Research Square

Preprints are preliminary reports that have not undergone peer review.
They should not be considered conclusive, used to inform clinical practice,
or referenced by the media as validated information.

Efect of Continuios Glucose Monitoring Management Type 1 Diabetes: Meta-Analysis

Ihellogim Isis da Costa Ferreira
Universidade Federal da Paraíba
Brunna Hellen Saraiva Costa
brunna.costa@academico.ufpb.br
Universidade Federal da Paraíba
Eduard Dutra Dantas
Universidade Federal da Paraíba
Morganna Maria de Lima Batista
Annanda Fernandes de Moura Bezerra Batista
Ludgleydson Fernandes de Araújo
Universidade Federal do Delta do Parnaíba
Patrícia Serpa de Souza Batista
Universidade Federal da Paraíba

Article

Keywords: Type 1 diabetes, continuous glucose monitoring, self-monitoring of blood glucose, hypoglycemia, HbA1c

Posted Date: September 8th, 2026

DOI: https://doi.org/10.21203/rs.3.rs-10539077/v1

License: This work is licensed under a Creative Commons Attribution 4.0 International License. Read Full License

Additional Declarations: No competing interests reported.

Abstract

Methods

A systematic review and meta-analysis of randomized controlled trials was conducted according to Cochrane and PRISMA 2020 recommendations. Electronic databases were searched through April 2025. Eligible studies compared CGM (real-time or intermittently scanned) with SMBG in individuals aged ≥ 13 years with T1DM. Outcomes of interest included HbA1c, time in range (TIR), glycemic variability, severe hypoglycemia, and adverse events.

Results

Six randomized controlled trials involving 888 participants were included. Compared with SMBG, CGM was associated with a non-significant reduction in severe hypoglycemia (RR = 0.38; 95% CI: 0.05 to 2.75) and HbA1c (MD = − 0.24%; 95% CI: − 0.72 to 0.23). No significant difference was observed in adverse events (RR = 1.12; 95% CI: 0.88 to 1.43; I^2 = 0%). CGM significantly increased TIR by 1.61 hours/day (95% CI: 0.62 to 2.60; I^2 = 28%) and reduced glycemic variability (MD = − 4.78%; 95% CI: − 7.45 to − 2.10; I^2 = 61%).

Conclusions

CGM is a safe and effective strategy for improving clinically relevant glycemic outcomes in adolescents and adults with T1DM. Although no statistically significant differences were observed for HbA1c reduction or severe hypoglycemia, CGM significantly improved time in range and reduced glycemic variability without increasing adverse events. These findings support the incorporation of complementary glycemic metrics beyond HbA1c in clinical decision-making.

INTRODUCTION

Type 1 diabetes mellitus (T1DM) is a chronic condition that requires intensive glycemic management and is associated with a high risk of acute and long-term complications. Achieving optimal glycemic control while minimizing the risk of hypoglycemia remains a major challenge in clinical practice, particularly among individuals requiring continuous insulin therapy [1, 2].Globally, diabetes affects approximately 589 million adults aged 20 to 79 years, with projections reaching 853 million by 2050, representing a substantial increase in disease burden. In 2024, diabetes was responsible for approximately 3.4 million deaths and generated healthcare expenditures exceeding one trillion US dollars [3].

Self-monitoring of blood glucose (SMBG) has long been the standard method for glucose monitoring due to its accessibility and ability to detect hypo- and hyperglycemia. However, it provides only intermittent measurements and may fail to capture glycemic variability and asymptomatic hypoglycemia, in addition to being influenced by technical and user-related factors [4]. In this context, continuous glucose monitoring (CGM) has emerged as an important technological advancement in T1DM management, enabling real-time assessment of glucose levels and trends.

Currently, CGM systems include real-time (rtCGM), which continuously transmits glucose readings and provides alerts, and intermittently scanned CGM (isCGM), which requires sensor scanning to access glucose data [5]. Evidence suggests that CGM may improve glycemic control, particularly by increasing time in range (TIR) and reducing hypoglycemia; however, results across studies remain inconsistent, especially regarding glycated hemoglobin (HbA1c) [6].

In addition, complementary glycemic metrics such as TIR and glycemic variability have gained increasing attention, as they provide a more comprehensive assessment of daily glucose patterns. Despite their clinical relevance, evidence from randomized controlled trials evaluating these outcomes remains limited and not fully consolidated. Furthermore, challenges related to adherence, including alarm fatigue and user-related barriers, may influence the effectiveness of CGM in real-world settings [7, 8, 9].

To address these gaps, we conducted a systematic review and meta-analysis of randomized controlled trials to evaluate the efficacy and safety of CGM (rtCGM and isCGM) compared with SMBG in individuals with T1DM aged ≥ 13 years, focusing on clinically relevant outcomes including HbA1c, time in range, glycemic variability, severe hypoglycemia, and adverse events.

METHODS

This systematic review and meta-analysis were conducted in accordance with the Cochrane Handbook for Systematic Reviews of Interventions and the Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) Statement [10, 11]. The study was registered in the International Prospective Register of Systematic Reviews (PROSPERO) under protocol number CRD420251029695. Institutional review board approval was not required, as only publicly available data from previously published studies were used.

Eligibility Criteria

There were no restrictions regarding publication date or status. Studies were eligible for inclusion if they met all of the following criteria: (1) randomized controlled trials (RCTs); (2) compared capillary glucose monitoring (SMBG) with continuous glucose monitoring (CGM); (3) included individuals aged ≥ 13 years; and (4) reported at least one of the outcomes of interest. Studies published only as abstracts or conference proceedings were excluded.

