

Diabetes Management with Wearable Continuous Glucose Monitoring Trackers: A Systematic Review and Meta-Analysis of Randomized, Controlled Trials

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ABSTRACT

Introduction: Continuous glucose monitoring (CGM) has become an essential tool in diabetes management as it provides real-time information on blood glucose levels. Present study summarizes current evidence on the clinical outcomes, glycemic control, and patient-reported outcomes of CGM compared to non-CGM strategies among the included studies with diabetes.

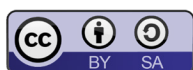
Methods: The systematic review was performed following the PRISMA guidelines. PubMed, Google Scholar, JAMA Network, and SpringerLink, etc. were searched for relevant research published after 2010. Included research assessed the use of CGM with non-CGM treatments, such as traditional therapy or self-monitoring of blood glucose (SMBG) for diabetics. The study's design, participant characteristics, intervention specifics, glycemic outcomes (i.e. HbA1c and duration in range), and quality of life were all included in the extracted data.

Results: Twelve studies (1916 subjects) based on randomized controlled trials and satisfied the inclusion criteria. Findings show that using a CGM is linked to notable improvements in glycemic control, as evidenced by falls in HbA1c readings when compared to non-CGM approaches. The studies had adequate heterogeneity: $I^2 = 32\%$, $\text{Chi}^2 = 16.08$, and $\text{Tau}^2 = 0.00$. An impact was found in the overall effect using a random effects model, with weighted mean difference (WMD) = 0.43; CI: 0.34-0.52 ($p < 0.001$). To evaluate the cause of heterogeneity and publication bias, meta-regression and Egger's regression were used.

Conclusion: This study highlights the potential of CGM devices to enhance diabetes management by improving glycemic control and patient outcomes. Despite several obstacles, CGM shows promise as a substitute for conventional diabetes treatment approaches. Future studies should address these issues and assess the long-term advantages of using a CGM in more detail. This study is registered in PROSPERO (Registration ID: CRD42024518635).

Key words: Diabetes management; Continuous glucose monitoring (CGM); Glycemic control; HbA1c; Systematic review; Meta-analysis

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INTRODUCTION

Diabetes management poses a significant challenge for millions globally, necessitating constant blood glucose control to prevent severe complications such as stroke, blindness, and heart disease. Continuous glucose monitoring (CGM) has emerged as a transformative technology in this realm, providing real-time data on blood glucose levels.^{1,2} By offering continuous feedback, CGM devices enable proactive diabetes management, helping individuals make informed decisions regarding insulin intake, meal planning, and lifestyle choices. Adoption of CGM in patients with diabetes mellitus has expanded rapidly in the past decade. With this rapid growth in CGM use, the advanced technologies and treatments for diabetes consensus summarized standardized CGM metrics, including time in range (TIR) and glycemic variability, and specified their target values for clinical care.³ CGM devices, which provide real-time data on blood glucose levels, offer a proactive approach to managing diabetes, enabling individuals to make informed decisions regarding insulin intake, meal planning, and lifestyle choices.

For individuals with diabetes, glucose management based on blood glucose meter (BGM) testing has been shown to be effective, but self-monitoring with self-titration of insulin is often underutilized in routine practice.⁴ Real-time CGM, by providing continuous glucose measurements, low and high glucose alerts, and glucose trend information, has the potential to better inform diabetes management decisions compared with episodic self-monitoring with a BGM.^{2,4} Real-time continuous glucose monitoring (RT-CGM) provides a wealth of information about the effects of food, exercise, and other lifestyle events on glucose levels. This information can provide feedback to the patient and assist in making salutary modifications to their behaviors, leading to short-term improvements in overall glycemic control that may be sustained in the long term.⁵

The focus of the present study is to investigate whether the use of CGM devices leads to a significant decrease in HbA1c levels, a key indicator of long-term glucose control, in individuals with diabetic patients. By including randomized controlled trials (RCTs) and controlled studies, this review analysis provides a comprehensive analysis of the efficacy and usability of CGMs across diverse patient demographics.

