

Does Wearing a Real-Time Continuous Glucose Monitor (RT-CGM) All the Time Matter? A Cross-Sectional Study of Use Intensity and Fear of Hypoglycemia

✉ Mehmet Gökhan Gönenli¹, ✉ Fadime Buket Bayram Kuvvet¹, ✉ Selin Çakmak Demir², ✉ Görkem Ayaş³,
✉ Ahmet Bahadır Ak¹, ✉ Hayri Kağan Gören¹, ✉ Oğuzhan Deyneli², ✉ Dilek Yazıcı²

¹Koç University Faculty of Medicine, Department of Internal Medicine, İstanbul, Türkiye

²Koç University Faculty of Medicine, Department of Endocrinology, İstanbul, Türkiye

³Koç University Graduate School of Health Sciences, İstanbul, Türkiye

ABSTRACT

Introduction: Fear of hypoglycemia (FOH) hinders optimal glycemic control in type 1 diabetes (T1D). Real-time continuous glucose monitoring (RT-CGM) can alleviate FOH; however, the minimum sensor wear time required is unclear.

Methods: In this single-center, cross-sectional study, we analyzed 43 adults with T1D who had used RT-CGM during the preceding 24 weeks. Participants were classified as continuous users (sensor active every week, n=26) or intermittent users (cumulative 4-12 weeks, n=17). FOH was measured with the validated Turkish hypoglycemia fear survey II. Group differences were examined with Student's t or χ^2 tests ($\alpha=0.05$). Pearson correlations and multiple linear regression were used to explore FOH predictors.

Results: Mean HFS II scores (continuous vs. intermittent) were 17.7 ± 13.1 vs. 14.5 ± 6.7 for behavior, 19.0 ± 13.7 vs. 20.4 ± 14.4 for worry, and 36.7 ± 22.1 vs. 34.9 ± 18.6 for total (no statistically significant difference was observed between groups). Higher HFS total correlated with poorer self-reported treatment adherence ($r: -0.32$, $p=0.04$) and showed a non-significant inverse trend with longer diabetes duration ($r: -0.27$, $p=0.08$). Worry scores were higher in participants who reported recent symptomatic hyperglycemia ($p=0.03$). In the multivariable model, RT-CGM use intensity was not an independent predictor of FOH ($\beta = -1.2$, 95% confidence interval: -9.5 to 7.1 ; $p=0.77$).

Conclusion: Partial RT-CGM use (4-12 weeks over six months) produced FOH scores comparable to uninterrupted use, suggesting that continuous wear may not be necessary for short-term psychological benefit. FOH remained linked to treatment adherence, diabetes duration, and recent hyperglycemic events. Larger prospective studies with objective wear time data are warranted to define the threshold at which RT-CGM confers additional FOH reduction.

Keywords: Diabetes mellitus type 1, continuous glucose monitoring, hypoglycemia, fear

Introduction

Real-time continuous glucose monitoring (RT-CGM) is considered the most effective technological tool for reducing acute and chronic complications in type 1 diabetes (T1D) mellitus. Fear of hypoglycemia (FOH) affects 50-85 % of adults with T1D and represents a key psychological barrier to optimal glycemic control (1-3). To avoid hypoglycemic episodes, many people deliberately maintain higher glucose levels, driving their glycated hemoglobin (HbA1c) by 0.5-1.0 percentage points above target and lowering health-related quality of life by up to 25% (4,5). In large observational cohorts, individuals with high FOH scores show a 60% increase in deliberate hyperglycemia and a 2.3-fold rise in diabetic ketoacidosis (6-9).

RT-CGM supplies continuous glucose values, trend arrows, and customizable alarms that directly address FOH related concerns (10-13). Landmark trials such as DIAMOND, GOLD, and IMPACT demonstrated 38-55% fewer severe hypoglycemic events, an 8-15% increase in time in range, and a 15-30% reduction in FOH as measured by the hypoglycemia fear survey-II (HFS-II) (14-17). In DIAMOND, for example, RT-CGM lowered HbA1c by 0.6% while improving the HFS-II behavior and worry subscales by 23% and 28%, respectively (18,19).

