

THE ACCEPTABILITY OF CONTINUOUS GLUCOSE MONITORING IN A
NATIONAL DIABETES PREVENTION PROGRAM PILOT INTERVENTION

By

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Abstract -

Prediabetes is a widespread and ever-increasing metabolic condition involving dysglycemia. Failure to treat prediabetes can lead to the development of Type 2 diabetes, and both prediabetes and Type 2 diabetes can present multiple negative health consequences for afflicted individuals. Common approaches to prevention and management of prediabetes involve lifestyle modification, specifically regular physical activity at a minimum of 150 minutes per week, and modest weight loss of 5-10% body fat. These are the primary outcome measures of the National Diabetes Prevention Program (NDPP), a Centers for Disease Control and Prevention-recognized intervention designed to educate those affected by prediabetes on the topics of diet and physical activity to help slow and reverse the deterioration of participants' glycemic health. However, these goals are often not met, increasing the likelihood that the affected individual's condition progresses to Type 2 diabetes. Continuous glucose monitoring (CGM) is a method of biological feedback, typically prescribed to those affected by persons with insulin-dependent Type 1 and Type 2 diabetes. CGM allows the user to track their glucose levels continuously for a period of up to 10 days, and in doing so, the user can make more informed decisions about their behavior to benefit their glycemic health and self-efficacy towards their condition. A brief one-hour CGM intervention was introduced to a cohort of 13 NDPP participants affected by prediabetes in a pilot study to understand the acceptability of integrating CGM into the NDPP. Participant surveys and focus groups were administered to understand experiences of participants and gauge acceptability. There was overwhelming support for further use of CGM in the NDPP, and participant responses reflected an enriched experience while using CGM and a greater understanding of the interplay between diet, physical activity, and glycemic control as a result of CGM.

Background -

Prediabetes, a rising worldwide epidemic (1) is a metabolic condition characterized by fasting blood glucose concentrations higher than 70-100 mg/dL, but not enough to qualify as diabetes, which is ≥ 126 mg/dL (1). Prediabetes is associated with a host of health risks and dysfunctions in the body (2), similar in nature to that of Type 2 diabetes, including nephropathy and chronic kidney disease, neuropathies such as cardiac autonomic activity dysfunction, retinopathy, and macrovascular disease (2).

Within the US, a total of 96 million people (38% of the US population) over 18 years of age are estimated to have prediabetes, of which 80% are unaware of their condition (3). More than twenty-six million people aged 65 or older in the US are estimated to have prediabetes (3). Between five and ten percent of individuals with prediabetes develop Type 2 diabetes every year; up to 70% of all people with prediabetes eventually develop diabetes (4). In the US, racially and ethnically minoritized groups — including those of Asian, Hispanic, and African descent — are diagnosed with prediabetes and Type 2 diabetes at greater rates than those of Caucasian descent (4). The incidence of prediabetes is rapidly rising and focusing efforts on treatment and prevention will be critically important towards improving health outcomes.

Both prediabetes and Type 2 diabetes affect tens of millions of people in the US and are expected to increase in prevalence significantly over time (3). Understanding more about prediabetes and the individuals diagnosed with this condition is important towards improving therapeutic efforts and health outcomes.

Prediabetes begins to manifest when the body's cells exhibit insulin resistance, meaning a certain amount of insulin signaling triggers weaker and weaker responses as the frequency of

exposure continues (1, 4). In order to compensate for this, the pancreas begins to increase insulin secretions and beta-cell mass (4). After a certain point, the pancreatic beta cells are no longer able to fully compensate for the insulin resistance (3). As a result, fasting and post-load blood glucose concentrations cannot be maintained and will rise (1, 4). Once fasting blood glucose concentrations rise above 100 mg/dL, the individual may be considered to have prediabetes, and may advance to Type 2 diabetes if left untreated (1, 4).

Screening for prediabetes should be prioritized in individuals exhibiting risk factors which include: family history of diabetes, cardiovascular disease, overweight or obese, sedentary lifestyle, previously identified impaired fasting glycemia (IFG), impaired glucose tolerance (IGT), and/or metabolic syndrome, age over 45, hypertension, high triglyceride levels, low high-density lipoprotein (HDL) cholesterol concentrations, history of gestational diabetes, polycystic ovary syndrome, and those on antipsychotic therapy for severe bipolar disease and schizophrenia (5).

Current treatment is focused primarily on lifestyle change to ultimately reduce body weight by 5-10% (1). In doing so, fat mass, blood pressure, blood glucose concentrations, LDL cholesterol concentrations, and triglyceride levels may all be improved, along with potentially avoiding Type 2 diabetes and reversing prediabetes (5). Recommendations for exercise are moderate-intensity physical activity for 30-60 minutes daily, five times a week (5). Diet modifications include calorie restriction, increased fiber intake, potential limitations for carbohydrates, and, for improving blood pressure, to lower sodium intake and avoidance of excess alcohol consumption (5). Besides lifestyle intervention, there are a number of pharmacological therapies available, though these are typically reserved for high-risk populations and individuals indicating progressive deterioration of their glycemic health despite lifestyle improvements (5). High-risk patients include those with: a combination of IFG, IGT, and/or metabolic syndrome, deteriorating glycemic health, cardiovascular disease, nonalcoholic fatty liver disease, history of gestational diabetes, or polycystic ovary syndrome (5). Antidiabetic drugs such as metformin, thiazolidinediones, and α -glucosidase inhibitors may be prescribed, as well as non-diabetic drugs such as orlistat (4). Other treatments include bariatric surgery for sustained weight loss, though this is only helpful for morbidly obese individuals (4).

A program for encouraging lifestyle change has been developed to assist with the reversal of prediabetes in at-risk individuals called the National Diabetes Prevention Program (NDPP) (6). This is advertised as a “partnership of private and public organizations working to prevent or delay the onset of Type 2 diabetes” (6). This program makes it easier for people with prediabetes to participate in high-quality intervention to help reduce their risk of developing Type 2 diabetes through promotion of modest weight loss and increased physical activity (6). This program follows a 12-month lifestyle intervention program and introduces participants to literature on self-efficacy, physical activity, and diet (6).

