Effect of CGM Initiation Approach on Time In Range in People with Type 2 Diabetes

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1. Abbreviations

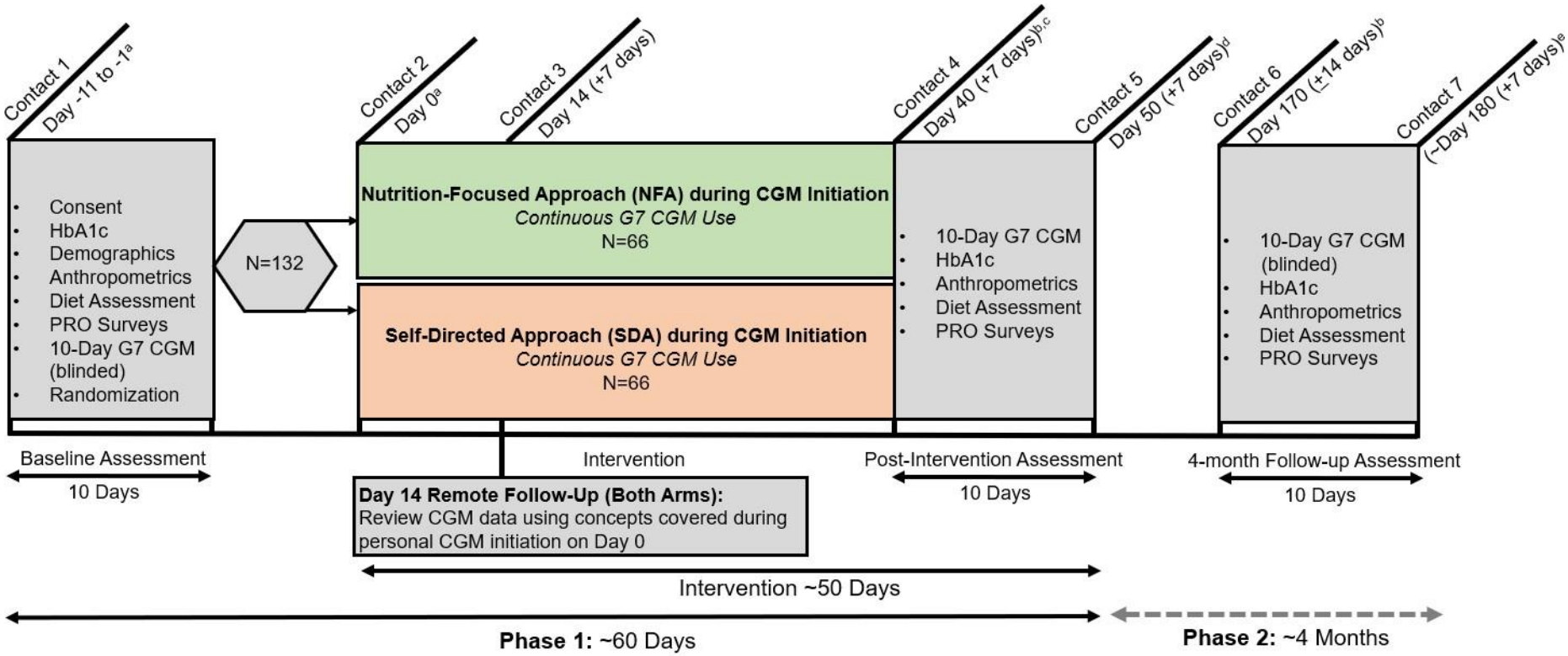
Abbreviation	Definition
AE	Adverse event
ADA	American Diabetes Association
ASA24	Automated self-administered 24-Hour dietary assessment tool
BGM	Blood glucose monitoring
BMI	Body mass index
CGM	Continuous glucose monitoring
CI	Confidence interval
EMR	Electronic medical record
HbA1c	Glycated hemoglobin
HCP	Healthcare provider
HEI	Healthy eating index
HIPAA	Health insurance portability and accountability act
IRB	Institutional review board
ICF	Informed consent form
ID	Identification
IDC	International Diabetes Center
ITT	Intention to treat
MOP	Manual of procedures
NFA	Nutrition-focused approach
PP	Per protocol
PRO	Patient reported outcome
PWD	People with diabetes
RDN	Registered dietitian nutritionist
SAE	Serious adverse event
SDA	Self-directed approach
SOC	Standards of medical care

T2D	Type 2 diabetes
TIR	Time in range
UPIRTSO	Unanticipated problems involving risks to subjects or others

2. Protocol Summary

Title:	Effect of CGM Initiation Approach on Time In Range in People with Type 2 Diabetes
Population:	Adults ≥18 years with T2D who are not using insulin or other anti-hyperglycemic agents with a known hypoglycemia risk
Intervention:	Use of a nutrition-focused approach versus a self-directed approach during CGM initiation
Phase 1 Objective:	To evaluate the effect of using a nutrition-focused approach versus a self-directed approach during CGM initiation on CGM-derived metrics, dietary intake assessment, and patient reported outcomes
Phase 2 Objective:	To evaluate the impact of discontinuing CGM for 4 months after the completion of the Phase 1 study intervention on CGM-derived metrics, dietary intake assessment, and patient reported outcomes
Phase 1 Outcome Measures:	*Primary:* Differential change in CGM-derived TIR (% time with glucose 70-180 mg/dL) from baseline to post-intervention between NFA and SDA arms *Secondary:* Difference in total Healthy Eating Index score during the post-intervention period between NFA and SDA arms
Phase 2 Outcome Measure:	*Primary:* Change in CGM-derived TIR (% time with glucose 70-180 mg/dL) from post-intervention to 4-month follow-up for combined NFA and SDA arms
Design:	Two month non-pivotal, randomized, parallel group, two-arm, prospective, pilot study. 1:1 randomization to either NFA or SDA during CGM initiation. Follow-up assessment four months after discontinuing CGM.
Total Study Duration:	Approximately 22 to 26 months (18-24 months to complete Phase 1 and 4 additional months to complete the Phase 2 follow-up)
Participant Duration:	Phase 1: Approximately 60 days Phase 2: Approximately 120 days

3. Study Schema



[a] Non-CGM baseline assessments should be completed on Day -11. The 10-day blinded CGM assessment at baseline should be completed Day -11 to Day -1; however, if the CGM sensor does not capture at least 7 days of glucose data, a second sensor will be required, and the baseline assessment window may be extended. Day 0 is when the intervention begins. There may be several days between Day -1 and Day 0 to account for repeat sensor wear and scheduling flexibility. The difference between Day -1 and 0 should be as short as possible.

[b] On approximately Day 40 and Day 170, a 10-day CGM assessment begins and one ASA24 diet assessment is completed.

[c] The Post-Intervention and 4-Month Follow-up CGM assessments should last approximately 10 days; however, if the CGM sensor does not capture at least 7 days of data during the Post-Intervention and 4-Month Follow-up assessments, the window may be extended to accommodate additional CGM data collection.

[d] Contact 5 is the Study Completion visit; it should occur approximately 10 days after Contact 4.

[e] Contact 7 is the last Follow-up contact; it should occur approximately 10 days after Contact 6.

4. Schedule of Activities

	Baseline (10 days)	**Intervention** (~50 days *including* the 10-day post-intervention period)		**Post-Intervention Assessment & Study Completion** (10 days)		**Follow-Up Assessment** (10 days)	
Study Phase	**Phase 1**					**Phase 2**	
Contact	1	2	3	4	5	6	7
Visit Type	Clinic (Day -11)	Clinic	Remote	N/A	Clinic	Clinic	N/A
Study Day(s)[1]	-11 to -1	0	14 (+7)	40 (+7)	50 (+7)	170 (±14)	180 (+7)
Consent	X						
HbA1c	X				X	X	
Demographics	X						
Up to 10-Day Blinded G7 CGM Assessment	X					X	
Blinded G7 CGM Data Downloaded and Saved		X					X[6]
ASA24 Diet Recall	X	X[4]		X[5]	X	X[5]	X
DietID Diet Recall	X				X		
PROs: Diabetes Distress, Diet Adherence, Efficacy Surveys, and Diabetes Self Care	X				X	X	
PROs: Intervention Fidelity and Post-Intervention Surveys					X		
Diabetes Medication Assessment	X	X	X		X	X	

BP, Weight, Height[2]	X				X	X	
Randomization[3]	X[3]						
Participant Receives Randomization Assignment		X[3]					
CGM Initiation / Education (based on randomization arm)		X	X				
Continuous Real-time G7 CGM Use		◄		X	►		
Real-time G7 CGM Data Downloaded and Saved			X		X		
Up to 10-Day Real-time G7 CGM Assessment Begins				X			
Adverse Events	◄			X	►	X	

[1] If indicated, up to seven or 14 days can be added to or subtracted from the specified contact date to allow for scheduling flexibility; [2] Height at baseline only; [3] Randomization occurs for scheduling purposes only; the randomization assignment is ***not*** shared with the participant during Contact 1 and will not be shared at Contact 2 until a minimum of 7 days of blinded G7 CGM data are confirmed; [4] This ASA24 is considered part of the baseline assessment and should occur ***before*** any of the Contact 2 activities [5] Two ASA24 assessments on non-consecutive days should be completed during the post-intervention and follow-up periods, one should occur on approximately Day 40 and Day 170 and one on approximately Day 50 and Day 180 [6] Participants may have the option to return receivers via postal mail; if this occurs, data download will be delayed

5. Phase 1 Background

More than 37 million people in the United States have diabetes, and type 2 diabetes (T2D) accounts for 90-95% of all diagnosed cases. The number of adults diagnosed with diabetes has more than doubled in the last 20 years,[1] which suggests increasing burden on the economy, healthcare system, and families affected by the disease. Options to help manage T2D are more important than ever before.