Despite the growing evidence base, critical knowledge gaps remain regarding how much sensor wear is necessary to obtain psychological benefit. Most studies focus on uninterrupted use and overlook structured, intermittent protocols (20-22). The IN CONTROL study found



Address for Correspondence: Mehmet Gökhan Gönenli MD, Koç University Faculty of Medicine, Department of Internal Medicine, İstanbul, Türkiye
E-mail: mgonenli@ku.edu.tr ORCID ID: orcid.org/0000-0003-2925-7048

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sustained FOH improvements only among participants who used their sensor more than 85% of the time (23), whereas a multicenter analysis showed a clear dose-response relationship between sensor wear and FOH reduction (17). In addition, the interaction between insulin-delivery modality and RT-CGM adherence is poorly characterized; pump users typically achieve 88-95% adherence compared with 65-78% in pen users, yet the impact on FOH is uncertain (24,25).

Evidence-based guidance on prescribing and implementing RT-CGM is therefore urgently needed. The HypoCOMPaSS trial suggested that combining RT-CGM with insulin pump therapy yields the greatest FOH benefit (26), but a recent systematic review highlighted heterogeneous responses across patient sub-groups (20). These conflicting findings underscore the need for patient-centered RT-CGM strategies.

The present cross-sectional study addresses this gap by comparing continuous versus intermittent RT-CGM use intensity and examining their associations with FOH in adults with T1D. By clarifying whether partial sensor use is sufficient to alleviate FOH -and how insulin-delivery method modifies this relationship- we aim to provide practical guidance for diabetes teams and identify priorities for future research.

Methods

Study Design and Setting

This was a single-center, cross-sectional study carried out in the adult endocrinology clinic of Koç University Hospital between October 2023 and June 2025. The protocol was approved by the Koç University Committee on Human Research (approval number: 2023.357.IRB2.074, date: 19.10.2023) and complied with the Declaration of Helsinki. All participants gave written informed consent.

Participants

Adults (≥ 18 years) with T1D diagnosed for at least one year were screened consecutively. Inclusion criteria were:

1. RT-CGM use at any time during the preceding 24 weeks.
2. Ability to read and complete questionnaires in Turkish.

We excluded pregnancy, end-stage renal disease, cognitive impairment, or major psychiatric disease. Forty-three patients met the criteria and were enrolled.

Participants were divided, using device logs and patient diaries, into

- Continuous users - sensor worn every week during the 24-week window ($n=26$) and
- Intermittent users - cumulative wear 4-12 weeks ($n=17$).

Measures

Primary Outcome-Fear of Hypoglycemia

FOH was measured with the Turkish HFS-II. The version used in this study contains 32 items- 15 in the behavior subscale and 17 in the worry sub-scale - because the original Turkish validation removed worry item 19 for cultural reasons (27). Each item is scored from 0 (never) to 4 (always), giving sub-scale ranges of 0-60 and 0-68 and a total score

range of 0-128; higher scores reflect greater fear. There is no universally accepted cut-off for clinical FOH in the HFS-II-TR; therefore, scores were treated as continuous variables. In the validation study, internal consistency was excellent (Cronbach's α : 0.77 for behavior, 0.91 for worry, 0.90 for total).

Exposure - RT-CGM Use Intensity

Use-intensity was defined as above (continuous vs. intermittent).

Covariates

Age, sex, diabetes duration, body mass index (BMI), HbA1c, insulin-delivery method (pump vs. pen), private insurance status, self-rated treatment adherence (5-point Likert scale), number of symptomatic hypo- and hyperglycemia episodes in the past month, and prior structured hypoglycemia education were extracted from records or patient interviews.

Sample-Size and Power

A priori calculation (two-sided α : 0.05, power: 0.80) showed that 64 participants (32 per group) were needed to detect a moderate effect (Cohen's d : 0.5) in HFS-II total scores. Because only 43 patients were recruited, the study is underpowered and may incur type II error.

