Title: Feasibility Study of Automated Interactive Voice Response Telephone Calls with Community Health Nurse Follow-up to Improve Glycaemic Control in Patients with Type 2 Diabetes

Short running title: mHealth for Thai type 2 diabetes

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Conflicts of Interest

No conflicts.

Authorship statement

PP, LS, JA contributed to the study design and management of the project. PP, PR contributed to data collection and intervention delivery. PP, JA, LS, JS, NM analyzed the findings. PP, JA, LS, JP contributed to the reporting on the study. All authors approved the final version for submission.

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Abstract

Background: Thailand has a shortage of community health nurses for supporting the self-management of type 2 diabetes, which is prevalent and poorly controlled.

Aim: This study examined the feasibility and acceptability of a self-care assistance program for poorly controlled type 2 diabetes mellitus. The SukapapNet program consisted of Automated Interactive Voice Response calls to patients and automated follow up email notifications to their nurses.

Design: Single-arm pre-post trial.

Methods: Six nurses and thirty-five type 2 diabetes patients were recruited from primary care settings in suburban provinces in Thailand. The study was conducted from June 2017 to November 2017. We assessed patients before and after 12 weeks of the SukapapNet intervention.

Results: Mean glycated haemoglobin decreased by 0.9%. Patients reported reduced carbohydrate consumption, increased physical activity, increased medication adherence,

improved sleep quality, and more frequent foot care. Patients and nurses both recommended using the intervention, although nurses expressed concerns regarding increased workload.

Conclusions: The study program may improve outcomes in Thai type 2 diabetes patients.

Further study of the impact of technology upon nurses' workload is warranted.

SUMMARY STATEMENT

What is already known about this topic?

- Prevalence of type 2 diabetes is increasing in Thailand, and nurses who play an important role in health care at the community level are shortage.
- Mobile health strategies including short message service, automated telephonic
 monitoring and internet-based education have been successfully applied in Thailand with
 prenatal care, depression, Parkinson's disease, cardiac rehabilitation, and diabetes.
- Although mobile health is a promising way to bridge gaps in managing type 2 diabetes,
 an effect of automated mobile health with nurse follow-up has never been investigated in primary care settings.

What this paper adds:

- Automated Interactive Voice Response monitoring of diabetes patients with emailed updates to nurses is acceptable to Thai patients with poorly controlled type 2 diabetes.
- Mobile health strategies may also improve Thai nurses' ability to help diabetes patients with glycaemic control.
- To reduce burden for nurses, summaries of patients' responses should be emailed on a less-than-daily basis.

The implications of this paper:

This study contributes to the knowledge of how mobile health strategies may help Thai
patients with type 2 diabetes achieve glycaemic control, and increase nurses' engagement
with these patients.

- Innovative use of automated Interactive Voice Response with feedback to community health nurses should be further developed in Thailand.
- Future research should investigate a mobile health benefit to diabetes glycaemic control through a large-scale randomized controlled trial.

KEYWORDS

community, glycated haemoglobin, mobile health, nurse, type 2 diabetes

Trial registration: This trial is registered at clinicaltrials.gov under NCT03078764.

1. INTRODUCTION

Type 2 diabetes mellitus (T2DM) is a complex and escalating health problem in Thailand, where prevalence increased from 0.97% to 1.23% (or by 28%) between 2011 and 2015 (Ministry of Public Health, 2016). Good glycaemic control reduces risks for micro- and macrovascular complications (Fowler, 2011; UK Prospective Diabetes Study (UKPDS) Group, 1998). Thailand's national health policy directly encourages the use of interventions to reduce blood glucose in patients and most efforts focus on individual and group diabetes and self-care education (Mekwiwatanawong, Hanucharurnkul, Piaseu, & Nityasuddhi, 2013; Ounnapiruk, Wirojratana, Meehatchai, & Turale, 2014; Wattanakorn, Deenan, Puapan, & Schneider, 2013). While some of these programs are promising, they are time-intensive and require extensive nursing effort to longitudinally monitor and tailor adjustments. Such approaches are probably quite unrealistic to implement widely, given that there are fewer than two nurses per 1,000 Thais (Ministry of Public Health, 2017), with an even lower ratio in primary care settings. Even if some Thai T2DM patients have access to nursing resources, many do not receive education or regular follow-up due to barriers such as competing time demands and transportation difficulties.