Nutrition interventions have long been recognized as a critical component of diabetes management, with some interventions in people with T2D demonstrating up to 2% reductions in glycated hemoglobin (HbA1c).[2] Despite knowing that nutrition can be a powerful driver for improved glycemic outcomes, like HbA1c, people with diabetes (PWD) have described determining what to eat as the most challenging part of their treatment plan.[2] More specifically, one survey showed that 64% of people with T2D who do not use insulin rated food choices as having the "biggest impact" on their daily life.[3]

Current guidance from the American Diabetes Association (ADA) Standards of Medical Care (SOC) states there is no "one-size-fits-all" eating pattern, or ideal macronutrient distribution, that works for all people with diabetes.[2] A variety of eating patterns (e.g., Mediterranean, very-low-carbohydrate, vegetarian) have demonstrated good efficacy for PWD. However, diet quality is an important factor no matter which eating pattern someone chooses. Dose-dependent, inverse associations have been observed between higher diet quality and total or cause-specific mortality.[4] Specifically for people with T2D, one study showed mortality risk was 87% greater for people with the lowest quality diet compared to the highest quality,[5] and another study showed that higher quality diets, as part of an overall healthy lifestyle, were associated with a significantly lower risk of microvascular complications.[6] Diet quality has also been shown to impact glycemia in people with T2D, with lower quality diets showing nearly three-fold odds of poorer glycemic measures compared to higher quality diets.[7]

Diet quality can be assessed using several standardized approaches.[8] The Healthy Eating Index (HEI), which assesses the degree to which an eating pattern aligns with the Dietary Guidelines for Americans, is one well-recognized diet quality indice.[9] The HEI is a scoring method that includes (scores) 13 dietary components, with nine components for which greater consumption is desirable (e.g. total vegetables, whole grains) and four components for which lower consumption is desirable (e.g. added sugar, refined grains).[9] The HEI is density-based, meaning it considers diet quality from the perspective of how foods are consumed in relation to total kcals consumed (i.e. quality not the quantity of what is eaten). Therefore, calculation of the HEI requires comprehensive dietary intake assessment, such as from 24-hour recalls or food frequency questionnaires. The ASA24 (Automated Self-Administered 24-hour) recall is an example of a program that uses a validated approach to collect 24-hour dietary recalls and that also includes statistical analysis coding support to assist with the HEI calculations.[8]

The ADA,[2] the American Heart Association (AHA),[10] and other professional societies[11] indirectly address diet quality by encouraging core principles for any eating pattern. The ADA, for example, places emphasis on choosing more non-starchy vegetable intake, minimizing added sugars and refined grains, and choosing whole foods over highly processed foods whenever possible. It is reasonable to believe that adherence to these principles would improve diet quality.

People with T2D often learn about how food affects their glucose by performing intermittent

fingersticks. However, fingersticks provide only single moments in time and do not show the full extent of glucose changes surrounding food intake; this may partially explain why infrequent fingerstick glucose testing has not been associated with improved glucose management in people with T2D who do not use insulin.[12]

Continuous glucose monitoring (CGM) is an alternative to fingerstick glucose monitoring. A key benefit of CGM is its ability to show constant, real-time glucose and granular changes in glycemia over short and long periods of time. The ADA recognizes CGM as an effective tool to guide medical nutrition therapy and other lifestyle changes, and also states that CGM can provide insights into more personalized diabetes care.[13] The ADA calls out ten core metrics that should be considered when evaluating CGM data. There is specific emphasis on time in range (TIR), which is defined as more than 70% of time with glucose in the target range of 70-180 mg/dL; this applies to most people with T2D.[14] A seven to 14-day TIR percentage has been shown to correlate with HbA1c[15,16] and emerging data suggest TIR is also inversely associated with risk of diabetes-related complications.[17]

The beneficial impact of CGM on glycemia in people with type 1 diabetes and people with T2D who use insulin is well established.[13] However, the impact of CGM on glycemia in people with T2D who do not use insulin is less clear, and its effects may be somewhat different than what is seen in those who do use insulin (or medications with daily titrations). In the case of people with T2D who do not use insulin—and who remain on a stable medication regimen after starting CGM—the glycemic improvements are likely driven by lifestyle changes (since improvements would not be due to medication additions or daily medication titrations). The idea that lifestyle changes may drive glycemic improvements in people with T2D who use CGM has been considered by emerging research,[18-20] with some research specifically suggesting that CGM may enhance patient engagement and motivate or modify behavior changes.[19,21-24] Because CGM provides immediate, personalized feedback (real-time and retrospectively)—in an accessible, convenient manor—this device could be used specifically to optimize dietary changes in people with T2D who do not use insulin.

Limited research has been done to directly assess the impact of using CGM to guide food choices, specifically food changes that align with current evidence-based nutrition recommendations. Choe et al investigated the effect of using CGM to motivate lifestyle change focused on eating behaviors in adults who were T2D treated with basal insulin or less intense therapies.[25] In this study, fingerstick blood glucose monitoring (BGM) was the comparator and change in HbA1c was the primary outcome. The CGM arm showed a greater improvement in HbA1c compared to the BGM arm after 12 weeks (-0.6% versus -0.1%; $p<0.001$); however, changes in CGM metrics and detailed changes in food intake between groups were not reported.

HbA1c is commonly used to evaluate glycemic outcomes in clinical research. However, recent guidance recognizes TIR as an acceptable end point for clinical trials and a standardized approach to CGM data collection and reporting in clinical trials has been published.[14,26]

To date, it appears no research has been done to evaluate the impact of CGM on TIR when CGM is introduced specifically as a tool to guide glucose and high-quality food choices in people with T2D. Phase 1 of the following protocol describes a randomized pilot trial intended to explore the efficacy of using a theory-driven, nutrition-focused approach (NFA) during CGM initiation. This Phase 1 research will evaluate the difference between a NFA and a self-directed approach (SDA) during CGM initiation in people with T2D who are not using insulin. The SDA is intended to reflect usual care and the way CGM is often introduced to PWD.

6. Phase 2 Background

Limited research has been done to evaluate the impact of discontinuing CGM in adults with T2D, and it appears no research has been published on the impact of discontinuing CGM in people with T2D who do not use insulin and who have used CGM specifically for lifestyle changes.

The MOBILE study compared glycemic outcomes after eight months of CGM or BGM in adults with T2D using basal insulin.[27] At the end of eight months, the use of CGM resulted in greater glycemic improvements than the use of BGM. In a 6-month MOBILE study follow-up, participants originally randomized to CGM were re-randomized to either continue their CGM or discontinue their CGM. Discontinuation of CGM resulted in a loss of about one-half of the initial TIR gain (i.e. the 24% gain in TIR from the start to the end of the MOBILE intervention was reduced to a 12% gain in TIR by 6 months after the intervention); whereas, continuation of CGM resulted in a stable TIR.[28] Investigators speculated that given only minimal changes in insulin dose during the follow-up period, the reduction in TIR for the CGM discontinuation arm was likely due to behavioral changes related to lack of CGM data access. It is unclear when the TIR gain was lost over the 6-month follow-up period. It is also unclear which behaviors may have changed since neither objective nor subjective measurements were evaluated.

Similarly, in a small study (n=46), adults with T2D used a real-time CGM for 90 days; 90 days later about half of the adults (n=21) wore a blinded CGM.[29] Discontinuation of the CGM was associated with worsening glycemic control. Compared to the real-time CGM wear period and 90 days after CGM discontinuation, TIR was 15% lower during the blinded CGM wear period (67% vs. 82%; $p<0.05$).