Statistical Analysis

Analyses were performed with SPSS v26 (IBM Corp., Armonk, NY, USA). Kolmogorov-Smirnov test assessed normality. Data are expressed as mean $\pm$ standard deviation or median (interquartile range) and n (%).

Comparisons: Independent-samples t tests (or Mann-Whitney U) compared continuous variables; χ^2 (or Fisher's exact) compared categorical variables.

Associations: Pearson correlation (or Spearman when non-normal) examined links between FOH scores and covariates.

Multivariable model: Multiple linear regression estimated the independent effect of RT-CGM use-intensity (reference = intermittent) on the HFS-II total score, adjusting for all covariates listed above. Multicollinearity was checked (variance inflation factor < 2).

Two-tailed $p < 0.05$ signified statistical significance. Missing data were $\leq 5\%$ for all variables and were imputed by series mean (continuous) or mode (categorical).

Results

Participant Flow and Baseline Characteristics

Of the 63 adults screened, five were excluded (end-stage renal disease: 2, pregnancy: 2, major psychiatric disorder: 1), and 15 did not return a completed survey, leaving 43 participants for analysis (Figure 1). The mean age was 42.1 ± 11.5 years, and 67% were women. Twenty-six individuals (60%) wore RT-CGM continuously throughout the 24-week window, whereas 17 (40%) used it intermittently for a cumulative 4-12 weeks. Insulin-pump therapy was more common in continuous users (50% vs. 18%), while pen therapy predominated in intermittent users (82%). Private insurance coverage also differed (23% vs. 59%, $p=0.02$). All other demographic and clinical variables were comparable between the groups (Table 1).

Fear of Hypoglycemia Due to the Intensity of RT-CGM Use-Intensity

Mean HFS-II-TR scores were: behavior 17.7 ± 13.1 vs. 14.5 ± 6.7 ($p=0.37$), worry 19.0 ± 13.7 vs. 20.4 ± 14.4 ($p=0.75$) and total 36.7 ± 22.1 vs. 34.9 ± 18.6 ($p=0.79$) for continuous and intermittent users, respectively (Figure 2).

Bivariate Correlations

HFS-behavior correlated with HFS-worry ($r: 0.46$, $p=0.002$) and HFS-total ($r: 0.75$, $p<0.001$). Higher HFS-total was modestly associated with poorer self-rated treatment adherence ($r = -0.32$, $p=0.04$) and showed a non-

significant inverse trend with diabetes duration ($r = -0.27$, $p=0.08$). No correlation was observed for age, BMI, or HbA1c (Table 2).

Sub-Group Comparisons

HFS-worry scores were higher among participants who reported structured hypoglycemia education (23.2 ± 14.0 vs. 14.6 ± 11.0 , $p=0.03$) and those with at least one symptomatic hyperglycemia episode in the previous month (21.6 ± 14.1 vs. 14.0 ± 10.7 , $p=0.03$). FOH did not differ by sex, educational level, smoking, alcohol use, or household composition (Table 3).

Multivariable Analysis

After adjustment for prespecified covariates, RT-CGM use intensity was not an independent predictor of HFS-total ($\beta = -1.2$ points, 95% confidence interval: -9.5 to 7.1 , $p=0.77$). Only longer diabetes duration retained a modest negative association ($\beta = -0.35$ points year⁻¹, $p=0.049$). Model diagnostics were satisfactory (adjusted R^2 : 0.19 ; variance inflation factor <1.6) (Table 4).

Discussion

This cross-sectional study assessed whether wearing RT-CGM sensors every week for six months confers greater psychological benefit than wearing them only part of the time. Contrary to our a-priori expectation, FOH scores did not differ between continuous and intermittent users, even though the continuous use group contained a higher proportion of insulin-pump users. The finding challenges the common assumption of a strict dose-response relationship between sensor wear-time and psychological outcomes.

