

## Continuous glucose monitoring as a tool for psychological support – exploring metabolic control and psychological well-being after initial cgm implementation in adults with type 1 diabetes

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### Summary

**Aim:** The initiation of reimbursement for intermittently scanned continuous glucose monitoring (isCGM)/ continuous glucose monitoring (CGM) for those 26 and older could greatly benefit people with type 1 diabetes (PwT1D). The aim of the study was to assess changes in quality of life, metabolic control, fear of hypoglycemia and selected psychological parameters after 3 months of implementation of the isCGM/CGM in PwT1D aged 26 and above.

**Material and methods:** The study involved 57 PwT1D from five diabetology centers. To be included in the study, each participant had to be at least 26 years old, have a minimum of two years of diabetes history. Participants completed a set of validated questionnaires including the FSH-II, DDS, PSS10, DTSQs, WHO-5, PAID, DBQ, and a sociodemographic survey. They also downloaded pump/glucometer data and underwent HbA1c measurement at the beginning and again at the end of the study.

**Results:** PwT1D reported higher treatment satisfaction measured by DTSQs. Well-being assessment according to WHO-5 was also higher, and the level of diabetes burnout measured by DBQ, fear of hypoglycemia assessed by HFS-II significantly decreased. Diabetic distress measured by means of total score of DDS lowered. Participants scored also lower on PAID upon follow up. The HbA1c level after three months of using the CGM system was significantly lower.

**Conclusions:** The use of isCGM/CGM, even during relatively short observation, leads to improved quality of life, reduced fear of hypoglycemia and diabetes burnout, and lower HbA1c levels in PwT1D over the age of 26 who were naïve to this technology.

**Keywords:** continuous glucose monitoring, intermittently scanned CGM, reimbursement, Type 1 diabetes, Quality of Life

Abbreviations: body mass index (BMI); continuous glucose monitoring (CGM); Continuous Subcutaneous Insulin Infusion (CSII); Diabetes Burnout Questionnaire (DBQ); Diabetes Distress Scale (DDS); Diabetes Treatment Satisfaction Questionnaire status version (DTSQs); fear of hypoglycemia (FoH); Hypoglycemia Fear Survey-II (HFS-II); intermittently scanned CGM (isCGM); Multiple Daily Injection (MDI); Problem Areas in Diabetes (PAID); Perceived Stress Scale (PSS-10); people with type 1 diabetes (PwT1D); real time continuous glucose monitoring (RT-CGM); Self-Monitoring of Blood Glucose (SMBG); type 1 diabetes (T1DM), type 2 diabetes (T2DM); World Health Organization Well-Being Index (WHO-5)

## Introduction

The introduction of Continuous Glucose Monitoring (CGM) systems in 1999 marked a significant turning point in diabetes management. These systems have provided real-time glucose values since 2006, along with information on the direction and rate of glucose changes. This empowers patients to promptly address fluctuations in glucose levels and tailor their lifestyle for enhanced glycemic control [1]. The only intermittently scanned CGM device (is-CGM) [flash glucose monitoring device (FGM)], available and authorized for use in the European Union is Abbott's FreeStyle Libre 1 [2]. This device display current glucose levels, 8-hour historical data, and trend information when physically scanned by the user using a nearfield scanner. This system is currently being replaced by the FreeStyle Libre 2, which includes real-time (RT) functionality.

People with long-standing type 1 diabetes (T1DM) exhibit a significantly increased risk of cardiovascular events. The use of a isCGM /CGM system has been associated with improved glycemic control, as evidenced by reductions in A1C levels and decreased occurrence of hypoglycemia. Improving glycemic control through isCGM/

CGM systems may also reduce the risk and progression of vascular complications associated with T1DM [3,4]. By mitigating both short – and long-term complications, isCGM/CGM systems have demonstrated themselves to be a cost-effective tool for individuals with T1DM [5,6]. Additionally, CGM users are more likely to achieve target A1C levels compared to individuals relying solely on Self-Monitoring of Blood Glucose (SMBG) [7–9]. Real Time CGM + Multiple Daily Injection (MDI) can be considered an equivalent but lower-cost alternative to sensor-augmented insulin pump therapy and superior to treatment with SMBG+MDI or SMBG+ insulin pump therapy [10].

