# The Impact of Continuous Glucose Monitoring on Markers of Quality of Life in Adults With Type 1 Diabetes: Further Findings From the DIAMOND Randomized Clinical Trial

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*Diabetes Care 2017;40:736–741 | https://doi.org/10.2337/dc17-0133*


## OBJECTIVE

**Continuous glucose monitoring (CGM) improves glycemic control, but data are inconclusive about its influence on quality of life (QOL). We investigated the impact of 24 weeks of CGM use on QOL in adults with type 1 diabetes (T1D) who use multiple daily insulin injections.**

## RESEARCH DESIGN AND METHODS

**DIAMOND (Multiple Daily Injections and Continuous Glucose Monitoring in Diabetes) was a prospective randomized trial that assessed CGM versus self-monitoring of blood glucose (SMBG) only in 158 adults with poorly controlled T1D. At baseline and study end, participants completed QOL measures that assessed overall well-being (WHO-5), health status (EQ-5D-5L), diabetes distress (DDS), hypoglycemic fear (worry subscale of the HFS-II), and hypoglycemic confidence (HCS). At study end, CGM participants completed the CGM Satisfaction Survey. Linear regression analyses compared treatment group changes in QOL outcomes over time. Associations between CGM satisfaction and change in QOL outcomes and in glycemic control indices were assessed.**

## RESULTS

**The CGM group demonstrated a greater increase in hypoglycemic confidence ($P$ = 0.01) and a greater decrease in diabetes distress ($P$ = 0.01) than the SMBG group. No significant group differences in well-being, health status, or hypoglycemic fear were observed. CGM satisfaction was not significantly associated with glycemic changes but was associated with reductions in diabetes distress ($P < 0.001$) and hypoglycemic fear ($P$ = 0.02) and increases in hypoglycemic confidence ($P < 0.001$) and well-being ($P$ = 0.01).**

## CONCLUSIONS

**CGM contributes to significant improvement in diabetes-specific QOL (i.e., diabetes distress, hypoglycemic confidence) in adults with T1D, but not with QOL measures not specific to diabetes (i.e., well-being, health status). CGM satisfaction was associated with most of the QOL outcomes but not with glycemic outcomes.**


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*Received 18 January 2017 and accepted 18 March 2017.*

*Clinical trial reg. no. NCT02282397, clinicaltrials.gov.*

*This article contains Supplementary Data online at http://care.diabetesjournals.org/lookup/suppl/doi:10.2337/dc17-0133/-/DC1.*

Although real-time continuous glucose monitoring (CGM) has been linked to improved glycemic control in adults with type 1 diabetes (T1D), the impact on quality of life (QOL) remains uncertain. In randomized controlled trials, CGM has been shown to have no significant influence (1–3) or a small positive influence (4,5) on measures of diabetes-specific QOL (e.g., hypoglycemic fear). Similarly, the impact on non–diabetes-specific QOL (e.g., overall well-being) in randomized controlled trials has been observed to be minimal (5,6) or absent (4). In contrast, retrospective survey and qualitative interview data suggest that CGM may enhance aspects of QOL (7–9). The reasons for such disparate findings are not known, but as new and future CGM technology deliver better and more reliable accuracy while reducing the degree of burden on the user, QOL benefits may be more frequently observed.

The recently reported randomized trial Multiple Daily Injections and Continuous Glucose Monitoring in Diabetes (DIAMOND) assessed a CGM intervention (with use of the Dexcom G4 Platinum CGM System with an enhanced algorithm; Dexcom, Inc., San Diego, CA) in 158 adults with poorly controlled T1D who used multiple daily insulin injections (MDI) over a 24-week period (10). This study was the first large CGM trial to focus on patients with T1D who used MDI. The trial was completed by 102 (97%) of 105 patients in the CGM group and all 53 (100%) in the control group (who used self-monitoring of blood glucose [SMBG] only). At 24 weeks, CGM participants demonstrated significantly greater improvements in $HbA_{1c}$, less time at >180 mg/dL, less time at <70 mg/dL, and reduced glycemic variability than control group participants; CGM use was consistently high over the 24 weeks (93% used it ≥6 days/week in the last month of the study).

