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# **ASEAN Journal of Rehabilitation Medicine (ASEAN J Rehabil Med)**

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## **Present and Future of the ASEAN J Rehabil Med**

It has been a great and fruitful 16 years since I took the responsibility as Editor-in-Chief of the journal. It has been my mission to improve the quality of the journal and increase its reach. One notable change was changing the journal title, from Journal of Thai Rehabilitation Medicine to ASEAN Journal of Rehabilitation Medicine. This leads to the subsequent expansion of the editorial board and reviewers from Thai only members to those from South East Asian region. It is currently in tier 1 of the Thai Citation Index, using a full online journal submission, and made available in both electronic and print version. The electronic version enables readers from all around the world access the articles, which is published free of charge.

In this last issue of my role as the Editor-in-chief, I would like to thank the associate editors, editorial board, external reviewers, English expert, copy/layout editor and journal manager who are instrumental in bringing this journal to this stage. I enjoyed learning and doing this together with all of you and treasured those memories.

I would like to take this opportunity to introduce the new Editor-in-Chief of the Journal, Prof. Areerat Suputtitada, a Professor in Rehabilitation Medicine at Chulalongkorn University, Bangkok, Thailand. The President of the Rehabilitation Medicine Association of Thailand, reiterates the journal aims to publish high quality and impactful articles in rehabilitation medicine and related issues, as well as becoming an international cited journal in the near future. To achieve such aims, Prof. Areerat Suputtitada, has invited young and active researchers from not only SEA region but also other parts of the world to join the editorial board.

The new Editor-in-Chief and editorial board will start their roles in the beginning of the year 2023. I sincerely hope the new team will make the Journal more attractive to authors, readers and reviewers from the SEA region and other parts of the world and eventually be accepted in an international journal citation index.

Apichana Kovindha, MD, FRCPhysiatrT  
Editor-in-chief

## Focused Extracorporeal Shockwave Therapy Versus Prefabricated Insoles for Treatment of Plantar Fasciitis: A Randomized Trial

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### ABSTRACT

**Objectives:** To compare the clinical effectiveness of focused extracorporeal shockwave therapy (fESWT) and prefabricated insoles among patients suffering from plantar fasciitis (PF).

**Study design:** Pragmatic randomized open-label trial.

**Setting:** Rehabilitation Medicine outpatient clinic at a medical school hospital in Bangkok, Thailand.

**Subjects:** Patients suffering from subacute or chronic PF.

**Methods:** Participants were randomly allocated (1:1) to receive either 3 weekly sessions of fESWT (2,000 shocks/session of at least 0.2 mJ/mm<sup>2</sup>) or to wearing prefabricated insoles. All participants were advised to perform stretching of the plantar fascia and gastrocnemius muscle. The clinical outcome measured was an improvement in Foot Function Index (FFI) at 12 weeks. An analysis was done based on the intention-to-treat principle.

**Results:** Twenty-nine participants were enrolled and randomly assigned to either the fESWT (n = 14) or the insole group (n = 15). A mean and standard deviation (SD) of the improvement in total FFI at 12 weeks was 65 (25.8) points for fESWT and 65.2 (39.2) points for prefabricated insoles with an adjusted mean difference between two interventions of 14.9 (95%CI: -15.4 to 45.2).

**Conclusions:** The fESWT did not improve FFI compared with prefabricated insoles among patients with subacute and chronic plantar fasciitis. However, the results should be interpreted with caution because of inadequate statistical power.

**Keywords:** plantar fasciitis, focused extracorporeal shockwave therapy, prefabricated insole, foot function index

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### Introduction

Plantar fasciitis (PF) is one of the most common causes of heel pain. Statistically, its prevalence in the American population is approximately 10 percent. An estimated one million American patients visit a doctor for treatment of this condition annually,<sup>1</sup> and the cost of treating this disease in the US is approximately \$192-376 million per year.<sup>2</sup>

It is believed that the cause of PF is the degeneration of collagen tissue of the plantar fascia resulting from repetitive

microtrauma of the plantar fascia.<sup>3</sup> The classic symptom is the worst pain at the heel during the first few steps after waking.<sup>3</sup> However, some patients may experience more pain in their heels after walking a long distance.<sup>4</sup> For treatment of PF, stretching of the plantar fascia and gastro-soleus muscles plus strengthening of the intrinsic foot muscles are recommended.<sup>5-7</sup> The use of customized and prefabricated insoles is also common.<sup>8</sup> Other management methods include topical steroid injections, ultrasound, acupuncture,<sup>9-11</sup> and extracorporeal shock wave therapy (ESWT).<sup>10,12-14</sup>

ESWT is widely used in management of plantar fasciitis. The principle of ESWT is to stimulate blood supply flow to the injured area and to promote the release of growth factors for tissue regeneration and vascularization to reduce inflammation.<sup>13</sup> Previous studies have shown this to be effective in reducing pain by up to 60% and approximately 70% of patients experiencing great to excellent in pain relief.<sup>14,15</sup> A meta-analyses by Chang and colleagues reported that high- and moderate-intensity focused ESWT (fESWT) had reliably greater effectiveness than both low-intensity fESWT and radial ESWT (rESWT). They concluded that moderate-intensity fESWT (0.12 to 0.25 mJ/mm<sup>2</sup>) with mostly tolerable energy is the best option when using ESWT for PF.<sup>16</sup> Although fESWT seems to be a preferable treatment option, its use is limited due to the high cost of the devices which can be about 2 million baht (60,000 USD) in Thailand. Interestingly, no economic evaluation studies of fESWT for lower extremity musculoskeletal pain were found in a literature search.

Prefabricated insoles are commonly used as a non-invasive treatment for individuals with subacute to chronic PF. It is believed that insoles can support the medial longitudinal arch of the foot, prevent foot pronation, and decrease the strain on the plantar fascia.<sup>17</sup> Moreover, prefabricated insoles are much cheaper and less time is spent fitting them than customized insoles, although the effectiveness of both types has been reported to be similar.<sup>18</sup>

Both fESWT and prefabricated insoles have been proven to be an effective treatment for PF, but there have been no studies comparing the effectiveness of these 2 treatments.

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The current research primarily aimed to compare improvement in foot function index between fESWT and the use of prefabricated insoles among patients suffering from subacute and chronic plantar fasciitis, including an economic evaluation of these two interventions.

