Development and Effectiveness Testing of "Punsook": A Smartphone Application for Intermittent Urinary Catheter Users with Spinal Cord Injury

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ABSTRACT

Objective: To develop and evaluate effectiveness of a smartphone application to assist the self-management of intermittent urinary catheter users

Methods: This is experimental clinical research as part of a medical device trial. In phase 1, 10 intermittent urinary catheter users were recruited from spinal cord injury (SCI) patients who had been admitted to a rehabilitation ward at Siriraj Hospital. They used the preliminary version of "Punsook", a web-based application (app) for a smartphone, alongside usual intermittent urinary catheterization (IC), and gave feedback on their experiences. Their qualitative opinions were used to further develop a second version of the "Punsook" app. In phase 2, the new version was used by 35 participants, who were asked to complete an effectiveness questionaire after using the app, including providing details on their history of urinary tract infection (UTI), urinary leakage, and catheterization-related pain. This information was gathered at the end of first and third months in the second phase of the study.

Results: More than half the participants agreed at the end of the first month that every part of the app was acceptably pleasant. They liked the simplicity and ease of use of the app, accessibility, ease of return to use, and interest in the program. No statistically significant changes in urinary leakage, UTI, or pain were found.

Conclusion: The app was considered effective in terms of the positive user satisfaction with all aspects of the app. However, despite this positive reception, the app may not have contributed to an improvement in participant bladder control.

Keywords: Mobile application; intermittent urinary catheterization; spinal cord injuries; neurogenic bladder (Siriraj Med J 2021; 73: 99-107)

INTRODUCTION

World Health Organization (WHO) estimates from 2013 suggest that the incidence of global spinal cord injury (SCI) is 40 to 80 new cases per million of population per year. This means that every year, between 250,000 and 500,000 people suffer spinal cord injuries.[1] The average yearly expenses and lifetime costs for patients with paraplegia are about USD 526,066,[2] with sufferers experiencing a 2- to 5-fold higher mortality rate than healthy people.[1] In Thailand, the incidence of SCI is approximately 23 cases per million people per year, with an economic loss of more than THB 2.6 million per case where disability occurs.[3]

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Constrained mobility, the reduction of self-care performance, and limitation of the patient's vocation and social life can occur due to neurological dysfunction in SCI. These are also key determinants of various systemic complications in SCI that increase the morbidity and mortality rates. Urinary tract infection (UTI) is the important source of hospital re-admission in developed countries and can be a cause of mortality, even in developing countries.[1] Around 62% of people with SCI will experience an infection in their urinary tract within 1 year after a SCI and 95% will have suffered this within 20 years of the SCI.[4]

Severe problems of the urinary tract, for instance, infection, retention, leakage, stones, and reflux, may result from inappropriate bladder management. Prolonged exposure to such problems can lead to fatal renal failure.[1] Accordingly, certain bladder management methods can be applied. The individual treatment method for a patient is selected depending on many factors, for example, their sex, bladder, sphincter function, hand function, mobility competence, and sitting balance. Intermittent catheterization (IC) is one possible option. This involves the insertion of a urinary catheter into the bladder and its removal after completed urination using a clean or sterile technique. This method carries the least risk of urinary tract complications.[1] A study in the United States of America (USA) reported an educational program as a treatment option, comprising nursing observation, medical consultation, and the instruction of basic knowledge about UTI, and follow-up. Using this educational program coupled with regular IC was capable to decrease the rate of UTI and antibiotics treatment in the study cohort.[5] This indicated that IC is safe, effective, and worth applying.[6]

Currently, mobile phones (or smartphones) are commonly used to facilitate communication among SCI patients and whoever. Various health problems can be widely discussed and advice provided through internet networking for the benefit of patients' self-care, such as for smoking cessation, diabetic care, and body weight control. Nevertheless, there is currently little information shared about IC. To address this, a web-based self-management intervention was developed in English,[7] which included an online voiding diary, a journal, educational material, calls with a nurse, a forum, and smartphone app. It is clear that communication and information sharing between provider and the patient population is purposeful and warranted. Based on the success of that development, a web-based mobile phone application (app) was developed in the Thai language with the purpose of supporting self-management of IC users with SCI. Satisfaction with the app and effectiveness were evaluated.