In order to be certified by the CDC as an official NDPP course, 22 of 26 modules must be completed by participants (6). Sixteen modules must be completed in the first six months, where the introduction module is first, and after which modules may be presented in no specific order (6). The goal in this first half of the NDPP is to support participants in losing 5-7% body weight, and achieve a combined 150 minutes of moderate exercise per week (6). Six of ten modules should be completed in the last 6 months, where ‘Prevent T2—for Life!’ is the last module, and before which there is no specified order for other modules (6). The goal of this portion of the program is to maintain lost weight and/or potentially continue weight loss, and to maintain 150 minutes of physical activity per week (6). The CDC-suggested schedule is weekly NDPP

sessions for four months, (sessions 1-16) and biweekly sessions for two months, (sessions 17-20), followed by monthly sessions six months, wherein sessions 21-26 will be completed (6).

NDPP sessions are led by a lifestyle coach who engages participants to set goals, track their eating and activity, and assess progress (6). The lifestyle coach leads meetings based on the training guide which includes a session focus, participant learning objectives, materials checklist, things to do, module outline, and lifestyle coach script (6). Participants are expected to track their activity and weigh themselves at each meeting (6). They are also encouraged to track their diet and follow the lifestyle coach's suggestions for healthy living (6). The participants are given a notebook to help them follow the course which includes a participant guide for each module, a fitness log, an optional food log, a weight log, an action plan journal, and miscellaneous materials that may be useful in some of the modules (6).

The NDPP is a less intense derivation of its predecessor, the Diabetes Prevention Program, funded by the National Institute of Diabetes and Digestive and Kidney Disease. This was a randomized, controlled clinical trial conducted at 27 clinical centers around the US from 1996 to 2001 (7). This study enrolled 3234 participants (of which 45% were from racially and ethnically minoritized groups and 55% Caucasian) and randomly assigned individuals to the DPP, metformin, or placebo groups (7). The study found that individuals assigned to the DPP treatment group lowered their chances of developing Type 2 diabetes by 58% compared to the placebo group (7). The DPP treatment was also observed to be effective in all ethnic groups and genders (7). Furthermore, 5% of individuals from the DPP group developed diabetes each year compared to 11% in the placebo group (7). This initial trial showed promising results, and indicates a critically important route for combating diabetes development.

Another important facet of these types of interventions is retention. An analysis of 41,203 NDPP participants between 2012 and 2017 found that the median retention time was 28 weeks, and the median sessions attended was 16/26, which is slightly over half of the intended intervention (8). Weekly attrition was between 1-2%, and increased to approximately 3.5-5% between weeks 17 and 18, where the session frequency changed from biweekly to monthly (8). On average, 63.1% of NDPP participants remained through week 18, and 31.9% of participants were retained through week 44 (8). Lower retention in the program was associated with younger age and minority race/ethnicity, but not with sex (8). Additionally, lower retention was strongly associated with less weight loss and less physical activity over the course of the study (8).

The DPP is cost effective and is able to improve health outcomes of those who complete the treatment, as indicated by the results mentioned earlier (7). Studies of the efficacy of the NDPP indicate an average of 4.2% weight loss among in-person participants, and an average of 3.9% weight loss among virtual participants (9, 10). Evaluations of the intervention on diabetes incidence indicate that each kilogram of weight loss correlates to a 16% reduction in diabetes risk (11). Additionally, the program's use of participant guides for each session with homework and exercises, as well as the use of a lifestyle coach to engage the participants in each educational session, contributes to participant adoption of health behaviors necessary to prevent diabetes. Finally, the program is flexibly delivered in-person or remotely, as all of the tasks required of the participants may be done at home.

While the NDPP confers established benefits, there are a few limitations to its efficacy. First, the retention of participants over the course of the program declines, especially when the frequency of the sessions change (8). Finding ways to maintain engagement through these transitions is important, as each session attended is associated with an additional 0.3% weight loss (9). Additionally, as numbers of participants decline, engagement within the sessions can

decrease as well, as there are less people to participate in conversation and provide input. This problem may be exacerbated in an online modality where there is less pressure on participants to pay attention and engage, as they can turn their web cameras off and may more easily be distracted by their surroundings. Structuring education sessions in such a way that fosters constant participation and engagement may help to resolve this issue. The value of each education session may also vary depending on the lifestyle coach, as they may present the information of each module and communicate with the participants in unique ways, leading to varying results among participants depending on how well they are able to connect. The uniform structure of each module and the use of the training guide may help to relieve this, though, and the use of a group setting also facilitates greater participant input and connections with each other in the event they are unable to relate with their coach.

One method for helping individuals with Type 2 diabetes and prediabetes manage their conditions is the use of biofeedback. Biofeedback includes devices that provide physiological data to the user to inform behavior decisions for the purposes of improving health (12). Biofeedback is a process of training as opposed to a treatment, meaning this provides the tools for the individual to take action (12). A common form of biofeedback therapy is operant conditioning and feedback training, in which the trainer explains the biofeedback measures, and how the resultant data are related to the patient's physiology (12). In the case of those with Type 2 diabetes, being provided pertinent information about interstitial glucose concentrations can help guide the person's decisions with regards to what they eat, and how they exercise. A biofeedback device that can perform this task is a continuous glucose monitor.

Continuous glucose monitoring (CGM) is a method of tracking blood glucose concentrations constantly over a long period of time (13). This is accomplished through a continuous glucose monitoring device that is adhered to the belly or the back of the arm where fat is deposited (13). The monitor has a small catheter that is inserted below the skin and may measure interstitial glucose concentrations every five minutes for up to 10-14 days depending on the device (13). These readings are sent to a receiver or smartphone where the user can view their current interstitial glucose (used as an analog for blood glucose), a prediction of how the glucose concentration will change in the near future, and a graph of glucose concentration history (13). Together, this information can help inform the user of how their insulin use, diet, and physical activity affects their glucose levels. In the case of those with prediabetes, they will not be using exogenous insulin, and as such CGM will help them determine how diet and physical activity influence their glycemic levels.

