Effectiveness of a Drug Reminder Application on Adherence to Uric Acid-Lowering Therapy in Gout Patients: A Randomized Trial

Nattharadee Phutthinart[1], Wanwisa Chanapai[2], Wanruchada Katchamart[1]

[1]Division of Rheumatology, Department of Medicine, Faculty of Medicine Siriraj Hospital, Mahidol University, Bangkok, Thailand
[2]Division of Clinical Trials, Research Department, Siriraj Hospital Faculty of Medicine Siriraj Hospital, Mahidol University, Bangkok, Thailand

Abstract

Introduction: Almost half of gout patients fail to achieve target serum uric acid (SUA) levels due to poor adherence to urate-lowering therapy (ULT), leading to adverse outcomes and increased healthcare costs. Mobile health applications (apps) have become effective tools for improving medication adherence in patients with chronic diseases.
Objectives: This study aimed to evaluate the effectiveness of a drug reminder mobile app in improving adherence to ULT in gout patients with poor adherence.
Methods: We conducted an open-label, randomized controlled trial involving 54 gout patients with SUA > 6 mg/dL and poor adherence to ULT. Patients were randomly assigned to either the "Drug Diary" reminder app group (N=25) or the "Roo-Rak-Koh" patient education app group (N=29). Co-primary outcomes included ULT adherence (measured by the MTB-T questionnaire), pill count adherence, and the proportion of patients achieving the SUA target (<6 mg/dL). A stable ULT dose was maintained throughout the study.
Results: At 12 weeks, the proportion of patients with high ULT adherence and pill count adherence were higher in the drug reminder app group (63% vs 37%, p=0.102 for MTB-T and 96% vs 93%, p=0.615 for pill count). SUA target achievement was similar in both groups (48% vs 47.8%, p=0.89). However, SUA reduction was significantly greater in the drug reminder app group (-1.63 ± 1.18 vs -0.76 ± 1.24, p=0.01).
Conclusions: Mobile health applications, including drug reminder and patient education apps, may improve medication adherence. The integration of both apps could offer complementary benefits in gout management

Keywords: gout, mobile application, drug adherence

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Correspondence to:
Wanruchada Katchamart, MD
Associate Professor of Medicine
Division of Rheumatology, Department of Medicine
Faculty of Medicine Siriraj Hospital, Mahidol University
2 Wanglang Road, Bangkok Noi, Bangkok, Thailand, 10700
Tel: +66 2 419 7775 Fax: +66 2 418 3222
Email: wanruchada.kat@mahidol.ac.th
ORCID iD: 0000-0002-8952-5967
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Introduction

Gout is the most common inflammatory arthritis, caused by the deposition of monosodium urate crystals in joints, leading to inflammation, pain, and joint destruction.[1] Given the role of hyperuricemia in the etiology of gout, urate-lowering therapy (ULT) becomes the cornerstone treatment in gout. Recent clinical guidelines for gout treatment recommended a treat-to-target strategy using ULT to achieve a serum uric acid (SUA) level below 6 mg/dL (or 5 mg/dL in selected circumstances).[1-4] Despite these recommendations, only approximately 50% of patients with gout have achieved the treatment target.[4,5] In addition to suboptimal ULT dosing, recent studies indicate nonadherence to ULT as a major barrier to achieving this SUA target.[1,6]

Adherence to medications refers to the degree of conformity to treatment recommendations with respect to the timing, dosage, frequency, and duration of a prescribed medication.[7] Causes of drug nonadherence are classified as unintentional or intentional.[8] Unintentional nonadherence involves intending to take a prescribed medication but failing to do so for some reasons, including forgetfulness or carelessness. In contrast, intentional nonadherence involves making a reasoned decision not to take a prescribed medication based on perceptions, feelings, or beliefs. Nonadherence to medications is a common and complex problem that contributes to poor treatment outcomes in chronic diseases, including gout. For gout, achieving the therapeutic target of SUA is strongly associated with adherence to ULT.[9,10] However, adherence to ULT among patients with gout is poor, with adherence rates between 10 and 72%.[11-16] In Thailand, Asaiphanit et al. found that only approximately half of gout patients (43.4%) were adherent, while only one-third achieved the SUA target (29.2%).[6]

