Official title: Perspectives on Using a Nutrition-focused Approach When Initiating Continuous Glucose Monitoring in People With Type 2 Diabetes: a Qualitative Study

Brief Title: Nutrition-Focused Approach During CGM Initiation: A Qualitative Study

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My Diabetes CGM Study: Patient Interview Protocol

Semi-structured Interviews

Study Name: Perspectives on using a nutrition-focused approach when initiating continuous glucose monitoring in people with type 2 diabetes: a qualitative study

Principal Investigator: Holly Willis, PhD, RDN, CDCES

Co-Investigator: Meghan JaKa, PhD

Respondent Population: Study participants from IRB-approved study A21-292 who are in the nutrition-focused approach study arm only

Data Collection Method: Semi-structured interviews

Length: Approximately 20 minutes

Number: up to 15 respondents

Timeline: approximately 25 weeks from the start of the first interview; this is expected to occur approximately fall 2023 through spring 2024

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INTRODUCTION

Background

Food choices play a significant role in achieving glycemic goals and optimizing overall health for people with type 2 diabetes (T2D). Continuous glucose monitoring (CGM) provides a comprehensive look at the impact of foods and other behaviors on glucose. People with T2D may benefit from using CGM to guide food choices that help achieve their desired glycemic goals (e.g. their Time in Range (TIR); % time with glucose 70-180 mg/dL)). However, people with

T2D may encounter challenges with knowing how to use CGM data to make food choices, especially food choices that can maximize TIR *and* that are good for overall health (e.g. identifying food choices that keep glucose in target *and* that align with current evidence-based nutrition guidance for people with T2D[1]).

Obtaining benefit from CGM requires education, training, and support.[2] Many tools,[3] methods,[4] and programs[5] have been created to educate CGM users on effective use of the technology and its associated data. However, specific emphasis on evidence-based nutrition guidance has not been embedded into these trainings. Lack of education on the importance of achieving glycemic (and other health) goals by following evidence-based nutrition guidance could have consequences. For example, without nutrition guidance, a continuous glucose monitor could lead its user to choose low-quality (e.g. unhealthy) foods that keep glucose in the target range of 70-180 mg/dL (for example, choosing high-fat meats like bacon or highly-processed low-carb snacks, etc.) but these foods may be detrimental to other aspects of health and lead to unintended consequences.

The IRB has approved study A21-292 (also known as the My Diabetes Study), a randomized clinical trial to assess the impact of using a nutrition-focused approach (NFA), based on evidence-based nutrition guidance, or a self-directed approach during CGM initiation. The NFA was developed specifically for the randomized clinical trial study.

Interview Purpose

The purpose of these qualitative interviews is to provide a deeper understanding of the perspectives of people with T2D who receive a NFA when initiating CGM. More specifically, these interviews will help describe how the NFA may or may not have worked compared to how it was intended; the interviews will also provide information that can be used to help refine future NFA iterations.

Data from this qualitative research will be considered in partnership with the quantitative data collected as part of IRB-approved study A21-292. Together, this work will offer important insights into the efficacy of a NFA during CGM initiation in people with T2D. The qualitative research will help identify gaps in our understanding of how people with T2D use their CGM data to make food-related decisions and what factors influence their use of the CGM data.

Outcomes will provide the diabetes care community with considerations for how to present and position nutrition messages when initiating CGM in people with T2D.

Interview Questions

Primary Research Question: How do people with T2D who have received a NFA during CGM initiation use CGM data when making food-related decisions and what specific types of food-related changes, if any, do they describe making?

To describe how participants use CGM data when making food-related decisions after receiving a NFA during CGM initiation, the following topics will be assessed:

- Which specific CGM data were used and what was the thought-process when using it
- What specific food-related changes, if any, are described by participants as a result of the CGM data
- What helped or what got in the way of using CGM data to guide food-related decisions

Secondary Research Question: What is the overall experience of people with T2D who receive a NFA during CGM initiation?