Past research has shown the efficacy of CGM in encouraging healthy behavior among individuals with Type 2 diabetes. In a randomized control trial of 52 individuals, those assigned to a treatment group that included personalized feedback on CGM in relation to their physical activity exhibited greater frequency of moderate intensity physical activity as well as decreased frequency of sedentary/light activity (14). Other studies indicate that the use of CGM helps to reduce hemoglobin A1C (HbA1C) by a mean of 1.0% in less than 12 weeks (15). Individuals who wear their CGM device more frequently also seem to have greater improvements in HbA1c, as participants who wore their CGM device for over 48 days experienced a 0.5% greater average decline in HbA1C compared with those who wore their CGM device less than 48 days (16). In this same study, these trends lasted up to 24 weeks before attenuating, and even then, HbA1C did not return to baseline by 52 weeks (16). Thus, encouraging CGM and paying attention to how lifestyle factors influence glucose may confer improved health outcomes even in a short-term intervention format.

CGM use has been shown to increase user self-efficacy and engagement with lifestyle change, as well as positive glycemic trends independent of insulin therapy (15). However, most research on CGM efficacy has been conducted in individuals already diagnosed with Type 2 diabetes. As such, there is a lack of evidence supporting the use of CGM in people with prediabetes. The use of this type of biofeedback provides additional information to people with prediabetes who can use this information to modify their behaviors and potentially delay the onset of Type 2 diabetes or prevent it from ever occurring. The NDPP is centered around lifestyle changes such as diet and physical activity to modulate blood glucose concentrations and keep participants below 126 mg/dL, above which the individual qualifies for a Type 2 diabetes diagnosis. Providing NDPP participants with a tool that would allow them to view their glucose levels numerically, and visualize their glucose history and trends could prove to be a valuable tool to guide behavior change. Additionally, integrating CGM with the NDPP may also help to increase participant retention in the program. Lower retention has been associated with lower weight loss and less physical activity (8). However, interest and curiosity towards both the NDPP and glycemic health may be increased by allowing participants to see how their behaviors influence their glucose concentrations in real time, which can fluctuate significantly with each meal or bout of activity. In doing so, participant health outcomes may improve in the short term, as the use of CGM may lead to healthier behaviors, and also in the long term, as participants may be retained for longer periods and experience more modules of the NDPP to enrich their understanding of their lifestyle as it relates to prediabetes. However, the effects of introducing CGM into the NDPP has yet to be observed. As such, the objective of this study was to evaluate the acceptability of CGM in the NDPP through the administration of participant surveys in an NDPP-CGM pilot intervention.

Methods -

The pilot intervention occurred over a 15-week period while participants completed Weeks 2 to 14 of the NDPP program, and consisted of three main components: a one-hour CGM education session, two 14-day CGM wear periods, and participant surveys. The first CGM wear period was blinded while the second was unblinded. During the education session, participants learned to utilize CGMs to guide their eating and physical activity. Study participants completed questionnaires assessing self-efficacy, health-related quality of life, and acceptability of the CGM and the CGM education session. All study-related data was captured virtually via the study app MyDataHelps™ (CareEvolution@LLC) (17), or by trained interviewers who called participants on the phone.

The NDPP was administered by University of Arizona Cooperative Extension (18). Cooperative Extension provides the DPP lifestyle intervention to seven Arizona counties: Graham, Maricopa, Pima, Pinal, Santa Cruz, Yavapai, and Yuma, including remote services via Zoom statewide. The cohort being studied for this pilot intervention met via Zoom, and the CGM intervention was conducted remotely.

Participant recruitment began on November 1, 2022, during the second week of the NDPP educational sessions. Here, the CGM-NDPP pilot study was announced to NDPP participants, and they were provided with the opportunity to sign up as well as an eligibility screening, a consent form, and initial surveys. Eligible participants were those who were: participants in the Arizona Cooperative Extension Diabetes Prevention Program and were not paid to be involved (i.e., NDPP lifestyle coaches); willing to use a continuous glucose monitor;

available to attend a 1-hour education session after Week 8 of the NDPP and able to attend a 1-hour focus group between Weeks 9 and 10 of the NDPP; and able to read and write in English.

Respondents interested in participating in the pilot intervention that pass the eligibility screening and fill the consent form were asked to complete a baseline survey. The survey assessed self-efficacy using items from Block et. al. and health-related quality of life (HRQOL) from the Healthy Days Core Module (19, 20). Response options for self-efficacy questions were on a four-point Likert scale (see Appendix Item 1), while the HRQOL questions were summarized using the number of healthy days (out of the past 30 days) self-reported by the participant.

Figure 1. Timeline of pilot intervention evaluating acceptability of continuous glucose monitoring in the National Diabetes Prevention Project in the context of the NDPP schedule



Baseline data collection occurred during Week 7 of the NDPP. One week prior, materials were mailed by the University of Arizona Behavioral Measurement and Interventions Shared Resource (UA BMISR) to participants instructing them to collect their HbA1C, wear the Fitbit Charge 5, and apply a CGM for the 14-day blinded wear period. They were also instructed to self-report HbA1C using the A1cNow Self Check kit, body weight (in kg/lbs), and minutes of moderate-to-vigorous physical activity within the last week over a phone call from trained UA

BMISR interviewers. Participants were provided with self-addressed stamped envelopes to facilitate return of the equipment to the UA BMISR during Weeks 8-9 of the NDPP.

The CGM education session was also held during Weeks 8-9 of the NDPP. This brief one-hour intervention followed a format similar to the NDPP modules. Within this session, participants learned the purpose of tracking blood glucose, what continuous glucose monitoring was, and how they could utilize CGM to guide their eating and physical activity. Participants also applied their second CGMs for the unblinded wear period, and learned how to use the CGM application on their smartphones or other devices.

During Weeks 9-10 of the NDPP, participants were asked to complete an acceptability questionnaire and participate in a focus group. The 27-item acceptability survey (see Appendix Item 2) was sent out on day 10 of the CGM wear period and is based on the TakeCharge study and Liao & Schembre (21, 22). The survey covers four general categories: CGM Use, CGM Knowledge & Motivation, Prospects for Future Use of CGM, and Feelings Towards the Experience of Wearing CGM. Specific questions target aspects of the participants' experience such as motivation with regards to physical activity or diet; usability, convenience, and relevance of the CGM; and fear, guilt, and unhappiness upon seeing their glucose results. Responses for the 'CGM Use,' 'CGM Knowledge & Motivation,' and 'CGM Feelings' sections were rated on a five-point Likert scale (see Appendix Item 2), while the 'Future CGM Prospects' section was rated on a scale inspired by the TakeCharge study (see Appendix Item 2) (21).