## Methods

### Study design

This study was a pragmatic randomized open-label trial conducted at Phramongkutklo Hospital in Bangkok, Thailand from September 2019 to August 2020. The trial protocol was approved by the Institutional Review Board of the Royal Thai Army Medical Department (Number R082h/62) and was registered in the Thai Clinical Trials Registry (TCTR20210608002).

### Participants

Study participants were adults (age  $\geq 18$  years) presenting with significant pain (Numeric Rating Scale at least 4) and tenderness at the medial heel at for least 1 month before enrollment and who were able to communicate and to complete the questionnaires.<sup>19</sup> Exclusion criteria were a history of steroid injection at the heel and sole within 6 months before enrollment; a previous surgery at the heel and/or sole; midfoot deformities; diabetic neuropathy; arthritis at the ankle joint or the foot; polyneuropathy and entrapment disorder at the foot and ankle; a history of calcaneus fracture and retrocalcaneal bursitis; a previous wound at the heel; pregnancy; or bleeding disorders. All participants provided written informed consent.

### Sample size

The sample size calculation was based on a study by Traijeewornporn et al. (2016).<sup>20</sup> The sample size was determined using the clinical superiority design formula to compare the two independent groups in terms of mean difference of foot function. For an alpha level of 0.05, a power of 80%, and with an estimated drop-out rate of 20%, the target sample size was 76 participants (38 participants per group).

### Randomization

Randomization was performed by an independent researcher with the use of a computer-generated randomization list for a block of four randomization stratified by the onset of disease: subacute (1-3 months) and chronic ( $> 3$  months).<sup>21</sup> The random allocation sequence was concealed by an opaque envelope. Participants were randomly allocated 1:1 into 2 groups: focused shock wave therapy (fESWT) and prefabricated insole groups.

### Intervention

The fESWT group was treated with a Duolith SD1 T-top (Storz Medical, Switzerland) and received a total of 2,000 pulses at a rate of 4 Hz at each treatment session, once

a week for 3 consecutive weeks.<sup>22</sup> A stimulator head with stand-off II (long) which provides a penetration depth of 15 mm was placed on the maximal pain site of the infra-calcaneal heel and ultrasound gel was applied as the coupling media. The energy influx density started at 0.20 mJ/mm<sup>2</sup> and was then gradually raised to the highest level that the patient could tolerate.

The insole group received a pair of full-length prefabricated insoles with heel cup and medial arch support (Care Step<sup>®</sup>) to be placed inside any indoor and outdoor shoes they used for daily living. Additionally, both groups were advised to perform stretching of the calf muscle and plantar fascia, 10 sets/session for at least 3 sessions every day.<sup>23,24</sup>

### Outcomes

The clinical outcome measure was the level of improvement of the Foot Function Index (FFI) at week 12. The FFI is a self-administered questionnaire consisting of 23 items divided into 3 categories: pain (9 items), disability (9 items), and activity limitation (5 items).<sup>25</sup> A higher FFI score indicates a higher level of impairment. The Thai FFI has a high test-retest reliability (ICC of 0.92) and excellent internal consistency (Cronbach's alpha of 0.96).<sup>25</sup> Measurement of FFI was conducted at baseline, week 6, and week 12. The improvement of total FFI score at week 12 was considered as the primary outcome of this study. For the cost-effectiveness analysis from the healthcare provider perspective, costs incurred were calculated based on the labor cost, material cost, and capital cost.

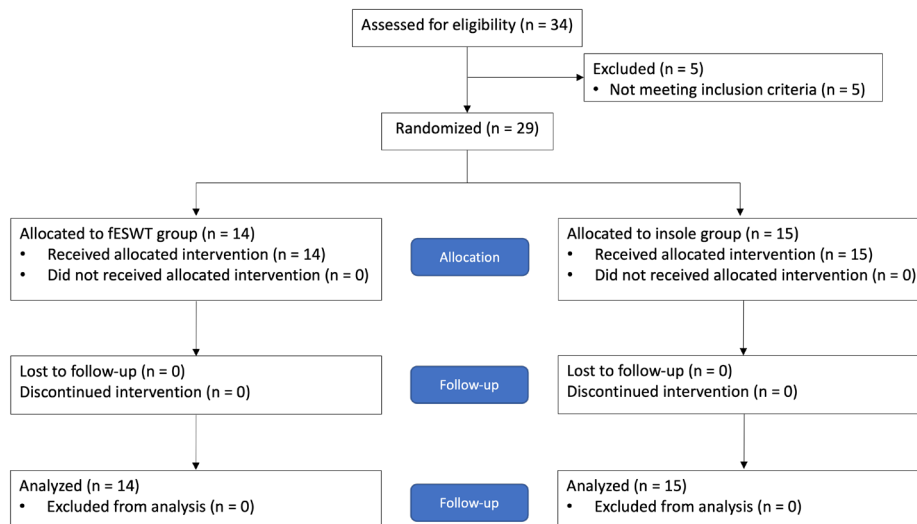
### Statistical analysis

The intention-to-treat principle was used for the statistical analysis. Baseline and clinical characteristics of both groups are shown as mean (standard deviation, SD) for continuous data and number (%) for categorical data. Normality of distribution and equality of variance of FFI scores were assessed to confirm that parametric tests could be used. The comparison of mean values of FFI between the 2 groups at three periods (baseline, week 6, week 12) was performed using repeated measure ANOVA. The improvement of FFI at week 12 between the two groups was compared using an unpaired t-test or linear regression model. A  $p$ -value  $< 0.05$  was considered to be statistically significant. The cost-effectiveness ratio of both groups was also calculated and compared.

## Results

Between September 1, 2019 and August 31, 2020, 29 participants were enrolled, with 14 participants randomly assigned to the fESWT group and 15 to the insole group. No participants were withdrawn from the study. All participants' data were included in the analysis (Figure 1). Some baseline characteristics, including age, sex, and body mass index (BMI), were unbalanced between the groups. The fESWT group had a higher mean age (59.5 vs. 50.5) and percentage