MATERIAL AND METHODS

This study was part of an experimental clinical research project and medical device trial. In phase 1 of study, we investigated the effectiveness of a new web-based app called Punsook, on a mobile phone for IC users. Qualitative remarks from users about the app were collected 1 month after the end of the first phase. The gathered data were sent to the Punsook application developers to guide further development of the app in a new updated version. However, problems arising during use the app were solved and minor changes in the app were done throughout the duration of the initial phase. In phase 2, the effectiveness of the new version of the app was evaluated (Fig 1).

Participants

SCI patients, both inpatients and outpatients, of the Department of Rehabilitation Medicine, Siriraj Hospital, during 2017-2019 who were IC users were invited to participate in this study by direct contact or in a phone call. The inclusion and exclusion criteria were outlined to each possible participant to identify the patients who were able to comprehend the issues and decide about their bladder management themselves. The participants were informed about the study rationale and their role should they choose to join the study. Researchers asked for written informed consent from these patients. If they agreed to join the study and provided this consent, they were then given access to the app.

Inclusion criteria

- At least 18 years old
- Had the ability to access the web-based smartphone app
- Understood Thai language

Exclusion criteria

- Had communication problems
- Had cognitive impairment.

Furthermore, patients who had never done catheterization by themselves were able to participate in the study if they met the other qualifying conditions.

At the beginning of both phases of the study, the participants' demographic data were collected. This included their diagnosis, patient characteristics, daily living function abilities, and their medication. Further information about the catheterization procedures and patient care was also gathered, including the frequency

