Research Article

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Performance and User Experience Evaluation of a Non-Invasive Glucose Monitoring Device

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Abstract

Background: *An accurate, low-maintenance, comfortable and easy-to-use glucose monitoring device might be the key to successful diabetes management. This research evaluated the performance of user experience with GlucoTrack®, a commercially available non-invasive device. Specifically, following one individual calibration, accuracy was assessed during a six month period equivalent to device sensors' lifespan.*

Materials and Methods: *GlucoTrack's accuracy during six months was evaluated in 17 type-2 diabetic patients. User experience and device acceptance were assessed using questionnaires obtained from 95 naïve people with diabetes who used GlucoTrack at home.*

Results: *GlucoTrack's overall mean absolute relative difference (ARD) was 22.8% and 98.0% of points were in the clinically acceptable zones A and B of the Clarke Error Grid. The 95% confidence intervals of ARD standard deviation values of the first and sixth months (15.3-17.2% and 16.6-18.7%, respectively) overlapped. A favorable response to the easiness of device use and measurement performance, as well as to the comfort of the device and its screen, were reported in 75%, 86%, 87% and 95% of the users, respectively. These results did not depend on age, gender and level of education. Additionally, 83% of users expressed willingness to use the device regularly and 75% stated they would measure their glucose more frequently compared to the use of invasive device.*

Conclusions: *GlucoTrack maintained its accuracy for six months, pointing to its low maintenance. The device was also highly accepted among diabetic patients. These findings attest the potential of GlucoTrack to enhance diabetic patients' glucose monitoring routine.*

Keywords: Non-invasive glucose monitoring, GlucoTrack, Diabetes, Self-monitoring of blood glucose, User experience.

Introduction

Self-monitoring of blood glucose (SMBG) plays two key roles in the lives of diabetic patients. First, SMBG enables immediate feedback regarding glycemic control that reveals hypo- or hyper-glycemia, which may require short-term adjustments in treatment regimens. The second role of SMBG is to provide long-term valuable information to better understand one's diabetes and to optimize glycemic control, thus reduce the long-term complications associated with diabetes [1-3]. SMBG can, therefore, encourage self-management and empower diabetic patients to make the necessary lifestyle changes. However, to fulfill its roles, SMBG should be conducted frequently and structurally (i.e. according to a fixed plan) [4-12].

Despite ample evidence pointing to clinical benefits following frequent SMBG in type-1 [13], insulin-treated type-2 [14] and non-insulin treated type-2 diabetes [12,15], SMBG is often under-utilized [4-12,16-18]. Low utilization rates are mostly attributed to painful skin lancing required by most commercially available invasive glucose monitoring devices [19,20].

Thus, there is a need for a painless and convenient device that has the potential to promote frequent glucose testing to provide tight glycemic control [21]. Adequately accurate and easy to use non-invasive (NI) glucose monitoring devices may be the answer [22,23]. Another important requirement, is device low maintenance, since most NI approaches require periodic calibrations that complicate their use [21].

One commercially available NI glucose monitoring device for home use is GlucoTrack® [24,25]. The device is intended to be used by type-2 diabetes and pre-diabetic patients. GlucoTrack consists of a main unit and a personal ear clip (PEC), where the

sensors are located (Figure 1A) [24,25]. The PEC is individually calibrated before its first use and its lifespan is six months due to mechanical wear-out. Ideally, to reduce its maintenance, the calibration should be valid for a duration that resembles the PEC lifespan. The present study evaluates GlucoTrack performance level and its maintenance during the PEC lifespan as well as assesses user experience and device acceptance (Figure 1).

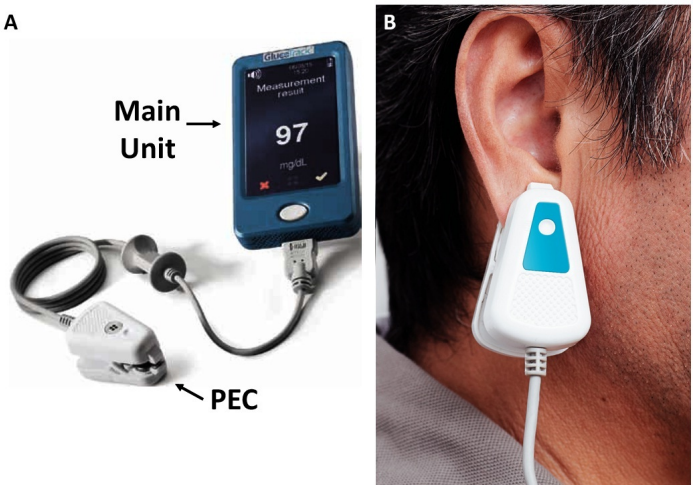

Figure 1: Glucotrack device. **A:** GlucoTrack device consisting of a main unit and a personal ear clip (PEC), on which sensors are located. **B:** Performing a measurement with GlucoTrack.

