psychosocial outcomes assessed by the Phase 1 survey include: mental health (depressive symptoms, anxiety symptoms, diabetes-related distress), stigma/discrimination, behavioral health, and social relationships. The primary diabetes clinical and healthcare outcomes assessed in the survey include: glycemic control, complications, medications (including costs), and technology (e.g., continuous glucose monitors, insulin pumps). The primary independent variables and correlates of these outcomes that are assessed in the survey include social and demographic characteristics, healthcare utilization, and diabetes history. Details of the survey content is provided in **Table 1** and the data collection instrument is available at https://osf.io/yfz6b/. As shown by **Table 2**, 43.5% of Phase 1 respondents have T2D, 48.2% have T1D (this group was over-sampled by design), 3.1% have LADA and 4.3% have GD (current or past).

Table 1. Domains and source of items measured in the quantitative survey (Phase 1) of the 3-D Study

Section of survey [number of questions]	Measurements and descriptions	Source of items and Name of instruments (if applicable)
Diabetes History and Other Health Conditions [8 questions]	Overall health, A1c, age of diabetes diagnosis, type of medication taken for diabetes, when last A1c test was, how well-controlled diabetes is for 6 months, and other comorbid health conditions	HRS, DAWN-2
Diabetes Complications [6 questions]	Chronic pain, diabetes complications, diabetic amputations, and diabetic eye disease or laser eye surgery from diabetes	HRS
Medications and Testing [8 questions]	Insulin usage, ITAs, checking blood sugar, monthly out-of-pocket costs, and cost barriers	HRS
Technology [9 questions]	Continuous glucose monitors, insulin pumps, technology access barriers, public visibility of diabetes, and technology hyper-awareness	HRS
Social Determinants of Health [8 questions]	Employment status, educational attainment, type of health insurance, household income, financial issues, and history of homelessness	HRS: PLQ, DAWN 2
Behavioral Health and Mental Healthcare [38 questions]	Exercise, sleep, alcohol and tobacco use, feelings at diabetes diagnosis (and if there was offered support), mental healthcare received in the past year, severe mental illness diagnosis, mood stabilizer/antipsychotic/anticonvulsant usage, traumas, and history of suicidal thoughts and attempts	GSA, NHANES, BRFSS, NSDUH, HRS: PLQ, BRFSS: ACE
Mental Health [18 questions]	Adapted American Diabetes Association Toolkit	PHQ-9, GAD-7, PAID-11, and HFS-II W.
Stigma and Discrimination [16 questions]	Discrimination, employment discrimination, social isolation/stigma, internal stigma, negative/incorrect assumptions, healthcare professional negative/incorrect assumptions, intersectional experiences of discrimination/stigma other than diabetes	DAWN 2, GDMQ-36, HRS, ITAS, HFS-II W, T1-DDS
Healthcare Use and Experiences [14 questions]	Emergency room visits, diabetes education/nutrition education class, provider satisfaction, main diabetes provider, length of time seen, and COVID-19 concerns	HRS, DAWN 2
Social Relations [13 questions]	Social network, social support, and diabetes impact	HRS: PLQ, HRS, DAWN 2

Demographics [6 questions]	Race/ethnicity, gender, marital status, and sexual orientation	NSDUH, BRFSS
Diabetes Type Specific Questions [45 questions]	type 1/1.5 (LADA)- Technology, Powerlessness, Negative Social Perceptions, Physician Distress, Friends/Family Distress, Hypoglycemia Distress, Management Distress, and Eating Distress [16 questions]	T1-DDS, DEPS-R
	T2D- Impact of diabetes on health and quality of life (QoL), care and support, self-management, involvement/role of family members, diabetes beliefs and attitudes. [11 questions]	DAWN 2, HRS
	Gestational diabetes- concerns about high-risk pregnancy, perceived constraints, GDM complications, support, and medication and treatment. [12 questions]	GDMQ-36, DAWN 2, HRS

*Acronyms for the name of surveys and instruments: HRS, Health and Retirement Study; DAWN 2, Diabetes Attitudes, Wishes and Needs second study; PLQ, Personal Lifestyle Questionnaire; GSA, Global Sleep Assessment; NHANES, National Health and Nutrition Examination Survey; BRFSS-ACE, Behavioral Risk Factor Health Surveillance System Adverse Childhood Experience Module; NSDUH, National Survey on Drug Use and Health; ADA, American Diabetes Association Toolkit; PHQ-9, Patient Health Questionnaire-9; GAD-7, Generalized Anxiety Disorder-7; PAID-11, Problem Areas in Diabetes-11; HFS-II W, Hypoglycemia Fear Survey-II; T1-DDS, Type-1 Diabetes Distress Scale; GDMQ-36, Quality of life questionnaire for women with gestational diabetes mellitus; ITAS, Insulin Treatment Appraisal Scale.