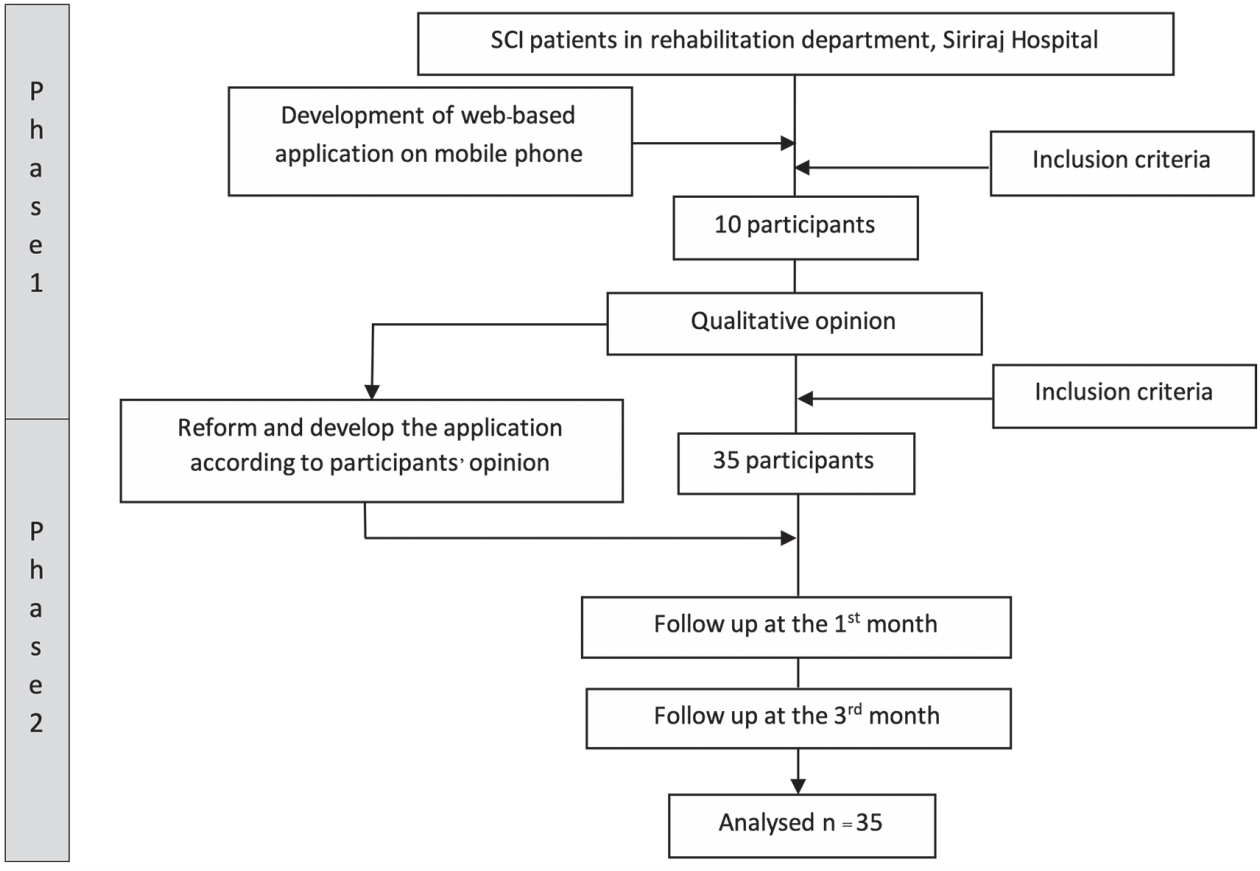

Fig 1. Flow chart of research process.

and interval of catheterizing, estimated urine output, and catheter-related adverse events (e.g., UTI, leakage, pain).

Sample size

Initially, 10 participants joined in phase 1 of the study to test the initial app and to give feedback and/or comments to aid the further development of the app in a new updated version. The power analysis was based on a similar study[8] that showed a confidence level of 95% for adequate bladder control, which was the most important objective in its usability questionnaire. However, our study inferred a slightly lower rate for the effectiveness of the app as 90% with an allowable error of 10%. Consequently, it was calculated that 35 patients were needed to participate in the second part of study (phase 2).

Intervention

In phase 1 of the study, the web-based smartphone app "Punsook" was developed in a collaboration between physiatrists and the Computer Engineering Department of King Mongkut's University of Technology Thonburi (KMUTT). The app consists of four parts: an electronic basic knowledge guidebook, frequently asked questions (FAQ), online voiding diary, and possible contact with a doctor. The FAQ was presented in a chatbot format. The questions covered elementary self-care management around urinary catheterization and other related conditions. The online voiding diary was useful for IC users to record their volumes of water intake and urine output. Also, voiding sensations and any abnormality of concern could be recorded. The application administrator was able to check the real-time records from the app and provide feedback to patients. The participants were asked to use this app alongside their usual regular IC practices. Besides, if they needed medical counsel, they could directly contact a doctor via the app.

One month after using the app, qualitative opinions were obtained from the participants as feedback. Most comments suggested improving the FAQ chatbot, e.g., by increasing the number of common questions and by making the answers easier to understand. In addition, some participants complained about the registration methods. Therefore, we reformed the homepage and modified the chatbot in the new version and then evaluated these updates in phase 2 of the study (Fig 2).