The focus group was conducted virtually and was optional for all participants. This one-hour session followed a semi-scripted format and was led by a trained interviewer with one research assistant present to take notes in addition to being transcribed. Questions prompted participants to explore their experiences wearing the CGMs in four topics over the course of one hour (see Appendix Item 3). Topic one was 'Understand the user experience of DPP participants wearing the CGM and receiving its output.' Topic two was 'Understand the user experience of DPP participants receiving the brief educational session and reading the handout.' Topic three was 'Identify the type of information that DPP participants need to use the CGM, and relate CGM output with diet and physical activity behaviors.' Topic 4 was 'Identify potential barriers to making recommended behavioral changes and areas where additional support may be required.' Prompt questions relating to each of the four topics would be posed to the group of participants, who would then be free to share their thoughts and experiences with minimal interjection from the interviewer. The next question would be presented to the group when discussion of the previous question by participants ceased naturally.

During Weeks 13 and 14 of the NDPP, the final data collection occurred. Participants self-reported their HbA1C using the A1cNow Self-Check kit, body weight (in kg/lbs), and minutes of moderate-to-vigorous physical activity within the last week during a phone call by trained UA BMISR interviewers. They were also asked to complete two interviewer-administered 24-hour diet recalls during the week, also during a phone call. Finally, the participants completed follow-up self-efficacy and HRQOL surveys.

Results -

Thirteen participants completed the baseline survey. Table 1 indicates the mean and range of responses for these surveys (see Appendix Item 1 for response options). Overall, participants responded 'Pretty Sure I Can' to the diet and physical activity efficacy questions. Participants responded 'Good' and 'Fair' most often when answering self-report questions about their health status. Participants also had a high number of healthy days, with a mean of 22 out of

30 possible days. Poor mental health prevented usual activities more than physical health for the group. This is also apparent in the range of responses for each of these categories. With regards to days where respondent physical health was poor, responses ranged from 0-10 days per month. However, the range for days where participant mental health was poor spanned from 0-30 days per month. Despite this, the usual activities of the participants were seldom restricted by poor physical or mental health.

Table 1. Mean and range of responses to the Baseline and Post-Intervention Self-Efficacy and HRQOL Questionnaire.

	Baseline		Post-Intervention	
	Mean	Range	Mean	Range
Self Efficacy				
Diet Efficacy: How confident are you that you can make or maintain lasting changes to your diet? (Maximum of 4 points)	2.8	1-4	2.9	1-4
Physical Activity Efficacy: How confident are you that you can make or maintain lasting changes to be more physically active? (Maximum of 4 points)	3.1	2-4	3.1	2-4
Quality of Life				
Health Status: Would you say that in general your health is excellent, very good, good, fair or poor? (Maximum of 5 points)	3.4	2-4	3	1-4
Physical Health: Now thinking about your physical health, which includes physical illness and injury, how many days during the past 30 days was your physical health not good? (Maximum of 30 points)	2	0-10	3.5	0-14
Mental Health: Now thinking about your mental health, which includes stress, depression, and problems with emotions, how many days during the past 30 days was your mental health not good? (Maximum of 30 points)	6.8	0-30	5	0-15
Usual Activities: During the past 30 days, approximately how many days did poor physical or mental health keep you from doing your usual activities, such as self-care, work, or recreation? (Maximum of 30 points)	2.8	0-10	3	0-8
Total Healthy Days (Maximum of 30 points)	22	0-30	21.5	9-30

Ten out of thirteen total participants completed the post-intervention survey assessing self-efficacy and HRQOL, and the recorded mean and range of responses can be viewed in Table 1. Similar to the baseline survey, participants generally responded ‘Pretty Sure I Can’ to the diet and physical activity efficacy questions. With regards to HRQOL, common responses included ‘Good’ and ‘Fair’ for the self-report question about health status. Again, this is similar to the baseline survey. Participants had a mean of 21.5 healthy days. Frequency of days with poor mental health was slightly greater than that of poor physical health, though the range for each of these categories were both very similar. With regards to days where respondent physical health was poor, responses ranged from 0-14. However, the range for days where participant mental health was poor spanned from 0-15. Days with poor physical health were slightly greater post-intervention, but days with poor mental health were drastically reduced compared to the baseline. Days where poor physical health or poor mental health inhibited usual activities were roughly the same from baseline to post-intervention. The mean or all three of these categories, as well as the overall number of healthy days were similar between baseline and post-intervention.

Twelve of thirteen participants completed the acceptability questionnaire. The mean and range of values of responses for each section can be viewed in Table 2 (see Appendix item 2 for response options). For the ‘CGM Use’ section, responses to each question were concentrated around ‘Agree’ and ‘Strongly Agree’ options with the exception of the ‘Privacy’ subsection.

Mean responses for nearly all questions were between 4 and 5, and the range was also 4-5 for nearly all subsections with the exception of a single response of 3 for the 'Tech Support' and 'Like' subsections from the same respondent. The most different section was the 'Privacy' subsection, where mean responses were most often 'Neither Agree nor Disagree' or 'Disagree' options of concern over their privacy.

The mean and range of values of responses for the 'CGM Knowledge & Motivation' section can be viewed in Table 2. Responses to each question were primarily 'Agree' and 'Strongly Agree' options. The most "negative" option selected among participants was 'Neither Agree nor Disagree' in response to the prompts, and this was only in the case of the 'Diet & Glucose,' 'Motivate Diet.' and 'Motivate Physical Activity' subsections. This combined with the mean response values indicates high levels of agreement in this section.

Responses for the 'CGM Feelings' section are more diverse than the 'CGM Use' and 'CGM Knowledge & Motivation' sections (Table 2). Participant responses were exclusively 'Agree' and 'Strongly Agree' for the 'Glucose Control' subsection, indicating a common feeling of control over prediabetes among participants. However, the range of responses to the 'Fear,' 'Worry,' 'Guilt,' and 'Unhappiness' subsections were each widely varied. Despite the mean of each subsection indicating an overall neutral feeling from participants, the wide range indicates that individual participants feel strongly in both directions.