The Phase 2 research will assess the impact of discontinuing CGM 4 months after the completion of the Phase 1 study intervention on CGM-derived metrics, dietary intake assessment, and patient reported behaviors and outcomes. Both groups, those who received the NFA and the SDA during CGM initiation, will be invited to participate. The Phase 2 research will help describe the effect of discontinuing CGM therapy in people with T2D who do not use insulin and who have used CGM specifically to initiate lifestyle changes. Some objective and subjective behavior changes will also be assessed, which may help explain potential changes in TIR.

7. Rationale and Objective

People with diabetes want to achieve their glycemic targets. One survey showed that 93% of people with T2D state that they are ‘very willing’ or ‘somewhat willing’ to do more to achieve better glycemic control.[30] Another survey reported that 42% of people with T2D said it is hard to know what food is healthy and 80% reported a desire for more nutrition information.[31]

Nutrition plays a profound role in human health.[32] Unfortunately, nutritional intake (as measured by diet quality) is quite poor in the United States.[33] The average diet quality score based on HEI-2015 is 58 on a scale that ranges from 0 of 100; this is equivalent to a letter grade of D. Higher quality diets are associated with better glycemic outcomes and reductions in comorbidities in people with T2D. At the same time, observational research has shown that very few people improve their diet quality after a T2D diagnosis, thus suggesting that additional strategies and/or interventions are needed to help improve dietary intake.[34]

CGM provides personalized, accessible glucose data, and CGM use has been shown to lead to better glycemic outcomes.[13] Various tools,[22] methods,[35] and programs[36] exist to educate CGM users on effective use of the technology and its associated data. However, specific emphasis on nutrition guidance has not been embedded into these trainings and, thus, potentially misses the opportunity to achieve the additional glycemic benefits associated with improved dietary intake.

Opportunities exist to assess whether presenting nutrition guidance during CGM initiation could improve glycemic outcomes and diet quality for the growing population of people with T2D. This research will help determine if it is useful to introduce the CGM as a device that can guide personalized nutrition recommendations with focus on diet quality (i.e. food choices that align with current evidence-based nutrition recommendations for PWD).

This work is important because it will show how CGM users respond to CGM data with and without nutrition guidance and whether there is added benefit for glycemic outcomes and diet quality with a nutrition-focused approach. This is different from other CGM studies because it will directly address nutrition as a driver for improved TIR, and it will also measure how diet quality changes.

Currently, CGM is only accessible to a limited number of people with T2D who do not use insulin but, there are some signs suggesting that expanded recommendations for CGM use and coverage may be coming.[20,37,38] When (if) that time comes, the diabetes care community would benefit from being prepared with researched approaches for initiating the technology, especially in a way that may promote improved diet quality.

This research will also fill a knowledge gap by providing insight into the dietary intake and eating patterns of people with T2D. Results of this research may allow future interventions in people with T2D to target nutrition areas where there is the greatest room for improvement and/or impact.

The objective of the Phase 1 research is to evaluate the effect of using a NFA versus a SDA during CGM initiation on CGM-derived metrics, dietary intake, and patient-reported outcomes (PROs) in people with T2D who do not use insulin. The objective of the Phase 2 research is to help explain any impact of discontinuing CGM use in people with T2D who do not use insulin.

8. Risk and Benefit

Known Potential Risks

CGM use: CGM use is a routine part of the care for many PWD. CGM users usually report less pain or discomfort with CGM than with capillary blood glucose testing. Mild pain on insertion of CGM may be experienced by subjects at low frequency. Known allergies to medical grade adhesives is an exclusion from participation. Cutaneous complications of CGM use are typically wear-related erythema, itching, and induration. The incidence of these complications is expected to be low, 0.13 to 0.15 events per week of wear-time, with the majority (79%) being mild.[39] Study discontinuation rate due to skin reactions is expected to be very low.

Blood samples: Blood sample for HbA1c is a standard care procedure which could occur regardless of participation in this study; however, the interval between the baseline HbA1c and the post-intervention HbA1c is shorter than what may be recommended by routine care (approximately 60 days rather than 90 days).

Blood samples for HbA1c may be collected by venipuncture or fingerstick. Venous blood draws may cause discomfort and bruising at the puncture site. Participants may also experience lightheadedness or fainting during

the blood draw and there is a slight risk of infection. The total blood volume needed for each HbA1c test is less than 5 mL. Blood sample by fingerstick may cause discomfort and bruising at the puncture site and there is a slight risk of infection. The total blood volume needed for each point-of-care fingerstick HbA1c test is minimal.

Privacy*:* The study requires use of web-based applications, which include providing personal information and personal health information. There is always some risk that data will be compromised, and that personal information will become available to unexpected parties. Several mechanisms are in place to protect personal information, including use of de-identified participant identification (ID) numbers whenever possible.

Surveys: Surveys will be used to collect information on food intake and other PROs. Sometimes survey questions can trigger uncomfortable feelings. Participants will be informed that they are not required to respond to questions that make them uncomfortable for whatever reason.

Known Potential Benefits

There is no guaranteed personal benefit from participating in this study. However, participants in both arms of the study may benefit from seeing and using their CGM data. CGM data may aid in a better understanding of how foods, behaviors, medications, and circumstances impact glucose values. Participants in the NFA arm may receive additional benefits because they will receive instruction and education on using CGM data specifically to adjust eating behaviors in ways that align with current nutrition recommendations.

Additionally, information from this study could lead to new and more effective methods for helping people with T2D manage their diabetes and/or adhere to nutrition therapies.

Analysis of Risks in Relation to Benefits

In this study, risks posed beyond standard care are minimal. The rationale for exposing study participants to the minor risks associated with CGM use, blood samples, privacy, and survey data collection is that these components of usual diabetes care are outweighed by the potential benefit to future people with diabetes (if this study can help define ideal approaches to CGM initiation in this population).

9. Phase 1 Study Objectives

Primary Objective
To evaluate the effect of using a NFA versus a SDA during CGM initiation on CGM-derived TIR.

Secondary Objective
To evaluate the effect of using a NFA versus a SDA during CGM initiation on dietary quality.

Exploratory Objectives
To describe the effects of using a NFA versus a SDA during CGM initiation on additional CGM-derived metrics, components of dietary intake, other markers of health, and PROs. To describe potential behavioral mechanisms associated with change in study outcomes.

10. Phase 2 Study Objectives

Primary Objective
To evaluate the impact of CGM discontinuation 4 months after the completion of the Phase 1 study intervention on CGM-derived TIR.

Exploratory Objectives
To describe changes in additional CGM-derived metrics, HbA1c, dietary intake assessment, medication use, and PROs 4 months after the completion of the Phase 1 study intervention and CGM discontinuation.

11. Phase 1 Study Outcome Measures

At the end of the Phase 1 intervention, differences from baseline will be assessed within and between study arms (primary outcome). The baseline period includes an approximately 10-day assessment before the intervention begins. The intervention begins on Day 0 and stops on approximately Day 50, this includes the 10-day post-intervention assessment. The post-intervention assessment period occurs approximately Day 40 to Day 50; during this time, participants continue in their intervention arm and continue using their CGM as instructed.

CGM-related outcome measures include approximately 10 days of CGM data collection during the baseline and the post-intervention assessment periods. CGM data is collected as follows:

- Baseline: Up to 10 days of CGM data from a Dexcom G7 sensor paired with a physically blinded Dexcom receiver
- Post-intervention: Up to 10 days of CGM data from a Dexcom G7 sensor paired with apps on the participant's personal cell phone (glucose data transferred to study team via cloud)

Of note, G7 data is identical whether data is pulled through a Dexcom receiver or a participant's personal cell phone. The only difference between the two scenarios is that the participant will not be able to view their glucose data during the baseline period (blinded data).