As per the literature research has highlighted the critical role of CGM in improving glycemic control and reducing the risk of diabetes-related complications.^{6,7} However, there remains a need for a systematic evaluation of these devices' effectiveness in lowering HbA1c levels. This meta-analysis aims to fill this gap by synthesizing data from studies published from Jan, 2010 to Dec, 2023, offering valuable insights into the impact of CGMs in diabetes management.

METHODS

We adhered to the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) standards guidelines when performing this analysis.⁸⁻¹⁰ These guidelines are intended to guarantee completeness, clarity, and transparency in the reporting of meta-analyses and systematic reviews.

We sought to offer a comprehensive and trustworthy synthesis of the existing data on the benefits of CGM devices in the management of diabetes by following PRISMA.

Literature Search

We conducted a comprehensive search using the following electronic databases: PubMed, Google Scholar, JAMA Network, and SpringerLink. The search covered studies published from Jan, 2010 to Dec, 2023 and included. Present study search strategy focused on studies involving diabetes and the use of wearable technology for continuous glucose monitoring. Specifically, we looked for studies that compared various wearable electronic devices, portable equipment, and continuous CGM in the context of tracking glucose levels. The search included the following keywords and MeSH terms: (("diabetes" OR "Diabetes Mellitus"[MeSH]) AND ("wearable" OR "Wearable Electronic Devices"[MeSH] OR "portable" OR "portable equipment" OR "wearable technology") AND ("continuous glucose monitoring" OR "CGM" OR "Continuous Glucose Monitoring Systems"[MeSH] OR "glucose monitoring" OR "glycemic monitoring") AND ("trackers" OR "tracking devices" OR "Monitoring, Ambulatory"[MeSH]) AND ("comparison" OR "comparative study" OR "comparison study")). By employing this search strategy, we aimed to gather a comprehensive collection of studies that evaluated and compared different wearable and portable glucose monitoring technologies for diabetes management.

Inclusion Criteria

To ensure a comprehensive review, studies included in this meta-analysis met several specific inclusion criteria. All types of studies were considered, provided they were conducted exclusively on human participants diagnosed with diabetes. The primary focus of these studies needed to be on the effectiveness, usability, or impact of CGM devices on diabetes management outcomes. Eligible studies that were required to be published in peer-reviewed journals were included to facilitate accurate data extraction and analysis.

Population

Studies included individuals diagnosed with diabetes, regardless of age.

Intervention

The studies encompassed randomized, controlled trials, focusing on the effectiveness, usability, or impact of CGM devices on diabetes management outcomes.

Comparison

Comparisons were made between individuals using CGM devices and those that do not use CGM and use other traditional methods.

Outcome

The primary outcome measured was the impact of CGM devices on the reduction of HbA1c levels, a key indicator of long-term glucose control. Key outcomes measured in the studies included long-term glucose control (HbA1c levels), glycemic variability, time in range (TIR), incidence of hypoglycemia and hyperglycemia, and overall health status. The effectiveness of CGM devices in improving diabetes management, reducing complications, and enhancing quality of life for individuals with diabetes was the primary focus in most of these studies.

Exclusion Criteria

Studies were excluded if they did not meet specific criteria to maintain the relevance and quality of the outcome. Specifically, studies conducted on animals rather than humans were excluded to ensure the focus remained on human diabetes management. Additionally, studies lacking relevant outcome measures or the necessary data for the review were also excluded. Furthermore, studies that did not investigate the effectiveness of wearable CGM devices on diabetes management were disqualified. Studies on animal and rodents, case reports/case studies, editorials, commentaries/viewpoints/opinion, conference abstracts, and rapid/scoping reviews were excluded.

Data Extraction and Quality Assessment

The data extraction process began with an initial screening of titles, abstracts, and full texts of articles to identify potentially relevant studies, following PRISMA guidelines. Studies that explicitly discussed the use of wearable trackers, including CGMs, for diabetes management were selected for further evaluation. Articles meeting the initial screening criteria were then subjected to a detailed full-text evaluation, examining their objectives, methods, participants, and results related to diabetes management outcomes. Any studies that did not meet the eligibility criteria upon full-text examination were excluded, with documented reasons for each exclusion.

