VDiSC Protocol Summary

PARTICIPANT AREA	DESCRIPTION
Title	Virtual Diabetes Specialty Clinic: A Study Evaluating Remote Initiation of Continuous Glucose Monitoring
Précis	This study will assess feasibility and efficacy of establishing a virtual diabetes clinic with a focus on introduction of CGM technology and ongoing CGM use to minimize such rate-limiting factors as geography, cost and access to specialty care
Objectives	The objective of this study is to evaluate a virtual diabetes clinic model, for adults with either T1D or T2D, that supports integration of CGM into diabetes self-management and use of decision support technology.
Study Design	Single-arm prospective longitudinal study
Eligibility Criteria	**Inclusion Criteria** • Age ≥18 years old • Diagnosis of type 1 diabetes or type 2 diabetes and using insulin therapy (at least 3 injections of insulin per day or insulin pump that is compatible with Tidepool software) *Multiple daily injection (MDI) users must be willing to use a device provided by the study that records the injection dosages and/or enter insulin dosing information through an app* • See a healthcare provider at least once a year • Resident of United States and plan to reside in the U.S. for the duration of the study *This requirement is due to virtual clinic license requirements and U.S. use restrictions for some study software and devices. Not all U.S. states may be eligible for inclusion due to virtual clinic license status.* • Use either an Android or iOS smartphone that is compatible with app requirements that are needed for the study • Access to a compatible computer with internet • Understand written and spoken English • Willing and able to follow the study procedures as instructed **Exclusion Criteria** • Use of real-time CGM (including Abbott Libre or integrated pump system) in last 24 months (interval blinded CGM use is acceptable) • Current use of any off-label glucose-lowering medications for diabetes type (Example: T1D use of non-insulin, anti-diabetic medications including SGLT2 inhibitors) *Use of such medications during the study will also be prohibited.* • Females who are pregnant, intending to become pregnant, or breastfeeding during the study • Current renal dialysis or plan to begin renal dialysis during the study • Active cancer treatment • Extreme visual or hearing impairment that would impair ability to use real-time CGM • Known adhesive allergy/prior skin reaction or skin reaction identified during the blinded CGM use phase that would preclude continued CGM use • Participation in a different diabetes management study during the study • Planned relocation to a state other than current state of residence during the study if virtual clinic is not licensed in the new state. *Individuals working routinely in a state other than current state of residence in the next six months are also ineligible if the virtual clinic is not licensed in that state.*

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Sample Size	The recruitment target is 300 initiating CGM.
Outcomes	**Primary Outcome:** Percentage of CGM use over 26 weeks **Secondary Outcomes:** Participant- reported outcomes including psychosocial and diabetes treatment satisfaction questionnaires; CGM metrics for hypoglycemia (<54 and <70 mg/dL), hyperglycemia (>180 and >250 mg/dL), time in range (70-180 mg/dL), mean glucose, and glycemic variability (coefficient of variation); HbA1c **Key Safety Outcomes:** Severe hypoglycemia, diabetic ketoacidosis, and hospitalizations
Participant Duration	Study participation will be up to 12 months.
Protocol Overview/Synopsis	Patient Population Adults ≥ 18 years with type 1 diabetes or type 2 diabetes using insulin therapy who are not CGM users will be enrolled. Potential participants may be recruited through insurance providers, primary care networks, or health care providers. Baseline Data Collection Baseline data collected will include demographics, height and weight, socioeconomic status, diabetes history, knowledge of and experience with diabetes devices, medical history and medications, and health-related physical activity. Questionnaires will collect information related to hypoglycemia awareness, treatment satisfaction, and psychosocial issues. Participant contact information will be collected. Contact information for the participant's diabetes healthcare provider will also be collected. HbA1c Participant will receive fingerstick HbA1c kits that will be sent to a central lab for measurement after enrollment and at 13 weeks, 26 weeks, 39 weeks, and 52 weeks. Contact between Study Team and Participant Each participant will be assigned to work with virtual clinic team members. Mental health service support options for diabetes-related mental health issues will be discussed as needed. Virtual clinic team members will check in with participants during study follow up to review CGM data and recommendations related to diabetes management. CGM Use Participants will use a blinded CGM device for a single sensor wear period prior to CGM initiation. Participants may be asked to use a blinded CGM for an additional sensor wear period(s) if enough CGM data are not available to establish a baseline that can be used as baseline comparator data. Virtual training will include CGM set up, sensor insertion, alerts and alarms, uploading data, and visualizing data. Changes in Insulin Dosing If the virtual clinic team believes that changes in insulin type or dosing should be considered, they will work with the participant to implement any such changes. Decision support tools, which include use of a mobile application, may be used if available to provide the virtual clinic team with potential recommendations regarding insulin use.