In January 2023 a significant breakthrough occurred for T1DM treatment in Poland, as the reimbursement of CGM systems was initiated for people with T1DM aged 26 and above, rapidly increasing its accessibility for Polish adults with T1DM [11]. Although there are already studies that link isCGM/CGM use with improvement in terms of diabetes distress, diabetes burnout, fear of hypoglycemia (FoH), and quality of life increase, its influence on the psychological well-being of patients and their satisfaction with treatment is worth further exploration [7,9,12–15]. FoH resembles a phobia, leading to behaviors to maintain hyperglycemia or excessive worry. However, the research on the impact of isCGM/CGM on FoH is inconclusive, highlighting the need for further investigation [7,9,16]. Another psychological issue of diabetes management is diabetes distress which encompasses the emotional challenges and anxieties associated with managing T1DM [13,16], and can serve as a barrier to the adoption of diabetes technology, especially in young adults [17]. According to a study by Markowitz et al. [18], the youth utilizing CGM systems exhibited higher levels of trait anxiety compared to non-CGM users. Conversely, adults randomized to the CGM systems group reported lower levels of both state and trait anxiety than those not using CGMs in the same study. In addition to the well-documented benefits for users and healthcare providers (HCPs), there are also benefits for parents, carers, and partners of people with diabetes, the majority of whom feel positively about CGM [19].

IsCGM/CGM systems are visible on the body, and some users might feel as if they look robotic, they make them feel self-conscious during intimacy with partners, draw attention, identify them as having T1DM, or being different from others [17]. Another concern is skin reactions caused by the adhesive pads used to secure the device, which persist despite technological advancements [20,21]. In addition, alarm fatigue might be a significant concern among CGM users and eventually lead to discontinuation [17]. Alarms sounding at inconvenient times and drawing unwanted attention can further increase diabetes distress [22,23]. Moreover, it has been reported that a significant proportion of CGM discontinuers cite lack of trust in the system and its accuracy as the main reason behind discontinuation [17].

The most prominent drawback was the economic burden associated with CGM [24]. It was shown that reimbursement of CGM on the country level was associated with temporary improvement in HbA1c in participants with a baseline HbA1c  $\geq 7.5\%$ , without increasing time in hypoglycemia [25]. RT-CGM reduced the need for assistance by ambulance due to hypoglycemia and reduced work absenteeism for parents after 24 months [25]. Other studies have underscored that reimbursement for CGM likely contributes to improved type 1 diabetes control at the population level [26].

Therefore, the aim of our study was to evaluate metabolic control, changes in quality of life, fear of hypoglycemia, and selected psychological parameters after 3 months of implementing an isCGM/CGM system in Polish people with T1DM above 26 years of age who have no prior experience with this type of glucose monitoring.

## Material and Methods

The study involved 57 people with T1DM from five Polish diabetology centers (Krakow, Zabrze, Poznań, Dąbrowa Górnicza, Rzeszów) recruited between March-September 2023. To be included in the study, people were required to be at least 26 years old, have a minimum two-year history of T1DM, receive treatment with MDI or Continuous Subcutaneous Insulin Infusion (CSII; excluding hybrid closed-loop systems), and provide a signed informed consent. The exclusion criterion from the study was the use of CGM for more than two weeks prior to the study.

Participants completed a set of validated questionnaires:

- Hypoglycemia Fear Survey-II (HFS-II)

consists of 18 items used to measure the people's worries about hypoglycemia and its negative effects in the past six months and its score ranges from 0 to 72 (0 [never worry] to 4 [always worry]) [6]. Cutoff point FoH  $\geq 20$  [27].

- Diabetes Distress Scale (DDS)

the original, 17-item DDS assesses diabetes distress for adults with T1DM or type 2 diabetes (T2DM); in Polish translation; mean item score 2.0 – 2.9 should be considered 'moderate distress,' and a mean item score  $> 3.0$  should be considered 'high distress.'; research indicate associations between DDS scores and behavioral management and biological variables (e.g., HbA1C) for DDS scores of  $>2.0$  [28].

- Perceived Stress Scale (PSS-10)

The PSS-10 determines how unpredictable, uncontrollable, and overloaded respondents find their lives. The scale also includes a number of direct queries about current levels of experienced stress. A total PSS-10 score from 0 to 40 is presented, with higher scores representing higher levels of stress. There are two subscales in the PSS-10.

1. Perceived helplessness (items 1, 2, 3, 6, 9, 10) – measuring an individual's feelings of a lack of control over their circumstances or their own emotions or reactions.
2. Lack of self-efficacy (items 4, 5, 7, 8) – measuring an individual's perceived inability to handle problems.

Higher levels of psychological stress as measured by the PSS-10 have been associated with elevated markers of biological aging, higher cortisol levels, as well as suppressed immune function, greater infection-induced release of pro-inflammatory cytokines, greater susceptibility to infectious disease, slower wound healing, and higher prostate-specific antigen levels [29].