The outcomes of interest included severe hypoglycemia and adverse events.

Data Sources and Search Strategy

A systematic search was conducted in SCOPUS, PubMed, SciELO, Cochrane Library, Web of Science, and the Cochrane Central Register of Controlled Trials up to April 2025, including studies published in English. The following search terms were used across databases: “Diabetes Mellitus, Type 1”, “Type 1 Diabetes”, “T1D”, “Real-time Continuous Glucose Monitoring”, “SMBG”, “Capillary Glucose Monitoring”, combined with “randomized”, “randomly”, or “RCT”. The complete search strategies for each database are provided in Supplementary Material 02.

Additionally, the reference lists of included RCTs and relevant reviews were manually screened. Two authors (BHSC and EDD) independently extracted the data using predefined criteria and quality assessment methods. Disagreements were resolved by consensus with a third author (PSSB).

Quality Assessment

The risk of bias in individual studies was assessed using the Cochrane Risk of Bias tool for randomized trials (RoB 2) [12] .Each study was classified as low risk, high risk, or some concerns across five domains: bias arising from the randomization process, bias due to deviations from intended interventions, bias due to missing outcome data, bias in the measurement of outcomes, and bias in the selection of the reported result.

The assessment was performed independently by two reviewers (BHSC and EDD), with disagreements resolved by consensus involving a third reviewer (PSSB). Publication bias was assessed through visual inspection of funnel plots. According to Cochrane recommendations, Egger’s test was not performed due to the small number of included studies ($n < 10$). The certainty of evidence was evaluated using the GRADE approach.

Statistical Analysis

Risk ratios (RRs) with 95% confidence intervals (CIs) were calculated for binary outcomes to compare CGM and SMBG. Continuous outcomes were analyzed using weighted mean differences between groups.

Heterogeneity was assessed using Cochran’s Q test and the I^2 statistic. Outcomes were considered to have low heterogeneity when $P > 0.10$ and $I^2 < 25\%$. A fixed-effects model was applied in cases of low heterogeneity; otherwise, a random-effects model using the DerSimonian-Laird method was employed.

Sensitivity and Subgroup Analyses

A leave-one-out sensitivity analysis was performed for outcomes with at least four included studies, such as HbA1c and severe hypoglycemia. This approach involved sequentially removing one study at a time and recalculating the pooled effect. The results demonstrated that no single study significantly influenced the magnitude or statistical significance of the findings, supporting the robustness of the results.

Subgroup analyses were conducted for primary outcomes (HbA1c and Time in Range) based on age groups: adolescents and young adults (up to 24 years) versus adults and older adults (over 25 years). As shown in Fig. 3, the beneficial effects of CGM were consistent across these

subgroups, with no significant differences in efficacy between age categories (P for subgroup differences > 0.05). Due to the limited number of studies, further formal subgroup analyses according to CGM modality (rtCGM vs. isCGM) or duration of use were not feasible.

RESULTS

Study Selection and Characterist

The initial search strategy identified 1,359 records. After removing duplicates and screening titles and abstracts, 19 articles were assessed in full text. Of these, six randomized controlled trials were included, comprising a total of 888 participants *(Figure 1)*.

The included studies encompassed a heterogeneous population ranging from adolescents to older adults. Boucher [13] and Laffel [14] focused on younger populations, with mean ages of 16.5 and 18.8 years, respectively, whereas Pratley [15] included older adults with a mean age of 68 years. The remaining studies included predominantly adult populations.

Sex distribution was overall balanced, with a slight male predominance in some studies [13,14,15], while others [16,17,18] included a higher proportion of women. Sample sizes ranged from 64 to 203 participants.

The list of articles assessed and reasons for exclusion is provided in Supplementary Material 02.

Pooled Analyses

Pooled analyses demonstrated that CGM was associated with a reduction in severe hypoglycemia compared with SMBG; however, this effect was not statistically significant (RR = 0.38; 95% CI: 0.05 to 2.75).

No significant difference was observed in adverse events between groups (RR = 1.12; 95% CI: 0.88 to 1.43; I^2 = 0%), indicating that CGM was not associated with an increased risk of adverse events.

Regarding HbA1c, CGM was associated with a non-significant reduction compared with SMBG (MD = –0.24%; 95% CI: –0.72 to 0.23; I^2 = 72%).

CGM significantly increased time in range (TIR), with a mean difference of +1.61 hours/day (95% CI: 0.62 to 2.60; I^2 = 28%). In addition, CGM significantly reduced glycemic variability, as measured by the coefficient of variation (MD = –4.78%; 95% CI: –7.45 to –2.10; I^2 = 61%).

A summary of the main findings is presented in Table 2.

Sensitivity Analysis

A leave-one-out sensitivity analysis was performed for outcomes including at least four studies.

For HbA1c, exclusion of individual studies did not change the direction of the effect. However, removal of the study by Heinemann [18] reduced heterogeneity from 72% to 31% and increased the magnitude of the effect (MD = –0.36%; 95% CI: –0.80 to 0.09), although the result remained not statistically significant.

For severe hypoglycemia, exclusion of the study by Heinemann [18] slightly attenuated the effect size (RR = 0.35); however, the result remained not statistically significant.

Overall, the sensitivity analysis suggested that the results were consistent in direction and not driven by a single study.

Subgroup Analysis by Age Group

Subgroup analyses were performed to evaluate the impact of age on the primary outcomes of HbA1c and Time in Range (TIR), categorizing participants into adolescents/young adults and adults/older adults (Figure 3).