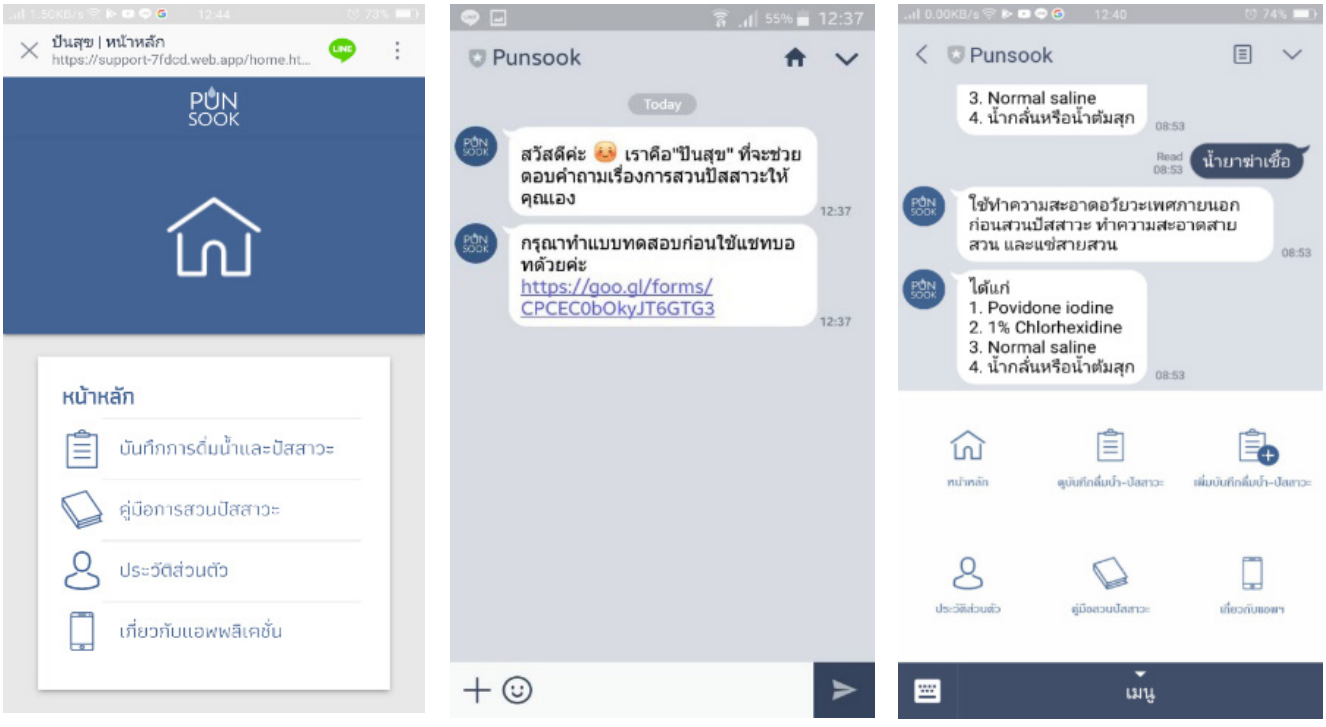

Fig 2. Features of web-based application

Measurement

Assessing the effectiveness of the smartphone app consisted of measuring user satisfaction and their views on its usability, and its ability to decrease the incidence of urinary complications. We hoped that satisfaction with the educational materials, active interaction with an expert, and regular diary recording might influence appropriate bladder management, improve bladder control, and decrease the incidence of urinary complications. We tried to develop the program based on the comments from phase 1 of the study. Then the effectiveness of the new app was measured in phase 2 of the study. Participants were asked to take part in a survey at the end of first month for assessing the effectiveness of the app and additionally at the end of the third month to evaluate their adherence to using the app.

The primary outcome was the satisfaction and applicability of the app. We assessed the user satisfaction toward each part of the program through a feasibility questionnaire, which was divided into 2 parts: user opinions on the information provided and user satisfaction with the whole program. There were 5 scales for the user rating: "strongly agree", "agree", "neutral", "disagree", "strongly disagree". In addition, if the participants did not use a certain part of the application, they could answer with "did not use". The answers "agree" and "strongly agree" represented acceptable satisfaction. The usability questionnaire evaluated the applicability of the program. Usability was evaluated in 5 aspects: ease of use, accessibility, ease upon return to use, interest, and improved ability to control their bladder. The choices were related to the duration of use for the participants' condition, and the options were: "All of the time", "most of the time", "a good bit of time", which were passable times, and "some of the time", "a little bit of the time", and "none of the time", which meant it did not meet expectations. The users were asked to complete the questionnaires after they had been using the application for 1 month and 3 months.