Table 2. Descriptive characteristics of Phase 1 Survey Respondents and anticipated Phase 2 Interview Sample of the 3-D Study

	Phase 1 Survey N=573	Phase 2 Qualitative Interview Sample N= 40
Demographic characteristics		
Age mean (range)	53.3 (19.0, 92.0)	49.3 (21.0, 75.0)
Race N (%)		
Asian	15 (2.6%)	5 (12.5)
Black	49 (8.6%)	3 (7.5%)
Latino	9 (1.6%)	3 (7.5%)
Native American	4 (0.7%)	2 (5.0%)
White	402 (70.2%)	23 (57.5%)
Another group	11 (1.9%)	1 (2.5%)
Not disclosed or missing	83 (14.5%)	3 (7.5%)
Gender N (%)		
Woman	307 (60.05%)	24 (60.0%)
Man	190 (38.30%)	24 (35.0%)
Transgender, non-binary or another gender	6 (1.66%)	2 (5.0%)
Missing	70.0% (12.2%)	0 (0%)
Household Income N (%)		
<25k	85 (14.8%)	9 (22.5%)
25-49k	88 (15.4%)	6 (15.0%)
50-74k	91 (15.9%)	3 (7.5%)
75k-99k	83 (14.5%)	8 (20.0%)
100k-149k	92 (16.1%)	4 (10.0%)
≥150k	101 (17.6%)	9 (22.5%)
Missing	33 (5.8%)	1 (2.5%)
Educational Attainment N (%)		
≦ High school/GED	109 (19.0%)	7 (17.5%)
Trade, vocational program, or certificate	37 (6.5%)	4 (10.0%)
Associate	54 (9.4%)	7 (17.5%)

Bachelor	164 (28.6%)	7 (17.5%)
Master or Doctorate (PhD, MD, JD, etc)	188 (32.8%)	15 (37.5%)
Missing	21 (3.7%)	0 (0%)
Diabetes characteristics		
Diagnosis N (%)		
Type 2	249 (43.5%)	20 (50.0%)
Type 1	276 (48.2%)	16 (40.0%)
Type 1.5 (LADA)	18 (3.1%)	1 (2.5%)
Gestational (Current and Past)	25 (4.3%)	2 (5.0%)
Diabetes - Type Unknown	5 (0.9%)	1 (2.5%)
Age of Diagnosis mean (range)	31.3 (0, 82.0) Missing: 10	31.9 (4.0, 72.0) Missing: 0
Years Since Diagnosis	15.3 (0, 67.0)	17.4 (1.0, 53.0)
A1c mean (range)	7.09 (3.4, 14.0)	7.17 (4.70, 12.0)
Good Control (<=6.4) N (%)	165 (28.8%)	21 (52.5%)
Poor Control (>=8.0) N (%)	86 (15.0%)	18 (45.0%)
Don't Know N (%)	66 (11.5%)	1 (2.5%)
Missing	8 (1.4%)	0 (0%)
Depression, anxiety, and diabetes-related distress		
PHQ-9 Score	9.4 (0, 29) Missing: 84	11.1 (0, 26) Missing: 2
Elevated depressive symptoms	115 (20.1%)	16 (40.0%)
GAD-7 Score	6.0 (0, 24) Missing: 50	8.2 (0, 21) Missing: 0
Elevated anxiety symptoms	61 (10.6%)	6 (15.0%)
PAID-11 Score	12.1 (0, 44) Missing: 52	16.8 (0, 39) Missing: 50
Elevated diabetes distress	141 (24.6%)	18 (45.0%)

Values are mean (range) for continuous variables and N (%) for categorical variables.