Methods

Device

GlucoTrack incorporates three independent NI technologies: ultrasonic, electromagnetic, and thermal [24,25]. Each technology measures changes in tissue parameters resulting from glucose excursions. The PEC must be calibrated before its first use to set a baseline for detection of physiological changes and to minimize the effects of individual quasi-stable factors, such as tissue thickness and structure. Calibration is performed following night fasting and takes approximately 30 minutes. This process involves three paired measurements of GlucoTrack with an invasive reference of finger capillary blood, with 10 minutes intervals between each pair. Spot measurements are conducted by placing the PEC on the earlobe for approximately 1 minute (Figure 1B). Visual and auditory feedback of glucose readings is then provided.

Clinical trials

Clinical trials were conducted in the diabetes unit of the Soroka University Medical Center, Beer-Sheva, Israel. The study protocol was approved by the local ethics committee and all subjects signed an informed consent form.

Study Protocol

The study consisted of two groups of type 2 diabetic patients: Clinic and Home. The purpose of the clinic group was to evaluate the accuracy of GlucoTrack during a period of six months from calibration. The home group was intended to assess user experience with GlucoTrack, including ease of device use and willingness to incorporate it to their monitoring routine. Exclusion criteria for enrollment included any conditions that may hamper the contact between the PEC and the earlobe, such as scratches, birthmarks and multiple piercing. Participants receiving dialysis were also excluded due to the imbalance in their water and minerals state [26]. For similar reasons, pregnant and nursing women were also excluded from the trial [27]. Subjects' characteristics in the clinic and home groups, which are typically used to represent the diabetic population (diabetes type, gender, BMI, and age) [28], are presented in Table 1. Calibration was performed using the HemoCue® Glucose 201 RT system (Ängleholm, Sweden).

As compensation for their effort, all participants were offered a free leasing contract for GlucoTrack device for a period of 3 years.

Table 1: Participant characteristics in each study group. BMI: Body Mass Index; NA: Not Applicable; SD: Standard Deviation.

	Clinic Group	Home Group
No. of participants	17	95
Education level	NA	Low education level:42 High education level:53
Diabetes type	Type 2: 17	Type 1:18 Type 2:77
Age [years] (Mean ± SD)	49-75 (61 ± 6.7)	18-88 (55.4 ± 13.3)
Gender	Male:7 Female:10	Male:51 Female:44
BMI [kg/m^2] (Mean ± SD)	21.9-42.5 (29.3 ± 4.8)	18.4-39.9 (29.4 ± 4.5)

Clinic Group

According to GlucoTrack intended use, the clinic group included 17 type-2 diabetic patients above the age of 18. The calibration process and measurements were conducted by a proficient research team. All glucose readings were obtained in real time based on the individual calibration.

During the study, participants were monitored in the course of 2-3 non-sequential trial days in each month. Each trial day lasted 8 to 10 hours, during which subjects received meals in order to produce variability in their glucose profiles (breakfast, lunch and fruits). Each trial day included approximately 16 simultaneous GlucoTrack-invasive measurements (Figure 2).

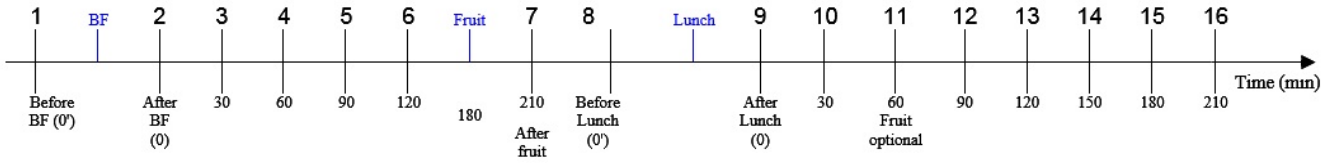

Figure 2: Trial day protocol. The numbers above the timeline refer to measurement number (1-16). BF= breakfast. Numbers under the timeline refer to the time from last meal, in minutes.