The secondary outcome was related to the app's ability to decrease the incidence of urinary complications. Catheter-related adverse events could be reported at the same time when the participants completed the feasibility and usability questionnaires. Scores based on the VAS were used to indicate the user's pain from catheterization. The number of UTI events and leakage rates during the last 3 months were accumulated.

Statistical analysis

Data were analyzed by PASW (SPSS) Statistics for Windows version 18. Descriptive statistics were used for the subject characteristics. Qualitative data are presented herein by the percentage and quantitative data by the mean and standard deviation (SD). The paired t-test was used to compare quantitative data, while the chi-square test was used for qualitative data. A p-value of <0.05 was considered to be statistically significant.

RESULTS

Table 1 presents the participants' characteristics and their urinary complications. In total, 35 patients were recruited in the study. Everyone completed the initial survey and no one was lost to follow-up. All of the patients used an IC until the end of study. The study cohort comprised 18 males (51.4%). The average age of the participants was 41.86 ± 15.1 years. Most were diagnosed with incomplete SCI (65.7%). Considering the duration of SCI, 77.1% were diagnosed as having SCI for more than one year. Most participants were independent in terms of performing the activities of daily living. The most commonly used medications were baclofen (54.3%) and oxybutynin (45.7%), with solifenacin and trospium chloride also reported in some cases. Some participants used other methods for bladder management along with IC; for example, some participants used an indwelling catheter when traveling, a condom at night, or sometimes they self-voided. Around 60% of all participants catheterized 4-6 times per day, with an interval of 4-6 hours between each time. However, 20–30% irregularly catheterized and did not measure the volume of urine output.

Feasibility

In the 1-month feasibility survey, the participants mostly commented that they were quite satisfied and thought that every part of the app was useful. The evaluation at the end of the third month found that the number of participants who did not use the program was still the same as in the first month, implying a good adherence to the app use by the users (Table 2). Also, the patients still used most parts of the app, except for the FAQ chatbot. In terms of the FAQ chatbot, 48% thought the information in it was useful, and 51.4% were in favor of keeping the FAQ chatbot (Table 2). Overall, the comparison between the users' opinions at the end of the first and the third month showed no statistically significant difference in opinion ($p = 0.47$ concerning the information in the app, $p = 0.63$ concerning the program itself) (Table 2).

Usability

By the end of the first month, most participants could access the different parts of the program and thought the app was easy to use. Likewise, they could return to use it quite efficiently even after leaving it for a while. Half the participants regarded the app as interesting. However, only 40% were able to control their bladder better even with using the advice from the app (Table 3). Two months later at the end of month 3, they still proficiently use the app, even if they had not used it for a while. A larger number of participants, however, stated that using the app was difficult. Controlling their bladder was the main issue that they had never managed to achieve.

Catheter-related pain

The averaged catheter-related pain score was collected by the visual analogue scale (VAS). The baseline pain score was 1.66 ± 1.8 (Table 4); whereas at 1 month and 3 months later, the pain intensity had increased to 1.8 ± 2.1 and 2 ± 2.2, respectively (Table 4). However, there was no significant difference between the scores after a longer duration of the study ($p = 0.74$ at the 1-month survey, $p = 0.44$ at the 3-month survey) (Table 4).

Leakage

Overall, 74% of the participants reported rarely suffering leakage (Table 4). We compared this parameter with the baseline result. There was no statistically significant difference at either the 1-month or 3-month survey points ($p = 0.79$) (Table 4).

Urinary tract infection (UTI)

Information on the history of UTI in the previous 3 months was gathered from the participants. Before joining the study, about 30% of the participants had previously experienced UTI (Table 4). The number of patients who had UTI was still the same as at baseline as reported in the first-month and the third-month surveys.

DISCUSSION

A web-based smartphone app for IC users with spinal cord injury (SCI) was developed for the first time in the Thai language for Thai patients. This app was intended to aid patients' self-management. Our preliminary reports had indicated that the views of the medical practitioners and the engineers who developed the app might have been different from the views and needs of the patients as end users. Therefore, the present study was carried out to assess the effectiveness of this app from the patients' point of view to determine their satisfaction level with the app.