Primary Outcome

Outcome	Assessment Method
1. Change in CGM-derived TIR (% time with glucose 70-180 mg/dL) from baseline to post-intervention	See CGM-related outcome measures described above

Secondary Outcome

Outcome	Assessment Method
1. Difference in total HEI score between groups during the post-intervention period	Automated Self-Administered 24-hour (ASA24®) survey-derived total HEI-2015* score; score based on two diet recalls per assessment period, collected via web-based survey (ASA24 Version 2022 or later)

*Survey-derived HEI-2015 scores may be replaced with a newer scoring option if both scoring and analysis code become available

Exploratory Outcomes

Outcome	Assessment Method
1. Change in other CGM-derived core metrics from baseline to post-intervention; including as described by the 24-hour period, daytime period (6AM to 11:59PM), and nighttime period (12AM to 5:59PM): • number of days CGM device is worn • % time CGM sensor is active • mean sensor glucose mg/dL • % coefficient of variation • glucose management indicator (GMI) • % time above >250 mg/dL • % time above >180 mg/dL • % time below <70 mg/dL • % time below <54 mg/dL	See CGM-related outcome measures described above
2. Other CGM-derived metrics: • Change in % time in tight range (% time with glucose 70-140 mg/dL) from baseline to post-intervention • % of participants reaching CGM-derived consensus targets during post-intervention[26] o % reaching >70% TIR (% time with glucose 70-180 mg/dL) o % reaching ≥5% improvement in TIR (% time with glucose 70-180 mg/dL) compared to baseline o % reaching >70% time TIR (% time with glucose 70-180 mg/dL) and reaching a ≥5% improvement in time in range compared to baseline	See CGM-related outcome measures described above
3. Describe HEI component scores by group during the post-intervention period	ASA24 survey-derived HEI-2015* component scores; scores based on two diet recalls per assessment period, collected via web-based survey (ASA24 Version 2022 or later)
4. Change in additional nutrition metrics from baseline to post-intervention • total energy intake • macronutrients and fiber	ASA24 survey-derived values based on two diet recalls per assessment period, collected via web-based survey (Version 2022 or later)

• select micronutrients	
5. Change in patient-reported outcome survey scores from baseline to post-intervention • Diabetes Distress Scale-17 Score • Diet Adherence • Efficacy Survey Score	Validated Diabetes Distress Scale Score,[40] Diet adherence survey score, Efficacy survey scores; surveys administered via REDCap
6. Change in HbA1c from baseline to post-intervention	HbA1c assessed by either point-of-care fingerstick or venous draw
7. Change in body mass index (BMI) and body weight from baseline to post-intervention	Calibrated clinic scale and stadiometer; BMI calculated from measured weight and height
8. Describe fidelity to the intended intervention, including dose and content delivered, content enacted, and satisfaction	Data collection from study staff via paper documentation; and participant surveys administered via REDCap
9. Describe post-intervention patient-reported behavioral mechanisms	Participant surveys administered via REDCap

12. Phase 2 Study Outcome Measures

The Phase 2 follow-up assessment period is approximately 4 months and begins the day after Phase 1 is complete (approximately Day 51 to Day 180).

CGM-related outcome measures include approximately 10 days of CGM data collection during the baseline, post-intervention, and follow-up assessment periods. CGM data collection for the baseline and post-intervention are described under Phase 1 Study Outcomes Measures. CGM data at follow-up will be collected in the same way as baseline, which is up to 10 days of CGM data from a Dexcom G7 sensor paired with a physically blinded Dexcom receiver.

Primary Outcome

Outcome	Assessment Method
1. Change in CGM-derived TIR (% time with glucose 70-180 mg/dL) from post-intervention to follow-up for combined NFA and SDA arms	See CGM-related outcome measures described above

Exploratory Outcomes

Outcome	Assessment Method
1. Change in other CGM-derived core metrics from post-intervention to follow-up: • number of days CGM device is worn • % time CGM sensor is active	See CGM-related outcome measures described above

• mean sensor glucose mg/dL • % coefficient of variation • glucose management indicator (GMI) • % time above >250 mg/dL • % time above >180 mg/dL • % time below <70 mg/dL • % time below <54 mg/dL	
2. Other CGM-derived metrics: • Change in % time in tight range (% time with glucose 70-140 mg/dL) from post-intervention to follow-up • % of participants reaching CGM-derived consensus targets during follow-up[26] o % reaching >70% TIR (% time with glucose 70-180 mg/dL)	See CGM-related outcome measures described above
3. Change in HbA1c from post-intervention to follow-up	HbA1c assessed by either point-of-care fingerstick or venous draw
4. Describe total HEI score by NFA and SDA group during the follow-up period	Automated Self-Administered 24-hour (ASA24®) survey-derived total HEI-2015* score; score based on two diet recalls per assessment period, collected via web-based survey (ASA24 Version 2022 or later)
5. Describe HEI component scores by NFA and SDA group during the follow-up period	ASA24 survey-derived HEI-2015* component scores; scores based on two diet recalls per assessment period, collected via web-based survey (ASA24 Version 2022 or later)
6. Change in additional nutrition metrics from post-intervention to follow-up • total energy intake • macronutrients and fiber • select micronutrients	ASA24 survey-derived values based on two diet recalls per assessment period, collected via web-based survey (Version 2022 or later)
7. Change in diabetes medication by class and dose from post-intervention to follow-up	
8. Change in body mass index (BMI) and body weight from post-intervention to follow-up	Calibrated clinic scale and stadiometer; BMI calculated from measured weight and height
9. Change in patient-reported outcome survey scores from post-intervention to follow-up	Validated Diabetes Distress Scale Score,[40] Diet adherence

• Diabetes Distress Scale-17 Score • Diet Adherence • Efficacy Survey Score	survey score, Efficacy survey scores; surveys administered via REDCap
10. Describe patient-reported behaviors/behavioral mechanisms at follow-up	Participant surveys administered via REDCap

13. Study Design

Phase 1: This is a non-pivotal, randomized, parallel group, two-arm, prospective study. This 60-day pilot study will evaluate the effect of a NFA versus a SDA during CGM initiation in people with T2D. It is hypothesized that the NFA arm will see greater improvement in TIR than the SDA arm, due to the potential for dietary improvements that come from the use of the NFA and its associated nutrition-focused CGM initiation materials. To test this hypothesis, participants will be randomized 1:1 to either the NFA or the SDA arm.

The intervention begins on Day 0, which is the day the G7 sensor is paired with apps on the participant's personal cell phone. The intervention follows participants for approximately 50 days, which includes an up to 10-day CGM wear period that is part of the post-intervention assessment (approximately Days 40 to 50). During the final 10 days, the participant is instructed to continue using the CGM device in accordance with the guidance provided based on randomization arm.

Phase 2: The follow-up period is designed to evaluate the impact of discontinuing CGM use. The follow-up assessment period begins the day after the Phase 1 post-intervention period ends, approximately Day 51. The follow-up assessment period passively follows participants for 4 months, which includes the 10-day blinded CGM wear period from approximately Day 170 to 180.

On approximately Day 170, participants will return to the clinic to initiate a Dexcom G7 sensor paired with a physically blinded Dexcom receiver and to complete additional assessments. It is hypothesized that glycemic improvements made during the Phase 1 intervention will be reduced during the Phase 2 follow-up due to the removal of real-time glucose feedback and other associated CGM data.

14. Participant Population

Phase 1: To be eligible for the Phase 1 study intervention, all participants must meet the following inclusion and exclusion criteria.

Inclusion Criteria

- Adults $\geq$18 years of age
- T2D diagnosis
- HbA1c 7.0%-10.0% at the time of screening. If a participant has an investigator-approved HbA1c test that was lab-analyzed within the sponsoring institution and that is within 7 days of the screening date, this value may be used.
- Taking no diabetes medication or taking stable-dose diabetes medication(s) for at least 30 days; willing to maintain stable diabetes medication regimen for the duration of the study
- Has a personal cellular-plan or wifi-connected smartphone that is compatible with required CGM apps and which will be consistently available for duration of the study
- Has not used a personal CGM system within 90 days
- Willing and able to wear CGM and use the associated CGM mobile apps throughout the duration of the study

- Willing and able to make diet/lifestyle modifications in response to CGM data
- Able to read and understand English
- Able to attend study visits and complete the requirements of study

Exclusion Criteria

- Currently taking or planning to take any form of insulin, sulfonylureas, meglitinides, or other anti-hyperglycemic diabetes medication that carry a known hypoglycemia risk
- Has used a personal CGM in the 90 days prior to consent
- Known allergy to medical grade adhesive or isopropyl alcohol used to disinfect skin
- Skin conditions that are not compatible with CGM wear
- Intended use of > 4g acetaminophen/day or hydroxyurea during the study
- Planning to become pregnant; pregnant; or lactating
- Current participation in another interventional clinical trial
- Unsuitable for participation due to any other cause, including but not limited to significant comorbidities, as determined by Investigator

Phase 2: To be eligible for Phase 2, participants must complete Phase 1 of the study.

15. Study Procedures

Recruitment and Screening

Several strategies will be used to identify prospective participants for Phase 1. The primary participant identification methods may include targeted query within the HealthPartners electronic medical record (EMR), health plan member database, and available research-specific databases (e.g. International Diabetes Center (IDC) research participant database, HealthPartners research databases). Additional recruitment methods, including several methods not listed here, may include use of study invitations shared in health clinics and in the community. Recruitment materials may be presented to potential participants as physical or electronic documents (e.g. via email, on websites, etc). All recruitment materials will be approved by the institutional review board (IRB).

Potentially eligible participants will have the option to complete online self-screeners (e.g. a brief questionnaire in REDCap) or undergo brief telephone screening. Any participants who meet initial screening criteria will be further screened by study staff for eligibility. Those who are eligible and express interest in study participation will receive additional study-related information, including a copy of the informed consent form (ICF). The ICF and other study-related materials may be shared by mail or electronically (e.g. email, EMR message, etc).