Mobile phone health applications (app) are becoming an effective way to support self-management, including improving medication adherence in patients with chronic diseases. Many studies have supported the effectiveness of mobile health apps in improving medication adherence in many chronic diseases, such as hypertension,[17,18] type 2 diabetes mellitus,[7] and HIV infection.[19]

To improve the standard of care in Thai patients with rheumatic and autoimmune diseases, we developed a Thai drug reminder application, called the "Drug Diary". The "Drug Diary" app features medication scheduling, reminders, tracking, and adherence assessment to help patients manage their medications. This app provides alerts to remind patients when it is time to take medications and generates monthly adherence reports. Although the mobile health apps could potentially improve drug adherence in patients with gout, especially those with unintentional nonadherence, its effectiveness is still unclear. This study aimed to explore the effectiveness of the drug reminder app "Drug Diary" in improving medication adherence in patients with gout, compared to the active control intervention using the patient education “Roo-Rak-Koh” app. We developed the “Roo-Rak-Koh” app to provide information related to various rheumatic and autoimmune diseases, including rheumatoid arthritis, spondyloarthritis, gout, calcium pyrophosphate dihydrate deposition disease, osteoarthritis, systemic lupus erythematosus, inflammatory myopathy, and osteoporosis. Educational information included medical history, medications, joint protection method, and musculoskeletal exercise. Both applications are free mobile phone applications available on both Android and iOS platforms and under the patent of Mahidol University.

Materials & Methods

Study design and population

This 12-week, pragmatic, open-labelled, randomized controlled study was conducted in the outpatient unit, Department of Medicine, Siriraj Hospital, Bangkok, Thailand. This trial was registered at Thai Clinical Trial Registry (Identifier: TCTR20200123002, registered on 23 January 2020). The study population consisted of 18-year-old or older individuals who met the 2015 ACR-EULAR Gout Classification Criteria[5] or Rome Criteria[20] with serum uric acid (SUA) greater than 6 mg/dL despite ULT treatment and having poor adherence to ULT based on the Medication Taking Behavior measure for Thai patients (MTB-T) questionnaire.[21] Patients must have sufficient ability to use Thai language and

have access to an Android or iOS smartphone device. Patients were excluded if they could not complete the questionnaires or were diagnosed with dementia or a psychiatric, visual, auditory, or neurological disorder, that interfered with smartphone use. Informed consent was obtained from all patients prior to enrollment. Eligible patients were randomly assigned in a 1:1 ratio using a computer-generated sequence with a block of four randomization to use the reminder "Drug Diary" app, or the patient education “Roo-Rak-Koh” app. This study was approved by the Scientific Ethics Committee of the Siriraj Institutional Review Board (COA Si no. 015/2020). All procedures were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Helsinki Declaration and its later amendments or comparable ethical standards.

Study Procedures

Baseline visit

The patients were instructed to download the app "Drug Diary" or the app "Roo-Rak-Koh". The researchers assisted patients in setting up their medication schedule and reminder on the app and demonstrated how to use the app. For patients in the patient education group, researchers demonstrated the educational functions in the application. All patients were asked to use the apps for 12 weeks and were reminded by telephone on days 3, 30, and 60. For ULT, the stable dose of ULT was maintained throughout the study. The exact number of pills that should be taken per 12-week prescription of each medication was prescribed. The patients were instructed to take only the pills that were prescribed at the initial visit.