**Figure 1.** CONSORT diagram of the study

**Table 1.** Baseline and clinical characteristics by treatment group

	fESWT (n = 14)	Insole (n = 15)
Age (years) <sup>1</sup>	59.5 (15.2)	50.5 (13.8)
Sex, female <sup>2</sup>	13 (92.86)	10 (66.67)
BMI <sup>1</sup>	23.85 (4.34)	26.73 (3.30)
DM, Yes <sup>2</sup>	1 (7.14)	1 (6.67)
Affected foot, bilateral <sup>2</sup>	5 (35.71)	6 (40.00)
Onset, chronic <sup>2</sup>	10 (71.43)	10 (66.67)
Arch of foot <sup>2</sup>		
Normal	12 (85.71)	11 (73.33)
Low	2 (14.29)	3 (20.00)
High	-	1 (6.67)
Hours spent standing per day <sup>1</sup>	3.89 (1.68)	3.73 (2.15)
Hours spent walking per day <sup>1</sup>	3.57 (1.45)	3.73 (2.02)
Hours spent running per day <sup>1</sup>	0.07 (0.18)	0.13 (0.29)
Pretreatment FFI score <sup>1</sup>		
Pain	42.71 (8.88)	41.53 (9.96)
Disability	43.64 (12.19)	44.13 (19.09)
Activity limitation	0.5 (1.28)	1.2 (3.17)
Total	86.86 (19.36)	86.86 (28.57)

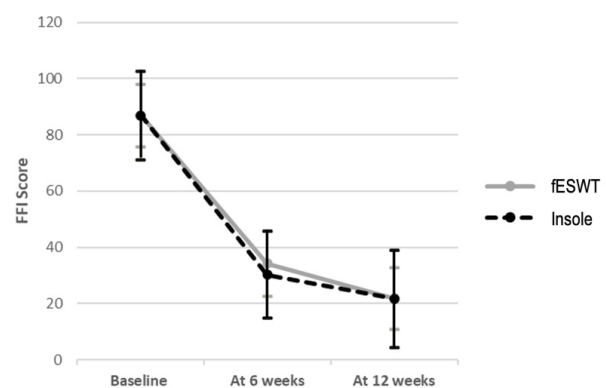
<sup>1</sup>Mean (SD), <sup>2</sup>n (%)

BMI, body mass index; DM, diabetes mellitus; FFI, Foot Function Index; fESWT, focused extracorporeal shock wave therapy

of females (92.9% vs. 66.7%) but had a lower mean BMI than the insole group (23.9 vs. 26.7). However, the mean total score of FFI at baseline was comparable between groups (Table 1).

The FFI scores of both groups showed normal distribution and equal standard deviation. There was no statistically significant difference in the mean FFI scores between the two groups over the 3 measures ( $p = 0.85$ ) (Figure 2). The crude and adjusted mean differences (fESWT minus Insole) of the total improvement of FFI at week 12 were 0.2 (95%CI: -25.3 to 25.7) and 14.9 (95%CI: -15.4 to 45.2), respectively. Additionally, no statistically significant difference was found for each subscale of FFI as shown in Table 2.

The total cost for fESWT and for insoles was 2,043 and 897 baht per participant, respectively. The incremental cost



**Figure 2.** Mean (95%CI) FFI score at baseline, 6 and 12 weeks by treatment group

CI, confidence interval; FFI, Foot Function Index; fESWT, focused extracorporeal shock wave therapy

of fESWT over the insole was 1,146 baht, and the incremental cost per effectiveness ratio (ICER) of fESWT compared with the insole was 1,146 baht/14.9 FFI score or 77 baht/FFI score.

All participants in the fESWT group were able to complete all treatment sessions, and those in the insole group reported using the insoles for the entire study period. Regarding the use of non-steroidal anti-inflammatory drugs (NSAIDs) as a rescue analgesic during 12 weeks of the study, one participant in the fESWT group used a single tablet of NSAIDs, while one participant in the insole group used five tablets of NSAIDs. No adverse effects were reported or identified in any of the participants.

## Discussion

To the best of our knowledge, this study is the first to evaluate the effectiveness of fESWT compared with prefabricated insoles among patients with subacute to chronic plantar fasciitis. The main results showed no statistically significant difference in FFI improvement at week 12 between the two groups in either crude or adjusted analysis. However, the adjusted mean difference of total FFI score (14.9 points)

was greater than the minimal important change (7 points).<sup>26</sup> Hence, if the sample size of the present study had been larger, the difference might have been statistically significant.

The findings of this study are similar to a study by Çağlar, which found that rESWT and customized insoles were effective modalities in pain reduction and foot function improvement in the treatment of plantar fasciitis, but that study found no difference in the short (4-week post-treatment) and mid-term (12-week and 24-week post-treatment) effects between the two treatments.<sup>27</sup> It should be noted the Çağlar study used rESWT which might have been less effective than moderate-intensity fESWT. Additionally, the present study used prefabricated insoles which differs from the study by Çağlar, but there has been evidence that the effectiveness of prefabricated and customized insoles to treat PF is similar.<sup>18,28</sup>

It is important to consider whether fESWT has a beneficial carryover effect for PF because the participants in this study received fESWT only once a week for 3 weeks, while the prefabricated insoles were used for 12 weeks. A study by Wang reported that participants in the fESWT group had a better clinical outcome and lower recurrence rate than those in the control group who had received other conservative treatment at the long-term follow-up (60-72 months).<sup>29</sup> Another randomized clinical trial which compared rESWT with a sham in 50 patients with chronic PF reported a positive effect of ESWT on reduction of pain score and improvement of quality of life at 1, 3, 6, 12, and 24 weeks after treatment.<sup>29</sup> Importantly, no long-term complications were reported in either of these two studies.<sup>29,30</sup>

In the cost-effectiveness analysis, fESWT was approximately 2 to 3 times more costly compared to using prefabricated insoles. When an adjusted mean difference was calculated, the cost of ICER of fESWT compared to insoles was 77 baht per FFI score, i.e., an additional cost of 77 baht was incurred for each one point in the FFI score. However, there is no consensus about the use of ICER to determine whether fESWT is less cost effective than insoles or not. Hence, choice of treatment option for PF might depend on the financial status and human resources of each individual hospital.

Strengths of the present study include that the outcome measure was FFI, a valid and reliable clinical measurement widely used in the study of foot problems. Additionally, no participants withdrew from the study, so there was no missing data. Finally, the cost-effectiveness analysis reported might help physiatrists or other specialists in selecting treatment options for patients with PF.

Several limitations of the present study do, however, need to be noted. Due to COVID-19-related measures by the Thai government (e.g., lockdowns, inter-provincial travel restrictions) and the hospital's controls during the COVID-19 outbreak in 2020, the present study was not able to achieve the targeted sample size within the time available (one fiscal year of funding). Therefore, this study had only 40% statistical power to establish the statistical significance of

the difference between the 2 interventions. In addition, the unequal baseline in age, sex, and BMI, requiring the use of linear regression in the statistical analysis, might have affected the clinical outcome. Extra physiotherapy sessions from other hospitals, level of compliance with stretching exercise recommendations, and time spent using the insoles were not monitored because this trial was designed as an effectiveness study (real-world practice), not an efficacy study (ideal and controlled circumstances). Additionally, the present study was not able to blind the participants regarding the treatments and FFI is a self-reported questionnaire that provides a subjective outcome. As a result, measurement bias probably occurred. Finally, all costs were calculated for a tertiary-care government hospital, so the results from this study might not be representative of other hospital settings in Thailand or elsewhere in the world.