Home Group

The home group included 95 GlucoTrack naive diabetic patients. This group consisted of both type-1 and type-2 diabetic patients since user experience do not depend on diabetes type. PEC units were individually calibrated for all participants at the beginning of the study by a proficient research team. Following calibration, subjects received a brief training of up to 30 minutes on device operation, focusing on correct PEC attachment and the general measurement process. Each participant received a GlucoTrack device to use at home or at home-like environments for 3 to 7 days. Participants were requested to use GlucoTrack at least 7 times a day. At the end of the study, participants completed questionnaires regarding their personal experience with the device. These questionnaires addressed the ease and comfort of attaching the PEC to the earlobe (PEC attachment is the only action required when performing a measurement, and therefore the most frequently performed task) and the experience with the screen display of the main unit. Participants were also asked to rate their willingness to use the device and to implement it in their daily routine. Participants' responses were provided on a 5-point Likert scale (fully agree, tend to agree, neutral, tend to disagree, and fully disagree).

Evaluation Methods

Clinic Group

The paired GlucoTrack and reference readings were analyzed as a function of time elapsed from calibration. Device performance was evaluated using Clarke Error Grid (CEG) Analysis [29], mean and median absolute relative differences (ARD), and mean absolute deviation (MAD).

To determine that the performance of GlucoTrack during the first month was maintained for six months, an equivalence test was used [30]. ARD standard deviations were used as a measure of precision and equivalence was inferred on the basis of confidence interval overlap. ARD values were compared between the first and sixth months by estimating ARD standard deviation and constructing a 95% non-parametric 2-sided confidence interval for them. Since observations did not follow a normal distribution curve, a non-parametric bias-corrected and accelerated (BCa) bootstrap resampling simulation was used (coded in R-studio Version 0.98.1049) for constructing the confidence intervals.

Home Group

Acceptance of new technologies has been shown to depend on demographic factors [31]. Thus, questionnaires were analyzed as function of gender, age (below 60 years old [n=59]; above 60 [n=36]) and level of education (low education level – 12 years or less [n=42]; high education level – more than 12 years [n=53]). Age sub-groups were stratified as was previously done by Zoungas et al. [32]. We focused on age and education level with emphasis on ease of use and accessibility since it has been proposed that interface designs should be made more accessible to older adults [33], that older adults differently learn how to use medical devices [34] and that users with more formal education tend to show greater user satisfaction with computerized systems as well as demonstrate higher perceived usefulness of them [35,36]. Feedback on users' tactile sensation during PEC attachment was analyzed as function of age and gender, since these factors have been shown to moderate touch sensitivity [37,38]. To examine whether the distributions of the 5-scale responses depend on these demographic factors, we performed a Chi-squared (X^2) test for each question separately.

Results

Clinic Group

Analysis of GlucoTrack performance during six months (17 participants, 4,510 paired readings) showed that 98.0% of readings were within the clinically acceptable A and B zones of the CEG,

Table 2: GlucoTrack performances in the course of 6 months of use. CEG: Clarke Error Grid; ARD: Absolute Relative Difference; MAD: Mean Absolute Deviation.

Time elapsed from calibration		CEG Zones							# of patients	Mean ARD [%]	Median ARD [%]	MAD [mg/dL]
		A+B	A	B	C	D	E	Total				
1st month	Percent [%]	98.6	54.2	44.4	0.0	1.4	0.0	100	17	21.4	17.9	28.7
	# of points	759	417	342	0	11	0	770				
2nd month	Percent [%]	98.5	53.8	44.7	0.0	1.5	0.0	100	17	23.2	18.8	29.7
	# of points	655	358	297	0	10	0	665				
3rd month	Percent [%]	98.0	51.1	46.9	0.0	2.0	0.0	100	17	23.2	19.5	31.0
	# of points	727	379	348	0	15	0	742				
4th month	Percent [%]	98.9	55.1	43.8	0.0	1.1	0.0	100	17	22.6	18.3	30.3
	# of points	822	458	364	0	9	0	831				
5th month	Percent [%]	96.1	47.9	48.2	0.1	3.8	0.0	100	17	24.1	21.1	33.9
	# of points	764	381	383	1	30	0	795				
6th month	Percent [%]	97.7	52.5	45.3	0.0	2.3	0.0	100	17	22.6	18.8	30.0
	# of points	691	371	310	0	16	0	707				
All	Percent [%]	98.0	52.4	45.5	0.0	2.0	0.0	100	17	22.8	19.0	30.7
	# of points	4,418	2,364	2,054	1	91	0	4,510				