For the 'CGM Prospects' section, there was unanimous agreement that CGM should be offered regularly with the NDPP, and all but one participant responded that they would wear the CGM again if possible (Table 2). Most participants responded that they would wear CGM every month, and that they would wear CGM every day for more than 3 months if they could.

Table 2. Mean and range of responses to each section of the Acceptability Survey fulfilled by 12 participants.

<u>CGM Use</u>	Mean	Range
Usability: CGM is easy to use and user friendly. (Maximum of 5 points)	4.4	4-5
Convenience: CGM is convenient for me to use in my everyday life. (Maximum of 5 points)	4.6	4-5
Value: CGM is useful and beneficial. (Maximum of 5 points)	4.8	4-5
Relevance: CGM provides information that is of interest to me. (Maximum of 5 points)	4.6	4-5
Motivating: I am motivated to use CGM to track my daily behaviors. (Maximum of 5 points)	4.3	4-5
Tech Support: There is adequate availability and quality of professional assistance throughout use of the CGM. (Maximum of 5 points)	4.5	3-5
Confidence: I feel confident that I use CGM correctly. (Maximum of 5 points)	2.5	4-5
Privacy: I am concerned about my privacy when using CGM. (Maximum of 5 points)	2.5	1-3
Recommend: I would recommend CGM to my friends and family. (Maximum of 5 points)	4.7	4-5
Like: I like using the CGM. (Maximum of 5 points)	4.6	3-5
<u>CGM Knowledge & Motivation</u>	Mean	Range
Educational Relevance: The information from the Participant Guide was relevant to me. (Maximum of 5 points)	4.3	4-5
Diet & Glucose: Using the CGM helped me better understand the connection between diet and glucose. (Maximum of 5 points)	4.6	3-5
Physical Activity & Glucose: Using the CGM helped me better understand the connection between physical activity and glucose. (Maximum of 5 points)	4.7	4-5
Motivate Diet: Using the CGM increased my motivation to make dietary changes. (Maximum of 5 points)	4.4	3-5
Motivate Physical Activity: Using the CGM increased my motivation to be more active. (Maximum of 5 points)	4.3	3-5
<u>CGM Feelings</u>	Mean	Range
Worry: Using a CGM causes me to be more worried about controlling blood sugars. (Maximum of 5 points)	3	1-4
Think Too Much: Using a CGM makes me think about prediabetes too much. (Maximum of 5 points)	2.5	1-5
Glucose Control: Using a CGM makes me feel like I have more control over my prediabetes. (Maximum of 5 points)	4.6	4-5
CGM Appearance: I do not like how a CGM looks on my body. (Maximum of 5 points)	2.5	1-4
CGM Noticeable: I do not like when people notice me wearing a CGM. (Maximum of 5 points)	2.2	1-3
Fear: Seeing high glucose levels made me feel afraid about my risk of being diagnosed with Type 2 diabetes. (Maximum of 5 points)	3.6	2-5
Guilt: Seeing high glucose levels made me feel guilty that I had done something to cause a high glucose level. (Maximum of 5 points)	3.2	2-4
Unhappiness: Seeing high glucose levels made me feel unhappy because my glucose is high when I don't think it should be. (Maximum of 5 points)	2.8	2-4
<u>CGM Prospects</u>	Mean	Range
CGM Again: If given the opportunity, would you wear the CGM again? (Maximum of 3 points)	1.2	1-3
Days in a Row CGM: If given the opportunity, how many days in a row would you be willing to wear CGM? (Maximum of 4 points)	3.3	2-4
Times per Year CGM: How many times per year would you be willing to wear CGM? (Maximum of 5 points)	1.3	1-2
CGM-DPP: Do you think CGM should be offered regularly as a part of the Diabetes Prevention Program? (Maximum of 3 points)	1	1

Four topics were covered in the one-hour focus group which was attended by nine of thirteen participants. The first topic was ‘Understanding the user experience of DPP participants wearing the CGM and receiving its output.’ The first question asked what participants liked about wearing the CGM. Participants overwhelmingly expressed that the ability to experiment with foods and physical activity to see how it affected the body was incredibly interesting. Having the data right away and conveniently accessible without being intrusive was also a common sentiment. This was expanded upon, with participants commenting that they would forget the device was on them at times. Others mentioned that they had gotten so accustomed to regularly checking their glucose levels that they missed the CGM once the wear period had ended. In response to aspects of CGM that participants disliked, participants responded that they would receive lots of notifications when the CGM lost service which was an annoyance. Additionally, the Dexcom application used to access the CGM data was clunky according to multiple participants. When asked to describe their feelings about being able to see their glucose levels continuously, participants said they felt in control, felt like they could make a significant difference in their glucose levels, comforted, and appreciated having the knowledge readily accessible. Responses from other participants were negative, however, saying they felt anxious when eating sometimes, worried about spiking their glucose levels, and multiple participants felt discouraged when performing physical activity but not seeing a change in their glucose levels. When asked about challenges experienced while wearing the CGM, participants said they had some trouble navigating the Dexcom application, specifically when trying to see their previous glucose levels. The other major challenge was the placement of the CGM on the waist being uncomfortable during times of activity.

The second topic was ‘Understand the use experience of DPP participants receiving the brief educational session and reading the handout.’ When asked about ways to improve the CGM education session for future participants, responses included having a follow up Q & A session to ensure participant questions get answered, clarifying instructions, and having a more streamlined form of communication with the research team.

The third topic was ‘Identify the type of information that DPP participants need to use the CGM, and relate CGM output with diet and physical activity behaviors.’ When asked to describe how they used the CGM data, a major response was that they would perform physical activity in response to seeing rising glucose levels. Participants also said they learned to exercise before eating to manage glucose better. The type of physical activity was also mentioned to affect how well they were able to influence their glucose levels, with walking being a common and effective physical activity method. Eating more balanced meals and including more protein in meals were major themes regarding diet modification as a result of the CGM. Multiple participants noticed their sugar spiking in response to foods that were thought to be healthy, which caused shock and additional modification of the diet. Participants were asked if wearing the CGM for 10 days was an adequate amount of time for them to benefit from the data, or if they would prefer to wear it for longer, and the overwhelming response (seven of nine participants) was that more time with the CGM would have been appreciated. Another common sentiment was that the wear period for the unblinded CGM was inconvenient due to being during the December holidays, so being able to wear it at a time when they are consuming a more typical diet would be appreciated.