Feasibility and usability surveys were performed and the findings fell in the form of a bimodal distribution. Most respondents expressed either satisfaction or rejection of the app. There were a number of reasons why some participants rejected using the app. At the beginning of the study, the knowledge guidebook and FAQ chatbot were launched before the online voiding diary. Accordingly, some participants in the first phase of the study spent too little time with this online voiding diary. At the

TABLE 1. Demographic data.

Characteristics	n = 35
Sex n (%)	
Male	18 (51.4)
Female	17 (48.6)
Age Year, mean (SD)	41.86 (15.1)
Education level n (%)	
Below high school	8 (22.9)
High school	7 (20)
Bachelor's	16 (45.7)
Master's / Doctor's	4 (11.4)
Completeness of lesion n (%)	
SCI Complete	8 (22.9)
SCI Incomplete	23 (65.7)
Unknown	4 (11.4)
Duration of SCI n (%)	
Less than 1 year	8 (22.9)
≥ 1 year	27 (77.1)
Level of SCI n (%)	
Cervical	6 (17.1)
Thoracic	9 (25.7)
Lumbar	17 (48.6)
Sacral	3 (8.6)
ADL bathing n (%)	
Dependent	5 (14.3)
Independent	30 (85.7)
ADL dressing n (%)	
Dependent	5 (14.3)
Independent	30 (85.7)
ADL toileting n (%)	
Dependent	7 (20)
Independent	28 (80)
ADL ambulation and transfer n (%)	
Dependent	8 (22.9)
Independent	27 (77.1)
ADL eating n (%)	
Dependent	2 (5.7)
Independent	33 (94.3)

Trospium chloride = 2, Solifenacin = 1, Gabapentin = 1

TABLE 1. Demographic data. (Continue)

Characteristics	n = 35
Medication n (%)	
Baclofen	19 (54.3)
Oxybutynin	16 (45.7)
Antibiotics	2 (5.7)
Amitriptyline	2 (5.7)
Not use	7 (20)
Other	4 (11.4) #
Other bladder management methods n (%)	
Indwelling	7 (20)
Condom	1 (2.9)
Absorbent product	1 (2.9)
Credé	1 (2.9)
Self-voiding	7 (20)
No other method	18 (51.4)
Frequency of catheterizing per day n (%)	
1–3 times	4 (11.4)
4–6 times	23 (65.7)
7 times or more than	8 (22.9)
Catheterizing intervals n (%)	
2-3 hours	4 (11.4)
4-6 hours	21 (60)
7-9 hours	0 (0)
10-12 hours	2 (5.7)
Varies	8 (22.9)
Urine output n (%)	
Less than 100 ml	3 (8.6)
100-399 ml	19 (54.3)
400 ml or more than	4 (11.4)
Unknown	9 (25.7)
Leakage n (%)	
Every day	9 (25.7)
Less than every day	26 (74.3)
UTI in last 3-month n (%)	
Never	22 (62.9)
1-2 times	11 (31.4)
3-4 times	2 (5.7)
5 times or more	0 (0)
Pain mean (SD)	1.69 (1.9)

Trospium chloride = 2, Solifenacin = 1, Gabapentin = 1

TABLE 2. Result of feasibility questionnaire.