Our result diverges from landmark trials such as IN CONTROL and the dose-response analysis by Heinemann et al. (17), both of which reported larger FOH reductions when wear-time exceeded 85% (24). Important methodological differences may explain the discrepancy. Those studies enrolled participants with impaired hypoglycemia awareness and followed them for 12 months or longer, whereas our cohort comprised unselected clinic attenders followed for six months. An initial phase of structured RT-CGM exposure may be sufficient for many patients to internalize glucose-trend information and develop safer self-management behaviors. Beyond this point, additional sensor use might yield diminishing psychological benefits.

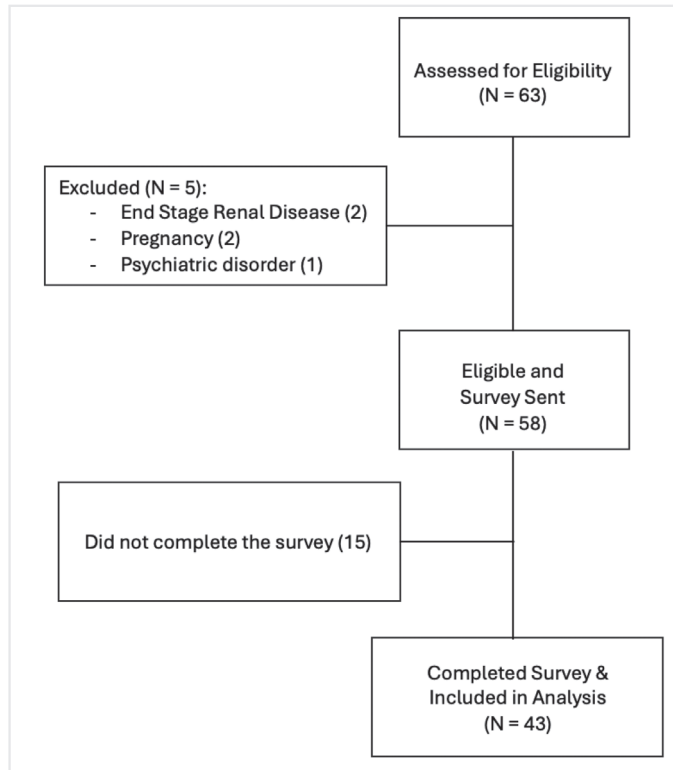


Figure 1. Participant flow chart for the cross-sectional RT-CGM study. Flow chart depicting the recruitment, exclusion, and retention of study participants. A total of 63 adults with type 1 diabetes were screened for eligibility. Five participants were excluded due to end-stage renal disease ($n=2$), pregnancy ($n=2$), and major psychiatric disorder ($n=1$). Of the 58 eligible individuals, 15 did not complete the survey. The final analytic sample comprised 43 participants who completed the fear of hypoglycemia survey and met all inclusion criteria.

Table 1. Baseline demographic and clinical characteristics, overall and by RT-CGM use intensity

Variable	Continuous use (n=26)	Intermittent use (n=17)	Total (n=43)	p value [†]
*Female sex, n (%)	19 (73.1%)	10 (58.8%)	29 (67.4%)	0.32
Age, y, mean $\pm$ SD	44.7 $\pm$ 12.3	38.1 $\pm$ 9.1	42.1 $\pm$ 11.5	0.06
Body mass index, kg m ⁻² , mean $\pm$ SD	24.1 $\pm$ 3.6	23.8 $\pm$ 3.7	24.0 $\pm$ 3.6	0.82
*Private insurance, n (%)	6 (23.1%)	10 (58.8%)	16 (37.2%)	0.01
*Insulin pump therapy, n (%)	13 (50.0%)	3 (17.6%)	16 (37.2%)	0.03
Diabetes duration, y, mean $\pm$ SD	19.2 $\pm$ 9.8	15.2 $\pm$ 9.5	17.6 $\pm$ 9.8	0.19
HbA1c, %, mean $\pm$ SD	7.4 $\pm$ 0.9	7.1 $\pm$ 1.0	7.3 $\pm$ 0.9	0.29