Data from the selected articles were extracted using a predefined template, capturing quantitative data on glycemic control measures, patient satisfaction, and other relevant details by authors. The extracted data were organized and summarized using RevMan software, with tables and forest plots created to present key findings on diabetes management outcomes. Citation management was handled with EndNote or similar software, ensuring that references from the selected studies were efficiently organized and managed.

To ensure the quality of assessment of the included studies, the JBI Critical Appraisal Checklist was used.¹¹ This checklist evaluated each study based on criteria such as study design, methodology, and reporting clarity. The authors independently assessed the quality of the studies, and findings were transparently reported, enhancing the credibility and validity of the analysis.¹²

Statistical Analysis

The primary aim of this meta-analysis was to evaluate the impact of continuous glucose monitoring (CGM) devices on reducing HbA1c levels (%) in individuals with diabetes. Employing a random-effects model, the study sought to estimate the average reduction in HbA1c levels between CGM users and non-users. Included studies provided continuous outcome data, focusing on changes in HbA1c levels before and after CGM device use. Moderate variability ($I^2 > 25\%$) in study results prompted meta-regression analysis to investigate potential factors influencing the effectiveness of CGM devices on HbA1c reduction.

A random-effects model was employed to calculate the overall effect size with a 95% CI, utilizing weighted mean differences (WMD). Methodological consistency was evaluated using Cochrane's Q statistic, while the I^2 statistic quantified the proportion of variability attributable to heterogeneity rather than chance alone. Results were visualized using forest plots, where each study's contribution to the pooled effect estimate was represented by marker size. Publication bias was assessed using funnel plots and Egger's regression test, adjusting for potential biases associated with small-study effects and publication bias.¹²⁻¹⁵ This meta-analysis utilized Review Manager (RevMan) software version 5.4.1 for statistical analyses, ensuring rigorous synthesis of findings on the efficacy of CGM devices in improving HbA1c levels among individuals with diabetes.

RESULTS

Search Results

A total of 3,912 records were identified through the database search. During the initial screening, 3,510 records were excluded as they did not meet the relevance criteria for the current analysis. Subsequently, 291 records were selected for further review. Of these, 88 full-text articles were assessed for eligibility based on the inclusion and exclusion criteria. Following the full-text evaluation, 76 articles were excluded for various reasons, and the remaining 12 studies were included in the qualitative synthesis.

These 12 studies^{4, 5, 16-25} were further included in the quantitative synthesis (meta-analysis), adhering to the systematic review process as depicted in the PRISMA flow diagram (Figure 1). The included studies were selected based on their relevance to the use of wearable trackers, specifically Continuous Glucose Monitors (CGMs), for diabetes management. This comprehensive screening process ensured that only the most pertinent studies were included for detailed analysis. The quality of assessment of the included studies, the JBI Critical Appraisal Checklist was used (Reference: Supplementary material).

Effects of CGMs

The meta-analysis synthesized data from twelve studies is used to evaluate the impact of continuous