PHQ-9, Patient Health Questionnaire-9 (0-27, ≥ 15 indicate elevated depressive symptoms).

GAD-7, Generalized Anxiety Disorder-7 (0-21, ≥ 15 indicate elevated anxiety symptoms).

PAID-11, Problem Areas in Diabetes-11 (0-44, ≥ 18 indicate elevated diabetes distress).

Fieldwork procedures for Phase 2

The bottom half of **Figure 2** shows selection of a subset of participants (~18%) who consented to be contacted for Phase 2. Selection criteria for interviewees were determined based on the results of the first stage of the study. We used maximum variation sampling (i.e., sampling people with either very high or very low values on target constructs)[30] in order to capture the breadth of experiences represented in the survey. The five Phase 1 constructs used to inform the sampling of Phase 2 sampling were: (1) diabetes control (indicated by self-reported A1c), (2) symptoms of depression and anxiety (measured using standardized screening scales the PHQ-9 and GAD-7, respectively), (3) symptoms of diabetes distress (measured by the PAID-11), (4) history of mental health treatment, and (5) social factors (e.g., reporting experiences of discrimination and stigma). In addition, we considered diabetes type and demographics (e.g., age, race, sex, educational attainment and household income) in constructing the Phase 2 sample to adequately represent the diverse patient population seen at Michigan Medicine.

Eligibility for the second phase of the study is conditional on (1) completing the Phase 1 survey, (2) providing contact information at the completion of the survey (this is the only way that the study team obtains identifiers; up to this point only DOCTR has contact information for participants), and (3) checking the box at the end of the survey stating that they are willing to be recontacted for Phase 2. Using the features described above, in March 2024 we selected the recruitment frame for Phase 2 (n=65 Phase 1 respondents, in anticipation of a ~20% refusal rate); the goal sample size for Phase 2 was 50 participants. This sample size was chosen given the multiple psychosocial features used to inform the sampling frame, and the desire for adequate representation across race/ethnicity, age, diabetes type, and indicators of socioeconomic status in the qualitative component.

Phase 2 recruitment involved contacting the n=65 selected participants via email and then telephone to assess interest. Batches of n=10 potential P2 respondents were released

every 2-3 weeks to the research staff for recruitment; this staggered approach facilitated problem-solving and team debriefing each week. Once the interview was scheduled, research staff sent a reminder email a few days before the interview to confirm. Interviews, beginning with the verbal informed consent, were audio-recorded using Zoom, which also produced an initial (unvalidated) transcript. All Phase 2 participants received a $25 gift card to thank them for their time and efforts.

As shown by **Table 2**, 40 individuals completed the Phase 2 interviews (62% response rate); these interviews are currently being transcribed and validated by research assistants (each transcript is validated by two independent raters to ensure accuracy) to prepare them for future analysis.

Phase 2 data collection instrument

Phase 2 consists of in-depth semi-structured qualitative interviews conducted by telephone or zoom. The data collection instrument was created by the study team, which includes a person with T1D and a clinical health psychologist that works with PWD and their families. The goal was to create an approximately hour-long semi-structured interview that addressed psychosocial factors that were (1) prevalent among the sample, based on the Phase 1 survey responses and (2) could provide insight regarding gaps, barriers, and promoters to psychosocial health for PWD. The instrument was revised in an iterative process, considering order of questions, stems vs. probes, and length. The content of the interview is summarized in **Table 3** and all data collection materials are available at https://osf.io/yfz6b/.

All staff involved in the Phase 2 fieldwork underwent training in qualitative interviewing by a team member (A.R.P.) with extensive experience in this method, including role-playing (i.e., simulated interviews) and piloting the instrument with multiple members of the study team. Interviewer bias was reduced through the implementation of a standardized interview guide and the systematic training of interviewers.