with 52.4% in the clinically accurate zone A. Total mean ARD was 22.8%, total median ARD was 19.0% and total MAD was 30.7 mg/dL (Table 2). The distribution of GlucoTrack performance during the six months of use is shown in Table 2. During each month at least 665 paired readings were collected. The unequal number of readings was due to inconsistent availability of participants. In any case, each subject participated in at least 2 monitoring sessions per month. Inter-monthly CEG analysis showed that above 97.5% of the cases were in the clinically acceptable A and B zones in all months, with the exception of the fifth month in which it declined to 96.1%. Mean ARD, median ARD and MAD values were also similar in all months but the fifth one, where a slight increase was observed (Table 2). Nonetheless, the clinical performance during the sixth month did not differ from that observed during months 1 to 4.

Figure 3 graphically presents mean ARD, median ARD and ARD quartile ranges for each month. The 95% confidence intervals of ARD standard deviation of the first month were 15.3-17.2% and those of the sixth month were 16.6-18.7%. The overlap in these confidence intervals signifies that GlucoTrack performance during the sixth month was equivalent to that of the first month.

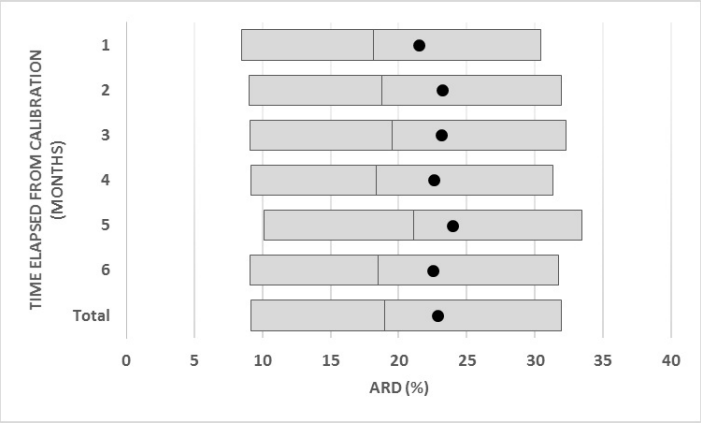

Figure 3: Device performance expressed as ARD (%) as a function of time elapsed from calibration. The left side of the boxplot represents quartile 25%, the middle line represents the median, and the right side quartile 75%. Black dots represent mean ARD.

Home Group

Ease of operation, ease of measurement, display convenience, PEC comfort (when attached) and device acceptance were assessed using questionnaires. The results are presented as frequency distribution charts in Figures 4 and 5. Generally, ratings of fully agree or tend to agree were considered as favorable responses.

Device ease of use

Overall, favorable ratings for device ease of use were reported by 75% of the users (Figure 4A). Unlike the question regarding measurement performance ease, this item refers to the general use of the device, including its various features, such as reviewing history charts and setting alerts. There was no statistically significant difference in the proportion of favorable and unfavorable responses between younger (39% fully agree and 44% tend to agree) and older (53% fully agree and 19% tend to agree) adults (X^2=7.88, p=0.09). Similarly, ease of use did not depend on the level of education (low education level: 52% fully agree and 26% tend to agree; high education level: 43% fully agree and 30% tend to agree; X^2=7.61, p=0.10).

Ease of measurement performance

Favorable responses to the easiness of measurement performance were observed in 86% of the users (Figure 4B). The proportion of favorable and unfavorable responses was independent of age (younger adults: 60% fully agree and 23% tend to agree; older adults: 63% fully agree and 27% tend to agree; X^2=2.04, p=0.72) and level of education (low education level: 65% fully agree and 21% tend to agree; high education level: 59% fully agree and 27% tend to agree; X^2=1.25, p=0.86).

