Enabling trust and agency in predictive glucose alerting: co-design and pilot testing of the BeaGL application in young adults living with type 1 diabetes

Hari Venugopalan, Samuel King, Salvador Lopez, Jun Min Kim, Grace Cheng, Tim Stewart, Sriram Magesh, Brendan Leung, Stephanie Crossen

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Hari Venugopalan[1] MS; Samuel King[1] PhD; Salvador Lopez[2] BA; Jun Min Kim[1] BS; Grace Cheng[1] BS; Tim Stewart[1] BS; Sriram Magesh[1] BS; Brendan Leung[1] BS; Stephanie Crossen[2] MD, MPH

[1] University of California, Davis Davis US
[2] University of California Davis Medical Center Sacramento US

Corresponding Author:
Hari Venugopalan MS

University of California, Davis
3061 Kemper Hall
Davis
US

Abstract

Background: Although continuous glucose monitoring (CGM) devices are now widely used among people with type 1 diabetes (PwT1D), the utility of these devices has not been specifically optimized for adolescents and young adults (AYAs).

Objective: We hypothesized that predictive alerting for hypo- and hyperglycemia would improve the user experience among young adult PwT1D using CGM.

Methods: We engaged in an iterative co-design and pilot testing process of our own novel predictive CGM alerting app – BeaGL – with a cohort of six young adults over 5 months.

Results: Qualitative feedback from participants emphasized the importance of simplicity and customizability within the app, which then led to experienced benefits of improved agency and reduced cognitive burden related to their T1D self-management. Although the pilot was not powered to detect statistically significant changes in CGM metrics, all participants demonstrated a trend toward reduced time in hypoglycemia (<70 mg/dl), severe hyperglycemia (>250 mg/dl), or both.

Conclusions: Future research should evaluate the benefits of customizable predictive CGM alerting among AYA PwT1D for both glycemic outcomes and quality of life via a larger, randomized trial.

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Authors: Hari Venugopalan, MS[1], Samuel King, PhD[1], Salvador Lopez, BA[2], Jun Min Kim, BS[1], Grace Cheng, BS[1], Tim Stewart, BS[1], Sriram Magesh, BS[1], Brendan Leung, BS[1], Stephanie Crossen, MD, MPH[2]
Affiliations: [1]Department of Computer Science, University of California Davis, Davis, CA; [2]Department of Pediatrics, University of California Davis School of Medicine, Sacramento, CA
Corresponding Author: Hari Venugopalan, hvenugopalan@ucdavis.edu
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Introduction

Adoption of continuous glucose monitoring (CGM) devices among people with type 1 diabetes (PwT1D) has increased dramatically over the last decade.[1] Due to convincing evidence of its ability to improve glycemic outcomes,[2] CGM initiation is now recommended even at the time of T1D diagnosis by both the American Diabetes Association[3] and International Society for Pediatric and Adolescent Diabetes.[4] Despite these advances, however, adolescents and young adults (AYAs) with type 1 diabetes (T1D) continue to have worse glycemic outcomes than any other age group.[1, 2, 5] Studies that focus on diabetes-related satisfaction and goals reveal that AYAs tend to prioritize their immediate psychosocial functioning and the need to minimize diabetes-related self-care burden above long-term glycemic outcomes, and this often drives decisions about diabetes technology use.[6, 7] Given this mindset as well as the many competing demands at this time of life, AYAs could particularly benefit from the customization of CGM alerting to minimize burden and optimize the timing and effectiveness of interventions for diabetes self-management.

CGM alerting can be divided into (1) threshold-based alerts and (2) predictive alerts. With threshold-based alerts, apps notify individuals once their glucose readings have crossed user-defined glucose thresholds (e.g., >250 mg/dl or <70 mg/dl). The reactive nature of these alerts results in individuals having limited agency in managing diabetes.[8] For example, an individual may already be experiencing symptoms of hypoglycemia by the time they receive an alert, and they also have limited time to act in order to reverse their current glucose trend.

Predictive alerts have the potential to provide users with more agency by alerting individuals based on predicted future glucose readings. Researchers have explored a wide range of techniques for predictive alerting, including those based on mathematical models of human physiology,[9-12] as well as machine learning.[13-17] However, despite the importance of the role of the individuals themselves in managing diabetes, past research has not focused on human factors such as how individuals perceive alerts, respond to them, and handle mispredictions in real time. Existing techniques have primarily been evaluated in simulation or by retroactively considering the past data of individuals with T1D.

