# The Use of Continuous Glucose Monitoring With Remote Monitoring Improves Psychosocial Measures in Parents of Children With Type 1 Diabetes: A Randomized Crossover Trial

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## OBJECTIVE

**This study aimed to explore the effect of continuous glucose monitors with remote monitoring on psychosocial outcomes in parents of children with type 1 diabetes.**

## RESEARCH DESIGN AND METHODS

**Children with type 1 diabetes, aged 2–12 years, along with their parents, were studied in a randomized crossover study. They participated in two 3-month periods using conventional blood glucose monitoring (control) or the Dexcom G5 Mobile continuous glucose monitoring (CGM) system with remote monitoring (intervention). The primary outcome was parental fear of hypoglycemia score assessed by the Hypoglycemia Fear Survey.**

## RESULTS

**Parental Hypoglycemia Fear Survey scores were lower while the child was using CGM with remote monitoring ($P < 0.001$). Furthermore, parental health-related quality of life and family functioning, stress, anxiety, and sleep measures also improved significantly after intervention.**

## CONCLUSIONS

**CGM with remote monitoring was found to improve multiple measures of quality of life, reduce family stress, and improve parental sleep.**


Hypoglycemia and fear of hypoglycemia limit the achievement of optimal glycemic control and impair quality of life of children with type 1 diabetes (1).

The benefits of continuous glucose monitoring (CGM) for glycemic control have been demonstrated (2); however, its impact on psychosocial outcomes in children and caregivers remains controversial (3–5). Despite reports of high satisfaction with CGM systems, this is not reflected in reduced hypoglycemia fear (3,4), and psychosocial measures are usually only included as secondary outcomes in trials involving CGM.

Remote monitoring has been shown to prevent prolonged nocturnal hypoglycemia (6). Recently, the first mobile-based CGM system with the ability to remotely track sensor glucose values was approved (7). The aim of this study was to investigate the

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impact of CGM with remote monitoring on psychosocial outcomes in parents of children with type 1 diabetes.

## RESEARCH DESIGN AND METHODS

Children diagnosed with type 1 diabetes for more than 1 year, aged 2–12 years, and one of their parents were recruited. Participants were required not to have used CGM during the preceding 6 months. At the time of the study, CGM was not publicly funded in Australia and usage was low. The protocol was approved by the Perth Children's Hospital Ethics Committee.

A randomized, prospective, open-label crossover design was used with participants spending 3 months in each of the two study arms (Supplementary Fig. 1). At the first visit and after each 3-month period, parents and children (aged 8–12 years) completed validated questionnaires regarding psychosocial factors and quality of life. This report details parental questionnaire outcomes only.

Participants and their parents were educated in the use of the Dexcom G5 Mobile CGM system at the first visit. This system allows transmission of sensor glucose values via Bluetooth to a mobile device. This information can be shared via "cloud" with up to five individuals who are able to remotely monitor the CGM reading in real time. Remote monitoring was set up for the parent who attended all the visits. Low alert of the CGM on the participant's device was set at 4.0 mmol/L. No specific alerts were set on the follower's device. Parents and children were permitted to change alerts during the study. Both intervention and control groups received the same follow-up. No specific education around insulin adjustment with trend arrows and alerts was imparted. Diabetes management advice was directed to the clinical and not the research team.

The CGM training was followed by a 2-week period where a minimum of 80% of valid sensor data was required for randomization. After randomization, participants used conventional blood glucose monitoring (control) for 3 months and the CGM system with remote monitoring (intervention) for 3 months in the order assigned at randomization. Randomization was computer generated using http://www.sealedenvelope.com/. The first 3-month period was followed by a 2-month "washout" period.

The primary outcome of the study was parental fear of hypoglycemia assessed by the parent version of the Hypoglycemia Fear Survey (8). Quality of life was measured using three Pediatric Quality of Life Inventory (PedsQL) modules: the PedsQL 4.0 Generic Core Scales, the PedsQL 3.0 Diabetes Module (9), and the PedsQL 2.0 Family Impact Module with two subscales (parent health-related quality of life [HRQL] and family functioning) (10). Parents also completed two questionnaires pertaining to stress, depression, and anxiety: the Depression Anxiety Stress Scale (DASS) (11) and the State and Trait Anxiety Inventory (12).

Sleep quality was assessed using the Pittsburgh Sleep Quality Index (13). Satisfaction with the CGM system was assessed using the CGM Satisfaction Survey after intervention (14).

$HbA_{1c}$ was assessed by an agglutination inhibition immunoassay (DCA Vantage; Siemens Medical) before and at the end of each 3-month period. The frequency of self-monitoring of blood glucose (SMBG) was determined through computer uploads of the blood glucose meter.

### Statistical Analysis

Continuous outcomes were analyzed using linear mixed models. Least squares means (LSM), based on the fixed terms in the model, and differences in LSM along with their 95% CIs were calculated. To analyze the change in frequency of SMBG, a generalized linear mixed model with a negative binomial distribution and log link was used. All data were analyzed on an intent-to-treat basis. *P* values $<0.05$ were considered statistically significant.

## RESULTS

The sample comprised 49 participants (31 females) and their parents. They had a mean (±SD) age of 9.5 years (±1.9), mean diabetes duration of 3.9 years (±2.5), and mean $HbA_{1c}$ of 7.7% (±0.7) (61 ± 8 mmol/mol). Twenty-one participants were aged <10 years (including three <6 years). Twenty-nine (64%) used an insulin pump. Remote monitoring was used by 48 (98%) parents; 35 (73%) had more than one follower, mostly both parents. Most parents chose a low alert between 3.1 and 5.3 mmol/L and a high alert between 8.0 and 20.0 mmol/L.

