

### Efficacy of a digital diabetes logbook: findings from a randomised controlled trial

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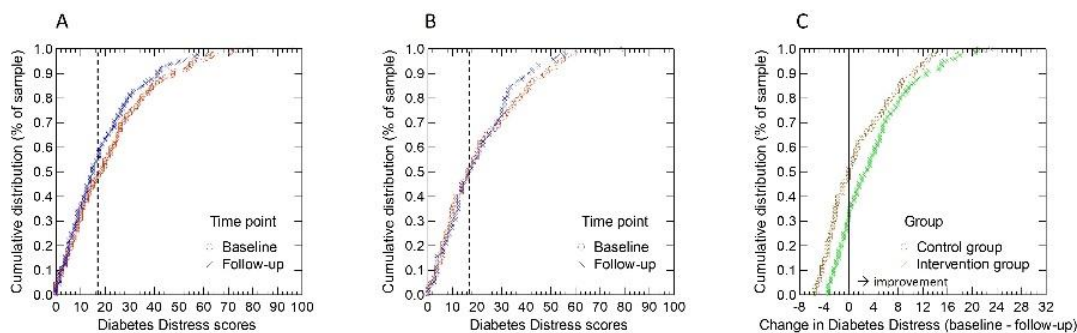
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**Background and aims:** The mySugr PRO app is a digital diabetes diary designed to help people with diabetes manage their glucose management and to reduce complexity and burden of diabetes management. The efficacy of the app was tested in a randomised controlled trial (RCT).

**Materials and methods:** An open-label, parallel group, RCT with a 3-month follow-up was conducted in 41 study sites across Germany. Eligible participants had to have type 1, type 2 or gestational diabetes and regularly perform self-monitoring of blood glucose. Randomisation was done in a 2:1 ratio, either to the intervention group, using the digital diabetes logbook (mySugr PRO) for 3 months, or to the treatment-as-usual control group without using an app. Primary outcome was reduction in diabetes distress at the 3-month follow-up as assessed with the Problem Areas in Diabetes (PAID) scale. Based on the power analysis, 396 evaluable participants were needed. Analysis with robust regression analysis was based on the intention-to-treat population.

**Results:** A total of 424 people with diabetes were randomized, 282 to the intervention and 142 to the control group (12.5% type 1 diabetes, 68.2% type 2 diabetes, 18.9% gestational diabetes, age:  $51.7 \pm 15.2$  years, 50% female, diabetes duration:  $9.5 \pm 10.8$  years, HbA1c:  $7.1 \pm 1.5\%$ , PAID:  $21.6 \pm 17.4$ ). The drop-out rate was very low with 6.4% and 397 participants completed the 3-month follow-up. Intention-to-treat analysis showed that diabetes distress improved from a median score of 18.59 to 15.00 in the intervention group and slightly increased from 16.25 to 16.56 in the control group. Baseline-adjusted diabetes distress at follow-up was significantly lower in the intervention group compared to the control group (model-based treatment effect:  $-2.20$ , 95% CI  $-4.02$  to  $-0.38$ ,  $p = 0.0182$ ) indicating that the intervention app significantly reduced diabetes distress (figure).

**Conclusion:** The popularity of diabetes apps seems to be inversely related to their evidence base of methodologically sound studies. This multi-centre RCT showed a significant reduction of ca. 10% in diabetes distress in users of the mySugr PRO app; this reduction was more pronounced in people with initially elevated diabetes distress. Thus, efficacy of the digital health intervention was demonstrated regarding improvement in psychosocial well-being.



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