The fourth topic was ‘Identify potential barriers to making recommended behavioral changes and areas where additional support may be required.’ When asked to describe difficulties experienced with making changes to the diet, multiple participants said they struggled with breakfast. They elaborated by saying that typical breakfast foods were not conducive to

stable glucose, and they had trouble finding high-protein foods that were both healthy and satiating to replace them. Indeed, satiety was a major theme, as many participants struggled to find low-glycemic-impact foods that kept them full and that help with building new recipes for balanced meals would be appreciated. In response to being asked about difficulties making changes to physical activity while wearing the CGM, most participants said that making any changes to physical activity was difficult due to the holidays. When asked about additional support that could be provided, participants stated that providing more detail about food and exercise options would be helpful, reiterating their previous sentiments about having trouble creating satiating meal ideas on their own.

The key points for the first topic of wearing the CGM were: enjoyment of experimentation with diet and physical activity, convenience and accessibility of CGM data, a sense of control over glucose levels, anxiety surrounding spiking glucose levels when eating, and discouragement when unable to lower glucose levels. The key points for the second topic of the education session were: desire for a follow up Q & A session to answer questions, and potentially creation of a streamlined method for participants to communicate with the research team to ask questions. The key themes for the third topic of relating CGM data with diet and physical activity were: performing physical activity in response to rising glucose levels, incorporating more protein into meals, and shock at seeing glucose levels spike after consuming foods thought to be healthy. The key themes for the fourth topic of barriers to making changes and additional support were: difficulty finding ideas for satiating meals that are conducive to glycemic health, having difficulty adjusting physical activity habits due to the holiday season, and desiring more assistance with creating balanced and satiating meals.

Discussion -

Participant beliefs that they could maintain lasting changes to dietary and physical activity habits remained largely unchanged pre- and post-intervention. Though there was not a trend towards greater self-efficacy as a result of the pilot trial, pre-intervention sentiments already reflected a level of confidence among participants that they could enact these lifestyle changes. HRQOL responses also remained largely consistent pre- and post-intervention. Again, pre-intervention responses reflected a general belief that participants viewed themselves in good health and had on average less than 4 days in the past 30 days where usual activities were affected by poor mental or physical health. The sample size of this pilot study is small, which limits the ability to draw any conclusions regarding changes to self-efficacy associated with use of CGM in the NDPP. The CGM is also a device that offers support only in the form of insight. While users may be more aware of how their habits affect their glucose, this knowledge does not necessarily confer an easier experience in applying lifestyle changes.

Participants largely seemed to enjoy wearing the CGM (Table 2). Indeed, survey responses indicated that they found the CGM helpful, convenient, relevant, and would recommend its use to friends and family. These findings were supported by focus group responses, wherein participants expressed their appreciation of the friendliness and convenience of CGM. Further comments from this group were that the CGM was non-invasive, and that they would forget the CGM was even there at times. Multiple participants expressed that they had gotten accustomed to checking their glucose levels often, and missed the ability to do so once the CGM wear period had ended. These comments and survey responses suggest that prospective CGM users without prior experience with the device are receptive to CGM, and quickly integrate

its use into their daily habits. This represents a positive outlook on further use and integration of CGM into the NDPP.

Participant responses also indicated that use of CGM helped them better understand the relationship between diet/physical activity and glucose, as well as increased motivation to make changes to their lifestyle habits (Table 2). Focus group responses supported these indications, with a great number of comments about how participants experimented with new foods and food habits to see how their glucose levels changed on the CGM. This same phenomenon occurred with physical activity too, where participants would attempt different modes of physical activity such as walking or bike riding, as well as finding different times to engage in physical activity to understand what options were the most efficacious according to the CGM. The exploration of the relationship between diet/physical activity and glucose levels among participants was facilitated by CGM, and may not have occurred otherwise, since they would not have a metric to quickly and conveniently measure the “success” of a certain habit. Additionally, results produced from CGM are tailored to the individual, which may be more efficacious, as they can now use their own experiences to inform their future pursuits rather than having to rely on the one size fits all template that is presented in the regular NDPP.

Feelings towards wearing and using the CGM were largely neutral to positive (Table 2). Responses to the survey and comments in the focus group showed a common feeling of greater control over glucose levels as a result of having access to CGM. This control also helped to generate feelings of comfort about glucose levels, and appreciation of having the CGM device among participants. Survey responses indicate that participants did not experience negative emotions often, or at least felt neutral when using the CGM. This was different from some responses gathered during the focus groups. Comments from participants included alarm at seeing high glucose levels, especially after consuming foods that were said to be low on the glycemic index in the CGM education session. This stemmed into sometimes feeling anxious when eating for risk of spiking glucose levels. Others felt discouraged when trying to make changes to diet and physical activity that were not positively reflected in the CGM. Frustration when seeing high glucose levels despite performing physical activity meant to lower glucose was also commonly mentioned. Despite these negative experiences, participants overall indicated that they would continue experimenting with diet and physical activity to see what was most efficacious and helpful. This disconnect between survey responses and focus group responses may be due to the group-nature of the focus group encouraging a cascade of similar opinions and experiences. Regardless, these negative feelings experienced did not seem to impact the individual past the short term, and instead the participants focused on what worked for them and what would be helpful for them as they moved forward. Additionally, expressions of positive feelings outweighed those of negative feelings in the survey responses and focus group alike.

The support for future use of CGM among participants in both the surveys and focus group was positive. Participants unanimously agreed that CGM should be offered as a part of the NDPP, and most said that they would wear the CGM again, and for extended periods of time (Table 2). This sentiment was also reflected in the focus group, with most participants expressing that they wanted more time with the CGM to keep experimenting with diet and physical activity. These responses are similar to that of the TakeCharge study, wherein participants were asked if they would wear the CGM again, and if so, how many times in a year, and how long each wear-period would be. Respondents said that they would indeed wear the CGM again, and for an average of 4 times a year, each time being 1-2 weeks (21). Such support for use of CGM, even in this small sample, presents a positive outlook on future prospects. With more time and guidance,

CGM users may be able to better understand the relationship between diet/physical activity and their own body's glucose levels to confer more efficacious results. Additionally, the opportunity to use CGM again at a later time in the NDPP program may help to retain a greater number of participants.