To describe how people with T2D experience the NFA and its associated nutrition-focused CGM initiation materials, the following topics will be assessed:

- Were participants satisfied with the NFA concept and the nutrition-focused materials (e.g. the CGM and Nutrition guide, the interactive presentation); why or why not

IRB Materials

1. Interview-specific study protocol
2. Participant invitation letter
3. Interview guide

METHODS

Setting & Population Description

Setting Description

The larger My Diabetes Study will take place at the International Diabetes Center in Minneapolis, MN. The qualitative interviews will be conducted over the phone.

Participant Description

Adults who have met inclusion criteria for the My Diabetes study and who have completed the study may be eligible.

Inclusion:

- Participant was randomized to the nutrition-focused approach arm of the My Diabetes study
- Participant completed all required study visits in the My Diabetes study; this includes the baseline visit, the two intervention visits, and the study completion visit
- Participant had at least 70% “Time CGM Active” on a 10-day Dexcom Clarity Report at study completion visit
- Participant is willing to be recorded during the interview

Exclusion:

- Participant was randomized to the self-directed approach study arm of the My Diabetes study
- Participant is deemed unsuitable for participation due to any cause as determined by the Investigator

Data Collection

Anticipated Response Rate and Sample Size

- Target number of completed interviews: up to 15
- Anticipated participation rate: 70%
- Total sample needed: approximately 21 in order to accommodate people who decline participation; expect approximately 30% may decline. (For reference, we expect N=66 people to complete the NFA arm of the My Diabetes study. It is expected that most people will meet all inclusion criteria.)
- Effort will be made to include participants from at least two different sexes and participants with point-of-care HbA1cs greater than and less than 8.5% at the start of the study.

Recruitment into Interviews Process

- Participants who have completed the NFA arm of the My Diabetes study will be invited to participate. Invitation will stop when the target number of interviews are complete.
- A verbal invitation or an invitation letter will be shared with study participants before their study completion visit in the My Diabetes study. The invitation will provide a brief description of the qualitative study.
- Participants who express interest in participating in the qualitative study interview, may be able to complete the interview immediately following the study completion visit in the My Diabetes study.
- IDC study staff working on the My Diabetes study will assess eligibility for participation in the qualitative interviews the day of the study completion visit. Eligibility assessment includes:
    - Confirm participant completed all study visits in the NFA arm of the My Diabetes study
    - Confirm participant had at least 70% “Time CGM Active” on Dexcom Clarity Report during study visit completion visit
    - Willing to be recorded
- IDC study staff will relay participant eligibility to a Center for Evaluation and Survey Research (CESR) team member.
- A trained CESR interviewer will provide the participant with a description of the study and purpose of the interview.
- The CESR interviewer will assess willingness to participate and be recorded.
- If participant is interested and available for the interview during the initial CESR contact, the CESR interviewer will provide consenting language and ask for a verbal consent (a waiver of written consent will be requested) to participate in the audio-recorded, semi-structured interview over the phone.

- If the participant is interested, but does not have enough time, interviews will be scheduled by CESR as soon as possible within 14 days of the study completion visit in the My Diabetes study.
- Recruitment will be closed when a maximum of 15 interviews have been completed.

Interview Process

- Interviews will be conducted within 14 days after a participant completes the My Diabetes study.
- After the participant provides consent, trained interviewers experienced in qualitative facilitation will conduct the interviews; all interviewers will be supervised by a Co-Investigator with extensive qualitative research experience.
- Semi-structured phone interviews will be recorded and transcribed with secure technology. Audio recording is done for accuracy and for taking additional field notes.
- Individual interviews are intended to last approximately 20-30 minutes and all of the interviews are expected to be completed within approximately 25 weeks of the first interview (this estimate is based on expected participant completion of the My Diabetes study and could change pending enrollment into that trial).
- CESR interviewers will confirm participant information and, as needed, provide participants with a brief reminder of the interview purpose before beginning the audio recording.
- CESR interviewers will inform the participants that they are experts in interviewing, but they are not experts in diabetes care.
- Audio recording will begin immediately prior to the first interview question.
- Each interview will start with a rapport-building question, followed by a transition question that brings participants to the primary area of focus.
- Interviewers will enter detailed field notes into REDCap during the interview; this will support circling back to prior discussion throughout the interview and enhance depth of responses collected.
- Interviewers will monitor timing of each question and when to proceed or ask additional probes to ensure the interview stays within the expected timing.
- If disconnected during the interview, interviewers will immediately pause the recording and call the participant back. They will confirm the correct participant, start the recording again and continue the interview. If the participant cannot be reached, a voicemail will be left and the interviewer will call back a few minutes later. If participant still is not reached and the interview continues at another time, the interviewer will restart at the appropriate root question and proceed from that point.
- Immediately following the interview, interviewers will document the interview length, review the completed audio, add any additional field notes to the study-specific REDCap database to aid in interpretation and analysis. Interviewers will remove protected health information, and they will download and save the audio recording and transcripts from the recording platform using an established file-naming convention.
- Contact information will be confirmed and incentive compensation will be processed and sent to participants after the interview is confirmed complete.