PEC comfort

87% of the respondents reported a favorable response regarding PEC comfort, indicating that it did not cause pressure or irritation (Figure 4C). The pattern of favorable and unfavorable responses was similar when comparing younger to older adults (younger adults: 61% fully agree and 22% tend to agree; older adults: 72% fully agree and 22% tend to agree; X^2=5.56, p=0.23). The results were also independent of gender (males: 67% fully agree and 24% tend to agree; females: 64% fully agree and 20% tend to agree; X^2=1.16, p=0.88).

Screen display

Favorable response towards the screen were obtained from 95% of participants (Figure 4D). There was no statistically significant difference in the distribution of favorable and unfavorable responses between younger and older adults (younger adults: 75% fully agree and 20% tend to agree; older adults: 69% fully agree and 25% tend to agree; X^2=5.40, p=0.24).

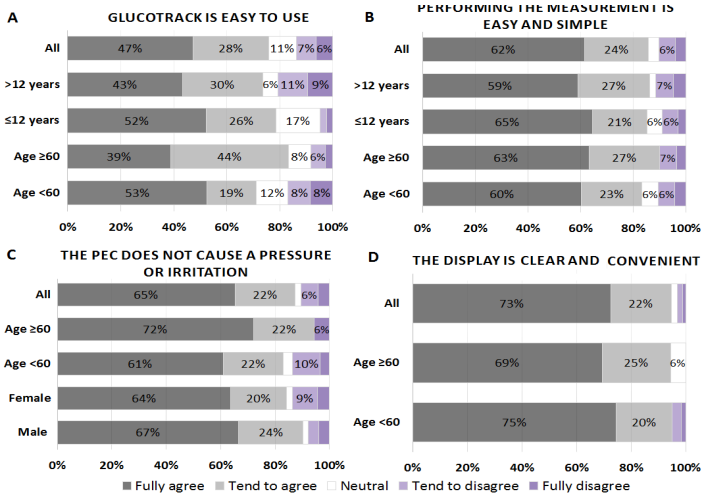

Figure 4: User experience with GlucoTrack as function of age, gender and level of education. Dark gray refers to the answer "fully agree", light gray refers to the answer "tend to agree", white refers to neutral answer, light purple refers to the answer "tend to disagree", and deep purple for "fully disagree". The numbers in the columns refer to the percentage of users to a specific response tendency (5% and less are not marked).

GlucoTrack acceptance

83% of the participants reported that they are willing to use the device on a regular basis (51% fully agree and 32% tend to agree; Figure 5A). 75% of the respondents stated that they would increase the frequency of glucose monitoring with GlucoTrack (50% fully agree and 25% tend to agree; Figure 5B).

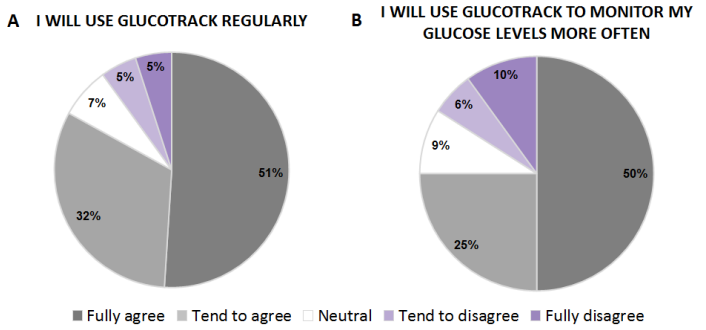

Figure 5: User acceptance of GlucoTrack device. Dark gray refers to the answer "fully agree", light gray refers to the answer "tend to agree", white refers to "neutral" answer, light purple refers to the answer "tend to disagree", and deep purple for "fully disagree".

Discussion

The present study evaluated GlucoTrack performance during a period of six months and examined user experience with the device and its acceptance. CEG analysis demonstrated that the majority of results obtained from GlucoTrack would lead to appropriate clinical action even after six months from calibration. The results obtained from users operating the device at home point to ease of use and high acceptability rates.