The following data were collected: demographic data (age, sex, educational level, occupation, body mass index, and comorbidities); history of alcohol use; characteristics of gout (diagnosis, duration of the disease, and number of gout flares); laboratory data (SUA level and glomerular filtration rate [GFR]); gout treatments (ULT dose and gout prophylaxis therapy), and other medications. Medication adherence was assessed using the Medication Taking Behavior measure for Thai patients (MTB-T) questionnaire, a medication taking behavior scale developed in the Thai language. The MTB-T score consists of six questions that are analyzed using a 4-point Likert scale. The total score is 24 points. A score of 24 indicates 'high adherence', scores of 22–23 suggest 'moderate adherence', and a score less than 22 is considered 'low adherence'. The scale showed good psychometric properties for medication adherence in Thai patients with various chronic diseases, including rheumatic diseases and musculoskeletal disorders [21].

Follow-up visit

All patients were instructed to bring all their leftover pills when they came to the clinic at 12 weeks of follow-up. SUA, GFR, and the frequency of gout flares were collected. The adherence to medication and the patient satisfaction with the apps were assessed. Adherence was assessed using MTB-T and the pill count rate (%). Pill count rate is a simple objective indirect measurement of patient adherence to medication intake[22]. The adherence rate was calculated using the following equation:

$$\text{Pill count adherence (\%)} = \frac{\text{Number of prescribed pills} - \text{Number of returned pills}}{\text{Number of prescribed pills}} \text{ X } 100\ \%$$

Medication adherence was defined as follows, the MTB-T questionnaire score of 24 or a pill count rate > 80% indicated 'high adherence', the MTB-T questionnaire score of 22-23 or the pill count rate range between 60-80% 'moderate adherence' and 'low adherence' if both previous conditions are not met. Patient satisfaction in both applications was measured using a visual analog scale (VAS) ranging from 0 (terrible) to 10 (delighted).

Outcomes

The co-primary outcomes were the proportion of patients with high adherence, according to the MTB-T score, the percentage of pill count adherence and the proportion of patients with SUA <6 mg / dL at 12 weeks. Secondary outcomes consisted of the proportion of patients with high adherence, based on pill count, changes in SUA level, GFR, and frequency of flare-up of gout, as well as patient satisfaction scores with both applications.

Data collection

Study data were collected and managed using REDCap (Research Electronic Data Capture) tools hosted at the Siriraj Center of Excellence in Bioinformatics and Data Management, Siriraj Hospital Faculty of Medicine Siriraj Hospital, Mahidol University.[23] REDCap is a secure web-based application designed to support data capture for research studies. It provides 1) an intuitive interface for validated data entry; 2) audit trails to monitor data manipulation and export procedures; 3) automated export procedures for seamless data downloads to common statistical packages; and 4) procedures for the importing of data from external sources.

Statistical Analysis

Descriptive statistics were presented for the baseline data. For all results, categorical variables were compared using the chi-square test or Fisher's exact test, as appropriate, while continuous data were compared using the independent T-test or the Mann-Whitney U test for data that were not normally distributed. The analysis was carried out using the intention-to-treat (ITT) method. Nonresponder imputation was used for models examining achievement of SUA when follow-up values were missing. A p-value of less than 0.05 was considered statistically significant. No adjustment was made for multiple comparison. All analyses were performed using the Statistical Package for the Social Science (SPSS) 20.0.

Results

Between July 2020 and May 2022, a total of 124 patients were screened for eligibility; however, 54 were eligible and randomly assigned; 25 in the "Drug diary" app group and 29 in the "Roo-Rak-Koh" app group. At 12 weeks, 24/25 (96%) patients in the "Drug diary" app group and 26/29 (90%) patients in the "Roo-Rak-Koh" app group completed the study (Figure 1). Baseline demographics, disease characteristics, comorbidities, treatments related to gout and the MTB-T scores were generally balanced between the groups (Table 1).