In the current study, we examined the QOL measures from the DIAMOND study, both diabetes specific and non–diabetes specific, administered to participants at baseline and at 24 weeks. We hypothesized that this newer generation of CGM leads to greater improvements in QOL markers, especially in diabetes-specific measures (which are known to be more sensitive to change than non–diabetes-specific measures), than what occurs in individuals who use SMBG alone. Such an outcome seemed probable because current CGM technology allows the individual to accomplish something that is not possible with SMBG: to quickly recognize and respond to glucose fluctuations as needed (and now with devices that are more reliable and less burdensome), thereby *1*) aiding the individual to regain or enhance a sense of personal control over glucose control and, more largely, diabetes and *2*) as overall glucose control improves, leading more directly to broad physical and psychosocial benefits, such as greater energy, better mood, or an overall sense of well-being. Therefore, we also expected that the CGM group would report broad satisfaction with the device and that such satisfaction would be associated with QOL improvement as well as markers of broad glycemic improvement.

## RESEARCH DESIGN AND METHODS

DIAMOND was a 24-week, two-group randomized trial conducted at 24 endocrinology practices in the U.S. For the complete study protocol, see the original trial results (10). Key aspects of the protocol are summarized below.

Major inclusion criteria were age ≥25 years, diagnosis of T1D being treated with MDI for at least 1 year, central laboratory–measured $HbA_{1c}$ 7.5–10.0%, and no CGM use in the 3 months pretrial. After successful completion of a run-in period that used a CGM device modified so that glucose values would not be displayed (referred to as blinded CGM), eligible participants were randomly assigned in a 2:1 ratio to either the CGM or control group (105 and 53, respectively).

Participants in both the CGM and control groups received a Bayer Contour Next USB meter and test strips. Participants in the CGM group were provided with a Dexcom G4 Platinum CGM and were instructed to use the CGM daily, calibrate the CGM twice daily, and verify the CGM glucose concentration with their meter before making diabetes management decisions. Participants in the control group were asked to perform home blood glucose monitoring with the study meter at least four times daily. Follow-up visits for both treatment groups occurred after 4, 12, and 24 weeks. The CGM group had an additional visit 1 week after randomization. The control group had two additional visits 1 week before the 12- and 24-week visits to initiate blinded CGM use for 1 week. Phone contacts for both groups occurred 2 and 3 weeks after randomization.

The psychosocial self-report measures were completed by all participants at baseline and again at study end (24 weeks). $HbA_{1c}$ was measured at baseline, 12 weeks, and 24 weeks at a central laboratory. At the same three time points, a series of other glycemic measures was assessed through CGM (blinded in the control group, unblinded in the CGM group); these included the percentage of time per day in the target range (70–180 mg/dL), in the hypoglycemic range (<70 mg/dL), and in the hyperglycemic range (>180 mg/dL).

### QOL Measures

To assess non–diabetes-specific QOL, two commonly used self-report measures were used: the World Health Organization (Five) Well-Being Index (WHO-5) (11) and the EQ-5D-5L (12). The WHO-5 is a five-item scale that assesses overall well-being; item responses are summed and multiplied by 4, resulting in a 0–100-point scale. The EQ-5D-5L includes five items to assess health status (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression) in three levels of severity (no, moderate, or severe problems) and one item to assess overall self-rated health on a visual analog scale from 0 (worst imaginable health state) to 100 (best imaginable health state).

Three diabetes-specific QOL self-report measures were completed: the Diabetes Distress Scale (DDS), the Hypoglycemia Fear Survey (HFS-II), and the Hypoglycemic Confidence Scale (HCS). The DDS is a 17-item scale that assesses worries and concerns specifically related to diabetes and its management and has been shown to be a good marker of diabetes-related QOL (13). The DDS yields a total mean-item score with four moderately intercorrelated subscale scores: distress concerning emotional burden, regimen management, problems regarding emotional support from others, and concerns about obtaining satisfactory medical care. The worry subscale of the revised, 18-item HFS-II assesses the frequency of common concerns regarding hypoglycemia (14), with items summed for a total scale score. The HCS is a nine-item questionnaire that yields a total mean-item score and evaluates the degree to which patients feel able, secure, and comfortable about their ability to stay safe from hypoglycemic-related problems (15).