Mobile health (mHealth) with automated Interactive Voice Response (IVR) could be used to provide better monitoring and support to diabetes patients, even in the context of limited resources. Using IVR, patients can regularly undergo assessments and receive self-management messages via phone. Nurses and other support persons can receive automated alerts about patients' IVR-entered data. Related mHealth-based IVR systems have been

implemented for chronic conditions in the United States (Aikens, Zivin, Trivedi, & Piette, 2014; Pfeiffer et al., 2015), and successfully pilot-tested in four low- and middle-income countries in Latin America (Piette et al., 2016).

A similar program may likewise be helpful in Thailand, given that other digital health communication strategies (e.g., SMS and emails) have been used to educate patients (McCann, Songprakun, & Stephenson, 2015; Wongrochananan, Tuicomepee, Buranarach, & Jiamjarasrangsi, 2015). In fact, IVR may serve a unique role in this context, particularly for patients with low literacy, insufficient access to internet-enabled phones, or a greater need for self-care messages. These ideas were supported by a study using IVR to enhance self-management for Thai T2DM patients (Kulnawan et al., 2011). To our knowledge, IVR-based monitoring has never been formally evaluated in primary care settings where Thai nurses are the primary providers, nor in terms of its impact on glycated haemoglobin as goal among patients with T2DM. We therefore designed the SukapapNet program to address Thailand's expanding shortages of personnel and resources for diabetes management.

The PRECEDE-PROCEED model (Green & Kreuter, 2005) guided our program development and selection of measures. According to this model, health behavior change interventions should address predisposing (intrapersonal variables), enabling (personal predisposition variables that encourage action) and reinforcing factors (consequences that sustain new behaviors such as rewards and/or symptom relief). In this study, predisposing factors included patients' health literacy, self-efficacy for self-managing their diabetes, hypoglycemic symptoms and psychological distress (depressive symptoms and diabetes-specific distress). Satisfaction with the IVR service availability and acceptability were two

enabling factors. Finally, we considered positive social and personal reinforcement (e.g., from improvements in physical well-being and psychological distress) as two reinforcing factors. The model also recommends process evaluation of how intervention is conducted. We summarized this in subsequent report covering call completion, week-to-week trends in self-management behaviors, and nursing interventions as measured through qualitative exit interviews.

The primary study outcome was glycated haemoglobin (HbA_{1c}) and fasting blood glucose (FBG). Potential mediating behavioral variables such as adherence to antihyperglycaemic medication and maintenance of healthy lifestyle behaviors (physical activity, low carbohydrate consumption, adequate sleep, and appropriate foot care) were also evaluated.

2. METHODS

2.1 Aims

The study aimed to evaluate the feasibility and potential efficacy of the SukapapNet program for improving glycaemic control and self-management among Thai diabetes patients. We also evaluated user satisfaction with the program from the perspectives of both nurses and patients.

2.2 Design

We conducted a single-arm, 12-week trial with assessments at baseline and immediate post-intervention.

2.3 Participants

We recruited outpatients from six primary care settings located in suburban Thai provinces who met the following criteria: ≥20 years of age, with poorly glycemic control as indicated

by $HbA_{1c} \ge 7.5\%$, current prescription for oral anti-hyperglycaemic medication, and access to and ability to use a touch-tone telephone. Six community health nurses were recruited from the primary care settings where these patients received care; each was responsible for six patients participating in the program. All nurses were already working in a non-communicable disease clinic, had access to email, and possessed a mobile telephone. Because this study was designed to simply pilot test the intervention in terms of acceptability and potential effect size, we chose a sample size of 36 patients and 6 nurses based primarily upon logistical considerations rather than estimation of sample size needed for hypothesis testing.

We screened seventy-four T2DM patients for eligibility. Of these, 30 did not meet HbA_{1c} entry criteria and 8 declined (82% of those eligible), leaving 36 patients (6 per nurse). One patient withdrew from the study (due to acute limb edema unrelated to study participation), leaving 35 cases. Participant recruitment and retention flow diagram is presented in Figure 1.

2.4 Intervention

SukapapNet was programmed using Asterisk (an open-source telecommunications programming language), and used a cloud-based computing and telecommunication platform. Call protocols and content were initially developed and studied in American English, prior to being modified to conform better with Thai clinical practice guidelines (Diabetes Association of Thailand, 2017) and cultural factors. After the automated Interactive Voice Response (IVR) and email content was translated into Thai, three Thai nurses with expertise in diabetes

and assessment independently reviewed the content to verify its appropriateness for the Thai clinical and cultural contexts. Finally, the IVR content was audiorecorded by the author.