Regarding HbA1c, a consistent reduction was observed across both subgroups, with a mean difference (MD) of –0.43% (95% CI: –2.05 to 1.19) in adolescents and young adults, and –0.34% (95% CI: –0.64 to –0.04) in adults and older adults (Figure 3A). The test for subgroup differences indicated no significant variation between these groups (P = 0.57; $I² = 0), suggesting that CGM effectiveness in lowering HbA1c is stable across different age ranges.

For Time in Range (TIR), CGM significantly increased hours per day in range for both subgroups, with a mean gain of 1.92 hours/day (95% CI: 0.84 to 3.00) in the younger population and 1.63 hours/day (95% CI: 0.72 to 2.53) in the adult and older adult population (Figure 3B). There

were no statistically significant differences between age-based subgroups (P = 0.64; I^2 = 0), reinforcing the technology's consistent benefit in improving daily glycemic control regardless of the patient's age.

Handling of Outcome Measures and Study Designs

For time in range (TIR), studies reported outcomes using different units, including percentage (%) and minutes per day. To ensure comparability across studies, TIR values reported in minutes per day were converted to hours per day by dividing by 60. Studies reporting TIR as percentage were not directly pooled with those reporting absolute time-based units. Therefore, only studies reporting TIR in comparable units were included in the same meta-analysis, and no standardized mean differences were calculated due to the clinical interpretability of absolute measures.

Regarding glycemic variability, only studies reporting the coefficient of variation (%CV) were included in the quantitative synthesis to maintain consistency in outcome definition. Studies reporting variability using other metrics, such as standard deviation (mg/dL) or MAGE, were not pooled due to differences in measurement scales.

For crossover trials, such as the study by Lind (GOLD) [17], data were extracted from the analysis phase corresponding to each intervention period. When paired data or within-participant correlations were not reported, the study was treated conservatively as a parallel-group design, using aggregated summary statistics, in accordance with Cochrane recommendations. This approach may underestimate the precision of the effect estimate but avoids unit-of-analysis errors.

Risk of Bias

The risk of bias for the six included randomized controlled trials was assessed using the Cochrane RoB 2 tool. Overall, the studies demonstrated a low to moderate risk of bias.

All included studies were rated as low risk for the randomization process, as they employed appropriate sequence generation and allocation concealment methods. Due to the nature of the intervention, blinding of participants and personnel was not feasible. However, most studies used intention-to-treat analysis, minimizing the potential impact of deviations from intended interventions.

Missing outcome data were generally low and balanced between the CGM and SMBG groups. Although lack of blinding could theoretically affect subjective outcomes, the primary endpoints, including HbA1c and sensor-derived metrics, are objective laboratory or device-generated data, reducing the likelihood of detection bias.

No evidence of selective reporting was identified, as the reported outcomes were consistent with pre-registered protocols. Visual inspection of the funnel plot for HbA1c suggested a symmetrical distribution of studies, although the small number of trials limits the definitive interpretation of publication bias.

DISCUSSION

Achieving optimal glycemic control while minimizing the risk of hypoglycemia remains a major challenge in the management of individuals with type 1 diabetes, particularly among those requiring intensive insulin therapy. Not surprisingly, there is considerable variability in how glucose monitoring strategies are implemented in clinical practice, especially regarding the use of continuous glucose monitoring (CGM) versus self-monitoring of blood glucose (SMBG).

Our meta-analysis, including six randomized controlled trials and a total of 888 participants, revealed several important findings regarding the efficacy and safety of CGM in this population. First, CGM was associated with a reduction in severe hypoglycemia compared with SMBG; however, this effect did not reach statistical significance. Second, CGM significantly improved time in range (TIR) and reduced glycemic variability, as measured by the coefficient of variation. Third, no statistically significant differences were observed in adverse events between CGM and SMBG. Finally, although CGM was associated with a reduction in HbA1c, this effect was not statistically significant in the primary pooled analysis.

Given the well-established clinical burden associated with severe hypoglycemia, including seizures, loss of consciousness, increased hospitalization rates, reduced quality of life, and risk of sudden death, even non-significant reductions may be clinically relevant. The direction of effect observed in our analysis is consistent with findings from major clinical trials, such as the DIAMOND [16] and CITY [14] studies, supporting the potential benefit of CGM in mitigating hypoglycemic risk and improving metabolic stability across different delivery methods.

Optimizing glycemic control beyond HbA1c has become increasingly relevant in contemporary diabetes care. In this context, TIR has emerged as a clinically meaningful metric, as it reflects daily glycemic exposure more accurately than isolated laboratory measures, as endorsed by the

International Consensus on Time in Range [19]. The significant improvement in TIR observed in our study, with an increase of approximately 1.6 to 1.7 hours per day, suggests that CGM may enhance real-time glucose management and facilitate more effective therapeutic adjustments to reach the recommended target of > 70% time in range.

Furthermore, our subgroup analysis (Fig. 3) demonstrated that these improvements were consistent across different age groups, showing that both adolescents and adults benefit equally from CGM technology, with no significant differences between these populations ($P > 0.05$). This finding is particularly relevant as it aligns with the results of the CITY trial [14], which specifically highlighted the transformative impact of CGM in adolescents and young adults, a group traditionally associated with lower adherence and higher glycemic variability.

Similarly, glycemic variability has gained attention as an independent marker of metabolic instability, being associated with oxidative stress and vascular complications. The significant reduction in glycemic variability observed with CGM (mean difference of − 4.78% in the coefficient of variation) reinforces its role in promoting more stable glycemic profiles, even in the absence of significant changes in HbA1c.