For the CGM group alone, satisfaction with CGM was assessed at 24 weeks with

the CGM Satisfaction Survey, a 44-item scale that yields a total mean-item score as well as two subscale scores that evaluate perceived benefits and perceived hassles (16). For each item, respondents indicated their degree of agreement or disagreement on a 1–5-point Likert scale, with a higher mean score indicating greater CGM satisfaction. Of note, items on the hassles subscale were reverse scored when combined with benefit items to provide the total mean score.

### Statistical Analysis

Analyses followed the intention-to-treat principle. The primary analysis was a treatment group comparison of the change in quality of life outcomes from baseline to 24 weeks that used linear regression models adjusted for baseline levels of the outcome and clinical site as a random effect. Analyses were repeated to include potential confounding variables of age, sex, and diabetes duration as covariates. Cohen's *d* effect size was calculated to determine the magnitude of the treatment group differences. Exploratory analyses assessed for interaction between the treatment effect on the change in QOL from baseline to 24 weeks and patient demographic baseline factors by including interaction terms in regression models. Finally, within the CGM group, associations between CGM satisfaction with change in QOL and glycemic control were assessed in linear regression models adjusted for clinical site. Given the large number of analyses, we adjusted for multiple comparisons by using the Benjamini-Hochberg procedure using a false discovery rate of 0.05 (17). The resulting adjusted *P* values are reported.

Initially, analyses were conducted without imputation for missing values (i.e., used the missing-at-random approach) and then repeated by using multiple imputation to supply values for missing data. Because missing data were minimal and no meaningful differences existed between the results of the analyses with or without data imputation, only the results of the initial analysis that used the missing-at-random (nonimputed) data are presented. All statistical analyses were performed with use of SPSS version 19.0 software (IBM Corporation) except for imputation of missing data, which was conducted with NORM version 2 software (Pennsylvania State University) that imputes data through the expectation-maximization algorithm.

## RESULTS

Among the 155 participants who completed the trial and were included in the primary analysis, mean ± SD age was 48 ± 13 years (range 26–73 years), 45% were female, mean T1D duration was 12 ± 14 years, and baseline $HbA_{1c}$ was 8.6 ± 0.6% (range 7.5–9.9%) (Table 1).

### Group Differences in QOL Outcomes

CGM participants reported significantly greater increases in hypoglycemic confidence than SMBG participants, resulting in a mean ± SE cumulative difference of 0.23 ± 0.09 between groups ($P = 0.03$, $d = 0.40$) (Table 2). Of note, examination of the individual items revealed that the most striking group differences were in staying safe from serious hypoglycemic problems while sleeping (mean between-group difference 0.38 ± 0.13; $P = 0.02$) and while driving (mean between-group difference 0.20 ± 0.10; $P = 0.05$) as well as participants' rating of their partner's overall hypoglycemic confidence (mean between-group difference 0.29 ± 0.13; $P = 0.05$).

Modest decreases in diabetes-related distress in the CGM group and increases in the control group resulted in a mean ± SE cumulative difference for total distress of 0.23 ± 0.07 between groups ($P = 0.02$, $d = 0.44$). Significant group differences were found in two of the four areas of diabetes-related distress: regimen distress ($P = 0.04$, $d = 0.31$) and interpersonal distress ($P = 0.009$, $d = 0.51$). As shown in Table 2, these between-group differences for diabetes-related distress and hypoglycemic confidence all persisted in models that further adjusted for participant demographic factors.

In comparison, no significant group differences were observed in hypoglycemic worry or in the non–diabetes-specific QOL measures (WHO-5 and EQ-5D-5L). No consistent patterns of interactions between study arm and participant factors on change in the QOL outcomes were found (including participant age, sex, ethnicity, education level, time since diagnosis, baseline SMBG frequency, baseline glycemic measures [percent time in