After consent and baseline assessment, patients attended a 1-hour group diabetes education session provided by a research team member. The goal of this session was to summarize basic diabetes self-management principles and train patients how to use the IVR system. In addition, patients were provided with a health log booklet for recording their diabetes self-management behaviors.

Patients then received weekly IVR calls lasting 5-10 minutes each for the next 12 weeks. If the patient could not respond to the first call in a given week, then the system attempted up to call them back up to 8 more times (as needed) within the same week. Patients used their touch-tone telephone keypads to answer the audiorecorded IVR questions, which covered symptoms of hypoglycaemia and hyperglycaemia, diabetes medication adherence, carbohydrate consumption, physical activity, sleep quality, and foot checking. Examples of IVR feedback messages were provided in Table 1.

Nurses received a 1-hour standardized session from a research team member covering diabetes management and the system. Once the patients' calls began, their nurses began receiving a weekly e-mail report summarizing each IVR assessment that each of their patients completed. Nurses were expected to follow up with patients as needed to assess their IVR-reported problems, discuss self-care strategies, and elaborate upon the educational messages provided by the system.

2.5 Data collection

Data were collected from June 2017 to November 2017. The quantitative data were collected at the beginning of intervention and at the end of the 12-week follow up. Qualitative data were collected after intervention from semi-structure exit interviews. Also, feasibility was assessed by participant retention rate and call completion rate.

After patients gave written informed consent, they provided baseline blood samples for HbA_{1c} and FBG in their usual primary care setting. From medical records, we extracted data on patient age, gender, educational level, marital status, family income, personal/family history of chronic disease, number of hospitalizations, weight, height, waist circumference, and prescribed diabetes medications. Self-report questionnaires were pre-evaluated by two clinical nurse specialists and a nurse practitioner for appropriate content and wording.

Within one week after intervention was complete, patients again underwent HbA_{1c} and FBG tests, and repeated most of the baseline questionnaires. We re-reviewed their medical records to identify any changes in prescribed diabetes medications since baseline. They completed an adaptation of the Client Satisfaction Questionnaire. Semi-structured exit interviews were used to evaluate patients' overall experience of the program, perceived effects on their diabetes self-management, and usefulness of the weekly phone calls. From data automatically collected by the IVR system, call completion rate was calculated as percentage of calls that patients completed during 12 weeks that the system attempted to reach them.

After nurses provided written informed consent, their professional characteristics and attitudes regarding diabetes self-management were assessed. Within 2 weeks after

intervention ended, nurses completed a nurse-adapted version of the CSQ-8 and underwent a similarly adapted version of the semi-structured patient interview.

2.6 Instruments

2.6.1 The Diabetes Distress Scale (DDS)

We assessed the diabetes related distress using the emotional and regimen subscales from a Thai translation of the Diabetes Distress Scale (DDS) (Polonsky et al., 2005). The DDS is reliable and validated, and its indices correlate with related measures of emotional distress. Scores range from 10 - 60; higher scores indicate greater distress regarding emotional and regimen burdens (Cronbach's alpha = 0.90).

2.6.2 Self-management questionnaire

Self-management questionnaire included carbohydrate consumption, physical activity, and foot care. We measured carbohydrate consumption with the following item: "On how many of the past seven days did you eat a lot of sugary or starchy foods such as soft drinks, sweetened coffee or tea, fruit juice, candy, desserts, or extra rice or noodles?" Physical activity with the Stanford Leisure-Time Activity Categorical Item (L-Cat) (Kiernan et al., 2013), which asks respondents to classify their activity level by choosing one of six descriptive categories ranging from inactive (1) to very active and almost daily physical activity (6). Scores range from 1-6, and higher scores indicate greater physical activity. We measured foot care using the following item: "On how many of the past seven days and did you check your feet for sores, blisters, warmth, red areas and cuts?" Scores on both of these items can range from 0-7, with higher scores indicating more frequent self-care.

2.6.3 Medical adherence

Adherence to diabetes medication was measured using eight items on the Hill-Bone Compliance Scale (Kim, Hill, Bone, & Levine, 2000) that pertained to medication use, omitting the remaining items covering low-sodium diet and appointment-keeping. Items are paired with a 4-point Likert scale ranging from 1 (never) to 4 (always), possible scores range from 8-32, and higher scores indicate greater medication adherence (Cronbach's alpha: 0.59).

2.6.4 Sleep quality

We measured sleep quality using the PROMIS (Patient-Report Outcomes Information System) Sleep Disturbance-Short Form (Yu et al., 2012). This 4-item self-report instrument measures the quality of sleep-wake functioning (Buysse et al., 2010). Responses were scored on 5-point Likert scales, scores range from 4-20, and higher scores indicate greater sleep disturbance (Cronbach's alpha = 0.72).