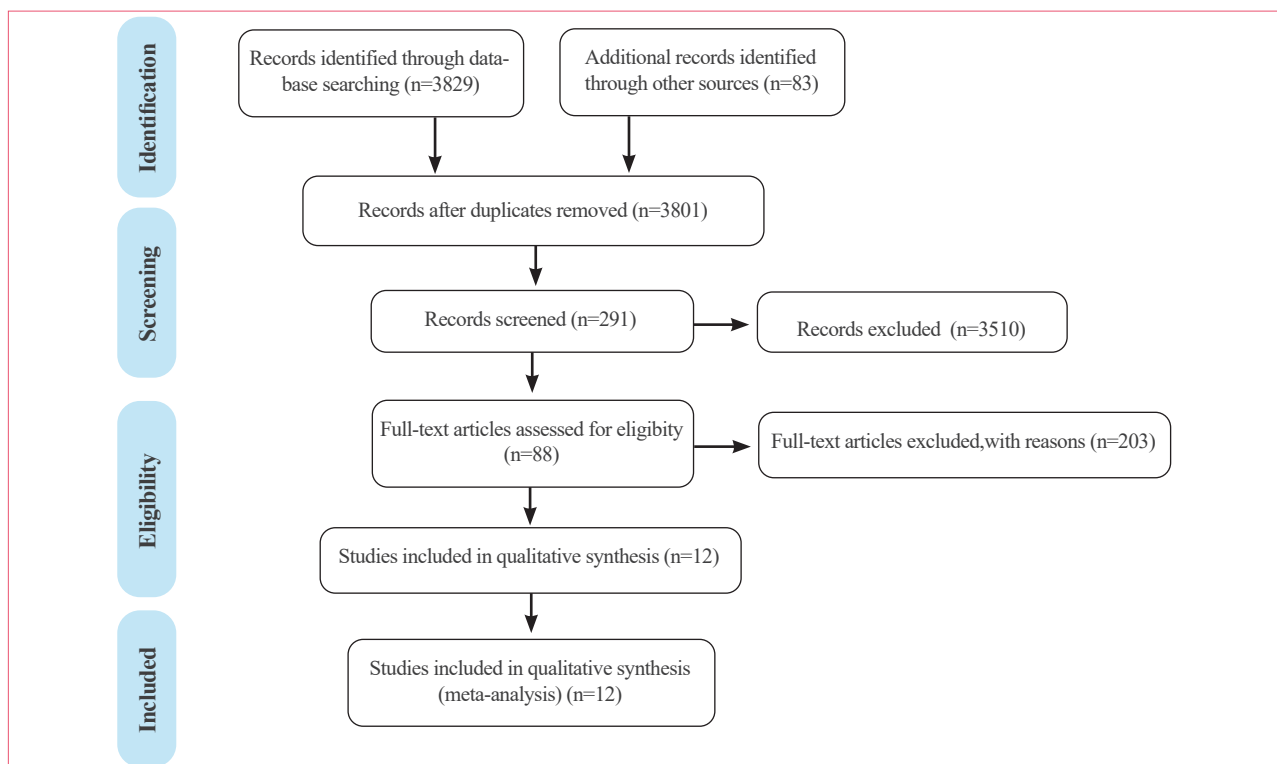


Figure 1. PRISMA Flow diagram for systematic review and meta-analysis of CGMs

glucose monitoring (CGM) devices on diabetes management. The analysis revealed that the use of CGM devices significantly improves glycemic control compared to non-CGM strategies such as self-monitoring of blood glucose (SMBG) or conventional therapy. The heterogeneity among the included studies was adequate, with a Tau^2 of 0.00, a Chi^2 of 16.08, and an I^2 of 32%. This level of variability suggests some differences across studies but not enough to undermine the overall conclusions. Overall effect ($N=1916$; $\text{WMD}=0.43$; 95%CI: 0.34-0.52; $p<0.001$), the overall effect of CGM use on HbA1c levels was statistically significant and highlights the effectiveness of CGM devices in improving glycemic control, which is critical for managing diabetes and preventing complications and results were depicted Figure 2. Patients who used CGMs consistently showed lower HbA1c levels, indicating that real-time glucose monitoring allows for more accurate and proactive diabetes management.

Heterogeneity observed and its meaning

Despite these promising findings, certain limitations must be considered when interpreting the results. The heterogeneity observed across studies, although moderate ($I^2 = 32\%$), underscores the need for more standardized reporting of CGM device characteristics and patient adherence metrics. Additionally, the exclusion of unpublished studies or those in non-English languages may introduce publication bias, even though statistical tests did not reveal significant evidence of such bias. Addressing these limitations in future research will be crucial to refining our understanding of CGM efficacy in diverse populations.