Table 3 Domains and questions included in the interview guide (phase 2) of the 3-D Study

Domains of Interview Instrument	Questions
1. Diabetes Management & Patient-Provider Relationship	a. What helps you stay engaged with managing your diabetes? b. Can you tell me something that is important to you when it comes to your diabetes that isn't likely to show up in your medical record: that is, something that matters to you but isn't a blood test, diagnosis, or medication? c. How do your interactions with your doctors make you feel about your ability to manage your diabetes well?
2. Comorbidities and Other Health Conditions	a. Do you have any other conditions besides diabetes? b. How do you prioritize taking care of your diabetes with your other health conditions, whether in terms of taking medications as prescribed, following treatment recommendations, or other aspects of care?
3. Mental Health	a. How does the day-to-day experience of managing your diabetes - for example, checking your blood sugar, thinking about carbohydrates in food, or thinking about insulin or medication doses - impact your overall mental health? b. Are there specific aspects of having diabetes that become more challenging for you during times when you feel distressed, sad, or anxious? c. Has there ever been a time when you felt you had to make a "trade-off" between your diabetes and your mental health? [Can you tell me a little bit more about that?] d. What types of behaviors, activities, or strategies have you found to be beneficial to both your diabetes and your mental health?
4. Stigma, Discrimination and Financial Strain	a. What are some of your thoughts, experiences, or feelings towards media representations of diabetes, particularly those that may be perceived as negative? b. How is diabetes viewed by the people you interact with the most? c. How have conversations with people with seemingly negative perceptions or misunderstanding about diabetes impacted you? d. How has the financial burden of taking care of your diabetes impacted you? e. Because of your diabetes, have you ever experienced poor treatment or negative attitudes from doctors or other medical staff? [Can you tell me more about that/those experiences?]

5. Family and Social Support	a. How has having diabetes affected your relationship with your family? b. What resources, people, or community supports have helped you adjust to living with diabetes? c. These last few questions are a little different than the ones previously. I'm going to read you four sentences that I'd like you to complete. i. The first sentence is: "When it comes to my diabetes, I wish my family and friends were MORE [fill in the blank]" ii. The second sentence is: "When it comes to my diabetes, I wish my family and friends were LESS [fill in the blank]" iii. The third sentence is: "When it comes to my diabetes, I wish my doctor was MORE [fill in the blank]" iv. The fourth sentence is: When it comes to my diabetes, I wish my doctor was LESS [fill in the blank]" d. Is there anything else you would like to share about your experiences with diabetes and mental health that we haven't discussed during this interview?

Linkage with healthcare records

The study team will work with DOCTR to link the survey data for Phase 1 participants to their Michigan Medicine healthcare utilization records for the calendar years 2023 and 2024. DOCTR will conduct this linkage and then return a dataset to the 3D Study team that does not have any personal identifiers, but it will have an anonymous code that will allow us to link these healthcare records to the Phase 1 survey responses. These data will be used to assess metrics of healthcare utilization, including referrals to social work/behavioral health, emergency department visits, hospitalizations, diabetes-related complications (e.g., hypoglycemic episodes, amputations) and other metrics of care quality.

Data analysis plans

Quantitative data analysis. We will use descriptive statistics (means for continuous variables and proportions for categorical variables) to quantify the prevalence of psychosocial outcomes in the Phase 1 and Phase 2 samples. Initially, this descriptive analysis will focus on four key psychosocial aspects of diabetes: symptoms of depression (PHQ-9), anxiety (GAD-7), diabetes-related distress (PAID-11), and indicators of diabetes-related stigma. As these variables are expected to be right-skewed, we will examine their distributions and apply transformations (e.g., mean standardize, median split) as appropriate to better meet the assumptions of the regression models described below.

Table 2 provides an illustration of these types of descriptive statistics: the left column shows the Phase 1 sample (n=573) and the right column shows the Phase 2 sample (n=40). Overall, 10.6% of Phase 1 participants have elevated anxiety symptoms, 20.1% have elevated depressive symptoms, and 24.6% have elevated diabetes-related distress. Next, we will examine whether these psychosocial outcomes vary as a function of diabetes type and clinical characteristics (e.g., duration of diabetes, diabetes treatment regimens (oral medications vs. insulin)). We will use chi-squared tests for categorical variables and ANOVA, T-tests, or

Wilcoxon tests (as appropriate, based on the variable distributions) for continuous variables. Finally, we will use linear and logistic regression to examine the association between the four key psychosocial outcomes and glycemic control (indicated by hemoglobin A1c), accounting for age, sex, socioeconomic status, and race/ethnicity. A1c will be modeled as both a continuous variable (standardized on the sample mean) and as a categorical variable (using clinically-relevant thresholds of <=6.4% for adequate control, >=8% for poor control). We will examine whether the relationships between psychosocial outcomes and glycemic control are modified by indicators of SODH (e.g., educational attainment, household income, self-reported financial strain). For all comparisons, the statistical significance will be evaluated using two-tailed tests with a p-value threshold of <0.05. Analyses will be conducted using RStudio statistical software.