2.6.5 Hypoglycaemic symptoms

Hypoglycaemia was assessed using a seven-item questionnaire covering the symptoms of low blood glucose symptom. The responses ranged from 0 "not at all" to 4 "6-7 days a week". The scoring range was 0-28; higher scores indicated more hypoglycaemic symptoms (Cronbach's alpha = 0.72).

2.6.6 Health literacy

Health literacy was assessed using a three item screener designed for this purpose (Chew et al., 2008). Scores range from 0-12; and higher scores indicate worse health literacy (Cronbach's alpha = 0.69).

2.6.7 Self-efficacy

We assessed self-efficacy using the Self-Efficacy for Diabetes Scale (Ritter, Lorig, & Laurent, 2016), which has eight items paired with 10-point Likert scales ranging from 1 (not at all confident) to 10 (totally confident). Total scores range from 8-80, and higher scores indicate greater self-efficacy (Cronbach's alpha = 0.84).

2.6.8 Depressive symptoms

Depressive symptoms were assessed by using the Patient Health Questionnaire-8 (PHQ-8) (Kroenke et al., 2009). Its eight items have 4-point Likert scales ranging from 0 (not at all) to 3 (nearly every day). Scores range from 0-24, with higher scores indicating greater depressive symptom severity (Cronbach's alpha = 0.77).

2.6.9 Social support

We assessed social support using items 3 through 8 from the Norbeck Social Support Questionnaire, which is a validated measure of number, type and quality of relationships (Norbeck, 1983). Items are scored on 5-point Likert scales ranging from 0 (not at all) to 4 (a great deal). Scores range from 0-32, with higher scores indicating better social support (Cronbach's alpha = 0.74).

2.6.10 Satisfaction

Patient and nurse satisfaction was assessed using the Client Satisfaction Questionnaire (CSQ-8; Attkisson & Zwick, 1982). Total scores can range from 8-32, and higher scores indicated greater program satisfaction (Cronbach's alpha = 0.88).

2.7 Ethical Considerations

This study was approved by the institutional review boards (IRBs) of the University of Michigan (HUM00118973) and Mahidol University (MUPH2016-130) and conducted under the concept of the Declaration of Helsinki.

2.8 Data Analysis

Data were analyzed using Stata 14 (College Station, TX: Stata Corp LP). We used the Shapiro-Wilk Test to assess normal distribution. We calculated means, standard deviations and percentages (when applicable) for normally distributed variables, and medians and interquartile ranges (IQR) for those with skewed distributions. Post-pre difference scores were evaluated for normality using the Shapiro-Wilk Test. We used paired student *t*-tests with alpha set at 0.05 to evaluate changes in glycemic control and self-care behavior. We calculated Pearson correlations to assess associations between change scores for HbA_{1c}, fasting blood glucose, weight and other variables. Effect sizes were converted into Cohen's *d* estimates, which we interpreted using cut-offs of 0.20, 0.50 and 0.80 as indicating small, medium and large effects, respectively. HbA_{1c} effects were represented in raw HbA_{1c} units to facilitate interpretation of clinical significance. Interviews were recorded and transcribed verbatim, coded and categorized for responses. Thoughts and feelings were documented in memos, and themes were extracted from data analysis and interpretation.

3. RESULTS

3.1 Participants characteristics

As shown in Table 2, the patients tended to be married women with less than a secondary school education, and annual household income ≤15,000 baht. Their ages ranged

from 31 to 67 years with mean 54.9 years. They tended to have no recent hospitalizations and mean diabetes duration was 6.1 years. All nurses were female. Their ages ranged from 35 to 46 years with mean 41.0 years and their years of experience caring for diabetes patients ranged from 8 to 21 years with mean 12.7 years.

Median baseline HbA_{1c} was 8.2% (7.9 - 9.3), and median fasting blood glucose was 152.0 mg/dL (131.0 – 190.0). Median weight was 66.0 kg (56.0 – 75.0), and median body mass index (BMI) was 27.0 kg/m² (23.5 - 28.7). Patients tended to report high carbohydrate consumption, low physical activity, a high degree of foot care, high medication adherence, and moderate sleep quality.