**Table 1—Participant characteristics by study arm**

| | CGM group (*n* = 102) | Control group (*n* = 53) |
|---|---|---|
| Age (years) | 46 ± 14 | 51 ± 11 |
| Diabetes duration (years) | 20 ± 13 | 24 ± 14 |
| Female sex | 46 (45) | 23 (43) |
| Race/ethnicity | | |
| White, non-Hispanic | 88 (86) | 42 (79) |
| Black, non-Hispanic | 6 (6) | 3 (6) |
| Hispanic or Latino | 5 (5) | 8 (15) |
| More than one race | 2 (2) | 0 (0) |
| Unknown/not reported | 1 (<1) | 0 (0) |
| Highest education* | | |
| Less than bachelor's degree | 44 (46) | 22 (43) |
| Bachelor's degree | 43 (44) | 19 (37) |
| Postbachelor's degree | 10 (10) | 10 (20) |
| $HbA_{1c}$ (%) | 8.6 ± 0.7 | 8.6 ± 0.6 |
| Number of SMBG tests/day (self-report) | 3.9 ± 1.3 | 4.1 ± 1.6 |
| ≥1 severe hypoglycemic events in previous 12 months | 7 (7) | 9 (17) |
| CGM use in the past | 17 (17) | 9 (17) |
| WHO-5 | 71.3 ± 14.7 | 69.1 ± 14.9 |
| EQ-5D-5L | 0.90 ± 0.11 | 0.89 ± 0.11 |
| Diabetes distress (DDS) | | |
| Total | 1.8 ± 0.7 | 1.7 ± 0.6 |
| Regimen distress | 2.1 ± 0.9 | 2.1 ± 1.0 |
| Emotional burden | 2.0 ± 0.9 | 1.9 ± 0.8 |
| Interpersonal distress | 1.5 ± 0.8 | 1.5 ± 0.7 |
| Physician distress | 1.2 ± 0.6 | 1.1 ± 0.3 |
| Hypoglycemic confidence (HCS) | 3.3 ± 0.6 | 3.2 ± 0.6 |
| Hypoglycemia fear (worry subscale of HFS-II) | 15.8 ± 12.3 | 17.3 ± 13.2 |

Data are mean ± SD or *n* (%). One hundred fifty-five participants completed the study from baseline to 24-week follow-up. *Data for education level were available for 97 of 102 participants in the CGM group and 51 of 53 participants in the SMBG group.

target range, percent time in hypoglycemia, percent time in hyperglycemia, and $HbA_{1c}$], and baseline levels of the QOL outcome).

### CGM Satisfaction and Associations With QOL and Glycemic Outcomes

As previously reported (10), satisfaction with CGM was high (mean ± SD 4.2 ± 0.4), with perceived benefits noted as very common (4.2 ± 0.5) and perceived hassles as relatively rare (1.7 ± 0.5). Adjusted for participant demographic factors, overall CGM satisfaction (total scale score) was moderately related to decreases in total diabetes-related distress (B = −0.31, $P < 0.001$) and hypoglycemic worry (B = −4.22, $P = 0.03$) and increases in hypoglycemic confidence (B = 0.49, $P < 0.001$) and overall well-being (WHO-5: B = 7.61, $P = 0.02$) (Table 3). On closer examination of the two subscales, perceived benefits and perceived hassles revealed that fewer mean hassles were significantly linked with the same five QOL measures in the expected directions (and the association with health status was now significant, $P < 0.05$), but fewer mean perceived benefits were significantly associated only with decreases in total diabetes distress (B = −0.18, $P = 0.02$) and increases in hypoglycemia confidence (B = 0.30, $P = 0.003$). No significant associations between CGM satisfaction and changes in any of the glycemic control measures were apparent.

## CONCLUSIONS

We found that CGM contributes to statistically significant greater improvement in diabetes-specific QOL measures (specifically, reductions in diabetes distress and increases in hypoglycemic confidence) in adults with T1D taking MDI compared with those who use SMBG only. Effect sizes for these group differences in diabetes-specific QOL were in the low/moderate to moderate range ($d = 0.31$–$0.51$), pointing to the practical significance of the findings. These results support the first of our two speculations about how CGM might positively influence QOL: CGM can help adults with T1D to regain or enhance their sense of personal control over their glucose control and, perhaps more broadly, their diabetes. Of note, the impact of CGM on these QOL outcomes was not moderated by any of the measured demographic factors (e.g., age, education), baseline glycemic indices, or