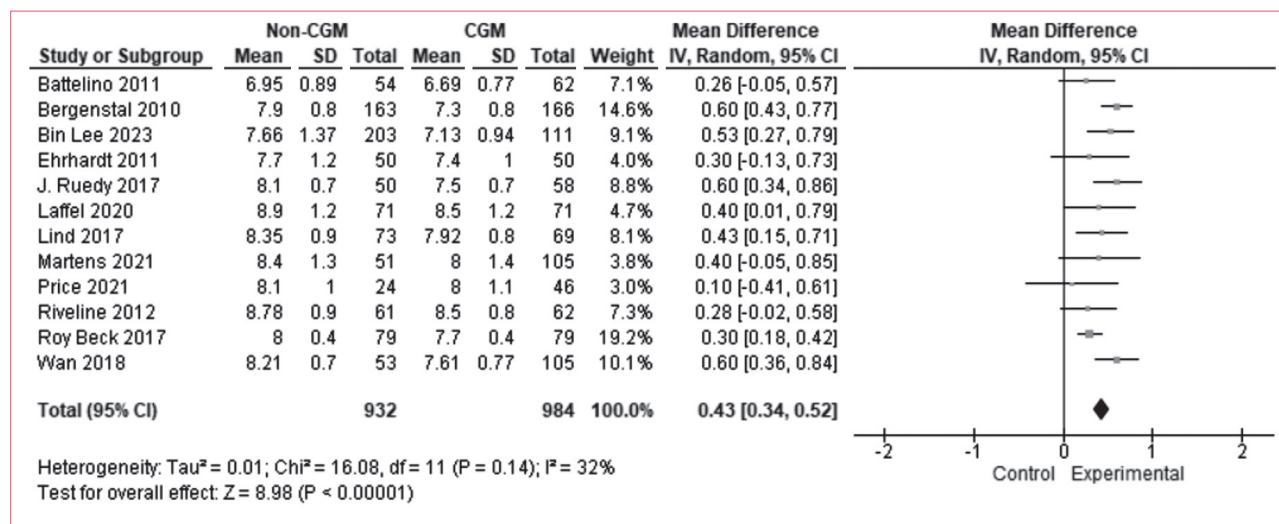


Figure 2. Forest Plot Comparing the Effectiveness of Continuous Glucose Monitors (CGMs) in Diabetes Management

Multicenter trials comparing different CGM formulations, methods, and dosages to conventional treatments, including insulin therapy and food management, should be the primary focus of future research. In order to effectively inform clinicians and optimize diabetes care regimens, comprehensive assessments should include measurements of quality of life, side effects, effectiveness, and patient views.

Findings from the meta-regression

The meta-regression analysis explored the impact of moderator variables like mean age, duration of diabetes, and BM on the effectiveness of continuous glucose monitoring (CGM) devices in reducing HbA1c levels among individuals with diabetes. The findings indicated that none of the moderator variables i.e mean age ($\beta = 0.005$; $p = 0.357$), duration of diabetes ($\beta = 0.005$; $p = 0.348$), and BMI ($\beta = -0.014$; $p = 0.401$) had a statistically adequate effect on the reduction in HbA1c levels. These variables were among the most commonly reported parameters across all studies included in the meta-analysis. This suggests that variations in these factors across different studies did not significantly contribute to the observed heterogeneity in CGM effectiveness. The analysis underscores the robustness of CGM devices in consistently reducing HbA1c levels across diverse patient demographics and health profiles, independent of age, duration of diabetes, or BMI. These findings provide valuable insights for clinicians and researchers aiming to optimize diabetes management strategies using CGM technology.

Based on the results from Egger's regression test, the analysis indicates no significant publication bias in the studies assessing the reduction in HbA1c levels among CGM users versus non-users (Figure 3). The p -value ($p=0.063$) suggests that the no relationship between the standard error and the mean difference in HbA1c levels is statistically insignificant. This implies that there is no substantial evidence of selective reporting or publication bias in the included studies. These findings support the

reliability of the meta-analytic conclusions regarding the effectiveness of CGM devices in managing diabetes.