Up to 300 participants may be consented in order to obtain 120 participants who provide at least seven days of baseline and post-intervention CGM assessment data. It is assumed that some participants will consent, but they will not be eligible for participation based on the required HbA1c inclusion criteria; some participants will consent but may be withdrawn (e.g. due to inadequate days of CGM data at baseline); and that there may be approximately 10% attrition during the intervention period.

Consenting

All participants must meet all eligibility criteria and sign the IRB-approved ICF to participate in the study. During the consent process, study staff will explain the research to the participant and the participant will have ample opportunity to review the ICF and ask questions before deciding whether or not to participate in the study. The participant must sign the ICF before any study procedures are initiated.

Of note, during the screening and consenting process, Phase 1 of the study will be described to potential participants as a study evaluating the effect of two different approaches used for introducing and initiating CGM. Details of the NFA and the SDA will *not* be described to participants in order to reduce the potential for influence if details of both study arms are described to all participants before randomization assignments are given. Phase 2 of the study will be described as an opportunity to understand what happens when someone who has used CGM stops using it.

Once the ICF is signed, a copy of the ICF will be given to the participant and a participant ID number will be assigned.

Screen Failure

Participants who sign the consent to participate and who do not meet inclusion criteria in the baseline assessment period (e.g. HbA1c or tolerance to CGM) will be considered a screen failure.

CGM Device Use

In alignment with guidance from the international consensus statement on CGM use in clinical trials,[26] CGM devices will be kept consistent between study arms and throughout the study.

The Dexcom G7 system will be used during the baseline, intervention, post-intervention, and follow-up assessment periods. The G7 system is commercially available and includes an all-in-one wearable sensor with transmitter, an overpatch, and either a Dexcom receiver device or two associated smartphone applications, G7 and Clarity, which send data via cloud. The G7 system will be used in accordance with the manufacturer-provided instructions throughout the study; however, during the baseline period and follow-up period, the glucose data will be physically blinded, and participants will not be able to see glucose data.

Phase 1: Baseline Period

Baseline assessments will begin during Contact 1. Any participant who meets HbA1c criteria is considered enrolled. Participants who do not meet HbA1c criteria will be considered a screen failure and will not be considered enrolled in the study. Demographic and anthropometric information will be assessed to describe the participants. At a minimum, age at enrollment, race, ethnicity, year of type 2 diagnosis, gender identity, sex assigned at birth, weight, height, blood pressure, medication assessment, education, and food security status will be collected.

Baseline assessments also include dietary assessments, PRO surveys, and a 10-day blinded G7 CGM assessment. Study staff will apply the G7 sensor for the participant and pair it with a Dexcom receiver

that will be physically blinded by the study team. The participant will receive instructions on how to care for the receiver and will wear the G7 sensor for up to 10 days; however, participants will not be able to see their glucose data during this time. Participants will be instructed to contact the study team if the sensor comes loose or falls off earlier than 10 days or for any other sensor-related concerns. A minimum of seven days of G7 sensor data is required. If a participant does not capture at least seven days of sensor data, the participant will have an option for study staff to pair another G7 sensor with the physically blinded Dexcom receiver, or the participant can choose to exit the study.

Randomization

Once at least seven days of baseline G7 sensor data are confirmed, participants will receive their randomization assignment to either the NFA or the SDA arm.

Given that enrolling participants takes several months to complete, randomly permuted blocks of size two, four, and six will be used to ensure that participants are assigned to the NFA and SDA arms in approximately equal proportions over time. Randomization will be carried out within strata defined by participant's most recently available HbA1c >8.5% vs. $\leq$8.5%. The participant randomization schedule will be generated by the study statistician using a random number generator. Participants will remain in their assigned study arm throughout the intervention.

Blinding procedures are not described since blinding is not possible in a study comparing two different instructional approaches; the study staff and participants will know what type of instruction they give or receive. However, study participants will not know the details of the type of education provided to the other study arm (i.e. participants in the self-directed approach arm will not know the other arm is receiving a nutrition-focused approach and vice-versa).

Phase 1: Intervention

The intervention compares the effects of two different approaches used during CGM initiation, the NFA or SDA. For both arms, the intervention will include one in-person and one remote study appointment. All care and instruction will be provided by IDC research staff serving as interventionists. Intervention study staff will receive verbal training and written materials describing how to deliver the NFA and SDA; and checklists will be used to ensure consistent delivery among study staff and within each study arm.

On study Day 0, participants who have met all eligibility criteria and who have at least seven days of blinded CGM data will receive Dexcom G7 systems that will be paired with apps on their personal cell phone. Study staff will assist the participant in applying the G7 sensor, as needed. All participants will be instructed to wear and use the G7 and the associated phone apps continuously throughout the intervention, including changing out the sensors every 10 days or as needed.
Intervention duration is expected to last approximately 50 days.

During the study intervention, participants in both arms will be instructed to remain on a stable diabetes medication regimen. Participants will be instructed to contact the study team for study-related questions, device-related adverse events, or changes in their diabetes care. Care related to the treatment of diabetes-related adverse events or adverse events associated with study-supplied devices may be provided by qualified and delegated IDC staff. Medical care that does not pertain to diabetes management will not be provided to study participants as a part of this protocol.

Nutrition-Focused Approach

Both the in-person (contact 2) and the remote (contact 3) intervention visits will be conducted by a registered dietitian nutritionist (RDN) with diabetes care experience. Full details for the NFA intervention components can be found in the NFA manual of procedures (NFA-MOP), which was designed specifically for this study. Use of the manual will help ensure that each participant receives similar messaging and materials.

In brief, the NFA arm participants will receive introduction to CGM with emphasis placed on using the CGM data to adjust food choices. The NFA will encourage food choices that align with evidence-based nutrition recommendations for PWD,[41] and that achieve internationally recognized glucose targets (e.g. glucose 70-180 mg/dL, and TIR > 70%).[42] The NFA does not include a rigid food plan, but rather a flexible eating pattern that can meet the needs of diverse participants. The theory-driven intervention content was designed to address the barriers believed to impact the use of CGM data to guide food choices and recognized behavior change techniques were applied across all intervention components.

Materials used to support the NFA include:

- Nutrition-focused CGM initiation guide
- Interactive CGM initiation presentation (used by the RDN during the in-person intervention visit)
- Non-starchy vegetable list (optional)
- Dexcom G7 manufacturer-provided materials

Optional educational materials or instructional resources may also be used from the following organizational websites:

- American Diabetes Association (https://diabetes.org/)
- Dexcom (https://www.dexcom.com/en-us)

Self-Directed Approach

Both the in-person (contact 2) and the remote (contact 3) intervention visits will be conducted by research study staff with diabetes care experience (e.g. registered nurse or RDN). Full details of the SDA intervention components can be found in the SDA manual of procedures (SDA-MOP), which was designed for this study. Use of the manual will help ensure that each participant receives similar messaging and materials.

In brief, the SDA arm participants will receive introduction to the Dexcom G7 and its accompanying phone apps using manufacturer-provided materials and resources. The SDA will encourage participants to use the device and apps in the way they feel most useful to them. The SDA is intended to reflect current CGM initiation practices, which focus on technical use of the CGM and a general review of CGM data.

Materials used to support the SDA include:

- Dexcom G7 manufacturer-provided materials
- Educational materials or instructional resources found on the Dexcom website (https://www.dexcom.com/en-us)

Phase 1: Post-Intervention Period

The post-intervention period is part of the intervention and is defined as approximately the final 10 days of study participation (approximately Day 40 to Day 50). During this time, the participant is instructed to continue to use the CGM device in accordance with the guidance provided based on randomization arm. The participant will also complete one of the two required ASA24 diet recalls during this time.

Phase 1: Study Completion

Study completion occurs approximately Day 50. At the study completion visit, the participant will complete the final post-intervention assessments, including an HbA1c, remaining dietary assessments, and PRO surveys.

Phase 2: Follow-Up Period

The Phase 2 follow-up is approximately four months and it begins the day after the Phase 1 post-intervention period ends; approximately Day 51 to Day 180. There is no intervention during Phase 2. Participants will manage their diabetes with their usual care team (not the study team), this may include adjustments to medications as needed; however, participants are asked **not** to use CGM during this follow-up period.

During contact 6 (approximately Day 170), participants will be asked to report any serious changes to health, changes to diabetes-related medications, and diabetes device use during the previous 4 months. Participants will complete additional assessments and study staff will apply a 10-day G7 sensor paired with a physically blinded receiver; the process and devices are the same as baseline.