*Percentages are column percentages. [†]Student's t-test for continuous variables; χ^2 test for categorical variables. SD: Standard deviation, HbA1c: Glycated hemoglobin, RT-CGM: Real-time continuous glucose monitoring

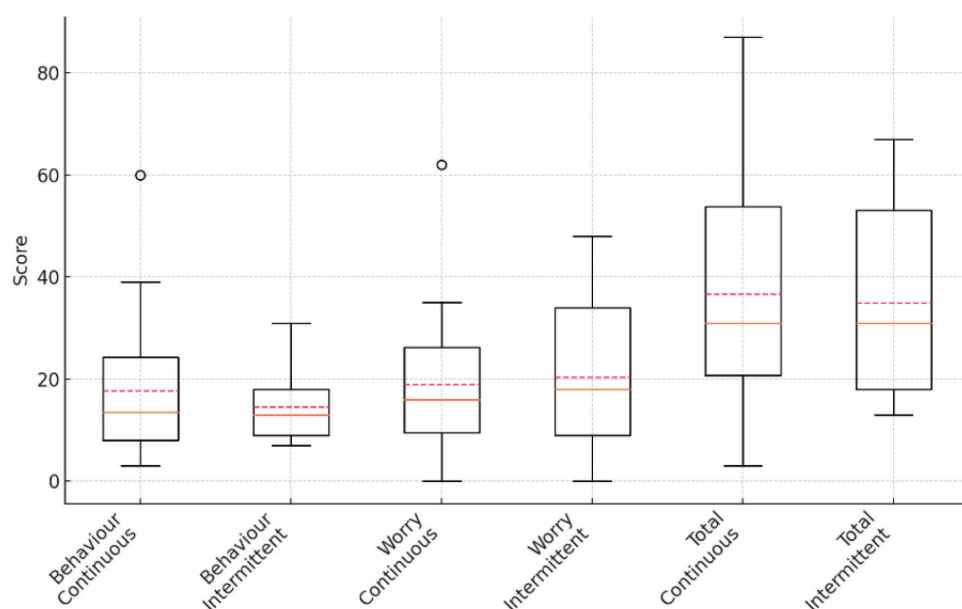


Figure 2. Fear of hypoglycemia scores by subscale and RT-CGM use-intensity

Box-and-whisker plots of hypoglycemia fear survey-II scores across subscales (behavior, worry, and total) compare real-time continuous glucose monitoring users (n=26) and intermittent users (n=17). The horizontal orange lines indicate the median, while red dashed lines represent the mean values. Boxes denote the interquartile range (IQR), and whiskers extend to 1.5× IQR. Outliers are plotted as individual dots. No statistically significant differences were observed between groups for any subscale (Student's t test; behavior p=0.37, worry p=0.75, total p=0.79)

Table 2. Pearson correlations between HFS-II scores and continuous covariates (n=43)

Covariate	HFS-behavior (r, p)	HFS-worry (r, p)	HFS-total (r, p)
Age (years)	0.08 (0.61)	0.04 (0.80)	0.06 (0.71)
Body mass index (kg m ⁻²)	-0.05 (0.76)	-0.11 (0.48)	-0.09 (0.58)
HbA1c (%)	0.09 (0.55)	0.14 (0.37)	0.12 (0.43)
Diabetes duration (years)	-0.22 (0.16)	-0.28 (0.07)	-0.27 (0.08)
Treatment adherence score [†]	-0.30 (0.05)	-0.28 (0.07)	-0.32 (0.04)
Symptomatic hypoglycemia (events · month ⁻¹)	0.15 (0.34)	0.18 (0.25)	0.17 (0.28)
Symptomatic hyperglycemia (events · month ⁻¹)	0.21 (0.18)	0.31 (0.03)	0.27 (0.09)