Qualitative data analysis. We will use the Rigorous and Accelerated Data Reduction (RADaR)[31] technique for qualitative data analysis to identify prominent themes related to psychosocial aspects of diabetes care. RADaR is an iterative process for analyzing qualitative data in a manner that moves between individual and team-based activities. We will use software, such as NVivo, to support qualitative analysis as warranted by the complexity of the research question being addressed. The analytic team will consist of 2-4 people, who will begin by listening to the audio recordings and reading the transcripts of the semi-structured interviews from Phase 2, then will create a spreadsheet of all data elements, with text organized by interview questions. This table will then be reduced as appropriate for the specific research question being addressed (e.g., analyses examining barriers to care will focus on those probes and responses that address that topic). The team will then begin generating codes, individually and refined collectively, that they will apply to the transcripts; they will create a definition and codebook, which will be revised as needed using a process of debate and consensus. The team will then define and apply the (sub)codes and identify illustrative quotes. Given the maximum variation sampling approach used for Phase 2, the team will examine whether and how themes

varied as a function of the quantitative characteristics (e.g., depressive symptoms, glycemic control) that informed the sampling frame for the qualitative component.

Ethics, Data Availability, and Dissemination

The protocol for this study was approved by the University of Michigan Institutional Review Board (HUM00223735) and complies with the Health Insurance Portability and Accountability Act (HIPAA) standards. All participants provided informed consent, whether written (Phase 1) or oral (Phase 2). All participants signed a HIPAA waiver as part of Phase 1 that permits researchers to work with DOCTR to link their survey data to their healthcare records (described above). The CDI Repository (REP00000214) was approved by the University of Michigan Medical School Institutional Review Board with a waiver of informed consent and HIPAA authorization. It uses retrospective data pulled from the Michigan Medicine electronic medical records and does not involve direct interaction with human subjects.

The 3D Study was pre-registered in the Open Science Framework (OSF) and all project and data collection materials are available at https://osf.io/yfz6b/. All data is kept on a password and two-factor protected server housed at the University of Michigan, in a folder that is only accessible by the project team. Only authorized research personnel (e.g., principal investigator, project coordinator, select research staff) have access to the identifying information on participants. All team members completed certification through the University of Michigan Program for the Education and Evaluation of Responsible Research and Scholarship (PEERRS).

Plans for data sharing were described as part of the informed consent process. De-identified data from Phase 1 survey will be made available through OpenICPSR (https://www.openicpsr.org/openicpsr/) within 6 months of completing data collection. To protect confidentiality, de-identified data from Phase 1 linked healthcare records and the Phase 2 semi-

structured interviews (recordings or transcripts) will not be publicly available, but will be available from the corresponding author on reasonable request.

Findings from the 3D Study will be disseminated to research audiences at scientific conferences (e.g., meetings of the Psychosocial Aspects of Diabetes, American Psychosomatic Society) and peer-reviewed publications. Results will be disseminated to leaders at Michigan Medicine through CDI. Finally, results and their implications will be disseminated to PWD and their families through partnerships with the CDI Patient Advisory Board, advocacy organizations (e.g., local chapters of the American Diabetes Association), and lay media outlets (e.g., Psychology Today, The Conversation).

DISCUSSION

It is established that psychosocial factors are a critical component of person-centered health care. However, these factors are under-recognized by healthcare providers, and even when they are identified, are often inadequately addressed. Preliminary data from the 3D Study demonstrates substantial psychological distress among adults with diabetes, consistent with prior studies. The sequential, explanatory mixed-methods design of the 3D study aims to identify modifiable gaps in addressing psychosocial aspects of diabetes care in a large academic healthcare system. Another strength of our study is the inclusion of diverse types of diabetes (i.e., T2D, T1D, LADA, GD). Particularly, psychosocial factors, such as stigma, may operate differently among individuals with GD, often tied to feelings of shame and guilt stemming from concerns around potential harm to the unborn baby. However, few studies have collected psychosocial measures on diabetes broadly (i.e., among people with GD, T1D, and T2D), in the same sample and with the same instruments, to assess this empirically. By aligning the data collection instruments, with those of these prior studies we add to the potential scientific value of the 3D study.