## Conclusions

The present study found no evidence that fESWT improved foot function index compared with prefabricated insoles among patients suffering from subacute and chronic plantar fasciitis. However, due to the small sample size, the study findings should be interpreted cautiously.

## Disclosure

The authors declare that they have no conflicts of interest related to the materials and equipment used in this study.

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## Effects on Physical Fitness and Stress between Dance Exergame and Home-Based Dance Exercise with Videos in Female Youths with Sedentary Behavior: An Assessor-Blinded Randomized Controlled Trial

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### ABSTRACT

**Objectives:** To compare the effects between dance exergame and home-based dance exercise with videos on physical fitness in female youths.

**Study design:** an assessor-blind randomized controlled trial.

**Setting:** Department of Physical Therapy, Faculty of Medicine, Prince of Songkla University, Songkhla, Thailand.

**Subjects:** Thirty female youths with sedentary behavior.

**Methods:** This study randomly divided the participants into the exergame group ( $n = 15$ ), which received a dance exercise program with the Just Dance game, or the video group ( $n = 15$ ), which received home-based dance exercise with videos. The exercise program for both groups started with 30 minutes, 5 times a week for two weeks then increased to 50 minutes, 3 times per week until the end of the program. Body mass index, percentage of body fat, muscle endurance, muscle strength, flexibility, agility and stress were measured at baseline, and then after 6 weeks of the exercise programs.

**Results:** After the 6-week program, the exergame group showed improvement in all physical fitness outcomes, while the video group showed no difference in body mass index, percentage of body fat or agility. When comparing between the exergame and the video groups, differences were found in arm and upper body muscle endurance and back muscle strength when compared to the video groups (11 vs 1,  $p$ -value = 0.012 and 27 vs 20,  $p = 0.032$ , respectively); but not in stress (3 vs 2,  $p = 0.102$ ).

**Conclusions:** In female youths with sedentary behaviors, a 6-week program of exercise with dance exergame shows different effects on improving physical fitness when compared with home-based dance exercise with videos.

**Keywords:** dance exergame, home-based exercise, physical fitness, youth, sedentary behavior

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### Introduction

Technology has made life more comfortable, but on the other hand, it has also resulted in reduced activity and energy consumption. This has led to a reduction in physical activity, and an escalation of sedentary behavior.<sup>1</sup> The World Health Organization (WHO) reported that 1 in 3 females had inadequate physical activity.<sup>1</sup> In Thailand, more than 1 in 5 female youths do not exercise or play sports; resulting in less physical activity than men.<sup>2</sup> Physical activity is important for both physical and mental health. A previous study found that most medical students lacked physical activity, and did not exercise.<sup>3</sup> This report reasoned that studying hard resulted in a lack of time and partners; wherein, the female students changed from positive to more negative health behaviors and lifestyles; resulting in decreased physical performance.<sup>3</sup>

There are many exercise programs for improving physical activity. Exercise motivation needs to be fun and interesting; hence, dancing is the most popular and widely used form of physical activity among young females; as it is more fun than traditional exercise.<sup>4,5</sup> Dance games involve both upper and lower body movements following the rhythm of the music, which contributes to body coordination while moving, and creates more energy than other exercises.<sup>6,7</sup> Exergames are an alternative exercise that uses body movements in conjunction with simulations from the game, which are effective in increasing physical activity in young people.<sup>7,8</sup> Using exergames can improve muscle endurance, muscle strength, cardiovascular fitness and psychological outcomes in healthy youths.<sup>9</sup> One study found that energy consumption, intensity and physical activity in dance games were similar to, or even greater than, standard exercises.<sup>10</sup> Just Dance is a popular dance game that requires interaction between the players and the game through feedback. The newer dance games

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focus on natural dancing using the player's own body as a controller. Players simply dance according to the characters in the game, and use their whole body to perform real dance movements.<sup>11</sup> Because of the synchronous movements to the tempo of music and animation players feel like they are playing a game, rather than exercising.<sup>12,13</sup>

Previous studies of dance games have focused on their effectiveness in energy expenditure and cardiovascular fitness.<sup>6,7</sup> However, it also has a positive impact on physical performance and mental status. Young people are interested in playing the exergame because it is fun, makes them feel as if they are playing a game rather than exercising, and also keeps their bodies moving more than traditional exercises.<sup>14</sup> Although, in Thailand, there are many different dances, a dance exergame has not been used to promote and prevent health problems. Therefore, the effect of a dance exergame on physical fitness and stress in female youths with a sedentary behavior needs to be further explored.

## Methods

### Study design

This prospective randomized controlled trial (RCT) was approved by the Human Research Ethics Committee (HREC), Faculty of Medicine, Prince of Songkla University (EC 60-422-30-2), and was registered at the Thai Clinical Trials Registry (TCTR20180420003) before the study commenced. The study was conducted at the Department of Physical Therapy, Faculty of Medicine, Prince of Songkla University; from January to May, 2018.

### Participants

The participants in this study were recruited by posters and internet advertisements. Inclusion criteria were female youths (15-24 years) with a sedentary behavior (mostly sitting or lying in various activities during the day: excluding sleep for an average of at least 8 hours per day, and those exercising less than 150 minutes per week). The participants who had contraindications to exercise, according to the Physical Activity Readiness Questionnaire (PAR-Q), or vision problems that affected their visibility of seeing the animation were excluded from our study.

The sample size was calculated from a pilot study of 10 subjects using the following formula:<sup>15</sup>

$$N_{group} = \frac{\left(z_{1-\frac{\alpha}{2}} - z_{1-\beta}\right)^2 \left[\sigma^2_{exergame} + \sigma^2_{\frac{video}{r}}\right]}{(\mu_{exergame} - \mu_{video})^2}$$

This study estimated the basis of arm and upper body muscle endurance of the 30 second, modified push-up test, at six weeks of program completion. The exergame group means = 2.74, SD = 5.50, while video group means = 0.70, SD = 2.90; and assuming 80.0% power and 5.0% signifi-

cance, to detect any clinically meaningful difference between groups on arm and upper body muscle endurance. Based on this calculation, the sample size was 12 people per group, so when combined with a 20.0% dropout rate, a minimum sample size of 15 people in each group was required for this study.