The absence of statistically significant differences in HbA1c should be interpreted with caution. Potential explanations include the relatively small number of included studies (n = 6), the limited sample size (n = 888 participants), and the heterogeneity across study populations. In particular, the inclusion of individuals at high risk of hypoglycemia, rather than those with poor baseline glycemic control, may attenuate the magnitude of HbA1c reduction. Additionally, the high heterogeneity observed ($I^2 = 72\%$) suggests variability in study design, participant characteristics, and adherence to CGM use.

Importantly, CGM was not associated with an increased risk of adverse events, supporting its overall safety profile. This finding may also reflect the relatively short duration of follow-up and the low incidence of adverse events across studies, as well as potential differences in outcome definitions.

Sensitivity analyses further support the robustness of our findings. Although the exclusion of individual studies reduced heterogeneity and slightly modified effect estimates, the overall direction of the results remained consistent, suggesting that the findings were not driven by a single study.

Despite the demonstrated benefits, the implementation of CGM in real-world settings remains challenging. Factors such as alarm fatigue, local discomfort at the insertion site, and the need for periodic sensor replacement may impact user experience and long-term adherence. In addition, behavioral, organizational, and psychosocial barriers have been described, particularly among adolescents and young adults, in whom adherence tends to be more variable.

Our findings are consistent with current recommendations from the American Diabetes Association [20] and the Brazilian Diabetes Society [4], which endorse CGM as a standard of care for individuals undergoing intensive insulin therapy, regardless of age, to optimize TIR and safety.

Therefore, while CGM demonstrates clear advantages in improving clinically relevant glycemic metrics, its long-term effectiveness depends not only on technological performance but also on sustained user engagement. In this context, strategies aimed at improving access, education, and adherence are essential to maximize the benefits of CGM in routine clinical practice.

CONCLUSION

These findings suggest that, in individuals with type 1 diabetes aged ≥13 years, the use of CGM is safe and may be beneficial in improving clinically relevant glycemic outcomes, particularly time in range and glycemic variability, compared with SMBG. Although no statistically significant differences were observed in HbA1c reduction or adverse events, CGM demonstrated consistent advantages in metrics reflecting daily glycemic control.

In addition, CGM was associated with a reduction in the risk of severe hypoglycemia, although this finding did not reach statistical significance. These results highlight the importance of incorporating complementary glycemic metrics beyond HbA1c in clinical decision-making.

Overall, these findings may inform clinical practice and support shared decision-making in the selection of glucose monitoring strategies for individuals with type 1 diabetes. Further studies are needed to better define the impact of CGM according to patient characteristics, device modality, and long-term adherence.

LIMITATIONS

This study has important limitations. First, the relatively small number of included randomized controlled trials (n = 6) and the limited sample size (n = 888 participants) restricted the ability to perform more detailed subgroup analyses and may have reduced the statistical power to

detect differences in some outcomes.

Second, there were variations in outcome definitions and measurement approaches across studies, including differences in CGM devices, duration of use, and criteria for defining hypoglycemia, which may have contributed to heterogeneity.

Third, differences in reporting formats for outcomes such as time in range (TIR) and glycemic variability limited the inclusion of all studies in pooled analyses. To address this issue, only studies reporting comparable units were included in each analysis, although this approach may have reduced the overall sample available for specific outcomes.

Fourth, the inclusion of crossover trials required conservative analytical assumptions when within-participant correlations were not reported, which may have underestimated the precision of effect estimates.

Finally, it was not possible to perform separate analyses according to CGM modality (rtCGM vs. isCGM), due to insufficient data, which may limit the applicability of the findings to specific clinical contexts.

Declarations

CONTRIBUTIONS

IICF and BHSC conceived and designed the study. IICF and PSSB performed the study screening. BHSC and EDD conducted the statistical analysis. IICF and BHSC proposed the study idea and registered the protocol in PROSPERO. BHSC wrote the first draft of the manuscript and was responsible for the statistical analysis and overall revisions. MMLB contributed to the writing of specific sections of the manuscript. AB contributed to the revision and translation of the manuscript. All authors interpreted the data, critically revised the manuscript for important intellectual content, and approved the final version of the manuscript.

Disclosures

The authors declare no conflicts of interest.

Funding Statement

This study was financed in part by the Coordenação de Aperfeiçoamento de pessoal de Nível Superior – Brasil (CAPES) – Finance code 001

Data Availability Statement

All data generated or analyzed during this study are included in this published article and its supplementary materials.

