

Study design and baseline characteristics for a cluster randomized controlled trial of a mobile health-based primary care program for Type 2 Diabetes in rural Thailand

Renu John, Methee Chanpitakkul, Devarsetty Praveen, Arpita Ghosh, Salyaveth Lekagul, Malulee Kaewhiran, Kriang Tungsanga, Vivekanand Jha

Background

Noncommunicable diseases (NCDs), particularly diabetes and chronic kidney diseases, pose a significant health burden in Thailand, especially among socioeconomically disadvantaged populations. The existing primary health care system in Thailand faces challenges in providing optimal care for NCDs due to an inadequate primary care. The SMART*health* program offers a technology-based solution to enhance NCD management through task-sharing among non-physician healthcare workers.

Objective

This study aims to adapt and implement the SMART*health* Diabetes program in rural Thailand to improve diabetes management. The main objectives are:

- 1) to adapt, validate, and integrate the SMART*health* diabetes program for improving the management of type 2 diabetes mellitus at the primary healthcare level, and
- 2) to determine the feasibility and acceptability of the SMART*health* diabetes program in rural communities of Thailand.

SMART*health* Diabetes - Study objectives & design

Objective 1: Intervention development (A+B)

Adapt and validate the SMART*health* Diabetes platform for diabetes management at the primary health care level.

Algorithm development and validation

- Updating of decision support tools
- Deployment of the algorithms on mobile platform
- Iterative testing, refinement, and validation of the platform

Integration with primary health care system

- Rapid health service assessment
- Workflow integration
- Addition of a new workforce training module

Evaluation of the platform

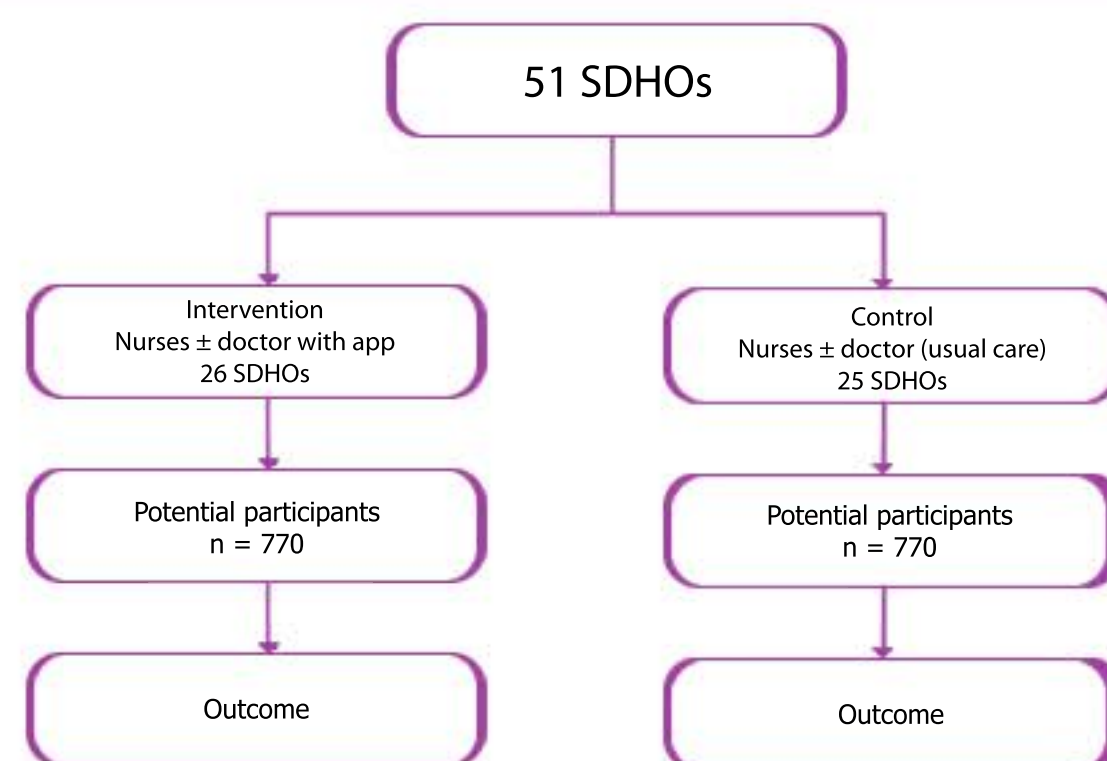
- Evaluation of the SMART*health* Diabetes platform through a trial component – cluster randomised control trial and process evaluation.

Objective 2: Evaluation of intervention (C)

Evaluation of the SMART*health* Diabetes platform to determine its effectiveness and feasibility

Method

A pragmatic, type 2 hybrid effectiveness or implementation, parallel -group cluster randomized controlled trial of 12 months duration involving 51 subdistrict health offices in rural communities of Kamphaeng Phet province, Thailand, is currently being conducted. The intervention arm will receive the SMART*health* Diabetes program, including workforce restructuring, clinical decision support system, and continuous performance monitoring, while the control arm will continue with usual practice.



Results

1. The data collection commenced in November 2022.
2. Among 1593 enrolled, baseline characteristics were compared between the intervention and control groups.
3. The intervention group had a lower mean BMI (25 ± 8 versus 26 ± 4.6), a higher waist-to-hip ratio (0.98 ± 0.3 versus $0.89 (\pm 0.1)$) and a lower eGFR (85 ± 13 versus 98 ± 16). The mean HbA1c was similar between the groups, with $7.3 (\pm 1.4)$ in the intervention group and $7.2 (\pm 1.4)$ in the control group. Participants will be followed up quarterly at 3, 6, 9 and 12 months after randomization. The 12-month follow-up will be completed in December 2024 and the results will be ready for publications in the first quarter of 2025.

Conclusion

The trial will explore a novel digital health intervention to enhance diabetes management in rural Thailand, providing insights for improving NCD care in low-resource settings globally.

SMART*health* Diabetes application