3.2 Changes in outcomes

Mean reduction in HbA_{1c} was 0.9% (p <0.001) and in fasting blood glucose was 14.9 mg/dL (p <0.001) (Table 3). As shown in Figure 2, HbA_{1c} reduced by at least 1.0% for half of the patients and by 0.5 – 0.9% for another 23% of the patients. Diabetes medication prescriptions changed for 20 patients during the study period. However, four of these patients had their dosage reduced, while 11 had their dosage intensified. Among patients whose diabetes medications remained unchanged, mean HbA_{1c} reduction was 0.6%.

As shown in Table 3, there were improvements in carbohydrate consumption (p <0.001), physical activity (p<0.001), medical adherence (p<0.001), sleep quality (p<0.001), hours of sleep (p<0.001) and frequency of foot care (p<0.001). Significant improvements also emerged for diabetes self-efficacy (p<0.001), distress (p<0.05) and depressive symptom severity (p<0.001). Overall, eight of the twelve self-care measures showed at least a moderate effect size in the desired direction. The absolute values of standardized effect sizes

ranged from 0.3 to 0.9; among the self-care variables, carbohydrate consumption showed the greatest improvement.

Pearson correlations between post-pre differences in the outcomes were performed. Change in HbA_{1c} was significantly associated with changes in fasting blood glucose and carbohydrate consumption (r = .54 and .56, both p < .001). Change in carbohydrate consumption was negatively correlated with changes in medical adherence (r = -.35, p < .05). Change in sleep disturbance was negatively correlated with change in health literacy, but positively correlated with change in depressive symptom severity (r = -.34 and .35, both p < .05 respectively). A non-significant trend emerged for change in fasting blood glucose to co-vary with changed carbohydrate consumption (p = .06). Effect sizes were large for changes in carbohydrate consumption and foot care (Cohen'd = -0.9 and 0.8, respectively), but not for changes in social support (Cohen'd = -.1).

3.3 Call Completion

Disregarding the one patient who withdrew at week 3, the system made calling attempts to the remaining 35 patients for 12 weeks, yielding a total of 420 possible "call-weeks." Patients completed calls during 71% of weeks in which a call was attempted. The leading reason given for incomplete calls was "technical problems." In addition, some patients reported that they unintentionally disconnected at least one IVR call by turning off their telephone (16.9%).

3.4 Participants' satisfaction and themes

Patients reported very high overall satisfaction with IVR (see Table 4). Most patients would definitely use the system again if it were offered, and would definitely recommend the system

to others. Although all nurses reported high program satisfaction, only 33% were willing to either continue using the system or recommend it to a friend. Themes emerged as follow;

3.4.1 Patient: Qualitative analysis of patient interviews (n=35) revealed 3 main themes.

3.4.1.1 Valuable reminders

Most patients reported that the regular weekly frequency of the IVR calls helped them to perform healthy behaviors. For example, "I like it, I felt it raised my consciousness" (47-year-old female), and "Receiving calls made me pay attention more than at the lecture because I had to answer...making me remember information" (53-year-old male). Some patients indicated that the IVR messages and health log booklets were helpful. For example, "I like both (the) IVR and the booklets. It seemed like I usually heard the messages from the IVR when I was eating," and "I put my personal health record booklet on the table, and it reminded me about what I should eat every time I saw it" (54-year-old male), and "Phone calls were better than booklets" (53-year-old female).

3.4.1.2 Satisfaction with the program

All patients reported that they enjoyed participating in the program, even though not all of them expected significant benefits. Some patients were surprised that the program helped them improve their self-care, because they had previously received instruction in diabetes management. For example, "I want this program, and will recommend it to my friends so they can take care of their health" (58-year-old female), "What I like most about the program is that they called me and I just listened to the content" (60-year-old female), "At first, I didn't believe this program was helpful....If I had believed the program at the

first 4 weeks, I would be better than this" (49-year-old male), "Because of the program, my consumption behavior changed the most; I eat less.... and more slowly" (54-year-old male), "This program changed my eating patterns...reduced snacks" (67-year-old female), and "I would join the program if it was continued" (58-year-old female)

3.4.1.3 System initially unpleasant

Many patients indicated that the phone connection was initially unstable. However, we were able to resolve this technical problem within the first 4 weeks of the trial. For example, "I heard the phone call, but when I pressed the number, the phone did not recognize my response when I pressed the number" (59-year-old female), "Sometimes, the system did not recognize me, even though I'd already answered the calls" (52-year-old female), "The system should be improved" (49-year-old male).

3.4.2 Nurses: We interviewed 5 (out of the 6) participating nurses and three themes were revealed.

3.4.2.1 System needs more patient engagement

Four nurses reported interest in continuing the program, citing a variety of reasons.