### Randomization and blinding

The participants were randomly divided into the exergame group or the video group by a computer, using block randomization with concealed allocation. Two physical therapists (TC, PP) who assessed were blinded to the exercise allocation.

### Intervention

The exercise programs in both groups were divided into two phases: first and second week; the participants exercised five days a week, and in weeks three to six participants exercised three days a week. The programs consisted of 5 minutes of warm-up and 20 minutes of workout for the first two weeks; increasing to 40 minutes for the next four weeks until the end of the program, with a cool-down period at the end of the exercise session (Table 1).

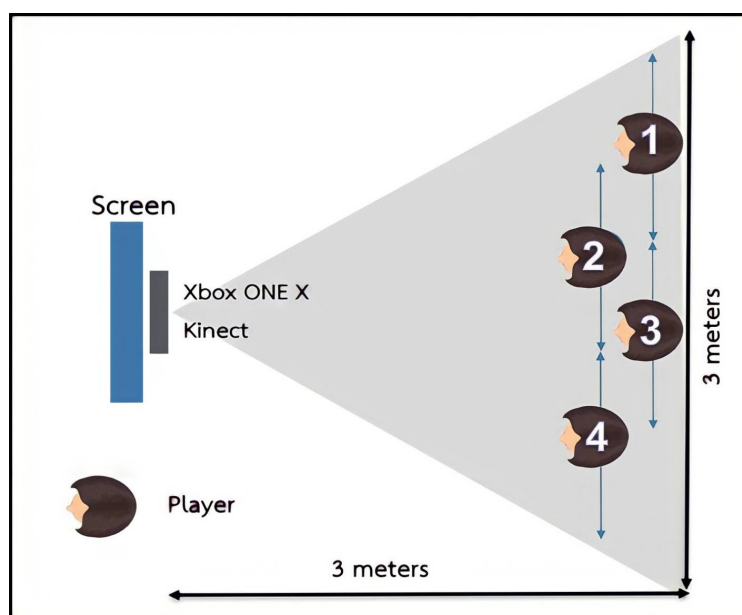
For the selection of songs in the programs using a variety of rhythms with effort determined by sweat droplets specified for each song in game. The researcher determined that 2 sweat droplets were used as warm-up and cool-down sessions, while 3 sweat droplets were used for workout sessions (Table 1). The sequence of songs was switched according to the difficulty of the choreography.

Before starting the programs, the researchers instructed participants to assess themselves on the level of intensity during exercise by rating their perceived exertion. These were defined as a moderate (level 12-14) or by a verbal level. If they became too tired while dancing, the participants kept stomping their feet until their tiredness subsided and were able to continue dancing again. In compliance with the exercise program, the participants received a logbook to check and record other physical activities; via time in hours spent each day. In the home-based dance exercise with videos group, the participants were given a logbook to record their hours of dance and their level of exhausted after each session.

The exergame group exercised with the Just Dance game (Ubisoft, Montreuil, France) connected to an Xbox One X device with a Kinect camera and motion detection system, by copying the movements of characters displayed on the screen in the research room. The physical therapist (KJ) who is a trainer determined the participant's standing position before the exercise for a more comprehensive capture (Figure 1). The participants were instructed on how to play, and also watched a demonstration. After this, the trainer selected the music before four participants stood in the designated positions to start dancing (Figure 1). During and after playing the game, the participants received feedback and score levels.

**Table 1.** Exercise programs of the exergame and the video groups

Phase	Session	Effort	Week	Time (minutes)	Genre of song	Tempo (beats per minute)
First	Warm up	2 sweat droplets	Week 1-6	5	Country pop Dance pop	119-120
Second	Work out	3 sweat droplets	Week 1-2	20	Korean pop Tango Hip-hop	125-128
			Week 3-6	30	Electronic dance Dance pop Electronic dance Rhythm and blues	128-153
Third	Cool down	2 sweat droplets	Week 1-6	5	Latin pop Country pop	123-124

**Figure 1.** Device setting for motion detection and numbers representing the player's standing position

In the video group, the participants received home-based exercise with video files of dance containing images, songs and choreography, similar to the exergame group. To equalize the intensity and duration of exercise for both groups at different phases, another physical therapist (NT) who guided the video group gave video files to them two times; in the first and the third week (Table 1).

### Outcome measurements

This study used the following outcome measures: arm and upper body muscle endurance were measured by using the 30 second modified push-up test; performed on a mat in a prone position on their hands and knees. When the participants heard the signal "start", they pushed up and down for as many repetitions as possible at their maximum speed within 30 seconds.<sup>16</sup> The test is to bend the elbows, lower the body until the chest touches the floor, try to keep the back straight all the time, the stomach does not touch the floor, then extend the elbows to push up to the starting position. Only the correct moves are counted.<sup>16</sup> Abdominal muscle endurance was performed on a mat in a supine position, with

90 degrees of knee flexion. The participants bent their bodies and scapular blades off the floor as much as possible within 60 seconds.<sup>16</sup> Leg muscle endurance was measured via the 60-second chair stand test. The participants sat in a chair, without a backrest, keeping both feet flat on the floor a shoulder-width apart, with crossed arms and both hands touching their shoulders. The participants stood up straight, legs stretched, and then sat back down into the starting position as many times as possible for 60 seconds.<sup>16</sup>

Back and leg muscle strength was measured using the back-leg-chest dynamometer test. This test required participants to stand on the base of a dynamometer, with their head and back straight, and both feet parallel and spread the width of their shoulders; with the chain adjusted to fit the participant. For back muscle strength, the participants bowed their heads slightly, stood with legs straight and held the handles. They pulled at full force while stretching their body up. In the leg muscle, strength test, the participants had to bend their knees at an angle of approximately 115 to 125 degrees, hold the handle slightly above the knee, and then exert full traction, while stretching both legs. Both tests were performed



two times and the best value was recorded in kilograms (kg).<sup>17</sup> Muscle flexibility was measured using sit and reach tests. The participants sat in a long sitting position with their backs and legs straight. The soles of both feet were attached to the sit and reach box with toes pointing up, both arms were then raised straight in a forward position, with their palms on the sit and reach box. Then the participants leaned forward as far as possible and used their fingertips to push the sliding ruler on the sit and reach box. The test was repeated 2 times; recording the best value.<sup>16</sup> Agility was measured using the zig-zag run. The participants ran around six poles, without their bodies touching them, in a zigzag manner before returning to the starting point as quickly as possible; the time was then recorded (in seconds).<sup>18</sup>

The percentage of body fat was measured by using Omron HBF-306C Handheld (Omron Healthcare, Illinois, United States of America). The researcher filled out the participants' height, weight, age and gender and instructed the participant to stand straight, spread their legs as wide as their shoulders, hold the device on both sides of the control panel and raise it 90 degrees. After pressing the start button, the display showed the percentage of body fat and body mass index.<sup>19</sup>

The stress test used the five-items of stress questionnaire (ST-5); Thai version, which has good validity. It includes 5 items comprising of sleep problems, decrease in concentration, irritability, boredom and do not want to meet people. The cut off score is divided into 3 levels: no problem (score < 4), might have a problem (score 5-6) and have a problem (score > 7).<sup>20</sup> All variables were tested before and at the end of the study at 6 weeks.