	Did not use		Strongly disagree		disagree		Neutral		Agree		Strongly agree	
	1st month	3rd month	1st month	3rd month	1st month	3rd month	1st month	3rd month	1st month	3rd month	1st month	3rd month
Was the information useful?												
Voiding diary	8 (22.9)	9 (25.7)	0 (0)	0 (0)	0 (0)	0 (0)	5 (14.3)	3 (8.6)	12 (34.3)	14 (40)	10 (28.6)	9 (25.7)
Knowledge	7 (20)	8 (22.9)	0 (0)	0 (0)	2 (5.7)	2 (5.7)	5 (14.3)	7 (20)	12 (34.3)	13 (37.1)	9 (25.7)	5 (14.3)
Contact with doctor	7 (20)	7 (20)	0 (0)	0 (0)	0 (0)	0 (0)	3 (8.6)	4 (11.4)	9 (25.7)	10 (28.6)	16 (45.7)	14 (40)
FAQ (Chatbot)	7 (20)	9 (25.7)	0 (0)	0 (0)	2 (5.7)	2 (5.7)	6 (17.1)	7 (20)	12 (34.3)	13 (37.1)	8 (22.9)	4 (11.4)
Were you satisfied with the parts of the program?												
Voiding diary	7 (20)	9 (25.7)	0 (0)	0 (0)	0 (0)	0 (0)	6 (17.1)	8 (22.9)	12 (34.3)	10 (28.6)	10 (28.6)	8 (22.9)
Knowledge	6 (17.1)	7 (20)	1 (2.9)	0 (0)	2 (5.7)	2 (5.7)	6 (17.1)	7 (20)	13 (37.1)	14 (40)	7 (20)	5 (14.3)
Contact with doctor	7 (20)	7 (20)	0 (0)	0 (0)	0 (0)	0 (0)	3 (8.6)	5 (14.3)	10 (28.6)	11 (31.4)	15 (42.9)	12 (34.3)
FAQ (Chatbot)	7 (20)	8 (22.9)	1 (2.9)	0 (0)	3 (8.6)	3 (8.6)	4 (11.4)	6 (17.1)	13 (37.1)	14 (40)	7 (20)	4 (11.4)

p value > 0.05, comparing number of each answer at the first month to that in the third month

TABLE 3. Result of usability questionnaire.

	None of the time		A little of the time		Some of the time		A good bit of the time		Most of the time		All of the time	
	1st month	3rd month	1st month	3rd month	1st month	3rd month	1st month	3rd month	1st month	3rd month	1st month	3rd month
Easy to use	4 (11.4)	5 (14.3)	3 (8.6)	2 (5.7)	4 (11.4)	5 (14.3)	6 (17.1)	7 (20)	7 (20)	8 (22.9)	11 (31.4)	8 (22.9)
Able to assess all around the part of program	4 (11.4)	4 (11.4)	2 (5.7)	0 (0)	3 (8.6)	6 (17.1)	7 (20)	5 (14.3)	9 (25.7)	9 (25.7)	10 (28.6)	11 (31.4)
Back to use program after leave for a while	4 (11.4)	4 (11.4)	2 (5.7)	1 (2.9)	1 (2.9)	4 (11.4)	6 (17.1)	6 (17.1)	12 (34.3)	9 (25.7)	10 (28.6)	11 (31.4)
Interesting and attractive to use	3 (8.6)	3 (8.6)	2 (5.7)	0 (0)	2 (5.7)	6 (17.1)	10 (28.6)	8 (22.9)	10 (28.6)	8 (22.9)	8 (22.9)	10 (28.6)
Can control bladder	13 (37.1)	13 (37.1)	5 (14.3)	3 (8.6)	2 (5.7)	4 (11.4)	8 (22.9)	7 (20)	3 (8.6)	3 (8.6)	4 (11.4)	5 (14.3)

p value > 0.05, comparing number of each answer at the first month to that in the third month

TABLE 4. Result of urinary complication.

	Baseline	1st month		3rd month	
Pain Mean (SD)	1.66 (1.8)	1.8 (2.1)	P = 0.74	2 (2.2)	P = 0.44
Leakage n (%)					
• Daily	9 (25.7)	10 (28.6)	P = 0.79	10 (28.6)	P = 0.79
• Non-daily	26 (74.3)	25 (71.4)		25 (71.4)	
UTI n (%)					
• UTI within last 3 month	12 (34.3)	11 (31.4)	P = 0.78	12 (34.3)	P = 1
• No UTI within last 3 month	23 (65.7)	24 (68.6)		23 (65.7)	

same time, half the participants used other methods for bladder management alongside IC; for example, some used indwelling catheterization while traveling outside their residence. Thus, these users had less chance to use and test the app. Consequently, they did not feel capable of expressing their opinion about the app when they had rarely used parts of the app. When some participants commented that they did not use a certain part of the app, this answer was not included in the satisfied status.