- Diabetes Treatment Satisfaction Questionnaire status version (DTSQs)

The Diabetes Treatment Satisfaction Questionnaire is a patient-reported outcome to measure absolute levels of satisfaction (status version: DTSQs) or changes over time in satisfaction (change version: DTSQc) with diabetes treatment regimens in people with diabetes. The status version of the questionnaire investigates the recent patient's satisfaction with the diabetes treatment, whereas the change version investigates the comparison between the current treatment with the previous one. The change version doesn't measure the diabetes treatment satisfaction level; thus it has to be used together with the status version. The status version has proved to be useful in clinical trials assessing satisfaction with new technologies for insulin delivery systems. The DTSQ is appropriate for people with T1DM or T2DM. The Diabetes Clinic Satisfaction Questionnaire (DCSQ) was also developed and is available for use to measure satisfaction with diabetes healthcare delivery in people with diabetes [30].

- World Health Organization Well-Being Index (WHO-5);

The raw score is calculated by summing up the results of the five answers. The raw score ranges from 0 to 25, with 0 representing worst possible and 25 representing best possible quality of life.

It is recommended to perform the Major Depression (ICD-10) Inventory or another test for depression if the raw score is below 13 or if the individual selected an answer to any of the five questions giving a score of 0 or 1. A score below 13 indicates poor well-being and is an indication for testing for depression according to the ICD-10 classification [31].

- Problem Areas in Diabetes (PAID);

a self-report questionnaire that consists of 20 items depicting difficult emotions related to diabetes (e.g., fear, anger, frustration) commonly experienced by person with diabetes. Each question has five possible answers with a value from 0 to 4, with 0 meaning "no problem" and 4 "a serious problem". The scores are added up and multiplied by 1.25, generating a total score between 0 and 100. People scoring 40 or higher may be at the level of "emotional burnout" and deserve special attention. Very low score (0-10) combined with poor glycemic control may indicate denial. In a clinical setting, the PAID can be administered routinely or as a diagnostic tool. [2]. The cutoff point for diabetes distress 40 [32].

- Diabetes Burnout Questionnaire (DBQ),

Diabetes Burnout test by William Polonsky: a short screening tool of 6 items in which more than two positive answers are treated as a cut-off point for possible diabetes burnout. Cutoff point for DB >2 [33,34].

The participants also filled in a sociodemographic survey, downloaded 14-day personal insulin pump/glucometer data, and underwent HbA1c measurement during diabetologist visits. All types of available and registered for the use in Poland CGM systems were included and the choice depended on the patients' and doctors' decision. The following CGM metrics were analysed: Time of using is /rtCGMS during past two

weeks, median glycemia from past two weeks, Time in Range (TIR), Time above Range (TAR; >180 mg/dl), Time Below Range (TBR; <70 mg/dl), CV and Estimated HbA1c.

A custom sociodemographic survey was designed for this study. In addition to questions about gender, age, relationship status, place of dwelling, education level, and professional situation, it requested information about the duration of diabetes, treatment method, acute and long-term complications of diabetes, and BMI.

After three months of isCGM/CGM use, participants repeated assessments and sent is-CGM reports. At the follow-up appointment, the set of questionnaires additionally included a survey regarding habits and experiences associated with using isCGM/CGM, which is presented in detail in the results section.

The study protocol and informed consent procedures were approved by the ethical committee of the Jagiellonian University Medical College (Number: 1072.6120.9.2023). The project was conducted according to the rules of the Helsinki Declaration. All participants provided written informed consent.

### *Statistical analysis*

Statistical analyses were conducted using R software ver. 4.3.2. The difference between the two groups was analyzed using either the Student's t-test or appropriate nonparametric tests. For comparisons within the same group at two different time points, a paired Student's t-test or its nonparametric counterpart was used, as appropriate. P-values <0.05 were considered significant.

## **Results**

The median age for the studied group was approximately 38 years, with a median duration of diabetes of 16 years. The mean BMI was 25.4 kg/m<sup>2</sup>. Males constituted slightly more than half of the study group (n=29, 50.9%) (Table 1). Most of the participants were in a formal relationship (n=36, 63.2%), while the percentages of those in non-formal relationships and those who were single were similar (n=11, 19.3% vs. n=10, 17.5%). About 40% of individuals inhabited small and rural settlements (n=24), with fewer participants from cities (n=22, 38.6%) and towns (n=11, 19.3%). None in the studied group had either a PhD or only primary education; the majority had higher education (n=35, 61.4%), with the rest having secondary or occupational education. Over 70% were either professionally active or on parental leave (n=40), whereas seven individuals were unemployed (12.3%). Eight individuals were retired or on a disability pension (14%), and the group included two students as well (3.5%). Two-thirds of the participants were treated with MDI, while the remaining were on CSII (n=19, 33.3%). Regarding acute complications of diabetes within the past year, ketoacidosis and severe hypoglycemia leading to loss of consciousness were reported in four (7.0%) and seven (12.3%) participants, respectively. Diabetic retinopathy was the most common long-term complication (n=10, 17.5%), followed by neuropathy (n=3, 5.3%). Baseline sociodemographic and clinical characteristics were presented in the Table 1.