The primary goal of this thesis was to understand the feasibility of integrating continuous glucose monitoring into the Diabetes Prevention Program. Due to being a pilot study, this project was conducted in an exploratory manner and lacks statistical power. As such, formal hypothesis tests were not conducted, which may be considered a weakness. However, through the use of surveys and focus groups, the sentiments of participants could be captured and analyzed to establish an initial understanding of how CGM may be used to help those affected by pre-diabetes. This study may be among the first to introduce the use of biological feedback, specifically continuous glucose monitoring, into the NDPP for persons with prediabetes, for whom CGM is not typically prescribed for its use. While this constitutes a strength in the sense that it is the first of its kind and pioneers a novel use for CGM and a novel approach to treating prediabetes, it may also be considered a weakness due to the fact that there are no other studies with which to compare results. Due to the small sample size, we are not able to generalize any findings to the greater population. However, it should be noted that the data that was collected was overwhelming and monolithic in support of CGM in the NDPP. Finally, the participants' unblinded CGM wear period occurred at the end of December, in which holidays such as Christmas and New Years are held. This may have produced circumstances in which participants' diets and physical activity habits were not necessarily representative of their usual behaviors during the rest of the year. Though the wear period was held during an atypical time, this may actually be viewed as a strength. The holiday season is one in which many traditions are adhered to, and introducing lifestyle modification is not recommended. However, the CGM was welcomed and overwhelmingly accepted among participants despite the holiday season, indicating the seamlessness of integration and value of CGM.

Future pursuits to be considered may be recruiting a larger cohort, or multiple diverse cohorts to gather more data on the feasibility of CGM in the NDPP. A larger cohort will enable a study into the efficacy of CGM with regards to the standard outcome measures of the NDPP such as average time spent performing physical activity each week and weight loss. Improving these outcomes is the ultimate goal of the NDPP, and understanding how CGM supports this pursuit would be quite compelling. A study of the decisions made by participants wearing CGM to control their glucose levels would also be interesting. More specifically, an analysis of the dietary habits of people wearing CGM and whether and how this influences glucose patterns, Hb1AC, and weight over the course of the NDPP, may be a future avenue. This approach could also incorporate physical activity by evaluating what types of exercise, length of activity, and times of initiation participants choose to incorporate and how this influences their glucose patterns, Hb1AC, and weight over time. This is interesting because certain habits such as walking in short intervals periodically, and decreasing intake at breakfast, were habits mentioned by multiple participants in focus groups that seemed to make a noticeable impact on glycemic health. A more in-depth analysis of these habits and more could produce easy-to-incorporate recommendations for those affected by prediabetes to follow that may increase weight loss and promote glycemic health.

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Appendix

Item 1. Answer matrix for the baseline and post-intervention self-efficacy and HRQOL surveys depicting all possible response options and their associated values.

<u>Self Efficacy</u>	Response (Value)			
Diet Efficacy: How confident are you that you can make or maintain lasting changes to your diet?	Not at all (1)	Might be able to (2)	Pretty sure I can (3)	Very confident (4)
Physical Activity Efficacy: How confident are you that you can make or maintain lasting changes to be more physically active?	Not at all (1)	Might be able to (2)	Pretty sure I can (3)	Very confident (4)
<u>Quality of Life</u>				
Health Status: Would you say that in general your health is excellent, very good, good, fair or poor?	Poor (1)	Fair (2)	Good (3)	Very good (4) Excellent (5)
Physical Health: Now thinking about your physical health, which includes physical illness and injury, how many days during the past 30 days was your physical health not good?	Numerical Response (1-30)			
Mental Health: Now thinking about your mental health, which includes stress, depression, and problems with emotions, how many days during the past 30 days was your mental health not good?	Numerical Response (1-30)			
Usual Activities: During the past 30 days, approximately how many days did poor physical or mental health keep you from doing your usual activities, such as self-care, work, or recreation?	Numerical Response (1-30)			

Item 2. Answer matrix for the acceptability survey depicting all possible response options and their associated values.