Evaluating human factors is crucial for predictive alerts since mispredictions can erode an individual's trust and discourage them from acting on future alerts.[18] Mispredictions or poorly configured alerts can also lead to alarm fatigue[19] and reduce the likelihood that an individual will respond to an alert. Such difficulties impact the mental health of individuals, which in turn affects their diabetes management.[20] Building alerting mechanisms that engender trust among individuals along with agency is essential for effective T1D management and may be particularly crucial for improving self-management among AYAs living with T1D.

In light of this necessity, we created a novel iOS application – BeaGL – to enable predictive CGM alerting, and then tested and adapted it via an iterative, user-centered co-design process with six young adults living with T1D and already using CGM technology. Our hypothesis was that this application would have acceptability and utility to young adult PwT1D, above and beyond the experienced utility of their baseline CGM systems and alerts.

Methods

<u>BeaGL Development</u>

We developed the BeaGL app to use simple linear regression to predict if an individual's glucose concentration could become dangerously high or low in the next 15 minutes. Specifically, BeaGL fits a straight line to the past 30 minutes of glucose values from CGM readings and extrapolates it to predict the glucose value after the next 15 minutes. We intentionally designed BeaGL to use linear regression rather than sophisticated deep learning models, such as neural networks, as part of our efforts to build trust among individuals and reduce their cognitive load. We reasoned that individuals would find it easier to visualize and interpret linear models, parameterized only by a slope and an intercept, as opposed to the millions if not billions of parameters in deep neural networks.[21]

User Trial

We conducted a 5-month user study among 6 young adults who used BeaGL to manage their T1D as they went about their day-to-day lives. Inclusion criteria for participation in the study were: (1) age ≥18 years, (2) diagnosis of T1D for ≥1 year duration (by self-report), (3) current use of a CGM device, and (4) use of a smart phone that connected to the CGM. Non-English speakers were excluded from this pilot due to the early stage of application development, with alerts and nudges available in English only at this time; however, our team hopes to test and adapt the application in future with non-English speaking PwT1D as well. Study participants were recruited from T1D groups at local colleges and universities, and underwent a standardized informed consent process. This study was reviewed and approved by the UC Davis Institutional Review Board.

At the time of study enrollment, participants completed a baseline survey about their T1D history, insulin regimen, and device use, as well as their concerns and priorities related to T1D self-management, and provided baseline CGM data or 30-day summary metrics. They then underwent an initial study visit, at which the research team downloaded and configured the BeaGL app on their personal mobile devices, enabled data-sharing between their CGM devices and the BeaGL app, and provided them with a smartwatch that could pair to their mobile device and was configured to receive alerts from the BeaGL system. They were also given CGM supplies (Dexcom G7 sensors or Dexcom G6 sensors + transmitters depending on which device they were using) at this time to prevent gaps in CGM data during the study.

For the next five months, participants went about their daily lives and used the BeaGL alerts however they saw fit. Each week they were texted a brief survey to report on their experience with and feedback about the app, so that the research team could make user-guided modifications to BeaGL as needed. At the end of each month, participants also completed a synchronous check-in with the research team (either in person or via Zoom) to give more detailed qualitative feedback about their experiences, and to receive orientation from the research team about any new modifications to the app. Completion of each monthly visit was compensated with a $50 gift card. Each month, the research team also pulled CGM data for each participant in order to calculate CGM metrics (e.g., time in hypoglycemic range <70 mg/dl and time in severe hyperglycemic range >250 mg/dl) for the prior 30 days.

BeaGL Adaptations

The first month of the study involved several adaptations to the BeaGL app, made in response to feedback from the participants. These adaptations fall into two major categories: how alerts were triggered, and how they were delivered.

Changes to how BeaGL alerts were triggered included bolstering communication with CGMs to make it more reliable and allowing users to customize alert thresholds. Initially, in order to keep our implementation simple, the BeaGL app relied on the cloud to communicate with CGMs. This design choice resulted in participants not receiving alerts when they did not have cell service or WiFi, with a particular participant reporting that they did not receive alerts while they were out canoeing. Accordingly, we updated the BeaGL app to be more reliable in triggering alerts by establishing an additional channel for communication over bluetooth. We also incorporated a mechanism to detect CGM disconnects and automatically attempt reconnection.

In our initial implementation, we hardcoded glucose thresholds corresponding to hypoglycemia and hyperglycemia (70 mg/dl and 250 mg/dl respectively), and BeaGL would trigger alerts whenever linear regression indicated that glucose levels would surpass these hardcoded thresholds within the next 15 minutes. After the first month, participants requested the option to specify their own thresholds, particularly for hyperglycemia. Upon modifying BeaGL to enable this customization, participants chose a wide variety of hyperglycemia thresholds (as low as 180 mg/dl for one participant and as high as 400 mg/dl for another). Most continued to use 70 mg/dl as their hypoglycemia threshold, with some increasing it to 80 mg/dl. Only one out of the six participants continued to use our initial thresholds, demonstrating the importance of customization to this cohort of young adult PwT1D.