The participant will receive instructions on how to care for the receiver and will wear the G7 sensor for up to 10 days; however, participants will not be able to see their glucose data during this time. Participants will be instructed to contact the study team if the sensor comes loose or falls off earlier than 7 days or for any other sensor-related concerns. If a participant reports fewer than seven days of sensor wear, the participant will have an option to return to the clinic so that study staff can pair another G7 sensor with the physically blinded receiver.

On approximately Day 180, participants will receive a study reminder to complete a final ASA24 diet recall and to return their physically blinded receiver to the study team (e.g. postal mail or in person).

Detailed Schedule of Activities

The study includes approximately seven contacts between study staff and study participants.

Contact	**Key tasks**
Contact 1: Baseline assessments Day -11 to Day -1 (plus additional days, if needed, to obtain at least seven days of G7 sensor data)	• Preliminary eligibility confirmed, consent signed • HbA1c to confirm eligibility[a] • Demographic/Diabetes self-care data assessment • Diabetes medication assessment • Height, weight, BP • Study team applies G7 sensor and pairs it with a physically blinded Dexcom receiver • ASA24 and DietID assessments

Baseline Assessment	• PRO surveys (Diabetes distress, diet adherence, efficacy) • Participant wears G7 sensor paired with a physically blinded Dexcom receiver for up to 10 days and returns to clinic[b] • Participant completes second ASA24 recall immediately before Contact 2 [a] As needed, participants will be contacted by study staff if their HbA1c does not meet inclusion criteria; instructions for sensor removal and options for returning the blinded receiver to the study team will be provided. [b] At least seven days of G7 sensor data must be obtained on the physically blinded Dexcom receiver. If a participant contacts the clinic to report the sensor has fallen off early/failed in fewer than seven days, the participant will be provided an option to return to clinic to pair another G7 sensor with the physically blinded Dexcom receiver, or the participant may choose to exit the study. Data from more than one G7 sensor may be an option to reach a total of seven days.
Contact 2: Participant receives randomization assignment and intervention begins Day 0 **Intervention**	• Eligible participants return to clinic with the physically blinded Dexcom receiver • Study team confirms at least seven days of CGM data were obtained* • Study team saves participant's CGM data • Diabetes medication assessment • Participant receives randomization assignment • Participant applies G7 sensor and pairs it with apps on their personal cell phone • Participant receives CGM instruction based on study arm assignment, NFA or SDA • Participant wears the G7 sensor and uses the real-time glucose data from the associated apps until study completion • Study team documents measures of intervention fidelity *Confirmation of at least seven days of G7 sensor data is required before the participant can receive their randomization assignment. If seven days of G7 sensor data are not obtained, no Contact 2 assessments will be completed. The participant will be provided an option to pair another G7 sensor with the physically blinded Dexcom receiver and return for Contact 2 assessments in approximately 10 days, or the participant can choose to exit the study. Data from more than one G7 sensor may be an option to reach a total of seven days.

Contact 3: Remote Follow-up Day 14 (+7 days) **Intervention**	• Study team saves participant's CGM data from Clarity website immediately before remote contact • Study staff contacts participant • Diabetes medication assessment • Study staff reviews CGM data with participant and reinforces the NFA or SDA messages based on participant's randomization arm • Participant wears the G7 sensor and uses the real-time glucose data from the associated apps until study completion • Study team documents measures of intervention fidelity

Contact 4: Post-intervention assessments begin
 	
Day 40 (+7 days)
 	
Intervention
	• Participant receives reminder from study team on approximately Day 40 to:
	  ○ Wear G7 sensor and use data from the associated apps for final 10-days of the study
	  ○ Complete first post-intervention ASA24 diet recall

Contact 5: Post-intervention assessments ends
 	
Day 50 (+7 days) (plus additional days, if needed, to obtain at least seven days of G7 sensor data)
 	
Post-Intervention Assessments & Study Completion
	• Study team confirms at least seven days of G7 CGM data collected between approximately Day 40 and Day 50
	  ○ If a participant has fewer than seven days of CGM data, the participant will be provided an option to continue in the study until seven days of data are obtained or the participant can choose to exit the study
	• Study team saves participant's CGM data from Clarity website
	• Participant completes post-intervention assessments, including:
	  ○ HbA1c
	  ○ Diabetes medication assessment
	  ○ Weight, BP
	  ○ Complete second ASA24 diet recall and DietID assessment
	  ○ PRO surveys (Diabetes distress, diet adherence, efficacy, intervention fidelity, post-intervention survey)

Contact 6: Follow-up assessments begin Day 170 (+14 days) **Follow-up Assessment**	• HbA1c • Diabetes medication assessment • Adverse event assessment • Weight, BP • Complete first follow-up period ASA24 diet recall • PRO surveys (Diabetes distress, diet adherence, efficacy, diabetes self-care) • Study team applies G7 sensor and pairs it with a physically blinded Dexcom receiver • Participant wears G7 sensor paired with a physically blinded Dexcom receiver for up to 10 days* *If a participant contacts the clinic to report the sensor has fallen off early/failed in fewer than seven days, the participant will be provided an option to return to clinic to pair another G7 sensor with the physically blinded Dexcom receiver. A

	minimum of seven days of sensor data is desired, but not required. Data from more than one G7 sensor may be an option to reach 10 days.
Contact 7: Follow-up assessments end Day 180 (+7 days) (plus additional days, if needed, to obtain at least seven days of G7 sensor data) **Follow-up Completion**	• Participant receives reminder from study team on approximately Day 180 to: ○ Return the physically blinded receiver to the clinic (e.g. postage-paid envelope) • Complete second follow-up period ASA24 diet recall

16. Study Device Management

Participants who terminate early or who are withdrawn at any point during Phase 1 or Phase 2 will be asked to return the Dexcom G7 receiver to the clinic, if applicable. Any unused G7 sensors may be returned to the clinic or disposed of properly by participant.

17. Early Termination and Participant Withdrawal

A participant can choose to terminate study participation and exit the study at any time and for any reason. Participants who request early termination will be asked for a reason for their decision.
A participant can be withdrawn from the study with or without their consent if deemed necessary based on adverse event(s) or for any other reason deemed appropriate by Investigators, such as non-compliance with study instructions. If a participant chooses early termination or is withdrawn, the Investigators will decide whether the participant may be eligible to complete final assessments.

18. Lost to Follow-Up

Multiple attempts will be made to contact participants who become lost to follow-up. Investigator discretion will determine whether a participant should be withdrawn if reasonable attempts for contact are unsuccessful.

19. Protocol Deviations

A protocol deviation occurs when the study is not conducted according to this protocol. All deviations will be documented in a study deviation log. Investigators and study staff will not knowingly deviate from this protocol except in the cases of protecting participant safety. The Investigators or delegated study staff will notify the IRB of protocol deviations in accordance with IRB policies and procedures.

20. Assessment of Safety

The following definitions will be used in the assessment of safety.

Adverse Event

Adverse Event (AE) is any unfavorable and unintended sign (including an abnormal laboratory finding), symptom or disease temporally associated with the intervention, regardless of whether it is considered related to the intervention.

Serious Adverse Event

Serious Adverse Event (SAE) is any adverse event that

(1) results in death;
(2) is life-threatening;
(3) results in inpatient hospitalization or prolongation of existing hospitalization;
(4) results in a persistent or significant disability/incapacity;
(5) results in a congenital anomaly/birth defect; or
(6) based upon appropriate medical judgment, may jeopardize the participant's health and may require medical or surgical intervention to prevent one of the other outcomes listed in this definition.

Life-threatening means the event places the subject at immediate risk of death from the event as it occurred.

Unanticipated Event

An unanticipated event is defined as an event, experience, or outcome that meets **all three** of the following criteria:

- is unexpected; AND
- is related or possibly related to participation in the research; AND
- suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized.

Unexpected means the nature, severity, or frequency of the event is not consistent with either:

- the known or foreseeable risk of adverse events associated with the procedures involved in the research that are described in the protocol-related documents, such as the IRB-approved research protocol, the ICF, and/or other relevant sources of information, such as product labeling and package inserts
- the expected natural progression of any underlying disease, disorder, or condition for the participant experiencing the adverse event, and/or the participant's predisposing risk factor profile for the adverse event.

Unanticipated Problems Involving Risks to Subjects or Others

Unanticipated Problems Involving Risks to Subjects or Others (UPIRTSO) means:

- any problem or event which in the opinion of the Investigator was unanticipated, serious; AND
- at least possibly related to the research procedures

Possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research.

Severity of events will be defined as:

- **Mild** requires minimal or no treatment and does not interfere with the participant's daily activities.

- **Moderate** results in a low level of inconvenience or concern with therapeutic measures. Moderate events may cause some interference with the participant's functioning.
- **Severe** interrupts a participant's usual daily activity and may require systemic drug therapy or other treatment.