Table 1 shows questionnaire baseline scores and the differences between the two arms. Parental fear of hypoglycemia scores were significantly lower after the intervention arm compared with the control arm, with lower scores in both the behavior and worry subscales after intervention.

There was no significant difference in general and diabetes-specific quality of life in the parent-proxy report. However, quality of life assessed with the Family Impact Module showed a significantly higher total score as well as a higher parent HRQL and family functioning subscore after intervention.

Parental stress level on the DASS scale was lower in the intervention arm as was state and trait anxiety. Likewise, parental sleep quality improved during intervention. Mean (±SD) CGM satisfaction score after intervention was 4.1 (±0.5), indicating high satisfaction.

Mean $HbA_{1c}$ was comparable after intervention and control, 7.8% (±0.8) (62 ± 9 mmol/mol) after each arm. SMBG frequency differed between intervention and control: 3.7 vs. 6.2 finger pricks per 24 h, respectively ($P < 0.001$). Mean CGM (±SD) sensor use was 74.8% (±11.9) over 3 months.

## CONCLUSIONS

This study demonstrated reduced parental fear of hypoglycemia when their child used CGM with remote monitoring. Along with this, there was also an improvement in family functioning as part of the PedsQL quality-of-life assessment with reduced parental stress and anxiety. Parental sleep quality improved. This is the first CGM study powered to assess psychosocial outcomes as a primary outcome. Previous pediatric studies that assessed fear of hypoglycemia, quality of life, and anxiety as a secondary outcome showed no significant reduction in these measures after CGM use compared with standard treatment (3,4). This may be related to the sensor technology and the lack of availability of remote monitoring at that time. The remote monitoring component of the Dexcom G5 Mobile system was not assessed separately, but it may have contributed to the improvement of the quality of life in caregivers as suggested in a survey of Nightscout users (15).

$HbA_{1c}$ was comparable after control and intervention. This could be attributed to the fact that there was no active effort to improve diabetes management

**Table 1—Quality-of-life outcomes at baseline and by study arm**

| Questionnaire (Parents $n$ = 49) | Component | Baseline | Control | | CGM | | | | |
|---|---|---|---|---|---|---|---|---|---|
| | | Mean ± SD | LSM | 95% CI | LSM | 95% CI | LSMD | 95% CI | $P$ value |
| Hypoglycemia Fear Survey | Total | 54.9 ± 14.7 | 53.2 | 49.0–57.4 | 44.7 | 40.5–48.9 | −8.5 | −12.7 to −4.4 | <0.001* |
| | Behavior | 24.3 ± 5.0 | 23.9 | 22.4–25.4 | 20.6 | 19.1–22.1 | −3.3 | −5.0 to −1.5 | <0.001* |
| | Worry | 30.6 ± 12.4 | 29.3 | 26.0–32.5 | 24.1 | 20.8–27.3 | −5.2 | −8.1 to −2.2 | <0.001* |
| PedsQL Generic | Total | 69.9 ± 18.8 | 73.9 | 69.5–78.2 | 76.4 | 72.0–80.8 | 2.6 | −0.9 to 6.1 | 0.150 |
| PedsQL Diabetes | Total | 63.7 ± 14.1 | 64.9 | 60.7–69.1 | 67.5 | 63.3–71.7 | 2.6 | −0.2 to 5.4 | 0.066 |
| PedsQL Family Impact | Total | 56.2 ± 18.6 | 59.0 | 53.8–64.3 | 64.7 | 59.4–69.9 | 5.6 | 2.1 to 9.1 | 0.002* |
| | Parent HRQL | 56.4 ± 20.6 | 59.2 | 53.5–65.0 | 66.0 | 60.3–71.8 | 6.8 | 2.3 to 11.4 | 0.003* |
| | Family functioning | 60.3 ± 21.0 | 61.5 | 55.9–67.2 | 67.1 | 61.5–72.8 | 5.6 | 1.7 to 9.5 | 0.005* |
| DASS | Stress | 12.4 ± 9.0 | 10.4 | 8.1–12.7 | 8.2 | 5.9–10.4 | −2.2 | −3.8 to −0.7 | 0.005* |
| | Anxiety | 5.9 ± 8.3 | 4.8 | 2.7–6.9 | 3.8 | 1.7–5.9 | −1.0 | −2.5 to 0.5 | 0.203 |
| | Depression | 6.1 ± 8.4 | 5.3 | 3.3–7.3 | 4.2 | 2.2–6.1 | −1.1 | −2.4 to 0.1 | 0.076 |
| STAI | State | 38.1 ± 11.7 | 38.1 | 34.8–41.3 | 34.5 | 31.2–37.7 | −3.6 | −6.4 to −0.7 | 0.014* |
| | Trait | 41.1 ± 9.9 | 41.7 | 38.8–44.5 | 38.2 | 35.3–41.1 | −3.5 | −5.4 to −1.6 | <0.001* |
| PSQI | Global | 7.7 ± 3.9 | 8.3 | 7.2–9.3 | 6.8 | 5.7–7.8 | −1.5 | −2.5 to −0.5 | 0.002* |

Baseline data are expressed as mean scores and SD. Postcontrol and post-CGM data scores are expressed as LSM and 95% CI. LSM differences (LSMD) and 95% CIs are derived from mixed models including period and sequence as fixed effects. PSQI, Pittsburgh Sleep Quality Index; STAI, State and Trait Anxiety Inventory. *$P < 0.05$ significant.

in this study group since the purpose of this trial was to determine the efficacy of the CGM system to improve quality-of-life metrics.

To conclude, CGM with remote monitoring reduces fear of hypoglycemia and improves other psychosocial metrics in parents of children with type 1 diabetes. Use of such systems has the potential to reduce the disease burden for those families.

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