<u>CGM Use</u>	Response (Value)				
Usability: CGM is easy to use and user friendly.	Strongly Disagree (1)	Disagree (2)	Neither Agree nor Disagree (3)	Agree (4)	Strongly Agree (5)
Convenience: CGM is convenient for me to use in my everyday life.	Strongly Disagree (1)	Disagree (2)	Neither Agree nor Disagree (3)	Agree (4)	Strongly Agree (5)
Value: CGM is useful and beneficial.	Strongly Disagree (1)	Disagree (2)	Neither Agree nor Disagree (3)	Agree (4)	Strongly Agree (5)
Relevance: CGM provides information that is of interest to me.	Strongly Disagree (1)	Disagree (2)	Neither Agree nor Disagree (3)	Agree (4)	Strongly Agree (5)
Motivating: I am motivated to use CGM to track my daily behaviors.	Strongly Disagree (1)	Disagree (2)	Neither Agree nor Disagree (3)	Agree (4)	Strongly Agree (5)
Tech Support: There is adequate availability and quality of professional assistance throughout use of the CGM.	Strongly Disagree (1)	Disagree (2)	Neither Agree nor Disagree (3)	Agree (4)	Strongly Agree (5)
Confidence: I feel confident that I use CGM correctly.	Strongly Disagree (1)	Disagree (2)	Neither Agree nor Disagree (3)	Agree (4)	Strongly Agree (5)
Privacy: I am concerned about my privacy when using CGM.	Strongly Disagree (1)	Disagree (2)	Neither Agree nor Disagree (3)	Agree (4)	Strongly Agree (5)
Recommend: I would recommend CGM to my friends and family.	Strongly Disagree (1)	Disagree (2)	Neither Agree nor Disagree (3)	Agree (4)	Strongly Agree (5)
Like: I like using the CGM.	Strongly Disagree (1)	Disagree (2)	Neither Agree nor Disagree (3)	Agree (4)	Strongly Agree (5)
CGM Knowledge & Motivation					
Educational Relevance: The information from the Participant Guide was relevant to me.	Strongly Disagree (1)	Disagree (2)	Neither Agree nor Disagree (3)	Agree (4)	Strongly Agree (5)
Diet & Glucose: Using the CGM helped me better understand the connection between diet and glucose.	Strongly Disagree (1)	Disagree (2)	Neither Agree nor Disagree (3)	Agree (4)	Strongly Agree (5)
Physical Activity & Glucose: Using the CGM helped me better understand the connection between physical activity and glucose.	Strongly Disagree (1)	Disagree (2)	Neither Agree nor Disagree (3)	Agree (4)	Strongly Agree (5)
Motivate Diet: Using the CGM increased my motivation to make dietary changes.	Strongly Disagree (1)	Disagree (2)	Neither Agree nor Disagree (3)	Agree (4)	Strongly Agree (5)
Motivate Physical Activity: Using the CGM increased my motivation to be more active.	Strongly Disagree (1)	Disagree (2)	Neither Agree nor Disagree (3)	Agree (4)	Strongly Agree (5)
CGM Feelings					
Worry: Using a CGM causes me to be more worried about controlling blood sugars.	Strongly Disagree (1)	Disagree (2)	Neither Agree nor Disagree (3)	Agree (4)	Strongly Agree (5)
Think Too Much: Using a CGM makes me think about prediabetes too much.	Strongly Disagree (1)	Disagree (2)	Neither Agree nor Disagree (3)	Agree (4)	Strongly Agree (5)
Glucose Control: Using a CGM makes me feel like I have more control over my prediabetes.	Strongly Disagree (1)	Disagree (2)	Neither Agree nor Disagree (3)	Agree (4)	Strongly Agree (5)
CGM Appearance: I do not like how a CGM looks on my body.	Strongly Disagree (1)	Disagree (2)	Neither Agree nor Disagree (3)	Agree (4)	Strongly Agree (5)
CGM Noticeable: I do not like when people notice me wearing a CGM.	Strongly Disagree (1)	Disagree (2)	Neither Agree nor Disagree (3)	Agree (4)	Strongly Agree (5)
Fear: Seeing high glucose levels made me feel afraid about my risk of being diagnosed with type 2 diabetes.	Strongly Disagree (1)	Disagree (2)	Neither Agree nor Disagree (3)	Agree (4)	Strongly Agree (5)
Guilt: Seeing high glucose levels made me feel guilty that I had done something to cause a high glucose level.	Strongly Disagree (1)	Disagree (2)	Neither Agree nor Disagree (3)	Agree (4)	Strongly Agree (5)
Unhappiness: Seeing high glucose levels made me feel unhappy because my glucose is high when I don't think it should be.	Strongly Disagree (1)	Disagree (2)	Neither Agree nor Disagree (3)	Agree (4)	Strongly Agree (5)
CGM Prospects					
CGM Again: If given the opportunity, would you wear the CGM again?	Yes (1)	Maybe (2)	No (3)		
Days in a Row CGM: If given the opportunity, how many days in a row would you be willing to wear CGM?	2 weeks or less (1)	2-4 weeks (2)	1-3 months (3)	More than 3 months (4)	Never (0)
Times per Year CGM: How many times per year would you be willing to wear CGM?	Every month (1)	Every 3 months (2)	Every 6 months (3)	Once per year (4)	Never (5)
CGM-DPP: Do you think CGM should be offered regularly as a part of the Diabetes Prevention Program?	Yes (1)	Maybe (2)	No (3)		

Item 3. Focus group script.

We've invited you to participate in this focus group to help us understand your experience using the continuous glucose monitor and receiving the related education session and materials. The goal of our study is to understand the feasibility of adding a brief CGM-focused interview to a structured diabetes prevention program like the Arizona Cooperative Extension Diabetes Prevention Program. I want to take this time to ask questions about your experiences wearing the CGM and receiving its output. I am also going to ask you about the type of information and support that you think others might need to use the CGM and relate the CGM output with diet and physical activity behaviors. Finally, I will ask you to share any barriers you experienced in making behavioral changes – specifically diet and physical activity – recommended by the DPP program, and what kind of support you think is needed. There are no right or wrong answers – I just want to hear your feedback and what you think.

At the end of the focus group, you will receive \$25 as a thank you for participating in the interview. The focus group will not take more than 60 minutes.

Do you have any questions before we begin?

If yes, answer any questions they may have.

If no, continue interview

To make sure we capture everything you say, I would like to audio-record this focus group discussion. Are you okay with me starting the audio-recording now?

If yes, start audio-recording and proceed.

If no, take notes on interview and do not start audio recording.

QUESTIONS:

Now we are going to ask you some questions.

Please remember, there are no right and wrong answers. We are only trying to understand your perspective.

TOPIC 1: Understand the user experience of DPP participants wearing the CGM and receiving its output

- What, if anything, did you like about wearing the CGM?
- What, if anything, did you dislike about wearing the CGM?
- Describe how you felt to be able to see your glucose levels continuously.
- What are some of the challenges that you experienced with wearing the CGM, if any?
 - Probe: how did you overcome them?

TOPIC 2: Understand the user experience of DPP participants receiving the brief educational session and reading the handout

Please tell ways in which we can improve the CGM education session for future participants.

- PROMPT: Were there any concepts that you found difficult to understand or confusing?

Describe your experience in using the “Glucose Tracking” sheet.

- PROMPT: What were the benefits or burdens of tracking your food intake and corresponding glucose level?

TOPIC 3: Identify the type of information that DPP participants need to use the CGM, and relate CGM output with diet and physical activity behaviors

Describe how you used the data from CGM, if at all.

PROMPT: did anyone make changes to your diet in response to seeing your glucose levels?

Follow-up: Can you describe a specific change you made?

PROMPT: did anyone make changes to your physical activity in response to seeing your glucose levels?

Follow-up: Can you describe a specific change you made?

Did you think you needed to wear CGM for more than 2 weeks to understand and benefit from the data or was this enough time? Explain.

TOPIC 4: Identify potential barriers to making recommended behavioral changes and areas where additional support may be required

Describe any difficulties you experienced in making changes to your diet while wearing the CGM, if at all.

- Probe: how did you overcome this difficulty?

Describe any difficulties you experienced in making changes to your physical activity while wearing the CGM, if at all.

- Probe: how did you overcome this difficulty?

What additional support and resources, if any, do you wish you had while wearing the CGM?

Is there anything else you'd like to share with us about the CGM or the education session, or anything