References

1. Almeida, A. M. et al. Diabetes mellitus tipo 1: uma revisão de literatura. *Brazilian J. Health Biol. Sci.* **v. 1** (n. 1), 1–18 (2024). [S. l.].
2. Rodacki, M. et al. Diagnóstico de diabetes mellitus. Diretriz Oficial da Sociedade Brasileira de Diabetes – 2024. São Paulo: Sociedade Brasileira de Diabetes, 2024. https://doi.org/10.29327/5412848.2024-1. ISBN 978-65-272-0704-7.
3. International diabetes federation. IDF Diabetes Atlas. Brussels, Belgium: International Diabetes Federation, 2024. Disponível em: (2024). https://diabetesatlas.org/. Acesso em: [23 mar. 2026].
4. Sociedade brasileira de diabetes. Diretrizes da Sociedade Brasileira de Diabetes: 2024–2025. São Paulo: Clannad, 2024. Disponível em: Acesso em: 2 maio (2025). https://diretriz.diabetes.org.br/
5. Elbalshy, M. et al. Effect of divergent continuous glucose monitoring technologies on glycaemic control in type 1 diabetes mellitus: a systematic review and meta-analysis of randomised controlled trials. *Diabet. Med.* e14854. https://doi.org/10.1111/dme.14854 (2022). [S. l.], v. 39, n. 11.
6. Hohendorff, J. et al. Impact of the initiation of isCGM soon after type 1 diabetes mellitus diagnosis in adults on glycemic indices and fear of hypoglycemia: a randomized controlled trial. *Front. Endocrinol. Lausanne* v. **15**, 1503891. https://doi.org/10.3389/fendo.2024.1503891 (2025).
7. Giani, E., Snelgrove, R., Volkening, L. & Laffel, L. Continuous glucose monitoring (CGM) adherence in youth with type 1 diabetes: associations with biomedical and psychosocial variables. Journal of Diabetes Science and Technology, Thousand Oaks, v. 11, n. 3, pp. 476–483, (2017). https://doi.org/10.1177/1932296816676280
8. Farfel, A., Liberman, A., Yackobovitch-Gavan, M., Phillip, M. & Nimri, R. Executive functions and adherence to continuous glucose monitoring in children and adolescents with type 1 diabetes. Diabetes Technology & Therapeutics, New Rochelle, v. 22, n. 4, pp. 265–270,

(2020). https://doi.org/10.1089/dia.2019.0341

9. Mastrototaro, J., Welsh, J. & Lee, S. Practical Considerations in the Use of Real-Time Continuous Glucose Monitoring Alerts. Journal of Diabetes Science and Technology, v. 4, n. 3, pp. 733–739, (2010). https://doi.org/10.1177/193229681000400326
10. Page, M. et al. A declaração PRISMA 2020: uma diretriz atualizada para relatar revisões sistemáticas. *BMJ*, [S. l.], v. 372, n. 71, 2021. https://doi.org/10.1136/bmj.n71
11. Sterne, J. et al. *RoB 2: uma ferramenta revisada para avaliar o risco de viés em ensaios clínicos randomizados* (BMJ,, 2019). [S. l.], v. 366, n. l4898https://doi.org/10.1136/bmj.l4898
12. Higgins, J. et al. Ferramenta da Colaboração Cochrane para avaliar risco de viés em ensaios clínicos randomizados. *BMJ* **v. 343**, d5928. https://doi.org/10.1136/bmj.d5928 (2011). [S. l.].
13. Boucher, S. et al. Effect of 6 months of flash glucose monitoring in youth with type 1 diabetes and high-risk glycemic control: a randomized controlled trial. *Diabetes Care Arlingt. v*. **43** (n. 10), 2388–2395. https://doi.org/10.2337/dc20-0613 (2020).
14. Laffel, L. et al. Effect of continuous glucose monitoring on glycemic control in adolescents and young adults with type 1 diabetes: a randomized clinical trial. JAMA, Chicago, v. 323, n. 23, pp. 2388–2396, (2020). https://doi.org/10.1001/jama.2020.6940
15. Pratley, R. et al. Effect of continuous glucose monitoring on hypoglycemia in older adults with type 1 diabetes: a randomized clinical trial. JAMA, Chicago, v. 323, n. 23, pp. 2397–2406, (2020). https://doi.org/10.1001/jama.2020.6928
16. Beck, R. et al. Effect of continuous glucose monitoring on glycemic control in adults with type 1 diabetes using insulin injections: the DIAMOND randomized clinical trial. JAMA, Chicago, v. 317, n. 4, pp. 371–378, (2017). https://doi.org/10.1001/jama.2016.19975
17. Marcus, L. et al. Continuous glucose monitoring vs conventional therapy for glycemic control in adults with type 1 diabetes treated with multiple daily insulin injections: the GOLD randomized clinical trial. JAMA, Chicago, v. 317, n. 4, pp. 379–387, (2017). https://doi.org/10.1001/jama.2016.19976
18. Heinemann, L. et al. Real-time continuous glucose monitoring in adults with type 1 diabetes and impaired hypoglycaemia awareness or severe hypoglycaemia treated with multiple daily insulin injections (HypoDE): a multicentre, randomised controlled trial. The Lancet, [S. l.], publ. online, 16 fev. (2018). https://doi.org/10.1016/S0140-6736(18)30297-6
19. Battelino, T., Dovc, K. & Bode, B. Continuous and Intermittent Glucose Monitoring in 2019. Diabetes Technology & Therapeutics. fevereiro de 2020;22(1_suppl). 10.1089/dia.2020.2501
20. American diabetes association. Standards of care in diabetes—2024. Diabetes Care, v. 47, supl. 1, pp. S1–S350. Disponível em: (2024). https://diabetesjournals.org/care/article/47/Supplement_1/S126/153939/7-Diabetes-Technology-Standards-of-Care-in. Acesso em: 2 maio 2025.

Tables

Table 1. Baseline characteristics of included randomized controlled trials.
The table summarizes demographic and clinical characteristics of the study populations, including sample size, intervention groups, sex distribution, and mean age.