First, they felt that the program enhanced awareness of patients' awareness of their diabetes.

Second, they reported that the program helped patients improve their glycaemic control.

Third, they noted that the program seemed to enhance patient-nurse relationships by triggering them to call their patients each week. For example, "For me, the program was good for patients because I could respond to patients when they had any problems without coming to see me...my patient told me she felt great and that it was like having a personal physician," "The program helped my patient with behavior modification. She used to eat a lot of

carbohydrates, but now she eats less," "Based on evaluation, 3 of my 6 patients learned to control their blood glucose levels without close monitoring... Because of the system."

3.4.2.2 System was burdensome

Although the system was seen as providing useful updates to nurses, five nurses discussed their concerns about the high number of emails that they received every week, and the length of instructions that the system gave them for supporting patients' self-management. For example, "This study included only 5 to 6 patients for me, so there was no problem. However, I have approximately 400 (diabetes) patients, so this might become a burden if it reports every problem (to me)," "The self-management support content in emails should be more concise. I printed all emails with reports for six patients every week, but I couldn't read them all. It's a lot."

3.4.2.3 System is not ideal for all (patients or nurses)

Qualitative data indicated that the program would be improved if it gave more careful consideration to patients' age and technological literacy. For example, "The system should be used for patients with glycemic control and with the agreement of nurses"... "my patients told me they sometimes asked their children to press the number", "This program can be (best) used with the new generation, and "Some patients were old" (35-year-old female).

4. DISCUSSION

This study demonstrated the feasibility of a system of IVR monitoring with community nurse feedback for Thai patients with poorly controlled type 2 diabetes. Willingness to enroll in the program was high. Call completion was as high as comparable previous studies (Aikens, Trivedi, Aron, & Piette, 2015; Gallegos-Cabriales et al., 2017) and higher than we have noted

among patients in Honduras and Bolivia (Piette et al., 2013; Piette et al., 2016). After 12 weeks of the program, patients demonstrated significant improvements in HbA_{1c} , carbohydrate consumption, physical activity, foot care, and sleep quality.

Although change in HbA_{1c} was associated with reduced carbohydrate consumption, it was not associated with changes in any other self-care behaviors. This is consistent with previous studies indicating that HbA_{1c} improvement occurs with low as opposed to normal carbohydrate diets (Kirk et al., 2008; Nielsen & Joensson, 2008). Consistent with previous studies, patients' depressive symptoms improved with self-management support (Piette et al., 2012; Piette, Weinberger, & McPhee, 2000). However, because our study had limited statistical power, these findings should be considered preliminary.

While our system of IVR monitoring and nurse prompting may improve HbA_{1c} , qualitative data indicated some key areas for improvement. Specifically, patients were appropriately concerned with the system's initial unreliability, and nurses were concerned about the burden of receiving a high number of prompts with lengthy messages.

4.1 Limitations

Although the strengths of this study were its high rates of recruitment and retention, implementation at multiple sites, and preliminary objective evidence of benefit, important limitations should be acknowledged. Because this study was designed to evaluate program feasibility, it did not include a control group. Extraneous factors such as the passage of time, increased clinical attention, and repeated assessment might also explain improvement. Study power may have been insufficient to detect statistically significant differences. Finally, most

participants were older adult suburban-dwelling females with low educational levels, which may reduce generalizability to other groups.

5. CONCLUSION

A system of IVR monitoring and nurse prompting is feasible and may improve HbA_{1c}. Despite the fact that glycated haemoglobin was associated with carbohydrate consumption, these findings are only preliminary. Thus, it requires verification in larger samples and a longer randomized controlled trial. Furthermore, the platform should be modified to be less burdensome to community health nurses. Improvements in nurses' support with short and concise message to their patients might result in better improved patient illness management behavior and glycated haemoglobin.

REFERENCES

- Aikens, J. E., Trivedi, R., Aron, D. C., & Piette, J. D. (2015). Integrating support persons into diabetes telemonitoring to improve self-management and medication adherence.

 **Journal of General Internal Medicine*, 30(3), 319-326. doi.org/10.1007/s11606-014-3101-9
- Aikens, J. E., Zivin, K., Trivedi, R., & Piette, J. D. (2014). Diabetes self-management support using mHealth and enhanced informal caregiving. *Journal of Diabetes and Its*Complications, 28(2), 171-176. doi.org/10.1016/j.jdiacomp.2013.11.008
- Attkisson, C. C., & Zwick, R. (1982). The client satisfaction questionnaire: psychometric properties and correlations with service utilization and psychotherapy outcome.

