Published on 31.10.2014 in Vol 1, no 2 (2014): JMIR Diabetes
Pre-Conceptional Glycemic Control and Adverse Pregnancy Outcomes

Clinical Utility of a Digital Therapeutic Intervention in Indian Patients With Type 2 Diabetes Mellitus: 12-Week Prospective Single-Arm International Study

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Abstract

Background: Digital therapeutics (DTx) is a medical device software intervention that uses evidence-based therapeutic interventions to prevent, manage, or treat medical disorders or conditions. Nevertheless, the clinical evidence for DTx in Indian patients with type 2 diabetes mellitus (T2DM) is limited.

Objective: The goal of this study was to assess the clinical utility of a digital therapeutic intervention in an Indian cohort of adult patients with T2DM.

Methods: This was a prospective, single-arm, digital intervention study in a cohort of 1000 adult participants with T2DM. Participants were given access to a digital therapeutic intervention for 12 weeks. The primary endpoint was change in HbA1c, FPG, PPBG, and BMI over 12 weeks (24 visits).

Results: Participants had a mean (SD) age of 45.3 (10.9) years, 67.1% (671/1000) were male, and 32.9% (329/1000) were female. The mean (SD) baseline HbA1c was 8.9 (1.2)%. Clinical and lifestyle parameters showed significant improvement (P<.001) at 12 weeks (24 visits) compared with baseline: HbA1c, −1.2 (−1.3 to −1.1)%; FPG, −29.4 (−32.1 to −26.7) mg/dl; PPBG, −50.7 (−55.2 to −46.2) mg/dl; and BMI, −0.7 (−0.8 to −0.6) kg/m2 (respectively). We mean changes in HbA1c, FPG, PPBG, and BMI over 12 weeks (24 visits) were −13.4 kg/dl, −29.4 mg/dl, −50.7 mg/dl, and −0.7 kg/m2 (respectively).

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Abbreviations

DTI: digital therapeutic intervention
FBG: fasting blood glucose
HbA_{1c}: glycated hemoglobin
HOMA-IR: Homeostatic Model Assessment for Insulin Resistance
PPBG: postprandial blood glucose
SMBG: self-monitoring of blood glucose
T2DM: type 2 diabetes mellitus

Edited by A Sharma; submitted 25.07.22; peer-reviewed by V Buss, Z Wu; comments to author 23.08.22; revised version received 24.09.22; accepted 11.10.22; published 31.10.22

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