### Statistical analysis

The data was non normal distribution from Kolmogorov-Smirnov test; thus, presenting the data with median and interquartile range (IQR). The Wilcoxon-Signed rank test and the Mann-Whitney U test were used for non-parametric data. Statistical significance was determined two-tailed  $p < 0.050$

## Results

Thirty participants were successfully recruited, and enrolled into the study (Figure 2). Age range at the enrollment was 21-23 years of age (Table 2). There was no significant difference in age, participants in the exergame group had a median age of 21, and the control group was 22 years old.

After six weeks of exercise, the comparison between the two groups showed a significant difference in the primary outcome that is arm and upper body muscle endurance ( $p = 0.012$ ) and back muscle strength ( $p = 0.032$ ). The exergame group had a significant improvement in all variables ( $p < 0.050$ ). Most of the participants in the exergame group reported they enjoyed exercising. However, in the video group, there were no significant differences in arm and upper body muscle endurance, agility, body mass index or body fat percentage (Table 3). Participants in the exergame group reported that they enjoyed exercising more with rhythm-based synchronous movements and in-game animations.

## Discussion

This study compared the effects of dance exergame versus home-based dance exercise with videos on physical fitness and stress in female youths with a sedentary behavior. At the end of the program, dance exergame showed different improvements in arm and upper body muscle endurance and back muscle strength compared to the home-based dance exercise.

The increase in arm and upper body muscle endurance was consistent with the study of Wojciechowski et al, which found that exergame improves upper extremity muscle endurance in adolescents.<sup>21</sup> According to a study by Ambe-gaonkar et al, modern or contemporary dance requires vigorous movement and endurance of upper body muscles.<sup>22</sup> Similarly, this study used diverse and modern music; such as, electronic dance, rhythm and blues (R&B) at the highest tempo 153 beats per minute. According to this study, the participants in the exergame group enjoyed exercise and was encouraged to continue exercising. Additionally, they enjoyed

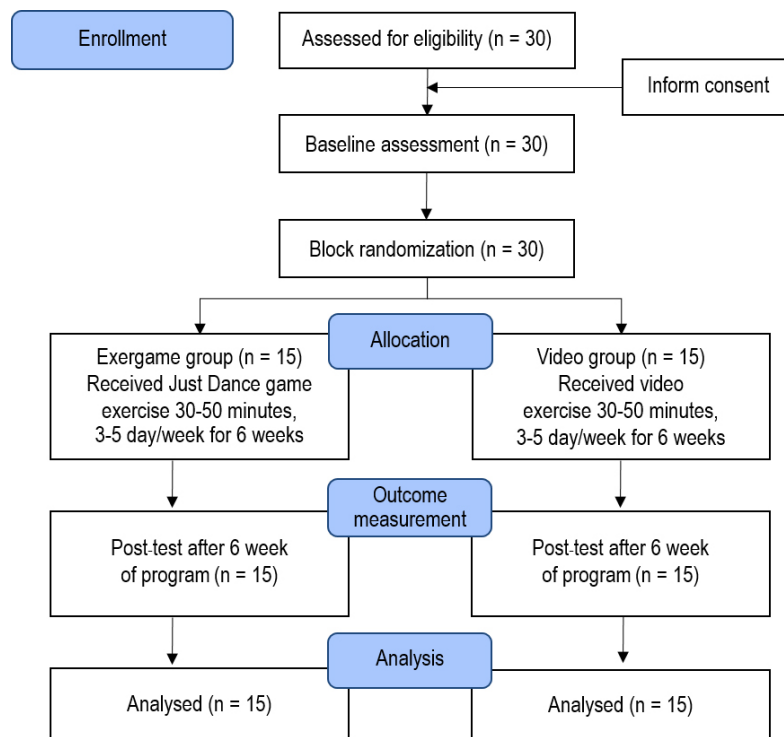
**Table 2.** Exercise programs of the exergame and the video groups

Variables	Exergame group (n = 15)	Video group (n = 15)	p-value
Body mass index (kg/m <sup>2</sup> ) <sup>a</sup>	21.0 (19.9, 23.1)	22.7 (19.1, 24.4)	0.836
Body fat percentage (%) <sup>a</sup>	28.6 (26.2, 31.1)	27.8 (22.8, 33.3)	0.678
Arm and upper body muscle endurance (time) <sup>a</sup>	7.0 (0.0, 9.0)	0.0 (0.0, 11.0)	0.502
Abdominal muscle endurance (time) <sup>a</sup>	13.0 (6.0, 25.0)	15.0 (0.0, 21.0)	0.519
Leg muscle endurance (time) <sup>a</sup>	39.0 (33.0, 44.0)	46.0 (40.0, 52.0)	0.051
Back muscle strength (Kg) <sup>a</sup>	48.0 (35.0, 58.0)	42.0 (38.0, 49.0)	0.329
Leg muscle strength (Kg) <sup>a</sup>	47.0 (36.0, 61.0)	50.0 (37.0, 58.0)	1.000
Flexibility (cm) <sup>a</sup>	5.0 (-1.0, 9.0)	9.5 (-2.0, 11.5)	0.340
Agility (sec) <sup>a</sup>	22.5 (20.8, 23.2)	22.2 (21.3, 22.8)	0.724
Stress (score) <sup>a</sup>	7.0 (4.0, 8.0)	4.0 (3.0, 7.0)	0.180

$p < 0.050$

<sup>a</sup>Median (Q1, Q3), test statistic by Mann-Whitney U test





**Figure 2.** CONSORT flowchart showing participants' progress through the phases of a parallel randomized trial of two groups