Interviewer Characteristics

- Master's, Bachelor's, or Associate's degree in health-related field
- Experience implementing phone-based surveys and/or qualitative interviewing
- Work as a phone interviewer, coordinator, or project manager in CESR
- Trained by researcher in qualitative data collection methods
- Not matched on any participant demographics
- No relationship (besides the existing HealthPartners/Park Nicollet relationship) will be established with the participants prior to study commencement

Interviewer Training

Example Training Session 1

- Project overview/objectives (5 min)
    - Background and rationale for interviews
    - Objective/research questions
    - How the data will be used
- Diabetes care context (10 minutes)
    - Use of CGM in people with T2D
    - Role of nutrition in diabetes care
    - Opportunities for integration between CGM technology and evidence-based nutrition guidance
- Refresher on semi-structured interview facilitation (20 minutes)
    - Rapport-building
    - Active listening
    - Field guide/note taking
    - Audio recording
- Overview of study-specific interview guide (10 min)

Example Training Session 2

- Demo interview (20 minutes)
- Two practice interviews (40 minutes)
- Homework: at least 3 practice interviews

Example Training Session 3

- REDCap Training (20 minutes)
    - Confirming hand-off from IDC
    - Phone script
    - FAQ
- Questions/discussion (10 minutes)
- Certification interview with an appropriate CESR team member
- Checklist of skills including
    - Rapport-building

- Listening
- Interviewer/interviewee speaking ratio
- Documentation/field notes
- Content-specific knowledge

Interviewer Supervision

- Interviews will be audio-recorded
- After each interviewer conducts their first study interview, a CESR Project Lead or qualitative co-investigator will listen to the audio and provide feedback and make any necessary adjustments to the interview process before subsequent interviews are conducted
- Interviewers, CESR project lead, and Investigators will meet after approximately the first half of the interviews are complete to review processes and listen to recordings as a group to help prevent drift in facilitation skills
- Following interview completion, the team will de-brief and cover lessons learned

Interview Guide Development

An interview guide will be developed by the Investigators with input from stakeholders, including diabetes care and education specialists. Interview questions will be created to address the specific research questions described above. Further, literature review, prior study-site research, and Investigator experience will inform question development.

- Root questions with a combination of structured and unstructured probes will be used to facilitate accurate, rich, and complete responses. Probes will be designed in a neutral way to avoid biasing responses.
- Interview questions will be open-ended and will consider information from the BCW framework and its associated COM-B model.
- The guide will be reviewed by an interdisciplinary team of diabetes content experts and, if possible, it will be pilot-tested with a proxy interviewee similar to the target population. It will be refined based on relevant feedback.
- The final interview guide may be slightly refined based on relevant feedback after the first two participants complete their interviews.

Data Analysis

- Transcripts of audio recordings and accompanying field notes will be analyzed in a qualitative software program (i.e., NVivo).
- Inductive thematic coding will be completed by the Investigators with support from CESR and other stakeholders, if possible.
- Emerging codes and themes will be organized and synthesized to draw data interpretation.
- A detailed code book and audit trail will be kept to increase reproducibility, trustworthiness and rigor, and to avoid issues of transferability.

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