Study (Year)	Study Design	Sample Size (CGM / SMBG)	Location	CGM Use	Outcome Focus	Population	Key Results (CGM Group)	Comparison Group
Lind et al., 2017 (GOLD)	Crossover RCT	161 / 161*	Sweden	Yes	Glycemic control, TIR	Adults with T1D	HbA1c: –0.43%; TIR: +1.7 h/day; Hypoglycemia: –0.9 h/day; CV: 36.6%	SMBG; CV: 39.6%
Beck et al., 2017 (DIAMOND)	RCT	105 / 53	USA	Yes	Glycemic control	Adults with T1D on MDI	HbA1c: –0.6%; TIR: +1.3 h/day; Hypoglycemia: –0.8 h/day; CV: 37%	SMBG; CV: 39%
Heinemann et al., 2018 (HypoDE)	RCT	75 / 74	Germany	Yes	Severe hypoglycemia	Adults with T1D at high hypoglycemia risk	Severe hypoglycemia: 3 vs 18; TIR: +1.3 h/day; CV: 36.2%	SMBG; CV: 39.1%
Pratley et al., 2020	RCT	103 / 100	Not reported	Yes	Glycemic control, hypo/hyperglycemia	Older adults with T1D	HbA1c: –0.3%; TIR: +2.1 h/day; Severe hypoglycemia: 0.5 events/person-year; CV: 37.2%	SMBG; HbA1c: stable; CV: 40.1%
Boucher et al., 2020	RCT	33 / 31	Not reported	Yes	Hyperglycemia and DKA	Adolescents/young adults with T1D	HbA1c: –0.4%; 1 DKA vs 3	SMBG
Laffel et al., 2020 (CITY)	RCT	74 / 79	USA	Yes	Glycemic control, quality of life	Adolescents/young adults with T1D	HbA1c: –0.37%; TIR: +1.7 h/day; PAID: –2.5; GMSS: +6.8; CV: 37.6%	SMBG; CV: 40.3%

Abbreviations: CGM, continuous glucose monitoring; rtCGM, real-time continuous glucose monitoring; isCGM, intermittently scanned continuous glucose monitoring; SMBG, self-monitoring of blood glucose; RCT, randomized controlled trial.
**Participants received both interventions during different study periods.*

Table 2. Clinical characteristics and main findings of included studies.

Outcomes	No. of Studies (Participants)	Effect Estimate (95% CI)
Severe hypoglycemia	6 RCTs (888 participants)	RR = 0.38 (0.14 to 0.56)
HbA1c	6 RCTs (888 participants)	MD = –0.24% (–0.72 to 0.23)
Time in range (TIR)	5 RCTs (413 participants)	+1.7 hours/day (1.1 to 2.3)
Glycemic variability	4 RCTs (350 participants)	Reduction of 1.5% to 2.7% (estimated)

The table presents study settings, populations, outcomes assessed, and key results for the CGM groups compared with SMBG.
Abbreviations: *CGM, continuous glucose monitoring; SMBG, self-monitoring of blood glucose; TIR, time in range; CV, coefficient of variation; QoL, quality of life; DKA, diabetic ketoacidosis.*

Table 3. Summary of findings (GRADE): CGM versus SMBG in individuals with type 1 diabetes mellitus aged ≥13 years.

Outcomes	No. of Studies (Participants)	Effect Estimate (95% CI)
Severe hypoglycemia	6 RCTs (888 participants)	RR = 0.38 (0.14 to 0.56)
HbA1c	6 RCTs (888 participants)	MD = −0.24% (−0.72 to 0.23)
Time in range (TIR)	5 RCTs (413 participants)	+1.7 hours/day (1.1 to 2.3)
Glycemic variability	4 RCTs (350 participants)	Reduction of 1.5% to 2.7% (estimated)

Summary of pooled effect estimates for efficacy and safety outcomes comparing CGM and SMBG.
Abbreviations: CGM, continuous glucose monitoring; SMBG, self-monitoring of blood glucose; RR, risk ratio; MD, mean difference; CI, confidence interval; TIR, time in range.