21. Safety Reporting

AEs and SAEs may be obtained by participant report, EMR notification, or incidental finding throughout the study. Participants will be asked to report changes to health or concerns related to study devices during study visits. AEs and SAEs will be documented in the participant's EMR; however, only reportable AEs and SAEs will be described in end-of-study reporting.

Reportable AE's include the following:

- Sensor-related reactions or infections requiring treatment by a medical provider and/or prescription medication
- Severe hypoglycemia defined as requiring assistance of another person due to altered consciousness, and requiring another person to actively administer carbohydrate, glucagon, or other resuscitative actions
- Severe hyperglycemia if the event involves diabetic ketoacidosis (DKA) or hyperosmolar hyperglycemic state (HHS), as defined in detail in Kitabchi et al[43] and summarized here:

Table 1—*Diagnostic criteria for DKA and HHS*

	DKA			HHS
	Mild (plasma glucose >250 mg/dl)	Moderate (plasma glucose >250 mg/dl)	Severe (plasma glucose >250 mg/dl)	Plasma glucose >600 mg/dl
Arterial pH	7.25–7.30	7.00 to <7.24	<7.00	>7.30
Serum bicarbonate (mEq/l)	15–18	10 to <15	<10	>18
Urine ketone*	Positive	Positive	Positive	Small
Serum ketone*	Positive	Positive	Positive	Small
Effective serum osmolality†	Variable	Variable	Variable	>320 mOsm/kg
Anion gap‡	>10	>12	>12	Variable
Mental status	Alert	Alert/drowsy	Stupor/coma	Stupor/coma

*Nitroprusside reaction method. †Effective serum osmolality: 2[measured Na^+ (mEq/l)] + glucose (mg/dl)/18. ‡Anion gap: $(Na^+) - [(Cl^- + HCO_3^-$ (mEq/l)]. (Data adapted from ref. 13.)

Table taken from Kitabchi et al[43]

Only reportable AEs and all SAEs will be recorded within an adverse event log with a description including the nature of the event, the date and time of onset and/or frequency, determination of non-serious versus serious, intensity (mild, moderate, severe), duration of the event, relationship to the intervention, the expectedness of the event, and outcome of the event. All reportable AEs and all SAEs will be reviewed and confirmed by a delegated medical doctor or equivalent. All AEs and SAEs must be resolved or deemed stable by a delegated medical doctor or equivalent before a participant completes or withdraws from the study.

Delegated study staff will report all reportable AEs, SAEs, and UPIRTSOs to the IRB in accordance with IRB policies.

22. Study Suspension or Discontinuation

This study will be suspended or stopped prior to completion if information becomes available during the study that indicates as such, this may include information related to adverse events or the potential for adverse events. The study may also be suspended or stopped prior to completion if recruitment

challenges or retention issues will impact the ability to properly analyze defined endpoints or for other reasons determined by the Investigator.

23. Statistical Considerations

Phase 1 Statistical Hypotheses

Primary Endpoint: Change in CGM-derived TIR (% time with glucose 70-180 mg/dL) from baseline to post-intervention.

> Hypothesis (alternative): Participants randomized to a nutrition-focused approach (NFA) will show a larger increase in CGM-derived TIR from baseline to post-intervention than participants randomized to a self-directed approach (SDA).

Secondary Endpoint: Difference in total HEI score between groups during the post-intervention period.

> Hypothesis (alternative): Participants randomized to a nutrition-focused approach (NFA) will show a higher total HEI score during the post-intervention than participants randomized to a self-directed approach (SDA).

Phase 2 Statistical Hypothesis

Primary Endpoint: Change in CGM-derived TIR (% time with glucose 70-180 mg/dL) from post-intervention to follow-up

> Hypothesis (alternative): Participants will show a reduction in CGM-derived TIR from post-intervention to follow-up.

Sample Size Determination

Phase 1 of the study will enroll at least N=132 participants with the expectation for an analytic sample size of N=120. This sample size is based on the N needed to adequately power the primary hypothesis with a realistic and clinically meaningful effect size for % TIR. Specifically, existing research on CGM initiation in people with T2D shows mean TIR of 59% with SD of 25% after intervention.

An analytic sample size N=60 participants per arm has 80% power (alpha=.05, two-sided) to detect an absolute differential change by study arm (i.e., more improvement in the NFA than SDA arm) of 12.9% from baseline to post-intervention (day 50). Justification to support a 12.9% difference in TIR requires converting A1c study data to TIR. The Mobile study showed a 0.4% decrease in A1c after CGM initiation in people with T2D using insulin; we expect a slightly smaller, 0.3%, improvement in our non-insulin using population. An eight-week nutrition intervention study showed a 1.2% decrease in A1c with the DASH diet; we expect a more conservative, 0.7%, improvement (in the NFA arm).

Using the A1c to TIR conversion (0.5% A1c reduction equals 10% TIR increase) suggests a 14% increase (difference) in TIR.

To account for approximately 10% attrition, the enrollment target will be set at N=66 per arm; total N=132.

The Phase 2 sample is dependent on the number of participants that complete Phase 1 and continue through the Phase 2 follow-up assessment period. It is expected that 90% of those completing Phase 1 (n=54/arm) will complete Phase 2 and have CGM data at follow-up. It is expected that 85% of those completing Phase 1 (n=51/arm) will complete Phase 2, have at least 7 days of CGM data at follow-up, refrain from CGM use during the follow-up period, and have no glucose-lowering medication changes during the follow-up period.

With an expected sample size of n=54 per arm for the intention to treat (ITT) sample in Phase 2, the primary analysis has 80% power (alpha=.05, two-sided) to detect an absolute change for pooled study arms of 0.27 standard deviation units of change in TIR from the end of the intervention to follow-up. For within-arm tests of change in this sample the primary analysis has 80% power (alpha=.05, two-sided) to detect an absolute change within a study arm of 0.39 standard deviation units of change in TIR from the end of the intervention to follow-up.

Populations for Analysis

The analysis for Phase 1 will follow a modified intention to treat perspective, with an analysis of CGM metrics that includes only participants with at least seven days of CGM data at both baseline (approximately day -11 to -1) and post-intervention (approximately day 40 to 50).

The analysis for Phase 2 will follow a modified intention to treat perspective, with an analysis of CGM metrics that includes only participants with at least seven days of CGM data at both post-intervention and follow-up. This sample is utilized to assess the effect of discontinuation of CGM utilized in phase 1. A per-protocol (PP) analytic sample will consist of participants with at least seven days of CGM data at both post-intervention and follow-up who did not use CGM, and who did not require changes to glucose-lowering medications during the follow-up period. This PP sample is utilized to assess the effect of discontinuation on patients not utilizing CGM and having no medication adjustments during the follow-up period.

General Approach for Statistical Analyses in Phase 1

Baseline characteristics of study participants will be summarized with mean and standard deviation for interval data and proportions for categorical data. For analyses that do not concern total HEI or HEI component scores, the analytic models will utilize general and generalized linear mixed model repeated measures analysis to estimate differential change by study arm from baseline to post-intervention period. The link function and error distribution selected for each model will be based on the distribution of the endpoint. Each model will include fixed effects for study arm, time, their interaction, variables used in stratification, and a random intercept for patient. Each model will report the model-derived estimate (and 95% confidence interval) for the endpoint by study arm and by time period (baseline, day 50).

The key analytic test for the primary endpoint will be based on planned contrasts reflecting the interaction of study arm and time period and will report and test model-derived estimates of differential change by study arm along with 95% confidence intervals. For the primary outcome, statistical comparisons will be made between and within arms and for study arm by time interaction with significance assessed at $p < 0.05$. A final Statistical Analysis Plan will specify further analytic detail and inclusion of any additional covariates.

For analyses of total HEI score and HEI component scores, mean scores will be computed separately at

each time point (pre-intervention, post-intervention) and for each study group. Confidence intervals for means will be based on a Monte Carlo approach implemented with code developed for the HEI-2015 utilizing a population ratio method appropriate for ASA24 data (e.g. HEI2015_ASA24-2016_MC_PopulationScore.sas). Note: if additional versions of HEI scoring, coding, and analysis become available, these may be used (e.g. HEI-2022).

Analysis of Primary Endpoint

The analysis of the primary endpoint tests whether patients randomized to a nutrition-focused approach (NFA) will have a larger increase in CGM-derived TIR from baseline to post-intervention than patients randomized to a self-directed approach (SDA). A general linear mixed model repeated measures analysis will estimate differential change by study arm from baseline to post-intervention period in TIR. The analytic model will include fixed effects for study arm, time, their interaction, variables used in stratification, and a random intercept for patient. A final Statistical Analysis Plan will specify any additional covariates to be included in the model.