This study has several limitations. First, it is conducted within a single academic medical center, limiting generalizability to other settings. Second, the study relies on self-reported data, which is subject to both recall error and reporting bias; however, we plan to link these data to healthcare records which will allow us to quantify and account for these threats to validity. Third, the response rate for the quantitative survey was low, even compared to online surveys in general[32], which may have introduced selection bias; the 40-minute survey length may have contributed to this lower response rate. We will examine the ways in which the survey sample differs from the CDI registry (i.e., demographic and diabetes characteristics) to quantify and potentially account for this bias by creating sampling weights. Fourth, while the survey assessed a wide range of experiences of PWD, it did not solicit information from families or healthcare workers, who are also important for addressing psychosocial care gaps. Future studies should seek input from these stakeholders as well. Fifth, while DOCTR employed a systematic approach to sending recruitment emails that was based on their experience with prior studies, we cannot entirely rule out the possibility that emails may have gone to spam folders, resulting in a lower response rate. Alternative recruitment approaches, such as mailed letters, were not employed due to financial constraints of the project. Finally, while the sample reflects the demographics of Michigan Medicine and Washtenaw County, it is not representative of the larger US population.

The 3D Study will integrate qualitative interviews, quantitative survey measures, and clinical healthcare records to generate a comprehensive understanding of the psychosocial care needs of PWD. This knowledge will be shared with advocates and various stakeholders throughout the healthcare system, with the goal of informing the implementation of programs, policies and partnerships to improve psychosocial care outcomes for PWD.

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AUTHOR CONTRIBUTIONS

B. Mezuk (BM), the PI of the study, led the conceptualization, methodology, and funding acquisition, supervision, and edited every draft of the manuscript. C. DeVries (CD), the Study Coordinator, contributed to conceptualization, methodology, investigation, formal analysis, and data curation, and also wrote the first draft of the manuscript. A. Rodríguez-Putnam (ARP), research staff, contributed to methodology, investigation, supervision, and data curation, and edited the manuscript drafts. A. Ewen (AE), K. Mannor (KM) and C. Zhong (CZ), research staff, supported data curation, formal analysis, and methodology. B. Flores (BF), E. Spring (ES), A. Miller (AM), and P. Choudhary (PC), research assistants, contributed to data curation, investigation, and writing, with BF and PC writing sections of the original draft. R. Messina (RM), a Co-Investigator (Co-I), contributed to methodology, supervision, and reviewing manuscript drafts.

CD and ARP contributed equally to this paper.

BM is the guarantor of this work and accepts full responsibility for the overall content, including the conduct of the study, access to the data, and the decision to publish.

COMPETING INTERESTS

The authors declare that they have no competing interests to report.

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Figure legends

Figure 1 Title: Study Design of the 3-D Study: An Explanatory Sequential Mixed Methods Design.

Footnote: T1D, Type 1 Diabetes; T2D, Type 2 Diabetes; GD, Gestational Diabetes; PWD, people with diabetes; CDI, Caswell Diabetes Institute.

Figure 2 Title: Flowchart of participant recruitment into the 3-D Study

Footnote: This flowchart illustrates the participant recruitment process for Phases 1 and 2 of the 3-D Study. For Phase 1, the flow begins with target sample of diabetes patients seen at UM and details the steps leading to the final sample of survey respondents (N=573, 5% response rate). Participants in Phase 2 (N=40, 62% response rate) were targeted for recruitment based on their responses to Phase 1 on five features: (1) diabetes control (e.g., self-reported A1c), (2) symptoms of depression and anxiety (e.g., GAD-7, PHQ-9), (3) symptoms of diabetes distress (e.g., PAID-11), (4) history of mental health treatment, and (5) social factors such as experiences of discrimination and stigma. We also considered demographic characteristics (e.g., age, race, sex, educational attainment and household income) in constructing the Phase 2 target sample.