**Table 3.** Comparison of the variables within groups and between groups at baseline and 6 weeks (n = 30)

Variables	Compare within group						Compare between group with post-test
	Exergame group (n = 15)			Video group (n = 15)			
	Pre-test	Post-test	p-value <sup>a</sup>	Pre-test	Post-test	p-value <sup>a</sup>	p-value <sup>b</sup>
Body mass index (kg/m <sup>2</sup> )	21.0 (19.9, 23.1)	20.7 (19.5, 24.1)	0.041*	22.7 (19.1, 24.4)	21.9 (19.0, 25.2)	0.887	0.934
Body fat percentage (%)	28.6 (26.2, 31.1)	28.5 (25.1, 30.4)	0.006*	27.8 (22.8, 33.3)	28.0 (23.5, 34.5)	0.733	0.967
Arm and upper body muscle endurance (time)	7.0 (0.0, 9.0)	11.0 (6.0, 13.0)	0.001*	0.0 (0.0, 11.0)	1.0 (0.0, 7.0)	0.405	0.012*
Abdominal muscle endurance (time)	13.0 (6.0, 25.0)	27.0 (15.0, 35.0)	0.002*	15.0 (0.0, 21.0)	20.0 (0.0, 34.0)	0.005*	0.244
Leg muscle endurance (time)	39.0 (33.0, 44.0)	56.0 (50.0, 59.0)	0.001*	46.0 (40.0, 52.0)	54.0 (46.0, 60.0)	0.001*	0.633
Back muscle strength (kg)	48.0 (35.0, 58.0)	61.0 (52.0, 67.0)	0.008*	42.0 (38.0, 49.0)	51.0 (41.0, 56.0)	0.033*	0.032*
Leg muscle strength (kg)	47.0 (36.0, 61.0)	71.0 (57.0, 79.0)	0.001*	50.0 (37.0, 58.0)	64.0 (47.0, 68.0)	0.002*	0.097
Flexibility (cm)	5.0 (-1.0, 9.0)	8.5 (5.0, 12.0)	0.001*	9.5 (-2.0, 11.5)	11.0 (2.0, 13.0)	0.009*	0.648
Agility (sec)	22.5 (20.8, 23.2)	23.7 (21.1, 24.0)	0.009*	22.2 (21.3, 22.8)	22.8 (21.9, 23.1)	0.201	0.372
Stress (score)	7.0 (4.0, 8.0)	3.0 (2.0, 6.0)	0.028*	4.0 (3.0, 7.0)	2.0 (1.0, 4.0)	0.006*	0.102

Median (Q1, Q3), \*p < 0.050

<sup>a</sup>Wilcoxon-Signed rank test; <sup>b</sup>Mann-Whitney U test

dancing with other players, and that it could be based on scores and feedback on the accuracy of their choreography. On the other hand, the participants in the video group had to dance alone at home; which was less fun and exertive. A previous study, by Jerrold et al, studied muscles contractions

while dancing by electromyography (EMG), and found that the upper body muscles were active; particularly the biceps and triceps muscles.<sup>23</sup> When analyzing the choreography in this study, upper limb movements were mainly performed by the deltoid, pectoral, triceps, and biceps muscles. The rea-

sons mentioned above concluded that the exergame group improved arm and upper body muscle endurance differently than the video group. Although there were no significant differences between the two groups in abdominal and leg endurance, both groups found significant differences before and after training. The muscle contractions during dance showed that the rectus abdominis, obliques, quadriceps and hamstrings muscle have a lot of contraction.<sup>23</sup>

In addition, this study found that after 6 weeks the dance exergame group had different strength of back muscle than the video group. Although no differences were found between groups in leg strength, both groups showed significant differences before and after training. The dance exergame has a positive effect on fast reaction times, coordination and strength.<sup>24</sup> Dancing can improve back muscle strength due to continuous isometric contractions with fast-twitch concentric and eccentric contractions to control balance from several movements.<sup>25</sup> As dance exergame has free dance games and creates fun from the characters in the game as well as from the feedback and scores; which reflect the dancers, as they move their bodies as one with the characters on the screen.<sup>11</sup> Dance exergame sets the level of energy exertion of medium or vigorous. The length of the song and the complexity of the choreography process can change the physical challenge.<sup>26</sup> The fast tempo of songs and choreography is bound to encourage more fast-twitch fiber muscle contraction, and result in improved muscle strength.<sup>27</sup> Dancing in the research room with other players to make it even more fun, resulted in constant and consistent full exertion. Providing real-time feedback so players can adjust their movements to correct them. The increased expertise made dancing better, moving more vigorously than home-based exercise with video. However, in the past, the effect of dance exergame on back muscle strength has not been investigated directly.

Other physical fitness variables were not significantly different between groups. but muscle flexibility differed significantly in both groups before and after training. This was consistent with the study on the effects of dance exercise programs in sedentary, female university students, which also showed a similar increase in muscle flexibility.<sup>28</sup> Moving their body to the rhythm of the music is dynamic stretching through the stretch reflex to prevent changes in muscle length and maintain muscle tension.<sup>29</sup> In contrast, this study showed that decreased agility, possibly caused by the breaks between each song, meant that the participants had to keep marching, which may hinder continued movement. Decreasing agility may be due to inconsistency between the choreography and zigzag testing skills. Therefore, practical skills from intervention cannot be transferred to outcome measurements. A study on the effects of active video games in adolescents explains that non-stop shuffles require sustained movements sufficient for motor and nervous system adaptation; resulting in improved agility,<sup>30</sup> and that dancing continuously for 3 months can improve agility.<sup>31</sup> After 6 weeks

of training, both body fat percentage and body mass index decreased in the exergame group, but increased in the video group. Dance exergame in adolescent girls were found to significantly reduce total body fat and subcutaneous adipose tissue in the abdomen and legs.<sup>32</sup> Therefore, the percentage of body fat also decreased in the exergame group.

The present study compared stress levels between groups and found that there were not significantly different, but they differed before and after training within group. This was consistent with a study of medical students in Thailand, in which dance exercise can decrease stress; especially severe stress or major depression.<sup>33,34</sup> At least 30 minutes of continuous exercise stimulates the hypothalamus and pituitary glands to release endorphins, which have stress-reducing properties. Additionally, the serotonin, dopamine, and norepinephrine produced, also helps control mood, stress and relieves depression.<sup>35</sup>

Dance exergame may be feasible and acceptable in youth. It should be promoted through school activities. If adapted to home activities, parents should be informed about the benefits of dance exergame and guide them in making future purchase decisions. In Thailand, there are still widespread restrictions on access to dance exergame. Finally, the researchers recommend that any exercise that is interesting, fun and motivating can encourage youths with a sedentary behavior to be more physically active.