Analysis of Secondary Endpoint

The analysis of the secondary endpoint tests whether patients randomized to a nutrition-focused approach (NFA) will have higher total HEI score at post-intervention than patients randomized to a self-directed approach (SDA). Mean total HEI scores and 95% confidence intervals computed for each study group will be compared to understand study group differences.

Safety Analysis

The trial does not have formal safety endpoints or formal rules or statistical guidance on stopping due to safety concerns. The review and reporting of AEs and SAEs is detailed in the Assessment of Safety and Safety Reporting sections.

General Approach for Statistical Analyses in Phase 2

The general approach for the analysis of Phase 2 will follow the approach used for Phase 1, but with modifications to the contrasts computed. The analytic models will utilize general and generalized linear mixed model repeated measures analysis and include fixed effects for study arm, time, their interaction, variables used in stratification, and a random intercept for patient. Each model will report the model-derived estimate (and 95% confidence interval) for the endpoint by study arm and by time period. The link function and error distribution selected for each model will be based on the distribution of the endpoint. Analysis will be conducted with both the modified ITT sample for Phase 2 and the PP sample.

The key analytic test for the primary endpoint will be based on planned contrasts (effect slices) reflecting the change from the end of the intervention period to the follow-up period, with study arm data pooled. Model-derived estimates of change across these two periods will be reported along with 95% confidence intervals. For the primary outcome, effect slices will also be tested for within-study arm change from the end of the intervention period to the follow-up period. A final Statistical Analysis Plan will specify further analytic detail and inclusion of any additional covariates.

Planned Interim Analysis

Not applicable

Sub-Group Analyses

There are no planned sub-group analyses or analyses to assess heterogeneity of treatment effects.

Analysis of Exploratory Endpoints in Phase 1

Exploratory endpoints are listed in the section Phase 1 Study Outcome Measures: Exploratory Outcomes.

Analysis of exploratory endpoints will follow the analytic framework used for the primary endpoint and will report model-derived estimates and statistical testing of the interaction contrast. However, the test of this interaction is considered hypothesis-generating and is not necessarily powered adequately. Some exploratory analyses will be post-only analyses using the same analytic framework but will include only fixed effects for study arm and stratification factors, but not an effect for time or their interaction. There will be no control for multiple testing in exploratory analyses. In sensitivity analysis, models will adjust for key prognostic factors selected a-priori.

Analysis of HEI component scores will include computing mean component scores and 95% confidence intervals for each study group; these will be compared to understand study group differences. Radar plots will be used to display differences. Summaries of intervention fidelity and potential behavioral mechanisms will utilize descriptive statistics computed within each study group.

Linear regression and Pearson or Spearman correlations will assess associations between TIR and HEI, HbA1c and HEI, participant perception of diet quality and calculated total HEI score. Additional analysis specifications involving study arm comparisons for exploratory endpoints and detailed specifications of other exploratory analyses will be described in a final Statistical Analysis Plan.

Analysis of Exploratory Endpoints in Phase 2

Exploratory endpoints are listed in the section Phase 2 Study Outcome Measures: Exploratory Outcomes.

Analysis of exploratory endpoints will follow the analytic framework for Phase 2 used for the primary endpoint and will report model-derived estimates and statistical testing of the change from the end of the intervention to follow-up period in the pooled study arms and within each study arm via pre-specified contrasts. Some exploratory analyses will be post-only analyses using the same analytic framework but will include only fixed effects for study arm and stratification factors, but not an effect for time. There will be no control for multiple testing in exploratory analyses. In sensitivity analysis, models will adjust for key prognostic factors selected a-priori.

Analysis of HEI component scores will include computing mean component scores and 95% confidence intervals for each study group at follow-up. Summaries of potential behavioral mechanisms will utilize descriptive statistics computed within each study group.

24. Data Collection and Management

Source data for the study will be collected verbally, physically, or electronically direct from the participant, from the participant's EMR, from the participant's G7 CGM system and the Clarity website, from web-based platforms where data is entered directly by the participant or with assistance of study staff (e.g. ASA24, DietID, REDCap, etc).

Study staff will record data in accordance with the UNITE Study MOP (UNITE MOP). Study data will be stored as follows:

- on paper case report forms
- in the participant EMR
- as downloaded data files saved on secure, password-protected institutional computers (e.g. CGM data, dietary recall data, etc)
    - Diet recall via ASA24 and DietID will be directly entered into each website. ASA24 is a free, web-based dietary assessment tool that is run by the National Institutes of Health. ASA24 data is associated with study ID and does not capture any personally identifiable information from participants. DietID is a web-based dietary assessment tool used for clinical and research purposes. DietID is associated with unique access and does not require identifiable information from participants. Completed ASA24 and DietID surveys will be stored on web-based servers and periodically downloaded throughout the study.
- in REDCap, a 21 CFR Part 11-compliant data capture system. REDCap includes password protection and internal quality checks, including field validation to help identify inconsistent, incomplete, or inaccurate data. Data entered into REDCap will come directly from the original source data; or in some cases, REDCap may serve as the source data (e.g. protocol deviations; participant response to surveys via REDCap; participant supply management, etc.). REDCap maintains a built-in audit trail that logs all user activity and all pages viewed by every user, this includes entering data, exporting data, modifying a field, running a report, or adding/modifying a user, etc.

Data collection is the responsibility of the delegated study staff under the supervision of the Investigator. The Investigator is responsible for ensuring the accuracy, completeness, legibility, and timeliness of the data reported.

25. Data Monitoring

Investigators and delegated study staff will monitor study data for completeness and quality. Several strategies will be used to cross-check data accuracy and integrity, including staff checklists for each participant contact.

26. Data Sharing

As allowable by the governing IRB and organizational legal requirements, select, de-identified datasets for the completed project will be made available. All datasets will be shared in compliance with human subject protection and Health Insurance Portability and Accountability Act (HIPAA) privacy regulations.

This trial will be registered at ClinicalTrials.gov; trial results will be added to ClinicalTrials.gov after study completion.

27. Record Keeping and Retention

Clinical research records, including IRB records, and other records related to the study will be stored in a manner that ensures privacy, confidentiality, security, and accessibility while the clinical research is being conducted and after the study is completed.

The site will retain all study records, including HIPAA-related documents, after the study completion per institutional policy. Physical documents will be consolidated and stored in boxes in a secure location after study completion and electronic documents will be maintained in designated research study folders on the institutional drive in accordance with the institutional data retention guidelines. After the record retention period has been met, study-related materials may be destroyed.

28. Confidentiality and Privacy

Participants will be assigned a unique ID number after consent. Whenever possible, participant records and datasets will contain the unique ID only. The participant will be informed during the study screening process and via the ICF that their personal study-related data will be accessible by study staff and individuals within the International Diabetes Center throughout the duration of and after the study. Participants will be informed that by using CGM, their information will also be available to the CGM device manufacturer, Dexcom. Participants will need a personal account for use with the Dexcom systems. Participants will need to provide personal information (e.g. name, date of birth, email, etc) for the Dexcom accounts. Data in the Dexcom apps and associated websites is secure to the extent provided by the manufacturer. Participant data and any related records may also be made accessible to regulatory authorities or as required by law.

The confidentiality of all participant information and data are protected to the extent allowed by law. Records will be kept confidential in accordance with HIPAA privacy regulations. Investigators and personnel will not use data or records for any purpose other than conducting the study; however, de-identified participant data may be used for educational purposes and shared in medical journals, at scientific meetings, or in similar settings. No identifiable data will be used for future study without first obtaining IRB approval.

29. Ethics and Protection of Human Subjects

This protocol and any amendments, ICFs, recruitment materials, and all participant-facing materials will be submitted to the IRB for review and approval. Approval of the protocol and consent forms will be obtained before any participant is enrolled. Approval of protocol amendments and changes to the consent forms will be obtained before any changes are implemented. The decision of the IRB concerning the conduct of the study will be made in writing to the Investigator. A copy of the initial IRB approval letter will be provided to the study funder (American Diabetes Association) before commencement of this study.

This study will be conducted in full accordance with all applicable Federal and state laws and regulations including 45 CFR, and the HIPAA Privacy Rule. Any episodes of non-compliance will be documented. The Investigators will perform the study in accordance with this protocol, will obtain consent, and will report unexpected problems in accordance with IRB policies and procedures. Collection, recording, and

reporting of data will be accurate and will ensure the privacy, health, and welfare of research participants during and after the study.

30. Conflict of Interest

Study leadership in conjunction with the HealthPartners Institute has policies and procedures for all study group members to disclose conflicts of interest and to establish a mechanism for the management of all reported dualities of interest. Persons who have a perceived conflict of interest will be required to have such conflicts managed in a way that is appropriate to their participation in the design and conduct of this trial.

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