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Reductions in hyperglycaemic events following use of a digital diabetes logbook: results of a randomised controlled trial

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Background and aims: The digital diabetes logbook mySugr is designed to help people with diabetes manage their diabetes and to facilitate glucose management. Among the core features are motivational strategies to take care of diabetes, simple charts to reduce complexity of glucose management, and positive feedback loops for in-range glucose values. To test the efficacy and safety of the digital diabetes logbook, a randomised controlled trial (RCT) was conducted.
Materials and methods: The study was conducted as an open-label, parallel group, randomised controlled trial with a 3-month follow-up. A total of 41 study centres recruited eligible people with type 1, type 2 or gestational diabetes that regularly performed self-monitoring of blood glucose (SMBG). Participants were randomized to either the intervention group, using the digital diabetes logbook for 3 months, or to the treatment-as-usual control group without using an app. Power analysis revealed that 396 participants were needed. Anticipating a drop-out rate of 15%, the recruitment goal was 466 participants. In this analysis, we analysed the incidence rates of severe hypoglycaemic (<54 mg/dl) and severe hyperglycaemic (> 250 mg/dl) events per 1000 glucose measurements. A negative-binominal regression with group allocation as factor was performed.
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 ± 15.2 years, 50% female, diabetes duration: 9.5 ± 10.8 years, HbA1c: 7.1 ± 1.5%); 397 completed the 3-month follow-up. In the control group, 52.29 hyperglycaemic events (glucose > 250 mg/dl) per 1000 measurements occurred, while in the intervention group 35.02 hyperglycaemic events per 1000 measurements occurred. With the control group as reference, the incidence rate ratio (IRR) of IRR = 0.67 significantly favoured the intervention group (95% CI: 0.52 to 0.86, p = 0.0021) indicating that the intervention group had a 33% lower risk for severe hyperglycaemic events compared to the control group. Incidence rates of severe hypoglycaemic events (glucose < 54 mg/dl) were 4.54 and 3.42 events per 1000 measurements for the control and intervention group, respectively. The IRR of 0.75 significantly favoured the intervention group (95% CI: 0.57 to 0.99, p = 0.0484).
Conclusion: Use of the mySugr app significantly reduced the occurrence of severe hyperglycaemic and hypoglycaemic glucose measurments in study participants. The reduced risk for severe hyperglycaemic events was not at the expense of an increased risk for severe hypoglycaemic events. The study results indicate that use of the digital diabetes logbook was safe regarding hypoglycaemia and can help to improve glycaemic management.
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