We also made three broad adaptations to improve how we delivered alerts. First, we cleared stale alert notifications and updated the message in the notification to reflect the most recent CGM data. We also updated the format of our notification messages to be more person-centered, and simplified alert reminders by allowing users to customize when to receive them.

In our initial implementation, the BeaGL app displayed old notifications as well as the most recent notification, with the user able to clear out old notifications as desired. However, in the first month of our user trial participants expressed confusion when viewing old notifications in the app, and requested that this be changed. Accordingly, we updated the BeaGL app to automatically clear out stale notifications once glucose readings had stabilized, and also to update the current notification dynamically to display the most recent glucose data and prediction for that individual.

The participants also gave us feedback to make our alert messages more person-centered. Initially, we used a biohazard symbol as part of our alert notification to capture the attention of users. However, participants expressed that this symbol made them mo=re anxious about their diabetes, so we changed it to a dog icon (shown in *Figure 1*) which was better received. Participants also advised us to change the language in BeaGL alert messages so as not to equate individuals with their glucose levels, e.g., *"Your glucose is expected to go below 70 mg/dl"* instead of *"You are expected to go below 70 mg/dl"*.

Finally, we initially employed an algorithmic approach to send reminder alerts to participants when they did not respond to prior alerts. Feedback from participants after the first month revealed that they found these reminders to be disruptive and preferred to set a customized reminder frequency for themselves. We therefore simplified the app to remove this algorithmic approach and allow users to configure their own reminders. Screenshots from the BeaGL app are shown in *Figure 1*.