Home use of NI glucose monitoring devices aims to reduce finger pricking. Such devices generally require calibration using invasive methods [21,39,40]. Calibration procedures of other NI devices take a long time (e.g. 3 hours) [39] and in some cases require numerous invasive measurements (e.g. 65 measurements) [40]. Conversely, GlucoTrack's calibration process requires three invasive readings and takes approximately 30 minutes. In this study the validity of the current calibration process was tested for the entire lifespan of the PEC (six months, according to manufacturer specifications), based on a single calibration procedure. The overall mean ARD over the course of six months was 22.8% and 98.0% of points were in CEG clinically acceptable zones A and B. Further inter-monthly clinical evaluation of GlucoTrack using CEG analysis revealed that device performance during the sixth month was as good as that of previous months. However, there was an unexpected slight decrease in GlucoTrack performance during the fifth month that was attributed to one specific subject. Nevertheless, there was no trend of accuracy degradation as a function of time elapsed from calibration.

The stability of GlucoTrack performance during six months was further supported by a statistical evaluation. The overlap in the 95% confidence intervals of ARD standard deviation showed that GlucoTrack accuracy during the sixth month was equivalent to that of the first month, suggesting that the device maintains its accuracy level throughout the entire PEC lifespan without the need for PEC recalibration. These results point to device low-maintenance, and thus bear an important impact on user acceptance and subsequent device utilization. Presumably, the fewer the number of calibration points and the longer the interval between re-calibrations, the wider the acceptance of the device is likely to be.

Today there is clear recognition of the critical role of usability and human interface in medical devices [41]. This study further assessed user experience and device acceptance among diabetic patients using the device at home or home-like environments. Since user experience and acceptance of new technologies is known to depend on demographic factors [31], we assessed these parameters as a function of age, gender and level of education. Overall, our results demonstrate that 75% of the respondents reported favorable responses regarding GlucoTrack ease of use and 86% of the users also indicated that performing the measurement was easy. Both of these user experience parameters did not depend on age or education level. Thus, despite previous reports regarding difficulties in learning how to use medical devices among the older population [34] and greater satisfaction in users with more formal education [35,36], older adults and low-level educated individuals easily operated GlucoTrack device. In addition, more than 95% of the users reported a favorable response towards the screen display, a subjective tendency that did not depend on age, despite the susceptibility of older adults to suffer from eyesight deterioration [33]. This finding shows that GlucoTrack's design is accessible for older people as well. This is of great importance, since the prevalence of diabetes increases with age [42].

The current study has also investigated pain and skin reactions, which are important components of device acceptance among diabetic patients. Evidence for this notion are provided by studies evaluating GlucoWatch acceptance, showing that approximately 80% of the users stopped using GlucoWatch after 18 months because of skin reactions [43,44]. Our results indicate that the majority of users did not experience pressure or irritation while the PEC was attached to the earlobe. We further examined whether these results were gender-dependent since males and females experience pain differently [38]. Yet, no difference was found between males and females in this regard, suggesting that the device is unpainful across gender. Similarly, the results did not depend on age, despite the expected degradation of pain and touch sensations with age [37].

Further support for high device acceptance rates is gained by our findings that 83% of respondents were willing to use the device regularly and 75% believe they will monitor their glucose levels more frequently using GlucoTrack. The finding that participants are willing to use the device more frequently than invasive glucose meters concurs with the notion that a painless non-invasive procedure is more convenient and comfortable for long-term monitoring than invasive procedures, especially when carried out in a frequent and regular manner [45].

There are several limitations to this study. First, the accuracy of

GlucoTrack was evaluated on a small sample size. Nonetheless, the experimental design, in which each participant underwent 3 days of measurements during which approximately 16 measurements were obtained, produced a large dataset of paired invasive-noninvasive cases. Second, other factors could affect user experience and device acceptance, such as previous technological experience [46]. Future studies should examine how this and other factors affect user experience with GlucoTrack. Moreover, a larger sample size would have enabled to stratify participants to more than two education level or age subgroups. It should also be noted that the acceptance results may be biased by the use of an incentive to encourage subjects' compliance.

In conclusion, the present study shows that device performance is maintained over a period of six months. Furthermore, the device ease of use and its acceptance were unaffected by the tested demographic characteristics, indicating its suitability to a broad range of individuals. GlucoTrack's ease of use, comfort and low maintenance suggest that it may improve patients' glucose monitoring routine, assist them in better understanding their diabetes and empower them to make life-style and nutrition modifications.

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