At 12 weeks, the proportion of patients who had high ULT adherence based on MTB-T was numerically higher in the "Drug diary" app group compared to the "Roo-Rak-Koh" app group, (62% vs 37%, p= 0.102). Furthermore, the percentage of pill count adherence did not significantly differ in the 'Drug diary' app group (95.86% vs. 92.63%, p=0.615). The proportion of patients who achieved the targeted SUA < 6 mg/dL was similar between the groups (48% for the "Drug diary" app group vs 47.8% for the "Roo-Rak-Koh" app group, p=0.89) (Figure 2). There was a significant reduction in SUA and the number of flares of gout from baseline in both groups. Furthermore, the absolute reduction in SUA from baseline was significantly greater in the 'Drug diary' group (mean±SD -1.63±1.18 mg/dL vs -0.76±1.24mg/dL, p = 0.01) (Table 2). For patient satisfaction with applications, assessed using a 0-10 visual analog scale (VAS), the median satisfaction score (P25-P75) was similar between the groups [8.0 (8.0-9.0) in the 'Drug diary' app group and 9.0 (8.0-10.0) in the 'Roo-rak-koh' app group, p=0.48].

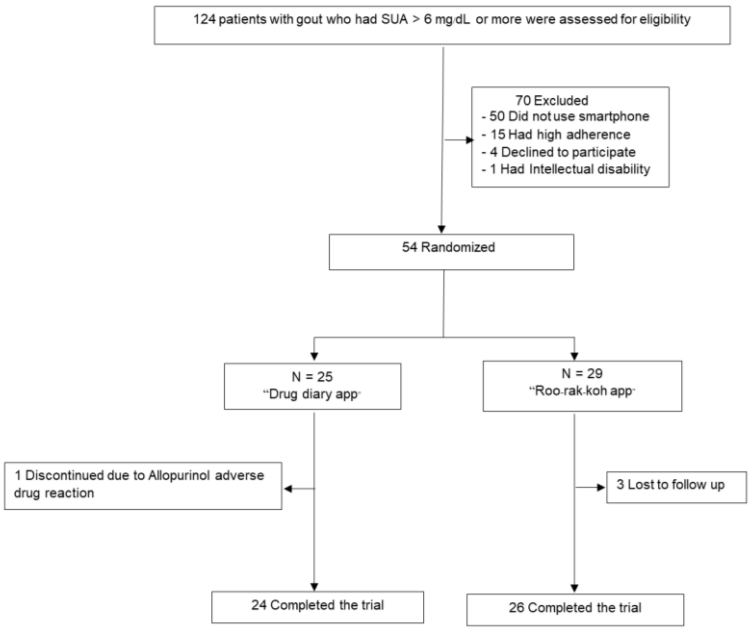

Figure 1. CONSORT flow diagram of patient screening, randomization, and study completion

Table 1 Patient demographic and baseline characteristics

	Total (n = 54)	**Drug diary (n = 25)**	**Roo-rak-koh (n= 29)**
Age (year), mean ± SD	56.41±13.60	53.56±15.25	58.86±11.73
Men, N (%)	45.00 (83.30)	19.00 (76.00)	26.00 (89.70)
Education (year), median (IQR)	12.00 (7.00-16.00)	12.00 (12.00-16.00)	12.00 (6.00-16.00)
BMI (kg/m^2), mean ± SD	26.92±4.18	26.82±3.74	27.00±4.60
Duration of gout (month), Median (IQR)	42.45 (23.10-103.40)	30.43 (23.10-83.93)	60.27 (23.20-119.33)
Serum uric acid (mg/dL), mean ± SD	7.41±1.32	7.78±1.66	7.09±0.84
eGFR (mL/min/1.73 m^2), mean ± SD	67.90±22.00	71.19±25.56	64.96±18.22
Comorbidities			
• **Alcohol use,** N (%)	21.00 (38.90)	8.00 (32.00)	13.00 (44.8)
• **Diabetes mellitus,** N (%)	11.00 (20.40)	4.00 (16.00)	7.00 (24.10)
• **Hypertension,** N (%)	28.00 (51.90)	13.00 (52.00)	15.00 (51.70)
• **Dyslipidemia,** N (%)	21.00 (38.90)	11.00 (44.00)	10.00 (34.50)
• **Cerebrovascular disease,** N (%)	2.00 (3.70)	2.00 (8.00)	0.00 (0.00)
• **Coronary artery disease,** N (%)	3.00 (5.60)	1.00 (4.00)	2.00 (6.90)
• **Other,** N (%)	14.00 (25.90)	5.00 (20.00)	9.00 (31.00)
Frequency of gout attack, median (IQR)	0.00 (0.00-2.00)	0.00 (0.00-2.00)	0.00 (0.00-2.00)