Table 1. **Baseline characteristics of the studied group.**

Variable	Options	N (%) / Mean $\pm$ SD / Median (IQR)
Gender (n, %)	Male	29 (50.9)
	Female	27 (47.4)
	Not specified	1 (1.8)
Age, years (median, Q1-Q3)		37.5 (29.5-46.0)
Duration of diabetes, years (median, Q1-Q3)		16.0 (9.0-25.0)
BMI, kg/m <sup>2</sup> (mean, SD)		25.4 $\pm$ 4.1
Relation status (n, %)	Single	10 (17.54)
	Formal relation	36 (63.2)
	Non-formal relation	11 (19.3)
Place of dwelling (n, %)	Village	24 (42.1)
	Town (less than 100,000 inhabitants)	11 (19.3)
	City (over 100,000 inhabitants)	22 (38.6)
Education level (n, %)	Primary	0 (0.0)
	Secondary/occupational	22 (38.6)
	Higher	35 (61.4)
	PhD	0 (0.0)
Professional situation (n, %)	Student	2 (3.5)
	Employed/parental leave	40 (70.2)
	Unemployed	7 (12.3)
	Disability pension	4 (7.0)
	Pension	4 (7.0)
Treatment method (n, %)	Multiple insulin injections	38 (66.7)
	Personal Insulin pump	19 (33.3)
Acute complications within a year (n, %)	Ketoacidosis	4 (7.0)
	Severe hypoglycemia leading to loss of consciousness	7 (12.3)
Longterm complications of diabetes (n, %)	Diabetic retinopathy	10 (17.5)
	Diabetic Kidney Disease	0 (0.0)
	Neuropathy	3 (5.3)
	Other	1 (1.8)
	None	7 (12.3)



Categorical variables were presented as numbers (percentages), continuous variables as median and interquartile range or mean and standard deviation.

### *isCGM/CGM results*

Detailed characteristics of participant' habits and experiences with an isCGM/CGM were shown on the Table S1 in the Supplemental Material 1. The vast majority of individuals were using the FreeStyle Libre 2 system (n=51, 89.5%), while three individuals used the Dexcom G6 (n=3, 5.3%). One person each used the FreeStyle Libre 1 and Eversense XL (n=1, 1.8% each). During the study (September 2023), an application update altered the requirement for scanning with the FreeStyle Libre 2 system. By the conclusion, seven persons had transitioned to using this RT-CGM system. The arm was the most popular site for sensor placement (n=52, 91.2%), with a few persons wearing the device on the abdomen (n=4, 7%). Over 90% of individuals found sensor insertion and removal easy or very easy (n=54, 94.8% and n=52, 91.2%, respectively). However, more than 10% of individuals found it difficult to remove glue residue after removing the sensor. Only one person (n=1, 1.8%) rated the pain upon insertion as moderate, while the rest found the sensation minimally painful (n=55, 96.5%). The same was true for sensor removal. More than 90% of participants (n=52, 91.2%) reported that their isCGM/CGM always or almost always worked for the minimal period declared by the manufacturer. About 75% (n=42) used the alarm option, with a median hypoglycemia threshold of 70 mg/dL and a median hyperglycemia threshold of 180 mg/dL. Most participants found this option helpful (n=33, 57.9%). Nearly 20% of users switched to vibrations only at night (n=11, 19.3%). Six individuals (n=6, 10.5%) were concerned that the device could wake up other household members and turned the sound off at night. The frequency of using trend arrows to understand changes in glycemia was often or very often used for 70.2% (n=40) and 54.4% (n=31) of participants, respectively. Over 50% of isCGM/CGM users never felt overwhelmed with the amount of data (n=30, 52.6%), while only two individuals felt overwhelmed often or very often (n=2, 3.6%). For the majority of participants, the isCGM/CGM met their expectations at least partially (n=37, 65%), though several individuals were partially dissatisfied (n=5, 8.8%). Ten persons (n=10, 17.6%) did not have an opinion. One-third of individuals rated their ability to use the isCGM/CGM as good with room for improvement (n=19, 33.3%), and nearly one-quarter assessed themselves as intermediate (n=14, 24.6%). Ten persons (n=10, 17.6%) felt that after three months of using isCGM/CGM, they were still beginners. When asked how their life had changed after three months of using isCGM/CGM, the majority stated that it had become easier or much easier (n=40, 70.2%), with singular cases of individuals who thought the opposite or did not see any change at all (n=1, 1.8% each).