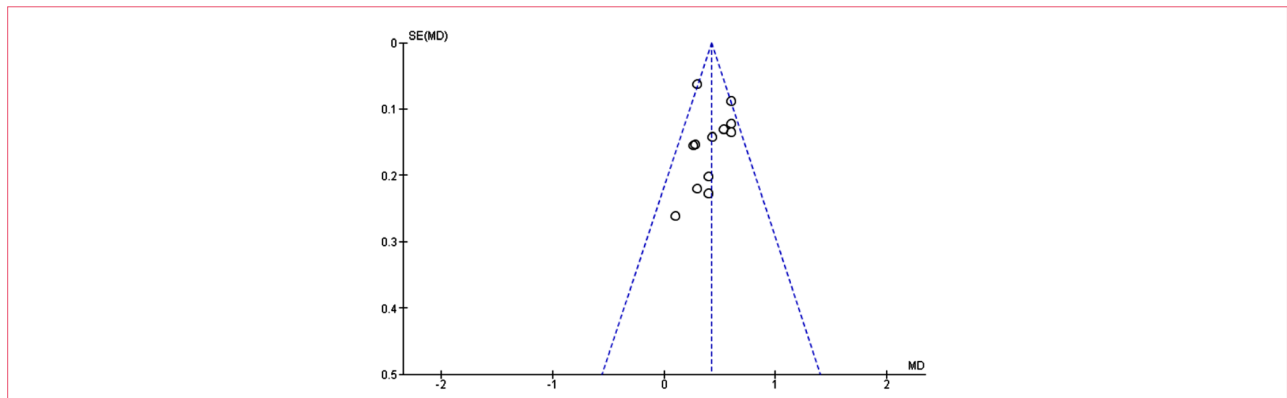


Figure 3. Funnel Plot Assessing Publication Bias in Studies of Wearable Trackers for Diabetes Management

DISCUSSION

The impact of continuous glucose monitoring (CGM) devices on diabetes management was rigorously analyzed through a systematic review and meta-analysis. The forest plot presented provides compelling evidence supporting the effectiveness of CGM technology in improving glycemic control among individuals with diabetes.

The pooled data from 12 studies, encompassing a total of 1916 participants (932 non-CGM users and 984 CGM users), reveals a statistically significant mean difference in HbA1c levels between the two groups. The overall effect size, indicated by a mean difference of 0.43% (95% CI: 0.34, 0.52), demonstrates a favorable reduction in HbA1c for those utilizing CGM devices. This significant reduction, with a test for overall effect showing $Z = 8.98$ ($p < 0.00$), underscores the potential of CGM technology to enhance long-term glycemic control.

The heterogeneity among the included studies was relatively low ($I^2 = 32\%$), suggesting a moderate level of consistency in the findings across different research contexts.¹⁴ This homogeneity strengthens the reliability of our conclusions and suggests that CGM devices are broadly effective across diverse patient populations and settings.

Examining individual studies, several demonstrated particularly notable benefits. For instance, Bergenstal et al.¹⁷ reported a mean difference of 0.60% (95% CI: 0.43, 0.77), highlighting the substantial impact of CGM on lowering HbA1c levels. Similarly, Ruedy et al.¹⁹ and Wan²⁵ both found mean differences of 0.60% (95% CI: 0.34, 0.86 and 0.36, 0.84, respectively), reinforcing the consistency of CGM's effectiveness.

Conversely, some studies, such as Ehrhardt et al.⁵ and Price²², reported smaller mean differences of 0.30% (95% CI: -0.13, 0.73) and 0.10% (95% CI: -0.41, 0.61) respectively. These variations could

be attributed to differences in study design, patient adherence, baseline HbA1c levels, or the specific CGM devices used.^{26,27}

The results of present meta-analysis indicate that CGM devices not only provide significant clinical benefits in reducing HbA1c levels but also highlight the importance of personalized diabetes management strategies. The variation in effect sizes across studies underscores the need for individualized patient assessments when recommending CGM technology.

CONCLUSION

The optimality of continuous glucose monitoring (CGM) devices over conventional diabetes treatment techniques is highlighted by the results of this systematic review and meta-analysis. As demonstrated by lower HbA1c values when compared to traditional medication or self-monitoring of blood glucose (SMBG), CGMs not only considerably improve glycemic control but also provide proactive decision-making with real-time feedback. Through the reduction of related adverse effects and improvement of patient outcomes, this development holds the potential to revolutionize the treatment of diabetes. Multicenter trials comparing different CGM formulations, methods, and dosages to conventional treatments, including insulin therapy and food management, should be the primary focus of future research. In order to effectively inform clinicians and optimize diabetes care regimens, comprehensive assessments should include measurements of quality of life, side effects, effectiveness, and patient views.