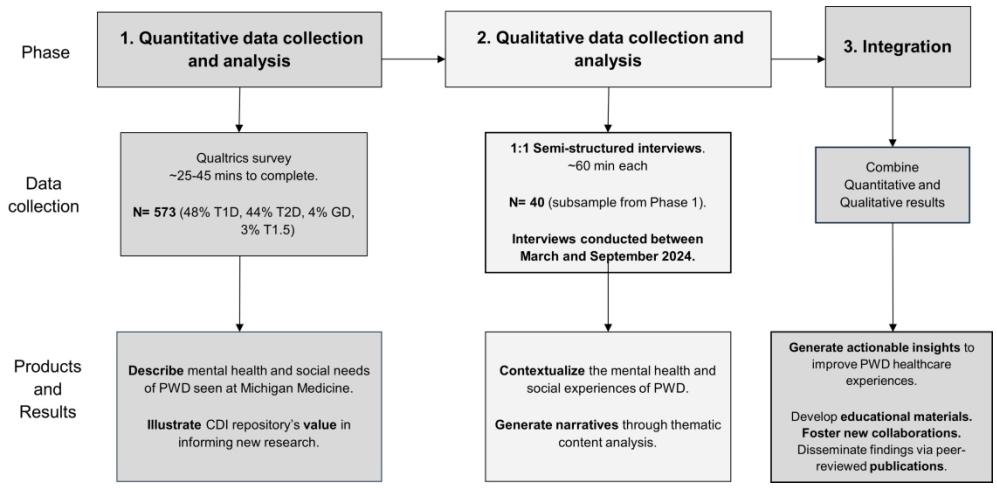

Figure 1. Study Design of the 3-D Study: An Explanatory Sequential Mixed Methods Design. T1D, Type 1 Diabetes; T2D, Type 2 Diabetes; GD, Gestational Diabetes; PWD, people with diabetes; CDI, Caswell Diabetes Institute.

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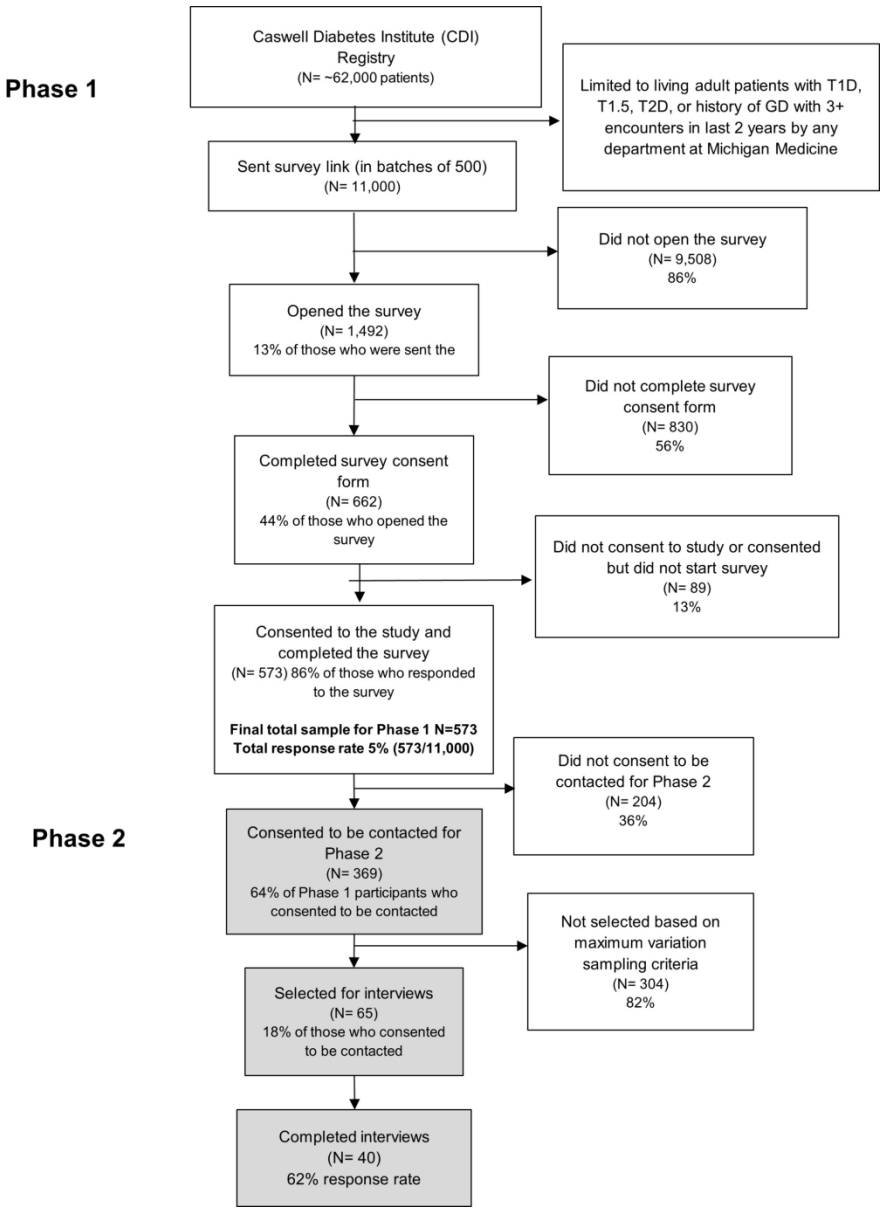

