

Protocol

Efficacy of a Personalized Mobile Health Intervention (BedTime) to Increase Sleep Duration Among Short-Sleeping Patients With Type 2 Diabetes: Protocol for a Pilot Randomized Controlled Trial

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Abstract

Background: A strong association exists between sleep duration and glycemic control in patients with type 2 diabetes (T2D), yet convincing evidence of a causal link remains lacking. Improving sleep is increasingly emphasized in clinical T2D treatment guidance, highlighting the need for effective, scalable sleep interventions that can affordably serve large populations through mobile health (mHealth).

Objective: This study aims to pilot an intervention that extends sleep duration by modifying bedtime behavior, assessing its efficacy among short-sleeping (≤ 6 hours per night) patients with T2D, and establishing robust evidence that extending sleep improves glycemic control.

Methods: This randomized, single-blinded, multicenter study targets 70 patients with T2D from 9 institutions in Japan over a 12-week intervention period. The sleep extension intervention, BedTime, is developed using the Theory of Planned Behavior (TPB) and focuses on TPB's constructs of perceived and actual behavioral control (ABC). The pilot intervention combines wearable actigraphy devices with SMS text messaging managed by human operators. Both the intervention and control groups will use an actigraphy device to record bedtime, sleep duration, and step count, while time in bed (TIB) will be assessed via sleep