Improvements in glycaemic control with a diabetes app: Comparison of real-world data with a randomised controlled trail

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Background & Aims

Treatment of diabetes mellitus requires considerable self-management effort. Digital tools can help to reduce the burden of self-management and have the potential to increase glycaemic control. A digital logbook (mySugr® PRO app) was evaluated in a randomized controlled trial (RCT).[1] The RCT demonstrated a significantly greater reduction in Diabetes Distress, the primary outcome, compared to the control group without app use. Furthermore, severe hypoglycaemic (<54 mg/dl) and hyperglycaemic (>250 mg/dl) events were reduced but effects of mySugr on glycemic endpoints need further evaluation.

This analysis aimed at:

1. Sub-analyses of the RCT data regarding improved glycaemic control
2. Comparison to real-world data (RWD) from the existing user base of the app.

Methods & Methods

RCT

The RCT was designed as a multi-center, parallel study with a 3-month follow-up including 342 participants with type 1 and type 2 diabetes.[2] Robust logistic regression analysis was used to assess whether the proportion of participants with type 1 or type 2 diabetes achieving an HbA1c ≤6.5% at 3-month follow-up differed between intervention and control group while controlling for baseline HbA1c.

RWD

To compare the RCT data to real-life, real-world data of existing users of the mySugr PRO app (n=348 type 1 diabetes, n=2,513 type 2 diabetes) were used to analyse changes in mean blood glucose before using the app (baseline) and the following 12 months after starting to use the app.

Propensity score matching

To increase comparability, real-world users were matched to RCT participants based on age, diabetes type, HbA1c and other demographics.

Table 1. Baseline characteristics of participants from the randomised control trials and real-world cohort.

	Randomised controlled trial		*Real-world cohort*
	Control group *(n = 117)*	Intervention group *(n = 225)*	Existing app users *(n = 2,861)*
Age (in years)	57.3 (14.2)	55.7 (12.7)	56.8 (9.7)
Gender			
Female	47 (40.2%)	85 (37.8%)	452 (15.8%)
Male	70 (59.8%)	140 (62.2%)	1047 (36.6%)
Body-mass index (kg/m²)	31.0 (6.3)	33.1 (7.3)	32.6 (6.1)
Type of diabetes			
Type 1 diabetes	16 (13.7%)	37 (16.4%)	348 (12.2%)
Type 2 diabetes	101 (86.3%)	188 (83.6%)	2513 (87.8%)
Diabetes duration (in years)	12.4 (12.4)	11.2 (10.1)	6.5 (6.9)
HbA1c categories[1]			
≤ 7.5%	69 (59.5%)	136 (60.7%)	1868 (65.3%)
7.6 – 8.0%	11 (9.5%)	27 (12.1%)	220 (7.7%)
8.1 – 8.5%	13 (11.2%)	21 (9.4%)	196 (6.9%)
> 8.5%	23 (19.8%)	40 (17.9%)	577 (20.2%)

Data are n (%), mean (SD). [1]Laboratory-measured HbA1c for the RCT, estimated HbA1c for the real-world cohort.

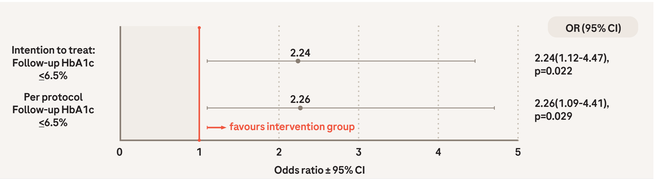

Figure 1. Odds ratio of achieving HbA1c ≤ 6.5% at follow-up in the randomised controlled trial

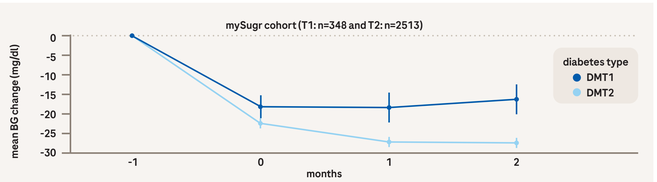

Figure 2. Reduction in mean glucose before and during three months of app use in people with type 1 and type 2 diabetes.

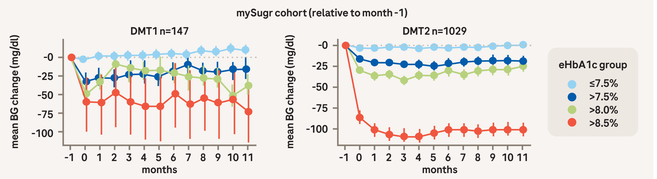

Figure 3. Reduction in mean glucose before and during 12 months of app use stratified by baseline eHbA1c in type 1 diabetes (left) and type 2 diabetes (right).

Results

Sample characteristics:

- Sample characteristics for the RCT and RWD cohort can be seen in Table 1.
- 2,681 RWD users were available for the analysis of 3-months of app use. 1,176 RWD users were available for the analysis of 12-months of app use (n=147 T1D, n=1,029 T2D)

RCT

The **chance to achieve an HbA1c ≤ 6.5% was nearly doubled in the intervention group** compared to the control group (Figure 1).

RWD

- Compared to the month before app use, **mean blood glucose levels significantly improved over a period of 3 months** (Figure 2)
  - Type 1: -16.3 mg/dl, 95% CI: -20.6 to -12.4, p<0.001
  - Type 2: -27.3 mg/dl, 95% CI: -28.7 to -25.9, p<0.001
- Across 12-months, those with an estimated HbA1c >8.5% at baseline showed the largest reductions in mean blood glucose compared to baseline (Figure 3).
  - Type 1: -73.2±95.6 mg/dl, 95% CI: -112.8 to -42.0, p<0.01
  - Type 2: -101.9±81.4 mg/dl, 95% CI: -109.0 to -94.5, p<0.0001
- Similar patterns of reduced mean glucose were found for those with an estimated HbA1c at baseline of >7.5% and >8.0% (Figure 3). Those with an estimated HbA1c at baseline of ≤7.5% showed no further improvement in mean blood glucose.

Conclusion

- The sub-analysis of the RCT revealed a **significant effect of the mySugr PRO app on the chance to reach optimal glycaemic control** 3 months after using the app.
- This result was **substantiated by real-world data indicating rather large reductions in mean blood glucose** shortly after starting to use the app
- Reductions were especially pronounced in those with high HbA1c at baseline. **These initial reductions were maintained across a period of 12 months** showing the long-term effects of using a digital diabetes logbook in people with elevated HbA1c at baseline.

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References:1. Ehrmann D et al. Efficacy of a Digital Diabetes Logbook for People With Type 1, Type 2, and Gestational Diabetes: Results From a Multicenter, Open-Label, Parallel-Group, Randomized Controlled Trial. Journal of Diabetes Science and Technology. 2024;0(0). doi:10.1177/19322968241239870 **2.** Ehrmann D et al.. Health care effects and medical benefits of a smartphone-based diabetes self-management application: study protocol for a randomized controlled trial. Trials. 2022;23(1):282.