### *Psychological results*

The results of psychological parameter changes showed an extraordinary shift in the overall psychological status of the participants in terms of their emotions con-



nected with diabetes. Overall treatment satisfaction measured by median score of DTSQs increased of three points after three months of using is/rtCGM (27.0 vs. 30.0,  $p=0.0013$ ) (Table 2). The median score on the unacceptably high glycemia subscale decreased by one point (3.0 vs. 2.0,  $p=0.001$ ), but no difference was observed in the unacceptably low glycemia subscale. At enrollment, approximately 42% ( $n=24$ ) of participants scored below 13 on the WHO-5 scale, indicating poor well-being and a need for depression screening. The mean well-being level improved by over one point, surpassing the cutoff for depression (13 vs. 14,  $p=0.043$ ), with only 30% ( $n=17$ ) requiring further depression evaluation. DDS results indicated a significant reduction in diabetes distress after three months of CGM use, with the total score improving from 2.7 to 2.0 ( $p<0.001$ ). Both median emotional burden (3.2 vs. 2.4,  $p<0.001$ ) and regimen distress (3.0 vs. 2.2,  $p<0.001$ ) scores decreased from high to moderate distress levels at follow-up. Interpersonal distress score also declined, from moderate to low level (2.0 vs. 1.5,  $p<0.001$ ). Median physician distress remained low at follow-up. So prominent change is hardly ever obtained in such a short period of time and indicates that for the majority of the participants, the diabetes distress was connected with the previous treatment method (instrumental/source distress), not with the very fact of having diabetes (core distress) nor with the doctor-patient relation [33]. No changes in PSS-10 results were observed, either in total raw scores, sten scores, or subscores, with the median sten score remaining at six after three months of after three months of using isCGM/CGM use. The total HFS-II score, decreased by nearly ten points (40.0 vs. 30.5,  $p=0.029$ ), while the median worry subscale score decreased by five points (17.5 vs. 12.5,  $p<0.001$ ). At enrollment, 47 participants (82%) had scores of 20 or higher, indicative of a significant fear of hypoglycemia; this number dropped to 44 participants (77%) at follow-up. This is an extraordinary shift in the patients' emotional functioning taking into account that fear of hypoglycemia is one of the major sources of diabetes distress and lowered quality of life in people with T1DM. Participants also showed a significant reduction in diabetes distress as measured by the PAID questionnaire (36.8 vs. 21.3,  $p=0.001$ ). At enrollment, nearly 46% ( $n=26$ ) scored at least 40, compared to 32% ( $n=18$ ) at follow-up. Meanwhile, 14% ( $n=8$ ) scored 10 or less at enrollment, with that number increasing to 40% ( $n=23$ ) after three months. The PAID questionnaire explores a broad spectrum of functioning with diabetes, and this significant change shows in how many various aspects of life the individuals experienced emotional relief after the after three months of using isCGM/CGM introduction. In terms of diabetes burnout, being a consequence of prolonged diabetes distress, the change also is immense. The DBQ median score was three times lower at follow-up (3.0 vs. 1.0,  $p<0.001$ ), dropping below the two-point cutoff. At enrollment, 30 participants (53%) had more than two positive answers, suggesting possible diabetes burnout, but after three months, all participants ( $n=57$ , 100%) scored below two points which is one of the most prominent changes described in literature in such a short time.

A comparison of the psychometric test results from enrollment and follow-up is presented in Table 2.

Table 2. Scores obtained in psychometric tests at enrollment and after three months of CGMS use.

Variable	Baseline	After three months	p – value
<b>DTSQs</b>			
Treatment Satisfaction (median, Q1-Q3)	27.0 (24.0-32.0)	30.0 (26.0-34.0)	0.013
Unacceptably high glycemia (median, Q1-Q3)	4.0 (2.0-5.0)	3.0 (2.0-4.0)	0.001
Unacceptably low glycemia (median, Q1-Q3)	2.0 (1.0-4.0)	2.0 (2.0-3.0)	0.829
<b>WHO-5</b>			
Total score (mean, SD)	13.1 ± 5.1	14.3 ± 4.6	0.043
<b>DDS</b>			
Total score (median, Q1-Q3)	2.7 (1.7-3.9)	2.0 (1.4-2.9)	0.001
Emotional Burden (median, Q1-Q3)	3.2 (1.8-4.2)	2.4 (1.4-3.4)	<0.001
Physician Distress (median, Q1-Q3)	1.25 (1.0-3.5)	1.5 (1.3-2.31)	0.386
Regimen Distress (median, Q1-Q3)	3.0 (2.0-4.2)	2.2 (1.6-3.2)	<0.001
Interpersonal Distress (median, Q1-Q3)	2.0 (1.33-3.33)	1.5 (1.0-3.0)	<0.001
<b>PSS 10</b>			
Total score (mean, SD)	17.9 ± 6.3	17.9 ± 6.0	0.940
Sten score (median, Q1-Q3)	6.0 (4.0-7.0)	6.0 (5.0-7.0)	0.870
Perceived helplessness	21.8 ± 9.4	20.8 ± 9.6	0.33
Lack of self-efficacy	6.4 ± 3.3	7.2 ± 3.3	0.05
<b>HFS-II</b>			
Total score (median, Q1-Q3)	40.0 ± 28.4	30.5 (20.0-43.3)	0.029
Behavior (mean, SD)	19.4 ± 8.4	18.9 ± 9.7	0.553
Worry (median, Q1-Q3)	17.5 (9.3-32.5)	12.5 (6.0-21.5)	<0.001
<b>PAID</b>			
Total score (median, Q1-Q3)	36.8 ± 23.6	21.3 (6.3-46.3)	0.001
<b>DBQ</b>			
Total score (median, Q1-Q3)	3.0 (1.0-5.0)	1.0 (0.0-1.0)	<0.001