Allopurinol, N (%)	51.00 (94.40)	24.00 (96.00)	27.00 (93.10)
Allopurinol dose (mg/d), median (IQR)	200.00 (100.00-300.00)	200.00 (125.00-300.00)	200.00 (100.00-300.00)
Benzbromarone, N (%)	3.00 (5.60)	1.00 (4.00)	2.00 (6.90)
Benzbromarone dose (mg/d), median (IQR)	42.80 (25.00-50.00)	42.80 (42.80-42.80)	37.50 (25.00-50.00)
Gout prophylaxis, N (%)	36.00 (66.70)	17.00 (68.00)	19.00 (65.50)
• **Colchicine,** N (%)	36.00 (66.70)	17.00 (68.00)	19 (65.50)
• **NSAIDS,** N (%)	1.00 (1.90)	0.00 (0.00)	1.00 (3.40)
MTB-T score (0-24), mean ± SD	22.45±8.18	21.52±1.83	23.25±11.06

Abbreviation: - BMI, body mass index; GFR, glomerular filtration rate; IQR, interquartile range; kg/m2, kilogram per square meter; mg, milligram; mg/dL, milligram per deciliter; ml/min/1.73 m2, milliliter per minute by body surface area; MTB-T, Medication-taking behavior questionnaire for Thai patients; NSAIDs, non-steroidal anti-inflammatory drug; SD, standard deviation

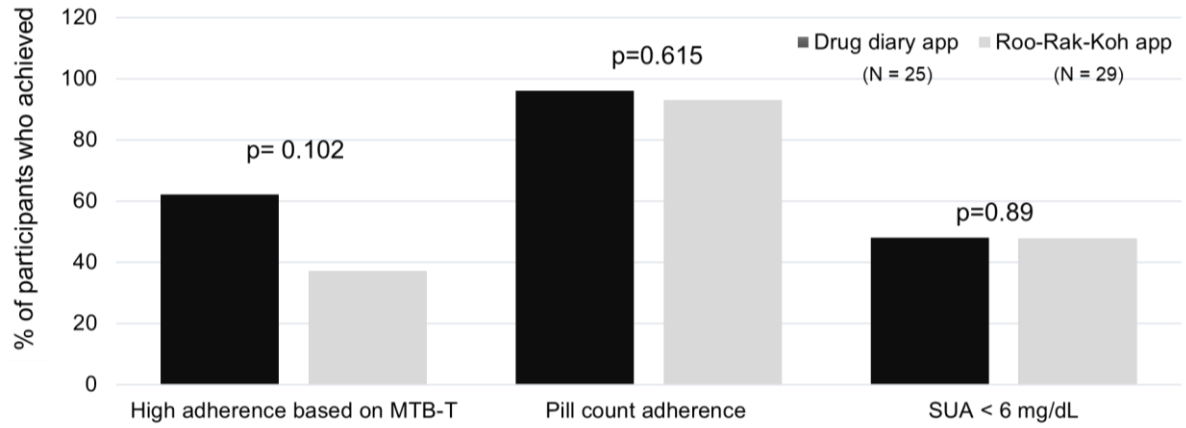

Figure 2. The proportion of patients who achieved the uric acid goal and urate-lowering therapy adherence at 12 weeks

Table 2 Comparisons of change from baseline in clinical and laboratory outcomes within and between groups