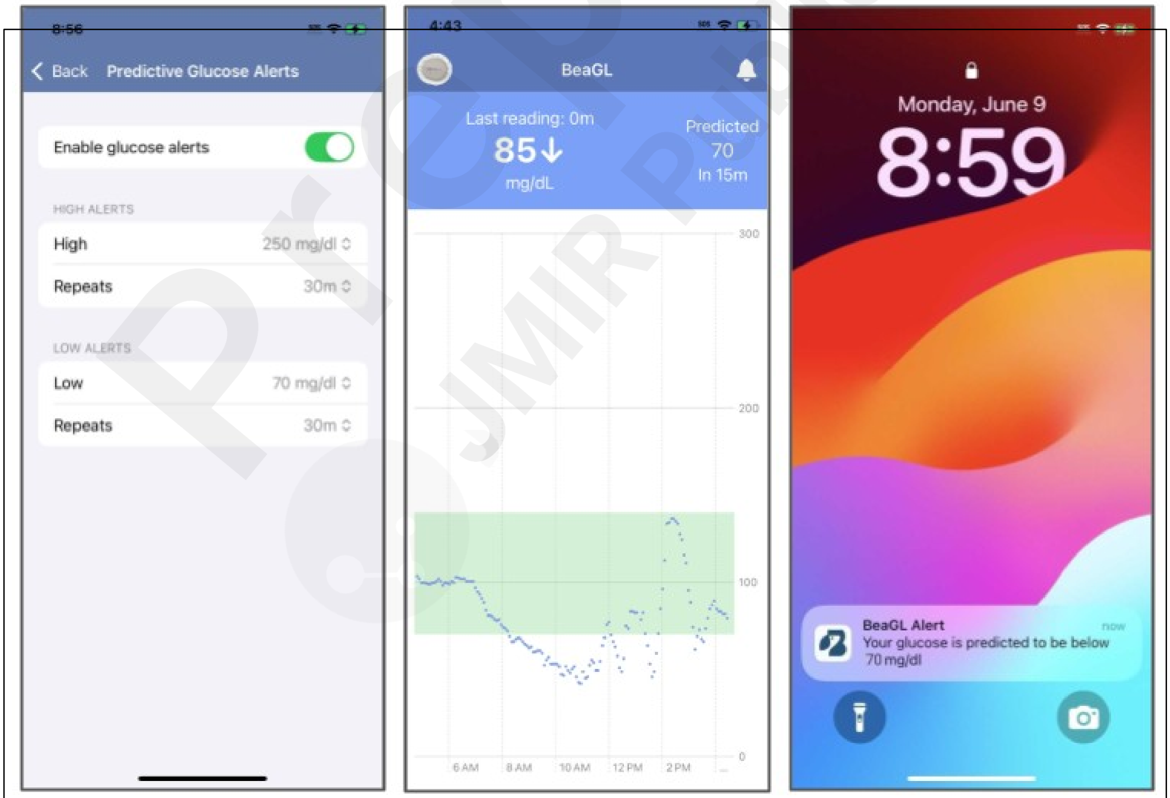

***Figure 1.* Screenshots from the BeaGL app on iOS.** Lefthand image shows the configuration screen for users to specify thresholds and repeat frequencies for predictive alerts. Center image shows the landing screen of the app where users can visualize their current glucose level along with their predicted level in the next 15 minutes. Righthand image shows an alert from the BeaGL app about impending hypoglycemia.

Our last adaptation to the BeaGL app was made in the fifth month of the study. For that month we disabled alerts on participants' smartwatches (alerts were only available on their phones) in order to better understand the role of the watches in the users' experiences via their qualitative feedback, and to isolate the effect of the app from the effect of the alert delivery method on participants' resulting glycemic metrics.

Data Analysis

This project was conceived as a co-design process and initial pilot study for the BeaGL app. Participants' baseline characteristics and survey responses were analyzed descriptively to characterize the study cohort, and feedback about user experiences with BeaGL was analyzed qualitatively by the study team in real time throughout the study. Although our small study population was not powered to detect statistically significant changes in CGM metrics, we did evaluate trends in CGM data over time for the participants, for the purpose of hypothesis generation for future studies. Specifically, percentages of time spent in hypoglycemia (<70 mg/dl) and in severe hyperglycemia (>250 mg/dl) were compared for each participant between baseline and study periods, and changes in these metrics were analyzed using paired t-tests.

CGM metrics were computed for each participant using the raw data from their CGM devices, with one exception: two participants did not grant us access to their raw CGM data from prior to the study, so their baseline CGM metrics were self-reported by them using the Dexcom Clarity portal. CGM data were not analyzed for month 1 of the study because during this time the BeaGL app was in ongoing development and most users were not receiving consistent predictive CGM alerts. Months 2-4 were analyzed individually and as a group (90-day period) since this time represented consistent BeaGL app and smartwatch access. Month 5 was analyzed separately because this represented the period when users had access to BeaGL on their phones but not their smartwatches. CGM data were not analyzed for any month in which a participant had <50% CGM wear time, as we expected the metrics generated from this data would not be representative of their true glycemic distribution.

Results

Study Population and Baseline Characteristics

Our participants ranged in age from 20-27 years (median 22 years), with T1D duration of 1-14 years (median 10.5 years). Baseline glucose management indicator (GMI) for participants ranged from 6.3 to 8.0% (median 7.4%), and baseline time in range (70-180 mg/dl) ranged 49% to 92% (median 62.5%). All were using Dexcom CGM devices connected to iOS mobile devices for glucose monitoring. Two were on multiple daily injection (MDI) insulin regimens using insulin pens; two were using the Tandem t:slim X2 insulin pump with the Control IQ automated insulin delivery (AID) system; and two were using the OmniPod 5 AID system. In our baseline survey, 5 of 6 participants reported using low threshold alerts and 3 of 6 reported using high threshold alerts on their CGM devices; 4 reported "always" responding and 2 reported "sometimes" responding to these alerts at baseline. As shown in *Figure 2*, participants reported varying levels of satisfaction and concern related to T1D self-management at baseline.