Variables of normal distribution were presented as mean and standard deviation; variables of non-normal distribution were presented as median and interquartile range. Abbreviations: DBQ – Diabetes Burnout Questionnaire; DDS – Diabetes Distress Scale; DTSQs – Diabetes Treatment Satisfaction Questionnaire status version; HFS-II – Hypoglycemia Fear Survey-II; PAID – Problem Areas in Diabetes; PSS-10 – Perceived Stress Scale; WHO-5 – World Health Organization Well-Being Index.

*Glycemic control and continuous glucose monitoring results*

At baseline, the median mean glycemia from the past two weeks, measured by glucometer, was 152 mg/dL. During this time, the median number of reported hypoglycemia episodes was three. The median percentage of glycosylated hemoglobin was lower after three months of using CGM compared to the baseline (7.3 vs. 7.1%,  $p=0.01$ ) (Table 3). However, no difference in the mean daily dose of insulin was observed. The mean daily frequency of glucometer measurements decreased more than six-fold at follow-up (6.5 vs. 1,  $p<0.001$ ). At follow-up, the median mean glycemia from the past two weeks reported by CGM was 154 mg/dL. The median time of using CGM was 96%, with a TIR of 68%. The median TAR was 25%, whereas the median TBR was 2%. The median CV in the studied group was 36%. Glycemic control and CGM metrics at the baseline and after three months were shown in Table 3.

Table 3. Glycemic control and continuous glucose monitoring metrics.

Variable	Baseline	After three months	p – value
HbA1c (%) (median, Q1-Q3)	7.3 (6.8-8.1)	7.1 (6.5-7.9)	0.010
Mean daily insulin dose (U) (median, Q1-Q3)	44.1 ± 17.1	42.5 (32.1-54.6)	0.840
Mean daily insulin dose per kg of body weight (U/Kg) (median, Q1-Q3)	0.59 (0.48-0.70)	0.55 (0.47-0.71)	0.75
Mean glycemia from past two weeks: glucometer (mg/dl) (median, Q1-Q3)	152.0 (139.8-178.8)		
Frequency measurements with glucometer per day (mean, SD)	6.5 ± 2.8	1.0 ± 1.0	<0.001
Episodes of hypoglycemia (median, Q1-Q3)	3 (1.0-6.5)		
Mean glycemia from past two weeks: CGM (mg/dl) (median, Q1-Q3)		154.0 (140.0-177.0)	
Time of using is – /rt-CGMS during past two weeks (%) (median, Q1-Q3)		96.0 (86.3-99.0)	
TIR (%) (median, Q1-Q3)		68.0 (54.0-78.0)	
TAR (%) (median, Q1-Q3)		25.0 (17.0-35.0)	
TBR (%) (median, Q1-Q3)		2.0 (1.0-4.0)	
CV (%) (median, Q1-Q3)		36.0 (32.0-40.4)	
Estimated HbA1c (%) (median, Q1-Q3)		7.0 (6.7-7.5)	

Continuous variables are presented as median and interquartile range or mean and standard deviation. Abbreviations: CGMS – continuous glucose monitoring system; CV – coefficient of variation of glycemia; HbA1c – glycosylated hemoglobin; TAR – Time Above Range; TBR – Time Below Range; TIR – Time in Range.

Additionally, glycemic control, continuous glucose monitoring metrics, and psychometric test scores at baseline and after three months were compared between individuals, categorized by their treatment method, as shown in Table S2 of Supple-