**Table 2—QOL outcomes by study arm from baseline to 24-week follow-up**

| | CGM group | | Control group | | Model 1 | | | Model 2 | | | |
|---|---|---|---|---|---|---|---|---|---|---|---|
| | Baseline | 24 weeks | Baseline | 24 weeks | Mean difference in change between arms | 95% CI | *P* value | Mean difference in change between arms | 95% CI | *P* value | Effect size (*d*) |
| WHO-5 | 71.28 ± 14.71 | 70.47 ± 16.68 | 69.06 ± 14.89 | 67.32 ± 16.86 | −1.26 | −5.42 to 2.91 | 0.62 | −1.63 | −5.88 to 2.61 | 0.50 | 0.12 |
| EQ-5D-5L | 0.90 ± 0.11 | 0.89 ± 0.10 | 0.89 ± 0.11 | 0.88 ± 0.10 | 0.00 | −0.03 to 0.03 | 0.86 | 0.00 | −0.03 to 0.03 | 0.92 | 0.00 |
| Diabetes distress (DDS) | | | | | | | | | | | |
| Total | 1.78 ± 0.65 | 1.61 ± 0.48 | 1.69 ± 0.62 | 1.78 ± 0.65 | 0.22 | 0.08 to 0.36 | 0.009 | 0.23 | 0.09 to 0.36 | 0.03 | 0.44 |
| Regimen | 2.09 ± 0.87 | 1.81 ± 0.68 | 2.08 ± 0.99 | 2.05 ± 0.87 | 0.25 | 0.05 to 0.46 | 0.04 | 0.26 | 0.05 to 0.47 | 0.04 | 0.31 |
| Emotional burden | 2.06 ± 0.90 | 1.93 ± 0.80 | 1.91 ± 0.83 | 2.03 ± 0.95 | 0.21 | 0.01 to 0.41 | 0.08 | 0.21 | 0.00 to 0.41 | 0.09 | 0.33 |
| Interpersonal | 1.54 ± 0.81 | 1.43 ± 0.61 | 1.45 ± 0.70 | 1.73 ± 1.04 | 0.37 | 0.16 to 0.56 | 0.009 | 0.37 | 0.16 to 0.58 | 0.01 | 0.51 |
| Physician | 1.19 ± 0.63 | 1.09 ± 0.25 | 1.12 ± 0.25 | 1.18 ± 0.69 | 0.10 | −0.04 to 0.25 | 0.21 | 0.12 | −0.03 to 0.27 | 0.15 | 0.18 |
| Hypoglycemic confidence (HCS) | 3.27 ± 0.57 | 3.47 ± 0.55 | 3.15 ± 0.57 | 3.18 ± 0.63 | 0.23 | 0.06 to 0.40 | 0.03 | 0.23 | 0.05 to 0.41 | 0.03 | 0.40 |
| Hypoglycemia fear (worry subscale of HFS-II) | 15.75 ± 12.30 | 13.48 ± 10.63 | 17.30 ± 13.22 | 17.73 ± 14.92 | 3.17 | 0.19 to 6.14 | 0.07 | 2.46 | −0.58 to 5.51 | 0.15 | 0.25 |

Data are unadjusted mean ± SD by group unless otherwise indicated. Model 1 values resulted from mixed linear regression models adjusted for baseline levels of the outcome and clinical site as a random effect. Model 2 values are further adjusted for the participant demographic factors of age, sex, and number of years since diagnosis. *P* values are adjusted for multiple comparisons by using the Benjamini-Hochberg procedure.

**Table 3—Associations between CGM satisfaction and change in QOL and glycemic control from baseline to 24-week follow-up (CGM group only)**

