SYSTEMATIC REVIEW OF THE LITERATURE ON DIABETES-RELATED MOBILE APPS, A MIXED METHODS APPROACH

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Background and Aims

The increasing availability of diabetes-related mobile applications highlights their potential to facilitate behavioural change, complement conventional treatments, and advance digital therapeutics.¹ Despite rapid technological progress², challenges persist due to individual variability in response and evolving regulatory frameworks in both the EU and the U.S.¹ However, strong clinical evidence supporting the effectiveness of these apps remains scarce.³

This study aimed to systematically assess the current landscape using an evidence-based approach.

Methods

A systematic search was conducted in PubMed (24.02.2024) using the keywords: *mobile application, m-Health, smartphone application, Al application,* and *diabetes*.

Additional resources were reviewed from leading diabetes organizations, including the ADA, EASD, IDF, JDRF, Diabetes UK, and the Endocrine Society.

Inclusion criteria focused on peer-reviewed studies evaluating glycaemic outcomes, mobile apps available in the Apple/Google stores within EU countries, and studies involving adults with diabetes.

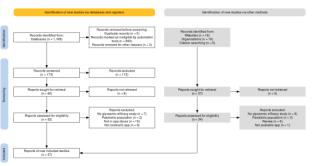


Figure 1 Systematic review flowchart

As suggested by the ADA/EASD consensus, diabetes apps can be categorized into five types: nutrition, physical activity, glucose monitoring, insulin titration, and insulin delivery. For our analysis, we followed the Endocrine Society's taxonomy—(1) data integration, (2) coaching, and (3) decision support (e.g., bolus calculators)—which reflects the intensity of user interaction.

Clinical evidence strength was assessed semiquantitatively using the Oxford Centre for Evidence-Based Medicine (OCEBM) criteria, that define 5 levels of evidence – 1 being the highest.

Results

From over 1,000 publications, 33 studies met our criteria: data tracking/integration platforms (n=7, 57% showing benefit), coaching and behavioral education platforms (n=12, 42% showing benefit), decision support platforms (n=8, 50% showing benefit).

Арр	Feature	Available studies	Efficacy in glycaemic goals	Level
GDm- Health	Tracking	RCT	Non-inferior (Improvement in neonatal)	1b
Habits- GDM	Tracking	RCT	Improvement (No effect in neonatal)	1b
Glucose Buddy	Tracking	RCT (Together with HCP input)	Improvement	2b
R Plus Health	Exercise Tracking	RCT (Intervention group older, follow up 84%)	No difference (De-escalation of medication)	2b
Nutritionist Buddy	Nutritional Suggestions	RCT	HbA1c improvement Higher % of participants de- escalated medication	1b
AspyreRx	Digital CBT	RCT	Dose-response reduction in HbA1c	1b
iCareD	EMR-integrated HCP feedback	RCT in T2	Not sustained Improvement	1b
Liva	Health Coaching	RCT (25% loss to follow up)	2-fold increase in HbA1c normalisation	2b
NexJ	Health Coaching	RCT (26% loss to follow up)	Faster but similar improvement	2b
WellDoc	Real-time feedback	Cluster RCT in community T2D	Reduced HbA1c	1b
	Treatment algorithms	Pilot RCT (low compliance, difference baseline HbA1c)	Reduced HbA1c	2b
d-Nav	Automated insulin titration system	RCT in T2D with insulin therapy (basal-bolus)	Greater reduction in HbA1c	1b
BlueStar	personalized digital coaching	Pragmatic RCT (underpowered and 35% drop-out rate)	No difference	2b
Diabeo	real-time monitoring basal/bolus suggestions	RCT but low adherence	HbA1c No difference in ITT Improvement in PP	2b

Behavioral coaching apps generally demonstrated lower levels of evidence, with only 25% of positive studies rated level 2 or above. In contrast, decision support apps, though fewer in number, exhibited a higher proportion (38%) of positive outcomes in studies rated level 2 or above.

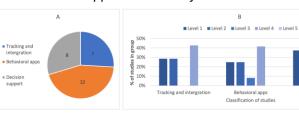
Conclusions

Many marketed diabetes apps lack robust clinical evidence. Higher intervention levels tend to be associated with stronger supporting data, while coaching-based approaches may enhance efficacy.

Al-enabled ² and high-risk ⁴ applications should undergo rigorous clinical evaluation akin to drug development.

Additionally, the establishment of a regularly updated registry is essential to track technological advancements and ensure patient safety.

Table Mobile apps with levels of evidence 1 or 2



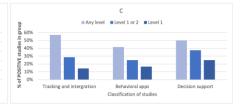


Table 2 Classification of apps (A). Distribution of studies based on levels of evidence (B). Percentage of positive studies statified by levels of evidence (C).







¹ Fleming GA, et al. Diabetologia. 2020

² Acosta JN. et al. Nat Med. 2022

³ Grunberger G, et al. Endocrine Practice. 2021

⁴ Beck RW, et al. The Lancet. 2019