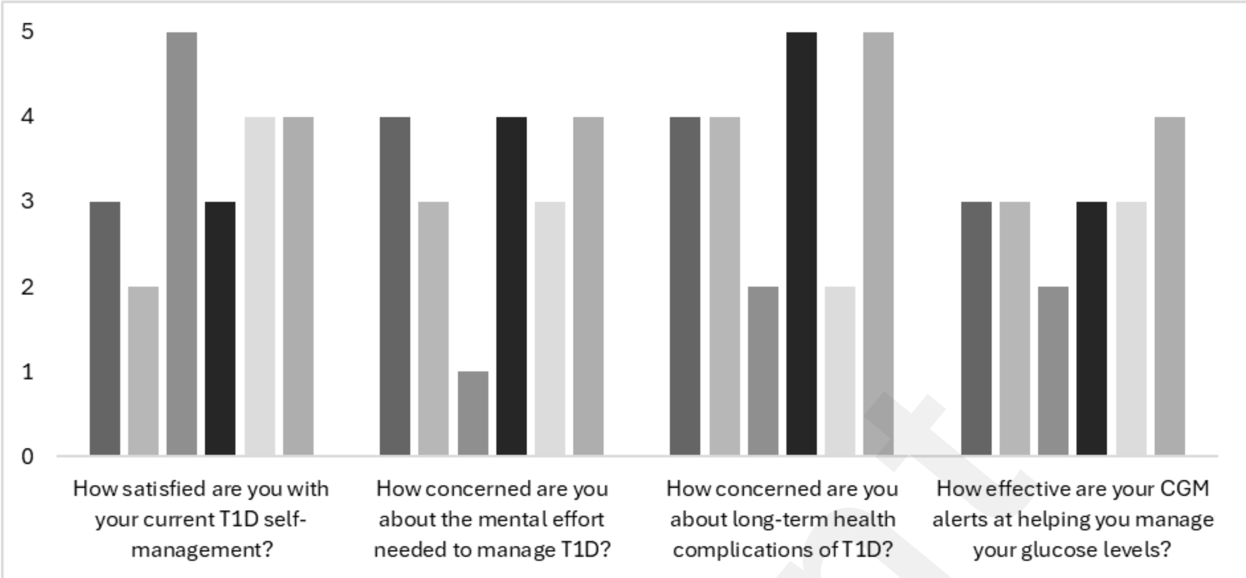

Figure 2. **Baseline survey results for all six study participants.** Responses on a 1-5 Likert scale from 1 = "not at all" to 5 = "very".

<u>User Feedback</u>

The major themes that emerged during our monthly interviews with young adult BeaGL users were *trust* and *agency*, as well as the impact of these two factors on *cognitive burden.* Early on in the study, our participants described needing to verify the accuracy of BeaGL's predictive alerts before they could trust the system enough to reduce their cognitive load for self-monitoring and T1D management. For some, this took the form of not acting on alerts to see what would happen without intervention, while others wanted to understand the underlying algorithm or programming for the app:

"When I first got the app, I used to wait 15 minutes to see if the alerts were accurate. Once I saw it was, I started trusting the system. I stopped worrying about fluctuations after this since I was confident the system would let me know."

"Once you told me that the secret sauce for what you do is least squares (linear regression), I worked out the math (for the predictions) myself to see if my glucose was going to go below 70 in the next 15 minutes. Once I did this a few times, I started trusting the system."

Once trust in the system was established, participants described how using BeaGL's predictive alerts improved their agency as compared to the threshold CGM alerts they had previously been using. Specifically, they described how college activities – e.g., attending classes, participating in discussions, doing lab work – often made it difficult for them to immediately act on glucose alerts, and how being in a hypo- or hyperglycemic state also affected their ability to take action. The 15-minute lead time provided by BeaGL's predictive alerts was perceived as very helpful for enabling them to manage their glucose levels effectively in an adaptable time frame:

"When working on...experiments, I typically spend around 30 to 45 minutes under the hood. The 15-minute lead time (from BeaGL alerts) lets me confidently wrap up my experiment, step out of the hood and pop in a glucose tablet for correction."

"I was walking across campus, and I got an alert. I was able to easily treat before going low."

One area of mixed participant feedback was related to the utility of smartwatch alerts. Participants generally reported that they did not think receiving alerts on the watch contributed to improved glycemic levels when using BeaGL. Several participants reported that they barely used the watch even after their watches had been configured to alert them. However, other users described situations where the smartwatch alerts were highly convenient and useful:

"I know that I previously said that the watch has been helpful while I'm at work. I said that because I'm not allowed to have my phone on me at work. This made the watch notifications helpful, since the vibration on my arm was enough for me to know that I had to pay attention to my diabetes. But I'm not always at work, and whenever I'm not at work, I usually don't even have the watch on me. So, I think the watch helps in some cases, but I mostly do fine without it too."

"The watch is certainly helpful while I'm at the gym. I don't have to take out my phone to check what's happening to my glucose. That being said, I can definitely live without the watch. I would characterize it as a nice-to-have rather than an essential."

Perhaps one of the most telling areas of user feedback for BeaGL was elicited when we proposed disabling BeaGL alerts and replacing them with better "tuned" threshold alerts on users' CGM devices. We were curious about whether increasing the threshold for low blood glucose alerts (or decreasing the threshold for high blood glucose alerts) could provide equivalent agency for users by giving them an extra time buffer to take action. One simple approach would be to set the threshold alerts for each individual to the mean CGM readings when BeaGL triggered their predictive alerts for hypo- and hyperglycemia.