 Evaluation and Program Planning, 5(3), 233-237. doi.org/10.1016/0149-7189(82)90074-X
- Buysse, D. J., Yu, L., Moul, D. E., Germain, A., Stover, A., Dodds, N. E.,... Pilkonis, P. A. (2010). Development and validation of patient-reported outcome measures for sleep disturbance and sleep-related impairments. *Sleep*, 33(6), 781-792. doi.org/10.1093/sleep/33.6.781
- Chew, L. D., Griffin, J. M., Partin, M. R., Noorbaloochi, S., Grill, J. P., Snyder, A., ...

 VanRyn, M. (2008). Validation of screening questions for limited health literacy in a large VA outpatient population. *Journal of General Internal Medicine*, 23(5), 561-566. doi.org/10.1007/s11606-008-0520-5
- Diabetes Association of Thailand. (2017). Clinical Practice Guideline for Diabetes 2017.

 Bangkok.

- Fowler, M. J. (2011). Microvascular and macrovascular complications of diabetes. *Clinical Diabetes*, 29(3), 116-122. doi.org/10.2337/diaclin.26.2.77
- Gallegos-Cabriales, E. C., Guti rez-Valverde, J. M., Salazar-Gonz elez, B. C., Villarruel, A. M., Veloz-Garza, R. A., Marinec, N., & Piette, J. D. (2017). Automated telephone calls in the follow-up of self-care in outpatients with type 2 diabetes: a feasibility study. *Health*, 9, 1529-1541. doi.org/10.4236/health.2017.911113
- Green, L. W., & Kreuter, M. W. (2005). *Health program planning: An educational and ecological approach* (4th ed.). New York: McGraw-Hill.
- Kiernan, M., Schoffman, D. E., Lee, K., Brown, S. D., Fair, J. M., Perri, M. G., & Haskell, W. L. (2013). The Stanford Leisure-Time Activity Categorical Item (L-Cat): a single categorical item sensitive to physical activity changes in overweight/obese women.
 International Journal of Obesity, 37(12), 1597-1602. doi.org/10.1038/ijo.2013.36
- Kim, M. T., Hill, M. N., Bone, L. R., & Levine, D. M. (2000). Development and testing of the Hill-Bone Compliance to High Blood Pressure Therapy Scale. *Progress in Cardiovascular Nursing*, *15*(3), 90-96. doi.org/10.1111/j.1751-7117.2000.tb00211.x
- Kirk, J. K., Graves, D. E., Craven, T. E., Lipkin, E. W., Austin, M., & Margolis, K. L. (2008).
 Restricted-carbohydrate diets in patients with type 2 diabetes: a meta-analysis.
 Journal of the American Dietetic Association, 108(1), 91-100.
 doi.org/10.1016/j.jada.2007.10.003
- Kroenke, K., Strine, T. W., Spitzer, R. L., Williams, J. B., Berry, J. T., & Mokdad, A. H. (2009). The PHQ-8 as a measure of current depression in the general population.

 *Journal of Affective Disorders, 114(1-3), 163-173. doi.org/10.1016/j.jad.2008.06.026

- Kulnawan, N., Jiamjarasrangsi, W., Suwanwalaikorn, S., Kittisopee, T., Meksawan, K.,

 Thadpitakkul, N., & Mongkung, K. (2011). Development of diabetes telephone-linked care system for self-management support and acceptability test among type 2 diabetic patients. *Journal of the Medical Association of Thailand*, *94*(10), 1189-1197.
- McCann, T. V., Songprakun, W., & Stephenson, J. (2015). Effectiveness of guided self-help in decreasing expressed emotion in family caregivers of people diagnosed with depression in Thailand: a randomised controlled trial. *BMC psychiatry*, *15*(1), 258. doi.org/10.1186/s12888-015-0654-z
- Mekwiwatanawong, C., Hanucharurnkul, S., Piaseu, N., & Nityasuddhi, D. (2013).

 Comparison of outcomes of patients with diabetes receiving care by way of three primary care practice models. *Pacific Rim International Journal of Nursing Research*, 17(1), 39-55.
- Ministry of Public Health. (2016). *Annual report 2016*. Department of Disease Control: Bangkok.
- Ministry of Public Health. (2017). Report on Public Health Resource. Retrieved from http://social.nesdb.go.th/SocialStat/StatReport_Final.aspx?reportid=662&template=1 R2C&yeartype=M&subcatid=18
- Nielsen, J. V., & Joensson, E. A. (2008). Low-carbohydrate diet in type 2 diabetes: stable improvement of bodyweight and glycemic control during 44 months follow-up.