Keeping a voiding diary for persons with spinal cord injury is very useful. By analyzing the volume and frequency of each voiding, along with other parameters monitored in the diary, the physician can assess the diary to form an initial opinion about the patient's urodynamic profile.[9] The online voiding diary is more convenient to keep up with as it involves active interaction. The data are directly sent to administrative staff for providing early feedback to the patients. While a paper diary is still quite common with many patients, electronic diaries are becoming more common and can yield better compliance.[10] However, Thai doctors usually assign this choice of method to the patients. If we are able to provide evidence to support the effectiveness of an online voiding diary in the Thai, this might help popularize this method which may improve patient compliance of a voiding diary.

The usage rates for the knowledge guidebook, online voiding diary, and FAQ chatbot decreased at the third month, which may have been due to the familiarity with these aspects built up over time. As patients gain more experience of intermittent catheterization, they need less guidance and are able to solve most problems by themselves. Moreover, the compliance with program use might indicate the effectiveness of the app. Generally, patients are more likely to persist with an intervention if they feel it can help them avoid a more negative health condition.[11] Consequently, we tried to find some method to improve those compositions in the app.

Contact with a doctor was the part of the app that attracted the highest satisfaction level, in part because of it being an interactive activity. Patients could freely contact a doctor about their medical issues. Apart from gaining knowledge or asking queries, they could obtain specific information on primary practice and access to the doctor appointment system. In this study, contact with the doctor appointment system was performed via the private doctor's LINE® (Naver Corporation, Tokyo, Japan) account. We plan to add this element into our app in future updates. However, this incurred a much higher expense in addition to the official contact account. Therefore, we tried to adjust the usability of the app in other ways. The FAQs for communicating with the doctor will be increased in the FAQ chatbot during major changing among the two phases of this research. Besides, we tend to continuously update the program as we go along to save time.

Bladder control problems affect the way a person holds or releases urine.[12] Therefore, the key factor determining bladder control is urinary leakage. However, patients may be concerned that leakage is a problem when it accidentally occurs and they cannot manage control. Overall, 40% of participants thought that they could not control their bladder at any time; although only about 26% of participants complained about leakage every day. This result suggested that the question of bladder control in the usability questionnaire might not represent the problematic leakage issue correctly. The

effectiveness evaluation will need to be more specific for the questionnaire to be able to reveal the actual problem. Thus, clarification of this question could improve the accuracy of the results. In addition, the applicability of the app did not represent the real rate of app use, which would typically not be enough to help the daily bladder control of the participants.

Limitations

There were some limitations of this study to mention. Firstly, many older Thai SCI patients were unable to access the web-based app through their mobile phone. Thus, many elderly could not be included in this study. Along with the small sample size, which led to a low power to detect small effects, non-significant results on the secondary outcome when comparing baseline to post-intervention follow-up were observed. Secondly, some participants had tetraplegia and poor hand function. Their caregiver did the IC instead of the patients themselves, and both the patients and their caregivers used the app together. Most these patients used only the FAQ chatbot and educational knowledge guidebook, while the catheter users often used the online voiding diary as well. Thus, their opinion was summarized in just one survey. Thirdly, our study lacked a control group for comparison between the traditional educational method and this app. Finally, we could not strictly enforce them to spend more time with this program. Therefore, the time expenditure with the app was different among the participants, which likely influenced their satisfaction levels.

CONCLUSION

We successfully developed a web-based smartphone app based on the requirements of SCI patients using intermittent urinary catheterization. According to the study participants, the effectiveness of this app was considered satisfactory and every part of the program was usable. The study findings suggested, however, that the app might not actually help to improve their bladder control. We need to constantly modify the application over time in order to meet the needs of the patients. Educational videos, pop-up ratings, and urological check-up recording might be interesting functions to add to the app. Additional qualitative opinions and actual time use data for using the app should be collected in a future study.

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