Improved glycemic control and diabetes distress after using an mHealth application:
a preparation-analysis for the **Digital Health Care Act in Germany**

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Background

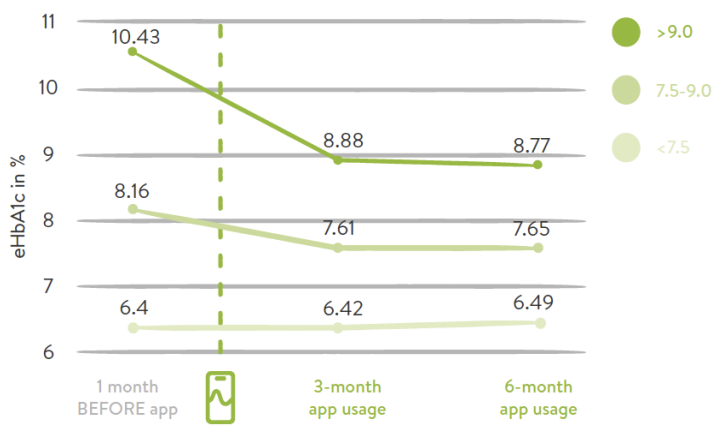
The German Digital Health Care Act[1] allows the prescription of mobile health applications by health care professionals. Therefore, apps must show efficacy on

1. medical outcomes
(e.g. changes in glycemic control)
2.patient-reported outcomes (PRO)
(e.g.changes in diabetes distress)

Aim of this work was to find indications for glycemic improvement as well as reduced diabetes distress for patients using a mobile health application for personal diabetes management.

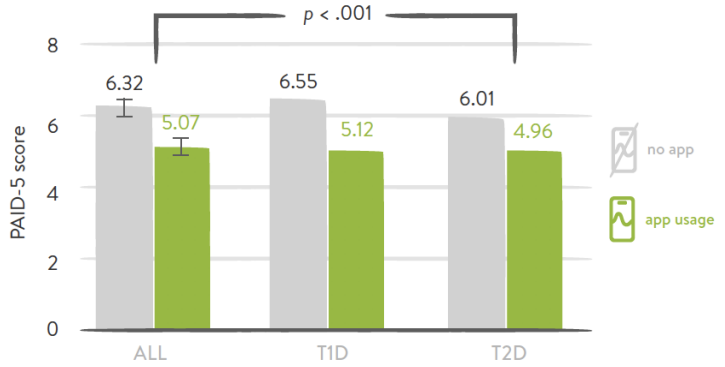
Results

1. The retrospective analysis of the collected real-world data shows an overall decrease in estimated HbA1c (eHbA1c) of 0.22% after six months. Sub-groups with baseline eHbA1c >=7.5 show a larger decrease.



Change in eHbA1c before and after app-usage (n=5920)

2. The results of the diabetes distress questionnaire (PAID-5) show significantly lower numbers for people using the app compared to the population from literature. Moreover, PwT1D show a stronger difference in the level of distress than PwT2D.



Difference in diabetes distress for patients without (n=824, 57% T1D, 43% T2D) /with (n=1099, 31% T1D, 65% T2D) app-usage.

Methods

1. Retrospective real-world data analysis on changes in **eHbA1c**[2] one month before and three and six months after initial app usage of users from Germany (n=5920). Division into three subgroups based on eHbA1c at baseline (<7.5%, 7.5%-9.0%, >9.0%).

2. Shortened **PAID-5 questionnaire**[3] completed by app users (n=1099) and tested (two-sided, unpaired t-test) against a comparative sample from literature[4,5](n=824) to show differences in diabetes distress.

Take-Away

For app users this preliminary analysis indicates a **positive effect** on glycemic control and diabetes distress by:

1. sustainable **reduction** in **eHbA1c** after 3 months.
2. significant **lower diabetes distress** compared to a sample without app usage.

These results are now being validated in a randomized controlled trial.

References

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