| | CGM benefits | | | CGM hassles | | | CGM total satisfaction | | |
|---|---|---|---|---|---|---|---|---|---|
| | B (SE) | 95% CI | *P* value | B (SE) | 95% CI | *P* value | B (SE) | 95% CI | *P* value |
| Δ WHO-5 | 4.55 (2.57) | −0.56 to 9.66 | 0.09 | −7.00 (2.39) | −11.75 to −2.25 | 0.01 | 7.61 (2.80) | 2.05 to 13.17 | 0.02 |
| Δ EQ-5D-5L | 0.02 (0.02) | −0.02 to 0.05 | 0.38 | −0.04 (0.02) | −0.08 to −0.01 | 0.03 | 0.04 (0.02) | −0.01 to 0.08 | 0.08 |
| Δ Diabetes distress (DDS) | | | | | | | | | |
| Total | −0.18 (0.07) | −0.32 to −0.04 | 0.02 | 0.31 (0.07) | 0.17 to 0.44 | <0.001 | −0.31 (0.08) | −0.47 to −0.16 | <0.001 |
| Regimen | −0.26 (0.11) | −0.48 to −0.03 | 0.04 | 0.46 (0.10) | 0.25 to 0..66 | <0.001 | −0.46 (0.12) | −0.70 to −0.22 | <0.001 |
| Emotional burden | −0.23 (0.12) | −0.48 to 0.02 | 0.08 | 0.47 (0.11) | 0.23 to 0.70 | <0.001 | −0.46 (0.13) | −0.73 to −0.18 | 0.003 |
| Interpersonal | 0.03 (0.08) | −0.14 to 0.19 | 0.74 | 0.07 (0.08) | −0.10 to 0.22 | 0.43 | −0.03 (0.09) | −0.21 to 0.16 | 0.79 |
| Physician | −0.11 (0.05) | −0.21 to −0.01 | 0.04 | 0.11 (0.05) | 0.02 to 0.21 | 0.03 | −0.14 (0.05) | −0.24 to −0.02 | 0.02 |
| Δ Hypoglycemic confidence (HCS) | 0.30 (0.09) | 0.11 to 0.48 | 0.003 | −0.44 (0.09) | −0.62 to −0.26 | <0.001 | 0.49 (0.10) | 0.29 to 0.70 | <0.001 |
| Δ Hypoglycemia worry (HFS-II) | −2.29 (1.56) | −5.38 to 0.81 | 0.16 | 4.13 (1.50) | 1.15 to 7.11 | 0.02 | −4.22 (1.73) | −7.66 to −0.78 | 0.03 |
| Δ $HbA_{1c}$ | −0.15 (0.15) | −0.45 to 0.15 | 0.33 | 0.21 (0.15) | −0.09 to 0.49 | 0.17 | −0.23 (0.17) | −0.57 to 0.10 | 0.18 |
| Δ % Time within range | 0.04 (0.03) | −0.02 to 0.09 | 0.21 | 0.01 (0.03) | −0.05 to 0.06 | 0.98 | 0.02 (0.03) | −0.04 to 0.09 | 0.50 |
| Δ % Time <70 mg/dL | 0.01 (0.01) | −0.01 to 0.02 | 0.48 | 0.00 (0.01) | −0.01 to 0.02 | 0.92 | 0.00 (0.01) | −0.01 to 0.02 | 0.73 |
| Δ % Time >180 mg/dL | −0.04 (0.03) | −0.10 to 0.02 | 0.21 | 0.01 (0.03) | −0.06 to 0.06 | 0.88 | −0.03 (0.04) | −0.11 to 0.05 | 0.43 |

Model values resulted from mixed linear regression models adjusted for baseline levels of the outcome (QOL and glycemic control) and clinical site as a random effect and participant demographic factors of age, sex, and number of years since diagnosis. *P* values are adjusted for multiple comparisons by using the Benjamini-Hochberg procedure. Δ, change.

poor baseline QOL. These findings suggest, therefore, that the reported improvements in diabetes distress and hypoglycemic confidence were consistent across participants and that benefits were not limited to specific subgroups or to those with low confidence or high distress at baseline.

Diabetes distress refers to the worries, concerns, and fears that are relatively common among individuals who struggle with a progressive and demanding chronic disease such as diabetes; high levels of diabetes distress have been linked to problematic diabetes management and poor glycemic control (13,18). In addition to reporting greater reductions in total diabetes distress than the control group, participants in the CGM group in the current study reported significantly greater drops on two of the four DDS subscales: regimen distress and interpersonal distress. CGM use not only decreased burden and concerns about the disease and its management but also contributed to a reduction in interpersonal tensions with family and friends around diabetes management.

Although previous behavioral and education-based interventions have been shown to have a positive impact on diabetes distress (19), DIAMOND is the first study in our knowledge to demonstrate that introduction of appropriate diabetes technology can positively influence this critical QOL dimension. However, the reported reduction in diabetes distress stands in contrast with three previous CGM studies that examined the impact of diabetes distress through the use of similar measures, all of which failed to show a CGM benefit along this QOL dimension (1,4,5). Although the improvement in distress was only modest in the current study, we believe that the benefit is real and speculate that the uniqueness of this finding may be due to the high degree of accuracy and reliability of the CGM used in the current study (20) compared with the CGM devices used in the prior studies; furthermore, ours is the only study that has focused exclusively on adults who use MDI.