mental Material S1. Although there was a trend toward a lower median HbA1c and a higher mean daily insulin dose at the three-month follow-up, these differences were not statistically significant. Those treated with MDI showed a significant increase in the Treatment Satisfaction subscale of the DTSQs (27.0 vs. 31.0,  $p = 0.01$ ) and a significant decrease in the Unacceptably High Glycemia subscale score (4.0 vs 3.0,  $p < 0.001$ ) after three months. Persons on MDI also showed improved well-being according to the WHO-5 (12 vs. 14,  $p = 0.01$ ). At enrollment, 19 participants (50%) scored below 13, and after three months, 12 participants (32%) fell below the cutoff point indicating depression. In addition, the MDI group was characterized by lower total DDS scores and all subscale scores, except for Physician Distress, which was low also at the beginning. The CSII group, on the other hand, showed significant improvement only in Emotional Burden. No differences in the PSS-10 scores were observed in either group, except for higher mean lack of self-efficacy in the CSII subgroup after three months of CGM use (4.9 vs. 6.9,  $p = 0.03$ ). Median total PAID scores and Worry subscale scores of the HFS-II were lower in both studied subgroups than at follow-up. Median DBQ scores were three times lower in both subgroups after three months of CGM use. In the MDI subgroup, 20 individuals (52%) had a DBQ score exceeding two points, while in the CSII subgroup, 11 individuals (53%) scored that high. After three months, none of the participants exceeded the cutoff point indicating diabetes burnout.

## Discussion

### *Continuous glucose monitoring*

In the present study, we evaluate the changes in metabolic and psychological parameters after three months of initiating an isCGM/CGM system in a group of Polish people with T1DM (Pw1DM) aged 26 and older who have no previous experience with this type of glucose monitoring. Our primary results show that even brief three-month use of sensors in individuals new to FGM/CGM systems significantly enhances their quality of life, with notable improvements in various metabolic and psychological parameters.

The uptake of this technology still remains low – according to T1DM Exchange data from 2016 to 2018, only 30% of Pw1DM use a CGM either alone or in conjunction with an insulin pump [34]. More recent data estimate that CGM is used by approximately 40–50% of Pw1DM [35]. Similar situation occur in other countries [35]. Since January 2023 and the initiation of reimbursement of isCGM/CGM in Poland for Pw1DM aged 26 and above the number of individuals using isCGM/CGM systems has started to increase.

Our study confirms a high acceptance of the technology in CGM-naïve individuals, with more than 60% of them reporting that the device met their expectations, and over 70% agreeing that it made their life easier or much easier. Many studies have shown that user satisfaction with CGM is high and that CGM contributes to improved diabetes-related quality of life (QOL) compared to self-monitoring of blood glucose (SMBG) [36]. There are multiple reasons for not accepting traditional blood glucose

meters (BGM). BGM requires person to prick their fingers multiple times daily, which is painful, cumbersome, and often a source of embarrassment. It involves carrying a significant amount of bulky supplies, the testing process is not discreet, and both person and observer may have concerns about sanitary conditions before and after performing the test. In our study number of BG measurements decreased significantly (Table 2). This reduction may also be attributed to a mandate by the insurer aimed at reducing costs associated with test strip reimbursement. Almost all participants in the studied centers were using isCGM (no scan requirement was introduced in October 2023). Costs are the main consideration for Pw1DM in Poland when selecting a glucose monitor (the precision of the device was the second most important attribute) [37].

### *Metabolic control*

Secondly, we have found a significant reduction of HbA1c level by 0.2% after just 3 months of isCGM/CGM use [38]. Pw1DM who can observe their glucose trends in response to different types and levels of activity, food intake, and insulin dosing patterns gain valuable insights into managing their condition. This often leads to behavioral changes in their insulin delivery and food (specifically carbohydrate) intake. Although it may appear insubstantial, the DCCT trial found that any decrease in HbA1c level, regardless of its magnitude, was always accompanied by a reduction in the risk of diabetic complications [39]. There has been an increasing number of trials demonstrating the efficacy of isCGM/CGM in improving diabetes-related outcomes. Notably, many (ALERTT1, GOLD, DIAMOND, SWITCH, CITY and WISDM studies) have demonstrated an HbA1c reduction, increased TIR, and reduced hypoglycemia [36,40–42]. RT-CGM can predict impending hypoglycemia and can alert and detect glycemic fluctuations, based on glucose trends and retrospective and real-time data generated. CGM is beneficial for individuals with hypoglycemia unawareness. However, it was also stated that lower accuracy of isCGM regarding hypoglycemia levels may result in overcorrection of hypoglycemia [43]. The use of CGM devices has been associated with reduced HbA1c level in children and adults with T1DM and in adults with T2DM treated either with insulin or a non-insulin therapy in many studies [40]. A meta-analysis of randomized controlled trials (RCTs) by Maiorino et al. demonstrated a similar to ours reduction in HbA1c when using isCGM or CGM systems [36]. An isCGM outcomes improve with an increased number of daily scans [44]. Of note switch from isCGM to rt-CGM could improve glycemic management in suboptimal controlled Pw1DM [45]. Moreover, switching from FreeStyle Libre 1 to FreeStyle Libre 2 improved treatment satisfaction and decreased the fear of hypoglycemia [46]. Considering that most of our participants were using isCGM (FreeStyle Libre 2), updating the system to rt-CGM in the future may further improve their outcomes [41,47].