We initially proposed running a month-long experiment where we did just this, disabling the BeaGL app on participants' devices and tuning the threshold alerts in their Dexcom apps. However, participants expressed reluctance about having to manage the false positive alerts they anticipated from this experiment – i.e., threshold alerts that were triggered even though they would not continue to drop or rise and so did not need corrective action. The participants expressed that the trust they had established with BeaGL's predictive alerts reduced the mental calculations they made to manage their glucose fluctuations, and they feared having to take back the cognitive load of deciding whether threshold alerts were false positives or legitimate and action-worthy.

This input helped to confirm our hypothesis that the BeaGL app could provide utility for young adults beyond the functionality of their baseline CGM devices and applications. In addition, responses to their weekly surveys – summarized in *Figure 3* – demonstrate that overall they perceived the app as helpful and effective. This was reinforced by the fact that all six participants asked the research team whether they could have ongoing access to the app after completion of the pilot study.

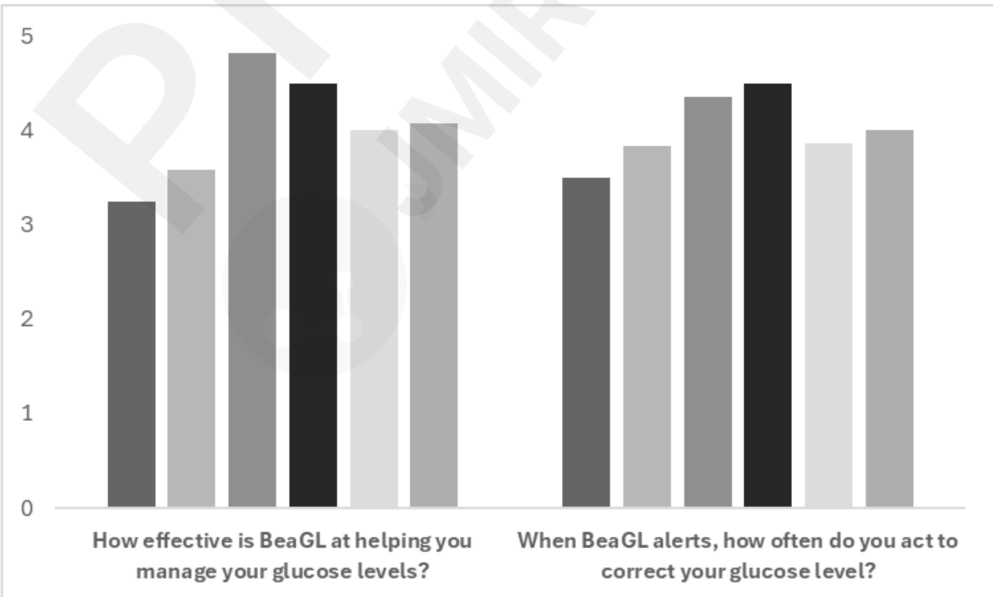

***Figure 3.* Mean scores on weekly surveys for all six study participants.** Responses on a 1-5 Likert scale from 1 = "not" or "never" to 5 = "extremely" or "always".

<u>Glycemic Changes</u>

Figure 4 shows the proportion of time spent in hypoglycemia for all participants at baseline, across

the three-month period (months 2-4) when alerts were enabled on their watches, and during the one month (month 5) when we disabled alerts on the watch. From baseline to months 2-4 we see a reduction in the proportion of time spent in hypoglycemia across 5 out of 6 participants, with the sixth participant showing a slight increase from a baseline of 0%. Two of the participants experienced a subsequent rebound in hypoglycemia frequency to near baseline levels during month 5 (without watch alerts), but this was not demonstrated in the rest of the cohort. Given the small sample size and baseline low rate of hypoglycemia (mean of 2.05% across the cohort), changes in this metric were not statistically significant when compared across time periods using a paired t-test.

