OP063 - Evaluating the efficacy of mySugr in a randomized controlled trial: baseline characteristics (ID 871)

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Background and Aims

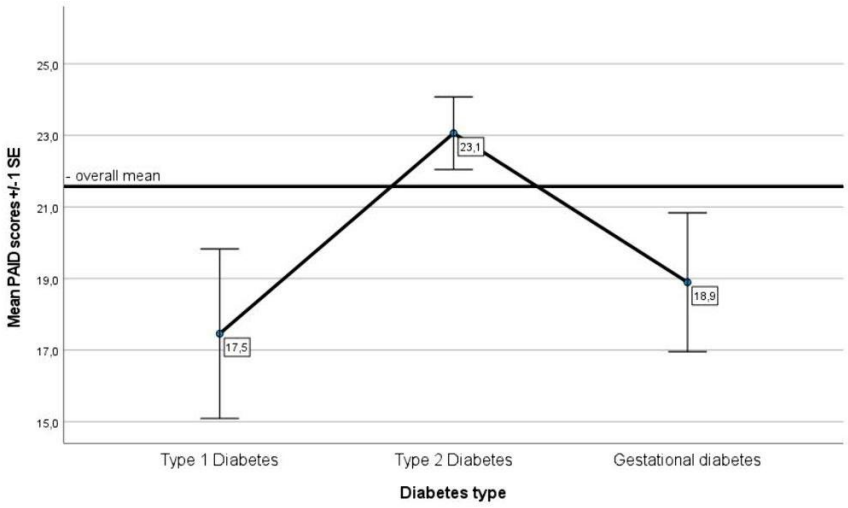
mySugr is designed to help people with diabetes manage their diabetes and to reduce burden of diabetes management. To test the efficacy of the mySugr app, a randomized controlled trial (RCT) was designed. Baseline characteristics are presented.

Methods

The RCT was designed as a multi-center, open-label, parallel study with a 3-month follow-up in Germany. Participants were randomized to either using the mySugr app or to the treatment-as-usual control group in a 2:1 ratio. Primary outcome is change in diabetes distress using the Problem Areas in Diabetes (PAID) questionnaire. Secondary outcomes include e. g. change in HbA1c and diabetes self-management (DSMQ). Power analysis revealed that 396 participants are needed to demonstrate a significant effect (p=0.05; power=80%) for an anticipated effect size of Cohen's d=0.3. A drop-out rate of 15% was assumed, leading to a recruitment goal of 466 persons.

Results

424 people with diabetes were randomized, 282 to the intervention group and 142 to the control group (age: 51.2±14.6 vs. 52.8±16.3; 13.1% vs. 11.3% type 1, 66.7% vs. 71.1% type 2, 20.2% vs. 16.2% gestational diabetes; PAID: 21.62±17.55 vs. 21.08±17.00; DSMQ: 75.33±13.84 vs. 73.69±15.53; HbA1c: 7.06±1.50% vs. 7.16±1.47%). Baseline characteristics did not significantly differ (all p>.05). There was a significant difference in PAID scores across diabetes types (p=0.03; Figure).



Conclusions

Randomization was successful (1.99:1 ratio), leading to comparable groups. Recruitment goal was achieved and could be stopped earlier due to lower-than-anticipated drop-outs. Participants had moderate levels of diabetes distress with people with type 2 diabetes having the highest diabetes distress.