This CGM trial was also the first in our knowledge to examine the dimension of hypoglycemic confidence, pointing to a potentially unique benefit of CGM. While improving glycemic control and reducing hypoglycemic risk, CGM may have also enhanced and supported patients' sense

of self-efficacy about hypoglycemia—that they can realistically be and feel safer than was previously the case. As was shown in the recent validation article, gaining confidence in one's own ability to avoid or address hypoglycemia is distinctly different from experiencing reductions in hypoglycemia fear (21). Indeed, we found that CGM did not significantly reduce hypoglycemic worry (one of the two critical aspects of hypoglycemia fear), which parallels the negative findings from three of the four published CGM trials that examined hypoglycemic worry (1,3,5), the one exception being the study by van Beers et al. (4).

Within the CGM group, broad satisfaction with the device was apparent. Indeed, mean CGM satisfaction (4.2) was substantially higher than that reported in previous studies: 3.9 $\pm$ 0.5 in the JDRF CGM Study (5) and 3.8 $\pm$ 0.6 in the van Beers et al. (4) study. In the current study, device satisfaction was associated with most of the diabetes-specific and non–diabetes-specific QOL outcomes but not with any of the glycemic outcomes, which suggests that the patient's perception of CGM satisfaction (which may contribute to whether the device continues to be used over time) may be more strongly influenced by the tangible sense that one is feeling better (i.e., QOL) than by the more abstract observation that one is doing better (i.e., that one's glycemic values have improved). If true, this association may have important clinical ramifications for addressing long-term use of CGM. To encourage ongoing use (especially for patients whose interest may be flagging), it may be valuable to aid patients in seeing where the device is helping to enhance their QOL, not just improving their glycemic control.

This study has several limitations. First, it included only adults with T1D who use MDI; therefore, whether similar findings might have been observed in other patient groups of interest, such as teens and insulin pump users with T1D or individuals with type 2 diabetes, remains unknown. Second, study participants were racially homogeneous, with the majority of participants being non-Hispanic white with a high education level (with more than one-half of the sample reporting college degrees). Third, the study was limited to a 24-week trial period, so we do not know whether such benefits would be maintained over longer periods. Finally, although the noted effect sizes were small/moderate to moderate, improvement within the CGM group itself was modest, and the potential clinical significance is unknown. Within these constraints, however, we conclude that CGM compared with SMBG only contributes to statistically significant improvements in diabetes-specific QOL as well as enhances glycemic control in this population of adults with T1D who use MDI.

**Acknowledgments.** The authors thank the DIAMOND study participants, trial staff, and investigators for participation. All DIAMOND clinic sites, study investigators, and study coordinators are listed in the Supplementary Data.

**Funding and Duality of Interest.** Dexcom, Inc. provided funding for the study to the Behavioral Diabetes Institute and to the Jaeb Center for Health Research. W.H.P. reports consulting fees from Dexcom and Abbott Diabetes Care. R.W.B. reports that his institution has received supplies for research studies from Dexcom and Abbott Diabetes Care. No other potential conflicts of interest relevant to this article were reported.

**Author Contributions.** W.H.P., D.H., K.J.R., and R.W.B. participated in the study design, had access to the data, contributed to the manuscript development, vouch for the accuracy and completeness of the data reported, and made the decision to submit the manuscript for publication. W.H.P. is the guarantor of this work and, as such, had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

**Prior Presentation.** Parts of this study were presented in poster form at the 10th International Conference on Advanced Technologies & Treatments for Diabetes, Paris, France, 15–18 February 2017.