Figures

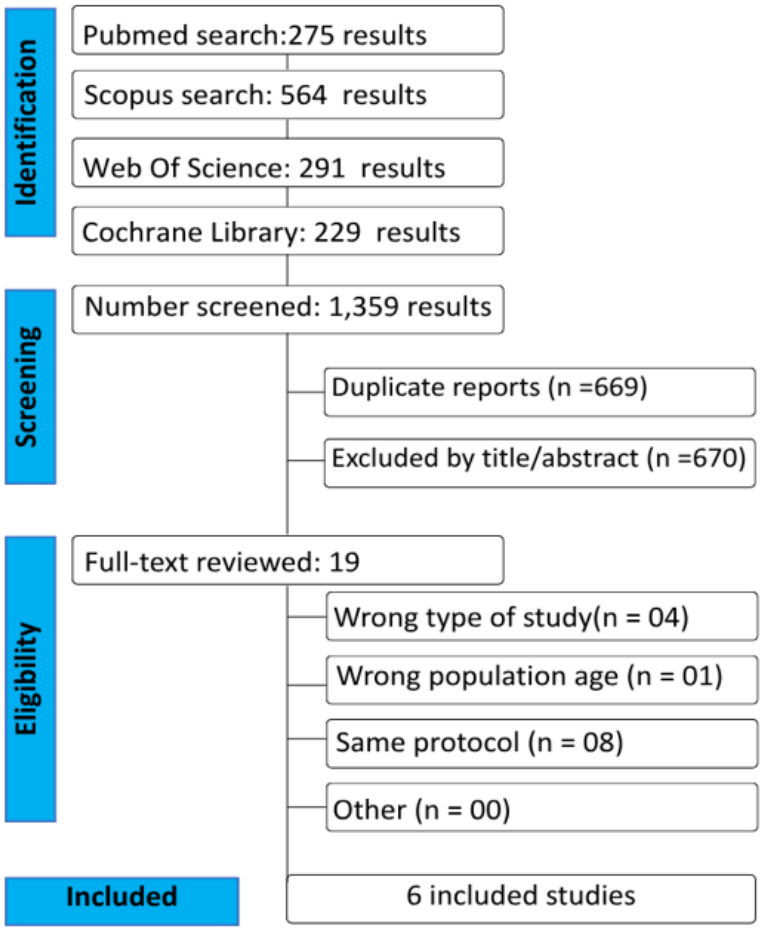
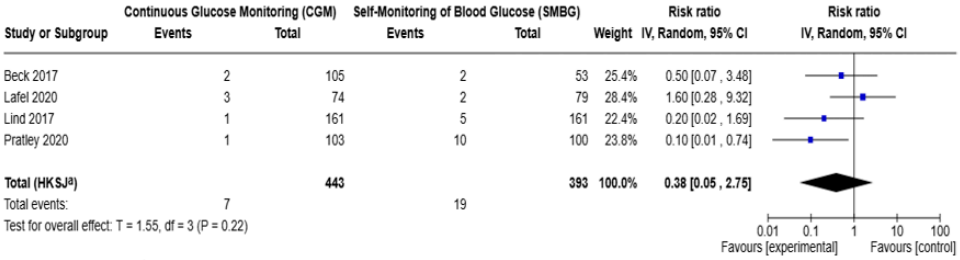
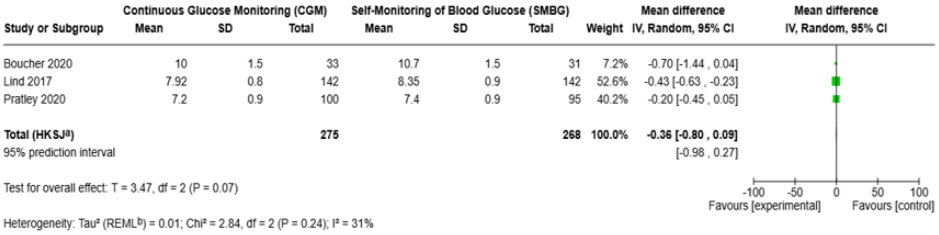
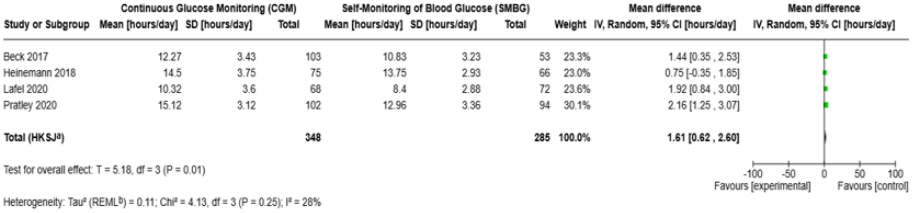


Figure 1

PRISMA flow diagram of study screening and selection.
Abbreviations: CGM, continuous glucose monitoring; SMBG, self-monitoring of blood glucose; PRISMA, Preferred Reporting Items for Systematic Reviews and Meta-Analyses.







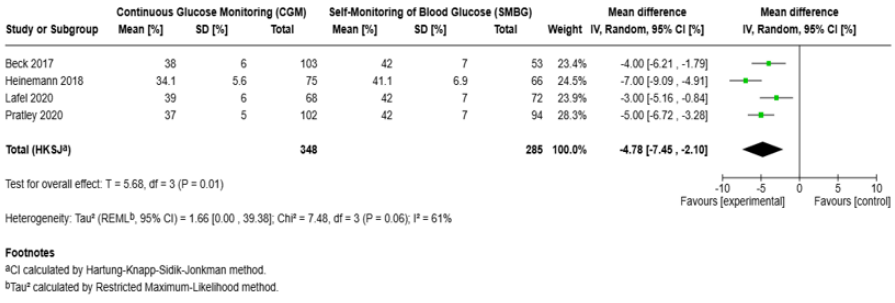
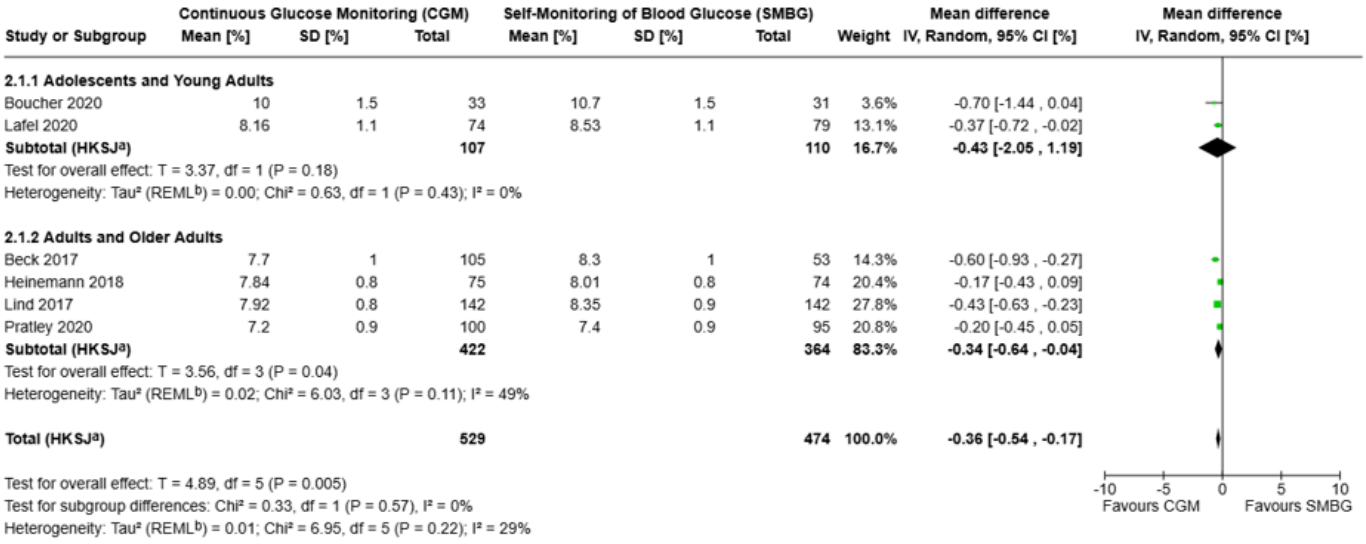