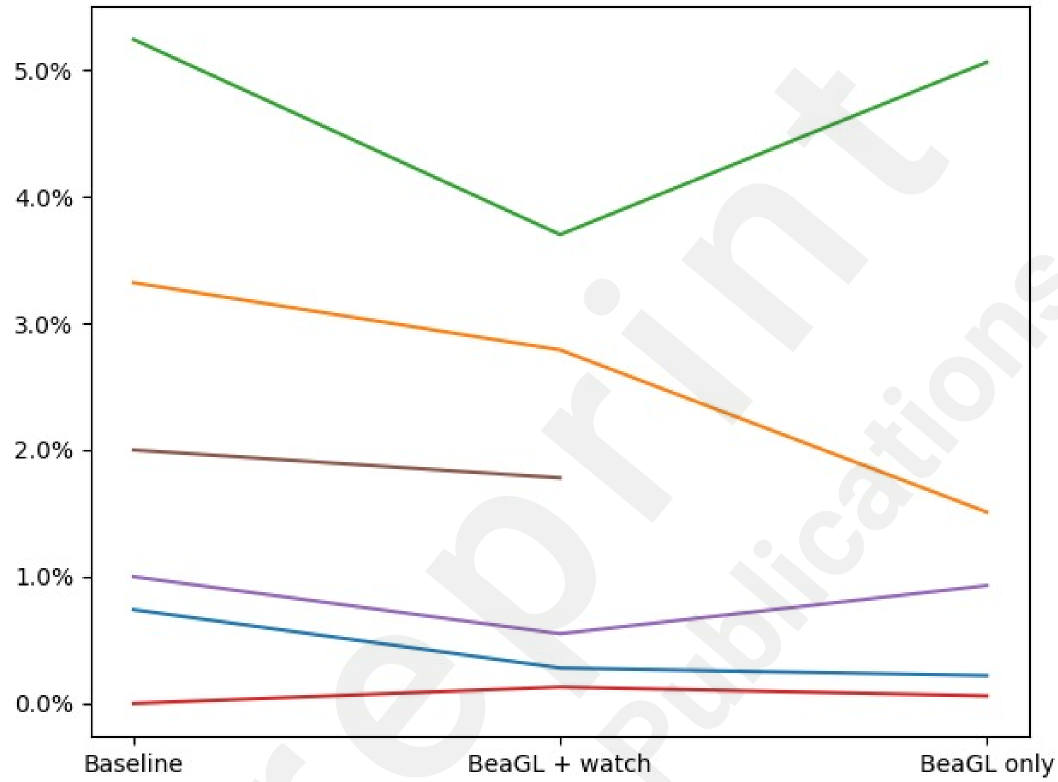

Figure 4. **Proportion of time spent in hypoglycemia (<70 mg/dl) for each participant at baseline, months 2-4 (BeaGL + watch), and month 5 (BeaGL only).** Paired t-tests comparing each time period to the others were not statistically significant.

Figure 5 shows the proportion of time spent >250 mg/dl for all participants at baseline, across the three-month period when alerts were enabled on their watches (months 2-4), and during the one month (month 5) when we disabled alerts on the watch. Similar to the trends for hypoglycemia, we see a decrease in time spent >250 mg/dl for 4 out of 6 participants, with slight increases for the remaining two participants who entered the study at <2% time >250 mg/dl. After disabling the watch alerts, two of the participants appeared to experience rebound increases in this time (one dramatic, one subtle), but that trend was not seen in the rest of the cohort. As with hypoglycemia, changes in time spent >250 mg/dl were not statistically significant across time periods, which is not surprising given the small sample size and low baseline frequency (mean of 11.64% across the cohort).