[†]Five-point Likert scale, 5: excellent adherence. HbA1c: Glycated hemoglobin, HFS: Hypoglycemia fear survey

Table 3. Group comparisons of HFS-II scores across selected categorical variables

Variable	Category	Behavior mean ± SD	p [†]	Worry mean ± SD	p [†]	Total mean ± SD	p [†]
Sex	Female (n=29)	17.9±12.0	0.21	21.4±14.1	0.20	39.3±20.5	0.12
	Male (n=14)	13.4±8.2		15.7±12.7		29.1±19.6	
Insulin-delivery modality	Pen (n=27)	17.6±11.3	0.35	18.5±11.7	0.51	36.1±19.3	0.95
	Pump (n=16)	14.4±10.5		21.4±17.1		35.8±23.3	
Structured hypoglycemia education	Yes (n=33)	16.5±11.8	0.89	21.3±15.1	0.02	37.8±22.2	0.17
	No (n=10)	16.0±8.4		13.9±5.8		29.9±13.0	
Symptomatic hyperglycemia (past month)	Present (n=32)	16.3±8.9	0.89	22.2±13.8	0.03	38.5±18.4	0.17
	Absent (n=11)	16.8±16.3		11.9±11.0		28.7±25.4	

[†]Independent-samples t-test. Bold p values indicate statistical significance at α: 0.05. SD: Standard deviation, HFS-II: Hypoglycemia fear survey-II

Table 4. Multiple linear regression predicting HFS-II total score (n=43)

Predictor (reference)	B ± SE*	95% CI	Standardized β	p
RT-CGM use intensity (continuous: 1, intermittent: 0)	-1.2±4.0	-9.5 to 7.1	-0.04	0.77
Diabetes duration (years)	-0.35±0.17	-0.70 to -0.01	-0.32	0.04
Age (years)	0.08±0.18	-0.29 to 0.45	0.07	0.66
Female sex (male: 0)	4.6±5.7	-6.9 to 16.1	0.13	0.44
HbA1c (%)	1.9±2.2	-2.6 to 6.4	0.14	0.39
Insulin pump therapy (pen: 0)	3.1±5.0	-7.1 to 13.3	0.10	0.54
Private insurance (no: 0)	5.8±5.3	-5.1 to 16.7	0.17	0.29
Treatment-adherence score [†]	-2.1±1.1	-4.4 to 0.2	-0.28	0.06
Symptomatic hypoglycemia (events · mo ⁻¹)	0.22±0.43	-0.66 to 1.10	0.09	0.62
Symptomatic hyperglycemia (events · mo ⁻¹)	0.58±0.36	-0.15 to 1.31	0.24	0.11

*B ± SE indicates the unstandardized regression coefficient (B) and its standard error (SE). [†]Five-point Likert scale; higher scores indicate better adherence. HFS-II: Hypoglycemia fear survey-II, RT-CGM: Real-time continuous glucose monitoring, HbA1c: Glycated hemoglobin, CI: Confidence interval
 The Turkish version of the hypoglycemia fear survey-II consists of 32 items, divided into behavior (15 items) and worry (17 items) subscales. Each item is rated from 0 (never) to 4 (always), with higher scores indicating greater fear. Cronbach's α values are 0.77 (behavior), 0.91 (worry), and 0.90 (total) (27).

Several recent real-world investigations support this interpretation. A 2023 systematic review and meta-analysis including 51 studies (8,966 adults with T1D) showed that reductions in FOH (HFS-worry subscale) occurred after as little as eight weeks of real-time CGM use, indicating that psychological benefits can emerge early (28). Similarly, the FUTURE cohort study (1,905 adults using intermittently scanned CGM) reported significant improvements in HFS-worry scores over 24 months among individuals with impaired hypoglycemia awareness (22.8 → 20.6, $p=0.002$), although adherence criteria were not specified (29). Another prospective study of 121 adults with severe hypoglycemia found increased confidence in managing low glucose after 12 months of isCGM use, with participants describing a greater sense of safety even with intermittent scanning (30). Together with our data, these studies suggest that for many adults, a partial use strategy may be psychologically adequate, especially when cost or device fatigue threatens long-term adherence.