### *Psychological effects*

Finally, extremely important observations come from the results concerning psychological parameters in the studied group of Pw1DM. Diabetes distress, diabetes

burnout, fear of hypoglycemia, depression, and reduced quality of life are phenomena concerning Pw1DM widely described in the literature in recent years. Studies indicate that the prevalence of diabetes distress concerns 40-60% of Pw1DM in different periods of their lives, in many of them symptoms of diabetic burnout begin to appear over time (60%) followed by depression and generally poorer functioning. A significant source of diabetic stress is fear of hypoglycemia, which appears in a way that impedes everyday functioning in about 25% of persons treated with insulin [48-50].

As William Polonsky describes, diabetes distress can stem from the very fact of having diabetes (core distress) or be caused by various external factors related to diabetes (source, instrumental distress). Reducing the level of diabetes distress, with the following diabetes burnout, and lowering the fear of hypoglycemia are key elements of proper treatment of a person with diabetes [33]. The recommendations of international associations [51] clearly indicate that the goal of treating Pw1DM should not only be the achievement of correct glycemic parameters (Time in Range, HbA1c, etc.), but also to help the person maintain a good quality of life, psychological well-being, and overall mental health [52]. Reducing the level of diabetes distress and other mentioned psychological parameters requires appropriate psychological and therapeutic interventions. Individuals in our group initially presented similarly elevated levels of diabetes distress, fear of hypoglycemia, diabetes burnout, depression, and reduced quality of life as Pw1DM in many studies devoted to this topic had obtained [51-55]. What turned out to be an extremely important discovery was the above-average rapid and significant reduction of these parameters. The changes described indicate that the main source of psychological distress for these Pw1DM were mainly issues related to factors lying on the side of the individual's treatment model.

In addition no changes in PSS-10 results were observed, either in total raw scores, sten scores, or subscores, with the median sten score remaining at six after three months of CGM use and the source of stress was not the relationship with the doctor either, which shows, that the participants in the studied population were in general stable life situation and no major additional factors influenced the change in their diabetes distress other than the change in the treatment method (initiation of the isCGM/CGM system). The main psychological burden seems to be the inability to constantly, painlessly control glycemia levels. Such a spectacular improvement seems to be a direct effect of the use of isCGM/CGM systems. No difference was found between diabetes distress in individuals using isCGM vs rtCGM [13]. The lack of significant differences in the obtained effects between the MDI and CSII groups further confirms these observations, indicating that it is not the method of insulin administration, but the possibility of safe and continuous monitoring of the glycemia level that is the source of such improvement in the observed psychological parameters, although in some individuals the observed improvement in psychological parameters was driven more by changes in individuals treated with MDI. In this subgroup of participants, in contrast to those treated with CSII, we observed an increase in overall treatment satisfaction and a reduction in the frequency of unacceptably high glycemia, as measured by DTSQs.

While some previous research indicates that improvements in quality of life, including reduced diabetes distress and increased glycemic confidence after using

CGM, are consistent across participants regardless of their baseline scores [40], other studies suggest that factors such as age, marital status, education, and income level can influence these outcomes [41, 42].

Long-term, regular daily use of CGM is required to maximize its benefits and value. Despite its disadvantages, such as cost, accuracy issues, and inconvenience (including alarm fatigue), the implementation of CGM in Pw1DM has been shown to be a cost-effective strategy [5,42].

In summary, it's essential to recognize that technology cannot replace psychological intervention, which remains necessary in many situations. However, identifying the source and type of diabetes-related distress is crucial. When the distress primarily stems from instrumental factors—such as suboptimal diabetes management—the introduction of new technologies can often provide rapid and meaningful relief, significantly enhancing the person's psychological well-being.

### Limitations

As with all cohort studies, there are limitations to this study. This was a prospective, observational, single arm study which is prone to biases typical of this study design. This includes lack of control group, differences in demographic characteristics, and Hawthorne effect that could have influenced the results. Due to the self-reporting of diabetes complications by individuals treated at different centers, establishing detailed and uniform classification criteria for diabetes complications was not feasible in this study. Because enrollment began about three months after the initiation of isCGM/CGM reimbursement for Polish Pw1DM aged 26 and older, most Pw1DM treated in the affiliated centers had already started using isCGM/CGM. As a result, they were ineligible for this study, significantly reducing the studied population. Finally, we acknowledge that we combined participants using isCGM with those using rt-CGM systems.

### Conclusions

The introduction of isCGM/CGM systems, even during relatively short observation, has significantly improved quality of life, reduced fear of hypoglycemia, alleviated diabetes-related distress and burnout, and lowered HbA1c levels in Pw1DM aged 26 and older who were previously naïve to this technology. Greater benefits were observed in individuals treated with multiple daily injections. These psychological and metabolic advantages support the widespread implementation of CGM in the majority of Pw1DM.

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