Figure 2

Forest plots comparing continuous glucose monitoring (CGM) and self-monitoring of blood glucose (SMBG) across clinical outcomes. Pooled effect estimates were generated using RevMan (Review Manager) software. (A) Severe hypoglycemia (Risk Ratio); (B) HbA1c (Mean Difference); (C) Time in range in hours/day (Mean Difference); (D) Glycemic variability as %CV (Mean Difference). Forest plots present individual study weights and pooled effect estimates with corresponding 95% confidence intervals calculated via random-effects models.

Abbreviations: CGM, continuous glucose monitoring; SMBG, self-monitoring of blood glucose; RR, risk ratio; MD, mean difference; CI, confidence interval; TIR, time in range; CV, coefficient of variation.



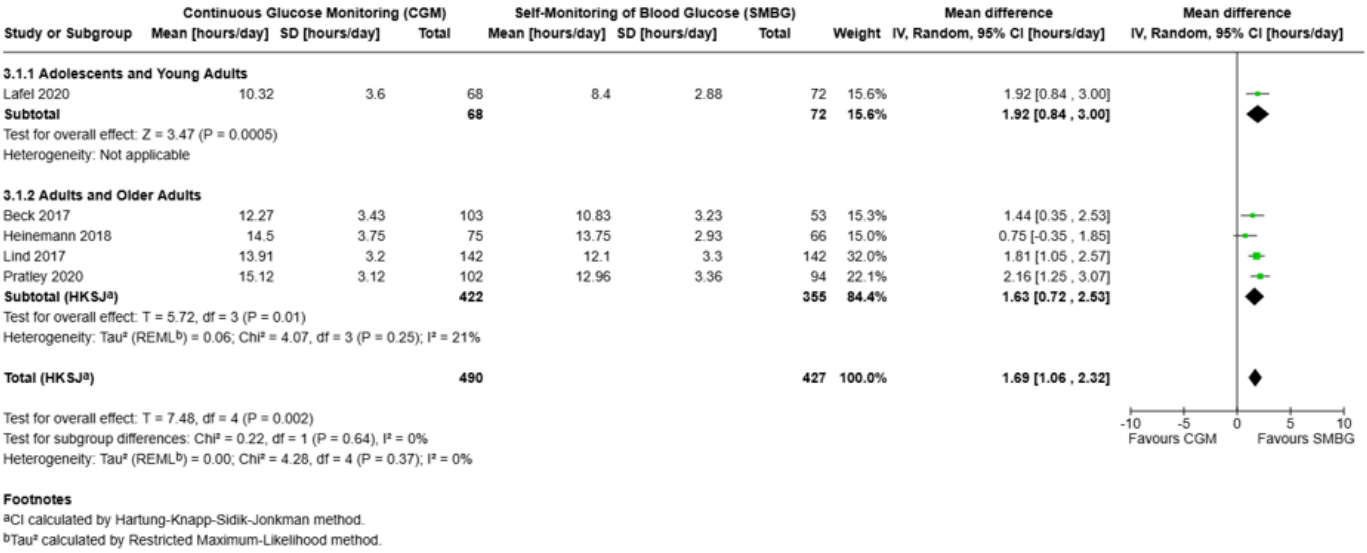


Figure 3

Forest plots comparing continuous glucose monitoring (CGM) and self-monitoring of blood glucose (SMBG) across clinical outcomes. Pooled effect estimates were generated using RevMan (Review Manager) software. (A) HbA1c (Mean Difference); (B) Time in range in hours/day (Mean Difference). Forest plots present individual study weights and pooled effect estimates with corresponding 95% confidence intervals calculated via random-effects models.

(A) HbA1c (%): The meta-analysis shows a significant overall reduction in HbA1c favoring the CGM group (MD: -0.36%; 95% CI: -0.54 to -0.17; $P = 0.005$). Subgroup analysis indicates a consistent benefit across age groups, with a -0.43% reduction in adolescents/young adults and a -0.34% reduction in adults/older adults (P for subgroup differences = 0.57).

(B) Time in Range (hours/day): CGM use significantly increased the time spent in range by an average of 1.69 hours per day (95% CI: 1.06 to 2.32; P = 0.002). The effect was consistent across subgroups (P for subgroup differences = 0.64), demonstrating the technology's effectiveness in both young and older populations.

Abbreviations: CGM, continuous glucose monitoring; SMBG, self-monitoring of blood glucose; MD, mean difference; CI, confidence interval; TIR, time in range; HbA1c, glycated hemoglobin.