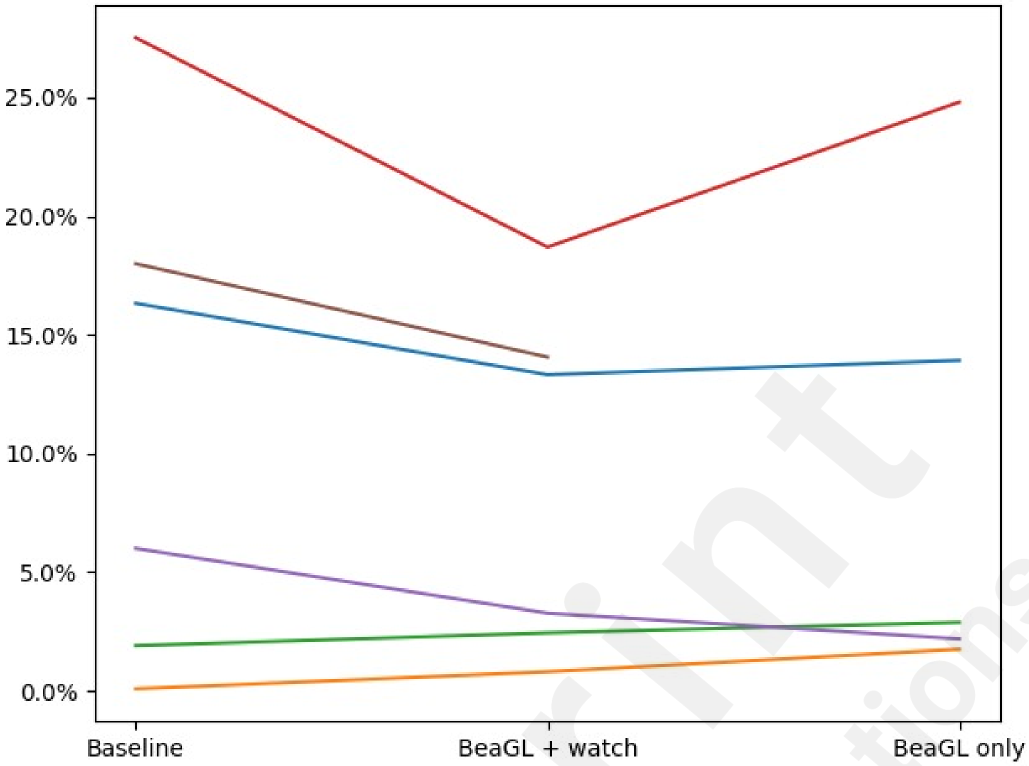

Figure 5. **Proportion of time spent in severe hyperglycemia (>250 mg/dl) for each participant at baseline, months 2-4 (BeaGL + watch), and month 5 (BeaGL only).** Paired t-tests comparing each time period to the others were not statistically significant.

Discussion

Summary Findings and Future Directions

Given the unique needs of the AYA population living with T1D, we undertook a co-design and pilot testing process for a simple application to provide predictive glucose alerts among young adult PwT1D using CGM technology. Our small cohort of participants – all current college students – had high baseline engagement with T1D self-management, as well as relatively low baseline GMI and high baseline time in range, although they represented a variety of insulin management strategies including MDI insulin regimens and two different AID systems. Findings from this study confirm that *customizable* predictive CGM alerting can improve agency and reduce cognitive burden for this population. In addition, we observed a decrease in time spent in either hypoglycemia (<70 mg/dl) or severe hyperglycemia (>250 mg/dl) for all 6 participants, with 3 demonstrating a reduction in both. However, these changes were not statistically significant given our small sample size, and in future a larger study should be undertaken to evaluate changes in glycemic metrics with sufficient statistical power. It also remains unclear how much the addition of a smartwatch – to receive predictive alerts without accessing one's smartphone – contributed to the utility of our application, as qualitative feedback on this feature was mixed, and we were not powered to detect quantitative changes in CGM metrics.

This study adds to the current literature by illuminating the user experience of young adult PwT1D around CGM alerting, and suggests that future research aiming to improve AYA agency, cognitive burden, and glycemic outcomes could employ small software additions to existing diabetes technology. Current alerting options on the Dexcom – the CGM device used by all of our study participants – include customizable threshold alerts and rise- and fall-rate alerts, but its only predictive alerting ("urgent low soon")[22] remains fixed and not customizable. The participants in our pilot study reported greater agency and utility from the BeaGL app due to its ability to customize predictive alert settings for both hypo- and hyperglycemia, more analogous to options that are currently available with the Medtronic Guardian 4 CGM system.[23, 24]

The limitations of this study stem primarily from its small sample size, which precludes the power to detect significant glycemic changes within our cohort, and also limits its generalizability among young adult PwT1D who do not resemble our cohort. Future research should explore the effects of the BeaGL app in comparison to standard CGM alerting among a larger, diverse cohort over a longer time frame, and evaluate validated patient-reported outcome measures (PROMs) at several time points in addition to detailed CGM glycemic data. It would also be useful to evaluate the impact of a smartwatch on glycemic outcomes and PROMs among AYAs using CGM via a larger, randomized study, as any demonstrated impact would aid in decisions about whether smartwatches should be considered beneficial, prescribable medical technology for PwT1D.

<u>Designing CGM Alerts: Trust via Simplicity</u>

Qualitative feedback from the participants of our study shows the impact of using simple algorithms when alerting young adult PwT1D about impending hypoglycemia or hyperglycemia. While deep neural networks have significantly enhanced various domains such as transportation, agriculture, healthcare, finance, and fraud detection,[25-30] explaining and interpreting their predictions continues to be a challenge.[31, 32] Although predictions from linear regression are not as accurate as those from neural networks in general, feedback from our participants shows that they are sufficiently reliable in making short-term predictions about glucose fluctuations. In addition to making accurate short-term predictions, the interpretability of these models engenders trust in their results, which is critical for improving device use and diabetes outcomes.[33, 34]

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We also wish to acknowledge Dexcom, who enabled us to purchase discounted CGM sensors to distribute to our participants in order to minimize data gaps during the study.

Conflicts of Interest

The authors report no conflicts of interest relevant to this project. Concurrent to this project, S.C. received research support from the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) via grants K23DK125671 and 1R01DK135000. The content of this manuscript is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

Data Availability

A subset of deidentified data from this study may be made available upon request. Please email the corresponding author.

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