The role of insulin-delivery modality warrants comment. As expected, pump therapy was more common among continuous users, mirroring registry data that show 88-95% RT-CGM adherence in pump users versus 65-78% in pen users (24,25). Nevertheless, insulin modality did not remain a significant predictor of FOH after multivariable adjustment. This finding contrasts with the randomized HypoCOMPaSS trial, where combining RT-CGM with pump therapy produced the largest FOH gains (26). Our observational design, shorter follow-up and inclusion of participants using next-generation pens may have diluted modality-specific effects.

Emerging data from automated insulin-delivery systems provide additional context. A 2024 real-world study of hybrid closed-loop therapy demonstrated 24.9% reductions in FOH despite average time in automatic mode of only 64.3% (31). Algorithms that attenuate both hypo- and hyperglycemic excursions may therefore magnify the psychological benefit of partial sensor use; some of our intermittent users may have experienced a similar effect through behavioral pattern recognition even without closed-loop automation.

Study Limitations

Key strengths include the use of a HFS-II-TR instrument, collection of objective wear-time logs, and adjustment for multiple clinical and socioeconomic confounders. Limitations, however, must temper interpretation. First, the sample was underpowered to detect small between-group differences; a priori calculation indicated that 64 participants would be required for 80% power. Recruitment was particularly challenging due to the limited accessibility and high cost of RT-CGM devices in our country, which restricted the eligible sample size. Second, our six-month window may be too short to observe incremental psychological advantages of continuous use. Third, sensor wear-time was classified categorically rather than as a continuous percentage; finer granularity might reveal threshold effects. Finally, FOH and treatment adherence relied on self-report and may be prone to recall or social-desirability bias.

Clinical Implications

For adult outpatients already familiar with RT-CGM, prescribing continuous wear may not be essential to achieve short-term FOH relief. Structured intermittent protocols- particularly when combined with targeted hypoglycemia education- could represent a cost-effective alternative, reserving full-time sensor use for those with persistent FOH or high hypoglycemic risk. Clinicians should therefore individualise wear-time targets, taking patient preference, insurance coverage, and technology fatigue into account.

Future Research

Prospective studies with larger samples and ≥12-month follow-up should validate the apparent plateau in FOH benefit beyond moderate wear-time and explore whether hybrid closed-loop systems shift this threshold. Mixed-methods designs incorporating qualitative interviews would help clarify which sensor features (alarms, trend arrows, retrospective reports) drive psychological improvement and for whom.

Conclusion

In this real-world cohort of adults with T1D, wearing an RT-CGM sensor for only 4-12 weeks over a six-month period yielded fearofhypoglycemia scores that were indistinguishable from those of users who wore the sensor continuously. FOH remained primarily associated with treatment adherence, diabetes duration, and recent glycemic excursions rather than with sensor wear-time or insulin-delivery modality. These findings suggest that structured intermittent RT-CGM protocols could meet short-term psychological needs in many patients, although larger prospective studies are required to confirm the wear-time threshold that confers additional benefit.

Ethics

Ethics Committee Approval: Ethical approval was obtained from the Koç University Committee on Human Research (approval number. 2023.357.IRB2.074, date: 19.10.2023).

Informed Consent: All patients received information regarding the study's details and provided written informed consent.

Footnotes

Authorship Contributions: Concept - M.G.G., F.B.B.K., S.Ç.D., O.D., D.Y.; Design - M.G.G., F.B.B.K., S.Ç.D., G.A., O.D., D.Y.; Data Collection or Processing - S.Ç.D., G.A., A.B.A., H.K.G., O.D.; Analysis or Interpretation - M.G.G., F.B.B.K., G.A., O.D., D.Y.; Literature Search - M.G.G., F.B.B.K., S.Ç.D., G.A.; Writing - M.G.G., F.B.B.K., O.D., D.Y.

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