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Online Supplementary Appendix A

University of Michigan Institutional Review Board

Letter of Invitation to Participate in Research

The 3-D's of Self-management and Mental Health: Diabetes, Distress, and Disparities

Dear_____,

The University of Michigan (UM) seeks to understand the needs of people with diabetes and their healthcare experiences. The purpose of our study is to research the mental health and social needs of people with diabetes seen at Michigan Medicine. Dr. Briana Mezuk is leading this study and Caitlan DeVries is coordinating the study.

Michigan Medicine records show that you are eligible to participate in a survey about people with diabetes. If you would like to join, we will ask you to complete this online survey. Below is an infographic that explains a little bit more about the study. Your participation in this study is voluntary. If you choose to join you may choose to stop at any time. Feel free to contact us at caitland@umich.edu or 734-615-9204 if you have questions.

Sincerely,

Dr. Briana Mezuk

&

Caitlan DeVries

THE DD STUDY

THE 3DS OF SELF-MANAGEMENT AND MENTAL HEALTH: DIABETES, DISTRESS, AND DISPARITIES

WHAT IS THIS STUDY ABOUT?

The goal of this study is to understand the emotional and social needs of people with diabetes and their healthcare experiences.

AT A GLANCE

- People with diabetes often experience burnout and poor mental health from managing their condition.
- Getting appropriate and timely emotional and social support from healthcare providers is challenging.
- This study seeks to understand the emotional needs of people with diabetes and to identify gaps in the healthcare system to address those needs.

WHO CAN PARTICIPATE?

- Adults over the age of 18 who have type 1, type 2, type 1.5 (LADA), or gestational diabetes.

WHAT IF I CHANGE MY MIND?

- Participation in the study is voluntary.
- Your decision to participate in the study will not impact your care at Michigan Medicine.

WILL I BE COMPENSATED?

- All participants will be entered into a raffle for a $100 gift card.
- If you also participate in a zoom interview afterward, you will receive an additional raffle ticket for another $100 gift card.

CONTACT US

Dr. Briana Mezuk, principal investigator
Caitlan DeVries, project coordinator
CaitlanD@umich.edu
734-615-9204
IRB # HUM00223735

WHAT IS INVOLVED? (25 MINS - 45 MINS)

- A survey will ask about your experiences living with diabetes, including questions about mental health, self-management behaviors (diet, exercise, medications, technology), stigma, eating behaviors, and burnout.
- Researchers will ask permission to view your Michigan Medicine health records once to understand better how people with diabetes navigate the healthcare system.
- After the survey, you may also be invited to participate in a private interview to discuss more about your experience living with diabetes which will take an additional hour.

BENEFITS AND RISKS

- While you will not personally benefit from this research, participating will help Michigan Medicine better address the emotional and social needs of people with diabetes.
- Some questions will ask about sensitive topics. You can skip any question you don't feel comfortable answering.

CONFIDENTIALITY

- Your data will be kept confidential. Your healthcare providers will not be told of your participation (or refusal to participate). Only members of the research team will have access to study data.
- Study data will be stored on a secure computer using a coded study identification number, not any identifying information.

University of Michigan, Caswell Diabetes Institute Logo