	Drug diary (n= 25)				Roo-rak-koh (n= 29)				
	Baseline	Follow up at 12 weeks	Mean change (95% CI)	p-value	Baseline	Follow up at 12 weeks	Mean change (95% CI)	p-value	**p-value between groups***
Serum Uric acid (mg/dL), mean ± SD	7.78±1.66	6.15±1.15	-1.63 (-2.11 to -1.14)	< 0.001	7.09±0.84	6.33±1.27	-0.76 (-1.23 to -0.29)	0.003	0.01
GFR (mL/min/1.73 m^2), mean ± SD	71.19±25.56	73.29±25.21	2.10 (-0.62 to 4.83)	0.125	64.96±18.23	64.99±17.63	0.03 (-2.09 to 2.15)	0.980	0.22
MTB-T, mean ± SD	21.52±1.83	23.56±0.87	2.00 (1.42 to 2.67)	< 0.001	23.25±11.06	22.76±1.09	-0.49 (-4.67 to 3.69)	0.813	0.26
No. gout flare, mean ± SD	0.84±1.11	0.04±0.20	-0.80 (-1.25 to -0.35)	0.001	0.86±1.06	0.41±0.73	-0.45 (-0.76 to -0.13)	0.007	0.18

Abbreviation: - GFR, glomerular filtration rate; kg/m2, mg/dL, milligram per deciliter; ml/min/1.73 m2, milliliter per minute by body surface area; MTB-T, Medication-taking behavior questionnaire for Thai patients; SD, standard deviation
*for change from baseline using independent-T test

Discussion

This study expands on previous work by directly comparing two digital interventions that target distinct mechanisms of nonadherence, reminder-based versus education-based, in a randomized controlled setting. We examined the effectiveness of health technology and mobile application to improve adherence in patients with gout, whose SUA target was not achieved due to nonadherence. The trial met the co-primary endpoint, in which ULT adherence improved with the drug reminder app, although this difference was not statistically significant ($p = 0.102$ for MTB-T and $p = 0.615$ for pill count). The "Drug diary" app was targeted at unintentional nonadherence, especially those with forgetfulness, using reminders to reinstate medication routines and tracking medication taking to promote adherence. Our findings were consistent with existing evidence, showing the benefit of mobile technology in improving medication adherence in patients with chronic diseases requiring long-term medical treatment.[23-25] However, the absolute difference in pill count adherence (96% vs 93%) may not be clinically meaningful, and we have acknowledged this limitation.

A systematic review of 13 randomized control trials (RCT) by Vervloet M, et al. showed the effectiveness of various electronic reminders, including short message service reminders, audiovisual reminders from electronic reminder devices, and pager messages in various chronic diseases, such as HIV, asthma, hypertension, glaucoma, and women who were taking oral contraceptive pills.[23] Using the same mobile technology as in our study, an RCT by Abu-El-Noor et al. showed that the mobile phone app resulted in an improvement in adherence to hypertension treatment after three months of intervention.[24] In patients with gout, Bunphong, K. et al. revealed that daily short message reminders significantly improved allopurinol adherence and SUA reduction, compared to weekly short message information related to nonpharmacologic treatment for gout.[25] Additionally, recent studies[26-28] have reported promising results, supporting the role of mobile apps in gout management.

Consistent with previous studies, high adherence to medications has a significant impact on SUA results, as shown in our study. Many studies support the association of good ULT adherence and SUA goal achievement. A large retrospective study by Halpern R, et al.[10] showed the association between allopurinol adherence and SUA level. The proportion of patients who had a well-controlled SUA level (<6.0 mg/dL) were approximately 50% in adherent patients and 25% in nonadherent patients ($p<0.001$). Rashid N, et al.[29] and Lee et al.[30] also reported that allopurinol adherence was associated with achievement of the SUA level goal. These results are suggestive of the impact of the promotion of UTL adherence that enhances the achievement of treatment outcomes.

Interestingly, patients in the patient education app group also had a higher adherence and a significant reduction in SUA and gout flare-up from baseline. Although forgetfulness is the most frequent barrier to adherence, lack of knowledge about their diseases and treatment is also one of the important reasons for poor adherence. Abhishek A. et al. reported that when gout patients received gout education, 100% wanted to receive ULT and 91% remained taking ULT five years after receiving education and 85% took ULT at least six days per week at five years.[9] These findings suggest that in addition to drug reminder, optimal gout education also significantly improves gout care.