Limitations

Despite the promising evidence, several practical barriers to CGM adoption must be addressed. One major limitation is the high cost of CGM devices, which may limit accessibility, particularly in low-resource settings. Additionally, consistent adherence to CGM usage remains a challenge for many patients. Sensors, often perceived as cumbersome, invasive, and costly, can deter regular usage. For instance, in the intervention group of one study, approximately half the patients required CGM usage for 15 to 20 days per month, while others needed 25 to 30 days per month.²³ This variability highlights the importance of tailoring CGM prescriptions to individual patient needs and economic considerations.

Previous clinical trials have also shown that while CGM devices can significantly reduce glycosylated hemoglobin in adults with Type 1 diabetes mellitus (T1DM), these benefits may not be uniformly realized in underserved or less-educated populations without robust education and training. For example, a small trial in such a population failed to achieve significant glycemic benefits.¹⁸ Furthermore, racial disparities persist in the adoption of CGM technology, contributing to inequities in glycemic control outcomes.

Declaration

We confirm that the manuscript has been read and approved by all the listed authors. We further confirm that the order of authors listed in the manuscript has been approved by all.

Ethics approval and consent to participate

Ethical approval was not required for the present study as it is based on the secondary data/information.

Consent for publication

All the listed authors give their due consent for the publication

Availability of data and material

The present study is based on the secondary data sources which are available at mentioned databases in public domain. We have used the data from published articles for our research. Please refer table 1.

Competing interests

There are no conflicts of interest declared by authors.

Table 1. Summary of Included Studies Evaluating the Impact of Wearable Trackers on Glycemic Control in Diabetes Management

Study and Year of publication	Study Design	Country	Duration	BMI	Mean age	Sample Size Experiment	Sample Size control
Battelino, 2011	RCT	USA	6	22.2	25.85	62	54
Bergental, 2010	RCT	USA	24	27.9	41.25	166	163
Bin Lee, 2023	PMCS Study	South Korea	24	22.54	39.75	111	203
Ehrhardt, 2011	RCT	USA	13	32.3	57.75	50	50
J. Ruedy, 2017	RCT	USA & Canada	6	33.5	67	61	53
Laffel, 2020	RCT	USA	17	29.05	17.5	71	71
Lind, 2017	RCT	Sweden & USA	28	27.1	44.65	69	73
Martens, 2021	RCT	USA	24	33.85	57.5	105	51
Price, 2021	RCT	USA	9	32.1	59.5	46	25
Riveline, 2012	RCT	USA	12	24.7	37.65	62	61
Roy Beck, 2017	RCT	USA & Canada	6	36	60	79	79
Wan, 2018	RCT	USA	6	27.35	48.55	105	53

RCT, Randomized controlled trial; PMCS Study, Propensity-matched cross-sectional study

Table 1. JBI Checklist Quality Assessment Table (Supplementary material)

	2011 Battelino	2010 Bergensal	2023 Bin Lee	2011 Ehrhardt	2017 J. Ruedy	2020 Laffel	2017 Lind	2021 Martens	2021 Price	2012 Riveline	2017 Roy Beck	2018 Wan
Were the criteria for inclusion in the sample clearly defined?	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Were the study subjects and the setting described in detail?	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Was the exposure measured in a valid and reliable way?	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Were objective, standard criteria used for measurement of the condition?	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Were confounding factors identified?	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	unclear	unclear
Were strategies to deal with confounding factors stated?	✓	✓	✓	✓	✓	unclear	✓	✓	✓	✓	✓	✓
Were the outcomes measured in a valid and reliable way?	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Was appropriate statistical analysis used?	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓	✓
Overall appraisal	include	include	include	include	include	include	include	include	include	include	include	include

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Authors' contributions

Patankar Chinmayee Nilesh and Jahnavi Hegde have contributed the data collection, analysis, and manuscript preparation. Ramesh Athe developed the study protocol, supervised the study, and guided in manuscript preparation.

AI Statement

We confirm that the AI hasn't been used to prepare the manuscript and approved by all the listed authors.

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