

# 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<sup>1</sup> 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.

## References

<sup>1</sup>Bundesministerium für Gesundheit., (2019) Gesetz für eine bessere Versorgung durch Digitalisierung und Innovation. Bundesgesetzblatt Jahrgang 2019 Teil I Nr. 49, ausgegeben zu Bonn.

<sup>2</sup>Nathan, D. M., Kuenen, J., Borg, R., Zheng, H., Schoenfeld, D., & Heine, R. J. (2008). Translating the A1C assay into estimated average glucose values. *Diabetes Care*, 31(8), 1473–1478.

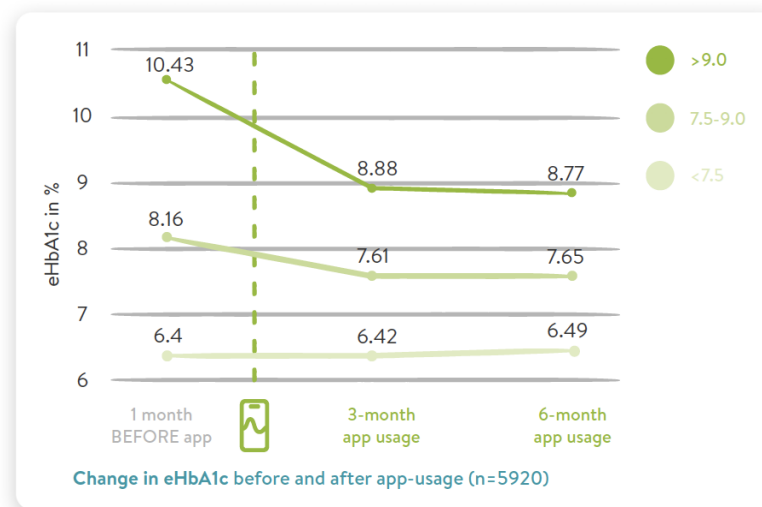
<sup>3</sup>McGuire, B. E., Morrison, T. G., Hermanns, N., Skovlund, S., Eldrup, E., Gagliardino, J., ... Snoek, F. J. (2010). Short-form measures of diabetes-related emotional distress: The Problem Areas in Diabetes Scale (PAID)-5 and PAID-1. *Diabetologia*, 53(1), 66–69.

<sup>4</sup>Ehrmann, D., Bergis-Jurgan, N., Haak, T., Kulzer, B., & Hermanns, N. (2016). Comparison of the efficacy of a diabetes education programme for type 1 diabetes (PRIMAS) in a randomised controlled trial setting and the effectiveness in a routine care setting: Results of a comparative effectiveness study. *PLoS ONE*, 11(1).

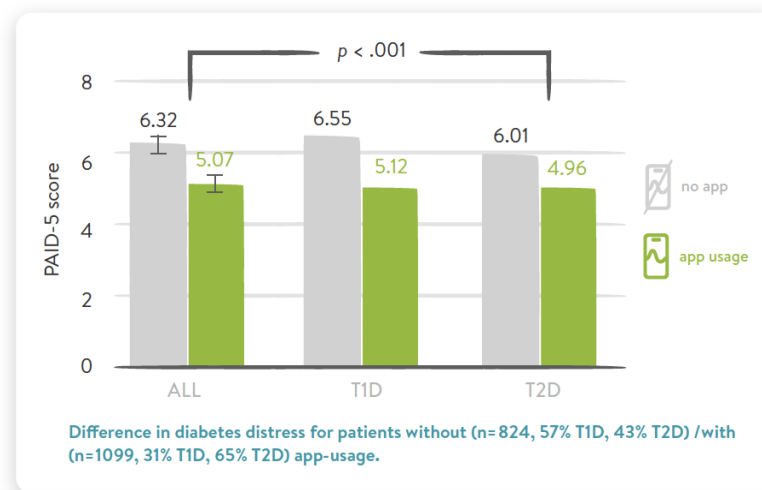
<sup>5</sup>Hermanns, N., Ehrmann, D., Schall, S., Maier, B., Haak, T., & Kulzer, B. (2017). The effect of an education programme (MEDIAS 2 BSC) of non-intensive insulin treatment regimens for people with Type 2 diabetes: a randomized, multi-centre trial. *Diabetic Medicine*, 34(8), 1084–1091.

## 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  $\geq 7.5$  show a larger decrease.



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.



## Methods

1. Retrospective real-world data analysis on changes in eHbA1c<sup>2</sup> 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<sup>3</sup> completed by app users (n=1099) and tested (two-sided, unpaired t-test) against a comparative sample from literature<sup>4,5</sup>(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.