 Nutrition & Metabolism, 5(1), 14. doi.org/10.1186/1743-7075-5-14

- Norbeck, J. S. J. (1983). Further development of the Norbeck Social Support Questionnaire: normative data and validity testing. *Nursing Research*, 32(1), 4-9. doi.org/10.1097/00006199-198301000-00002
- Ounnapiruk, L., Wirojratana, V., Meehatchai, N., & Turale, S. (2014). Effectiveness of a behavior modification program for older people with uncontrolled Type 2 Diabetes.

 Nursing & Health Sciences, 16(2), 216-223. doi.org/10.1111/nhs.12089
- Pfeiffer, P. N., Bohnert, K. M., Zivin, K., Yosef, M., Valenstein, M., Aikens, J. E., & Piette, J. D. (2015). Mobile health monitoring to characterize depression symptom trajectories in primary care. *Journal of Affective Disorders*, 174, 281-286. doi.org/10.1016/j.jad.2014.11.040
- Piette, J. D., Datwani, H., Gaudioso, S., Foster, S. M., Westphal, J., Perry, W., ... Marinec, N. (2012). Hypertension management using mobile technology and home blood pressure monitoring: results of a randomized trial in two low/middle-income countries.

 *Telemedicine and e-Health, 18(8), 613-620. doi.org/10.1089/tmj.2011.0271
- Piette, J. D., Marinec, N., Gallegos-Cabriales, E. C., Gutierrez-Valverde, J. M., Rodriguez-Saldana, J., Mendoz-Alevares, M., & Silveira, M. J. (2013). Spanish-speaking patients' engagement in interactive voice response (IVR) support calls for chronic disease self-management: data from three countries. *Journal of Telemedicine and Telecare*, 19(2), 89-94. doi.org/10.1177/1357633X13476234
- Piette, J. D., Marinec, N., Janda, K., Morgan, E., Schantz, K., Yujra, A. C. A., ... Aikens, J. E. (2016). Structured caregiver feedback enhances engagement and impact of mobile

- health support: a randomized trial in a lower-middle-income country. *Telemedicine* and e-Health, 22(4), 261-268. doi.org/10.1089/tmj.2015.0099
- Piette, J. D., Weinberger, M., & McPhee, S. J. (2000). The effect of automated calls with telephone nurse follow-up on patient-centered outcomes of diabetes care: a randomized, controlled trial. *Medical Care*, 38(2), 218-230.
- Polonsky, W. H., Fisher, L., Earles, J., Dudl, R. J., Lees, J., Mullan, J., & Jackson, R. A. (2005). Assessing psychosocial distress in diabetes development of the diabetes distress scale. *Diabetes Care*, 28(3), 626-631. doi.org/10.2337/diacare.28.3.626
- Ritter, P. L., Lorig, K., & Laurent, D. D. (2016). Characteristics of the Spanish- and English-Language Self-Efficacy to Manage Diabetes Scales. *Diabetes Educator*, 42(2), 167-177. doi.org/10.1177/0145721716628648
- UK Prospective Diabetes Study (UKPDS) Group. (1998). Intensive blood-glucose control with sulphonylureas or insulin compared with conventional treatment and risk of complications in patients with type 2 diabetes (UKPDS 33). *The Lancet*, *352*(9131), 837-853. doi.org/10.1016/S0140-6736(98)07019-6
- Wattanakorn, K., Deenan, A., Puapan, S., & Schneider, J. K. (2013). Effects of an eating behaviour modification program on that people with diabetes and obesity: a randomised clinical trial. *Pacific Rim International Journal of Nursing Research*, 17(4), 356-370.
- Wongrochananan, S., Tuicomepee, A., Buranarach, M., & Jiamjarasrangsi, W. (2015). The effectiveness of interactive multi-modality intervention on self-management support of type 2 diabetic patients in Thailand: a cluster-randomized controlled trial.

International Journal of Diabetes in Developing Countries, 35(2), 230-236. doi.org/10.1007/s13410-015-0354-8

Yu, L., Buysse, D. J., Germain, A., Moul, D. E., Stover, A., Dodds, N. E., ... Pilkonis, P. A. (2012). Development of short forms from the PROMIS sleep disturbance and sleep-related impairment item banks. *Behavioral Sleep Medicine*, 10(1), 6-24. doi.org/10.1080/15402002.2012.636266