## References

1. Bolinder J, Antuna R, Geelhoed-Duijvestijn P, Kröger J, Weitgasser R. Novel glucose-sensing technology and hypoglycaemia in type 1 diabetes: a multicentre, non-masked, randomised controlled trial. Lancet 2016;388:2254–2263
2. Vigersky RA, Fonda SJ, Chellappa M, Walker MS, Ehrhardt NM. Short- and long-term effects of real-time continuous glucose monitoring in patients with type 2 diabetes. Diabetes Care 2012;35:32–38
3. Little SA, Leelarathna L, Walkinshaw E, et al. Recovery of hypoglycemia awareness in long-standing type 1 diabetes: a multicenter 2 $\times$ 2 factorial randomized controlled trial comparing insulin pump with multiple daily injections and continuous with conventional glucose self-monitoring (HypoCOMPaSS). Diabetes Care 2014;37:2114–2122
4. van Beers CA, DeVries JH, Kleijer SJ, et al. Continuous glucose monitoring for patients with type 1 diabetes and impaired awareness of hypoglycaemia (IN CONTROL): a randomised, open-label, crossover trial. Lancet Diabetes Endocrinol 2016;4:893–902
5. Beck RW, Lawrence JM, Laffel L, et al.; The Juvenile Diabetes Research Foundation Continuous Glucose Monitoring Study Group. Quality-of-life measures in children and adults with type 1 diabetes: Juvenile Diabetes Research Foundation Continuous Glucose Monitoring randomized trial. Diabetes Care 2010;33:2175–2177
6. Riveline JP, Schaepelynck P, Chaillous L, et al.; EVADIAC Sensor Study Group. Assessment of patient-led or physician-driven continuous glucose monitoring in patients with poorly controlled type 1 diabetes using basal-bolus insulin regimens: a 1-year multicenter study. Diabetes Care 2012;35:965–971
7. Polonsky WH, Hessler D. What are the quality of life-related benefits and losses associated with real-time continuous glucose monitoring? A survey of current users. Diabetes Technol Ther 2013;15:295–301
8. Pickup JC, Ford Holloway M, Samsi K. Real-time continuous glucose monitoring in type 1 diabetes: a qualitative framework analysis of patient narratives. Diabetes Care 2015;38:544–550
9. Polonsky WH, Peters AL, Hessler D. The impact of real-time continuous glucose monitoring in patients 65 years and older. J Diabetes Sci Technol 2016;10:892–897
10. Beck RW, Riddlesworth T, Ruedy K, et al.; DIAMOND Study Group. Effect of continuous glucose monitoring on glycemic control in adults with type 1 diabetes using injections for insulin delivery: a randomized clinical trial. JAMA 2017;317:371–378
11. Hajos TR, Pouwer F, Skovlund SE, et al. Psychometric and screening properties of the WHO-5 well-being index in adult outpatients with type 1 or type 2 diabetes mellitus. Diabet Med 2013;30:e63–e69
12. Clarke P, Gray A, Holman R. Estimating utility values for health states of type 2 diabetic patients using the EQ-5D (UKPDS 62). Med Decis Making 2002;22:340–349
13. Polonsky WH, Fisher L, Earles J, et al. Assessing psychosocial distress in diabetes: development of the diabetes distress scale. Diabetes Care 2005;28:626–631
14. Irvine A, Cox D, Gonder-Frederick L. The fear of hypoglycaemia scale. In *Handbook of Psychology and Diabetes*. Bradley C, Ed. New York, Harwood Academic Publishers, 1994, p. 133–155
15. Polonsky WH, Fisher L, Hessler D, Edelman SV. Investigating hypoglycemic confidence in type 1 and type 2 diabetes. Diabetes Technol Ther 2017;19:131–136
16. Juvenile Diabetes Research Foundation Continuous Glucose Monitoring Study Group. Validation of measures of satisfaction with and impact of continuous and conventional glucose monitoring. Diabetes Technol Ther 2010;12:679–684
17. Benjamini Y, Hochberg Y. Controlling the false discovery rate: a practical and powerful approach to multiple testing. JR Stat Soc 1995;57:289–300
18. Fisher L, Glasgow RE, Strycker LA. The relationship between diabetes distress and clinical depression with glycemic control among patients with type 2 diabetes. Diabetes Care 2010;33:1034–1036
19. Sturt J, Dennick K, Hessler D, Hunter BM, Oliver J, Fisher L. Effective interventions for reducing diabetes distress: systematic review and meta-analysis. International Diabetes Nursing 2015;12:40–55
20. Bailey TS, Chang A, Christiansen M. Clinical accuracy of a continuous glucose monitoring system with an advanced algorithm. J Diabetes Sci Technol 2015;9:209–214
21. Polonsky WH, Fisher L, Hessler D, Edelman SV. Identifying the worries and concerns about hypoglycemia in adults with type 2 diabetes. J Diabetes Complications 2015;29:1171–1176