This study has several limitations. First, the sample size was smaller than expected due to the COVID-19 pandemic situation in Thailand, leading to difficulties in recruitment and follow-up process. Despite the limited sample size, this study still showed a potential benefit of the drug reminder app. Second, a blinded intervention was not possible. This could affect patient behavior, as shown in this study that patients in both groups had a significantly higher adherence at the end of the trial. The high adherence rate observed in this study may be influenced by performance bias and the Hawthorne effect, where patients increased their attention and adherence when participating in the study due to awareness of being observed. The similar proportion of SUA achievement in both groups may be attributed to this effect. Another explanation for high adherence in both groups is that the use of new technology, such as smartphone applications, is an attractive tool; therefore, most of the patients in this study were interested and enthusiastic about using these applications and complied with the study protocol. They also expressed great satisfaction with the use of both apps. Third, one of the primary outcomes, MTB-T, is a self-reported questionnaire. The medication adherence reported by MTB-T may

not truly reflect actual medication intake. However, the results revealed the benefit of this app in other disease-related outcomes, including SUA and the frequency of gout attacks. Lastly, this study had a short-term follow-up period, so the long-term benefit of these mobile health applications in chronic diseases is still unclear and merits exploration.

In conclusion, mobile phone health applications can improve medication adherence in patients with chronic diseases requiring long-term medical treatment. While a drug reminder app may support unintentional nonadherence, a patient education app may also enhance overall adherence. The integration of both apps could offer complementary benefits in gout management.

Disclosure

The authors declare that they have no conflicts of interest related to this work.

Availability of Data and Materials

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Ethics Approval

This study was approved by the Scientific Ethics Committee of the Siriraj Institutional Review Board (COA Si no. 015/2020).

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Authors' Contributions

NP, WC, and WK contributed to the study concept, design, material preparation, data collection, and analysis. The first draft of the manuscript was written by WK and NP. NP, WC, and WK critically reviewed and commented on successive versions of the manuscript and approved the final manuscript.

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Supplement

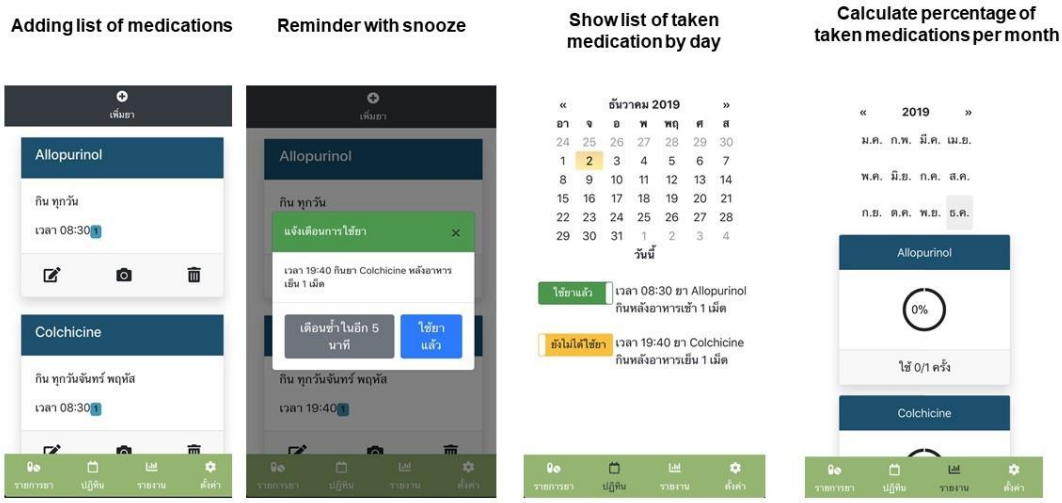

Figure 1 Screenshots of the Drug Diary app showing medication scheduling, reminder notification and adherence tracking feature

Figure 2 Screenshots of the Roo-Rak-Koh app showing educational content modules, including disease information and medication guides