



COMMENT ON KIM ET AL.

## The Effect of a Smartphone-Based, Patient-Centered Diabetes Care System in Patients With Type 2 Diabetes: A Randomized, Controlled Trial for 24 Weeks. *Diabetes Care* 2019;42:3–9

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We read with interest the article by Kim et al. (1), which demonstrated the potential benefits of a smartphone-based, patient-centered diabetes care system (mDiabetes) for improving glycemic control among patients with type 2 diabetes. We commend the substantial achievement of completing this trial but would like to add some comments concerning the interpretation of the results.

Intention-to-treat analyses are recommended for avoiding bias when estimating treatment effects, particularly when not all participants complete a trial. Of the 191 patients randomized in this study, only 172 patients were included in the full analysis. Nineteen (10%) patients who were excluded either withdrew, did not complete follow-up, or did not meet the inclusion/exclusion criteria. Patients who withdraw or are not adherent are likely to be systematically different from those who complete a study, thus excluding these randomized patients will have introduced bias. The

authors also did a per-protocol analysis that only included 151 (79%) who completed the study. Both this analysis and the main analysis are likely to have overestimated the treatment effect. An intention-to-treat analysis should include all the randomized patients, and if follow-up values are not available, a conservative assumption that uses baseline values and implies no effect of the intervention would minimize the bias (2).

Furthermore, as the authors pointed out, participants were not allowed to change their current oral antidiabetic medication or have additional medications that might affect glucose levels during the study period unless they required rescue therapy. Only insulin users in the mDiabetes group were instructed to follow a dose-titration algorithm based on glucose levels. However, one possible mechanism through which health care system interventions such as mDiabetes might work is via the

appropriate prescriptions and timely adjustments of antidiabetic medications.

The wide scalability and simple implementation of this innovative program highlight the potential for mobile health technology to circumvent the practical barriers of traditional health care office visits. However, the results as presented require a more cautious interpretation.

**Duality of Interest.** No potential conflicts of interest relevant to this article were reported.

### References

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