The limitations of this study were that all the female youths were from one location. The home-based dance exercise with videos might have a design bias as the participants in this group had to exercise alone, no supervision or feedback like in the exergame group, and youths prefer a group exercise to an individual exercise. To reduce the design bias, the dance exercise with videos should be conducted in group. Moreover, the sample size was rather small to confirm statistical significances of all outcomes mentioned as the sample size calculation was based on the arm and upper body endurance only. Additionally, heart rate was not measured to determine exercise intensity; it was just a self-assessment by the Borg scale. Long-term follow-up of both exercise programs may show changes more clearly for other variables. This study also did not track whether the participants continued to use dance after the study ended. Further studies should include other populations, more intensity of exercise, and long-term follow-up.

## Conclusions

After six-week of dance exergame and home-based dance exercise with videos can improve muscle endurance, muscle strength, muscle flexibility and decrease stress in female youths. However, dance exergame seems more effective in abdominal muscle endurance and back muscle strength. It is recommended that any exercise that is interesting and fun can motivate sedentary youth to get more exercise.

## Disclosure

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## The Feasibility of Vitamin B Complex Additive to Lidocaine for Myofascial Trigger Point Injection in Neck and Upper Back Muscles: A Pilot Trial

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### ABSTRACT

**Objectives:** To explore the feasibility and result of adding the vitamin B complex to lidocaine for a myofascial trigger point (MTrP) injection in reducing pain and disability in patients with myofascial pain syndrome (MPS).

**Study design:** A pilot randomized double-blind controlled trial.

**Setting:** Thammasat University Hospital, Thailand.

**Subjects:** Thirty-eight patients aged between 18 to 70-year-old with active MTrP on neck and upper back and pain less than 6 months.

**Methods:** The patients were randomly assigned into two groups. The treatment group ( $n = 20$ , side = 33) were treated with 0.4 ml mixture of vitamin B complex and 1% lidocaine (1:1 ratio) whereas the control group ( $n = 18$ , side = 29) was treated with 0.2 ml of 1% lidocaine only. The patients and assessors were blinded to the treatments assigned. Numeric rating scale (NRS) for pain and neck disability index (NDI) were rated by the patients at baseline and at the end of week 1, 2 and 4. A linear mixed effect model was used.

**Results:** The NRS and NDI scores were significantly decreased at the end of week 1, 2 and 4 but no significant differences between the two groups ( $p$ -value = 0.802 and 0.072, respectively). Post-injection soreness was mostly found with significant difference between the two groups ( $p = 0.042$ ).

**Conclusions:** Adding vitamin B complex to lidocaine for MTrP injection in neck and upper back muscles does not give better outcomes in pain and disability than injection with lidocaine alone. The feasibility and result of pilot study in term of design is useful, although vitamin B complex as an intervention should be reconsidered in preparation and adverse event.

**Keywords:** pain, myofascial pain syndrome, trigger point injection, lidocaine, vitamin B complex

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### Introduction

Myofascial pain syndrome (MPS) is defined as a regional pain syndrome characterized by muscle pain caused by myofas-

cial trigger point (MTrP), a tender spot in a palpable taut band of skeletal muscle fibers.<sup>1</sup> Pressure on MTrP can produce pain, referred pain, and local twitch response (LTR).<sup>1</sup> The most popular hypothesis by Travel and Simon is the pain caused by over releases acetylcholine in the synaptic cleft that stimulates sarcoplasmic reticulum (SR) to release a calcium causing sustained sarcomere contraction, and consequently increasing metabolic demand and local ischemia.<sup>1</sup> Impaired uptake of calcium into the SR in the setting of depleted ATP increases calcium concentration and subsequently increases contractile activity.<sup>1</sup> Mitochondria in muscle cell mainly produces ATP by the Krebs' cycle and electron transport chain (ETC).<sup>2</sup> Vitamin B is a co-enzyme in biochemical pathways of the Krebs' cycle. Vitamin B2 and B3 is a precursor of FADH<sub>2</sub> and NADH that electron carrier in the Krebs' cycle.<sup>2-4</sup>

Treatments of MPS include analgesic medication, physical modality, massage, MTrP injection, dry needling, and life-style modification.<sup>1</sup> Lidocaine and botulinum toxin MTrP injections are effective in reducing pain scores and have been shown to improve quality of life.<sup>1,5</sup> Overall, lidocaine is more cost effective than botulinum toxin injection,<sup>6</sup> reduces a pain scores within 2 weeks<sup>7,8</sup> and has less post-needling soreness than the dry needling technique.<sup>7-9</sup> Moreover, previous studies using hyaluronidase with lidocaine or ozone gas injected into MTrP was reported to reduce pain along treatment period.<sup>10,11</sup>

Nowadays, modern lifestyle of using a laptop or a smart-phone causes an abnormal ergonomic posture of neck and upper back which results in pain and tightness of related muscles. In a randomized controlled trial (RCT) of patients with severe osteoarthritis after total knee arthroplasty, an intramuscular injection of vitamin B plus diclofenac showed an analgesic effect superior to diclofenac alone.<sup>12</sup> Theoretically, the vitamin B helps increase the ATP production in a muscle cell that will improve the energy crisis at MTrP area. Therefore, the researchers did a pilot RCT to explore the feasibility and result of adding the vitamin B complex to lidocaine for a MTrP injection in reducing pain and disability in patients with MPS.

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## Methods

This pilot randomized parallel double-blind controlled trial was approved by the Human Research Ethics Committee of Faculty of Medicine, Thammasat University on 14<sup>th</sup> January 2019 (registration number MTU-EC-RM-2-220/61) and was registered in the Thai clinical trials registry (TCTR No. 20190308005).

### Participants

Patients with active MTrP in the neck and/or upper back as determined by the Travel and Simon criteria<sup>1</sup> were recruited at the Physical Medicine and Rehabilitation Outpatient Clinic of Thammasat University Hospital between May 2019 to July 2020. Inclusion criteria were age between 18-70 years and duration of MPS less than 6 months. Exclusion criteria were 1) dry needling, MTrP injection and vitamin B use within the past one month, 2) neck or shoulder surgery within the past year, 3) diagnosis of fibromyalgia, cervical radiculopathy or myelopathy, and bleeding tendency, 4) warfarin use, and 5) vitamin B or lidocaine allergy.

### Randomization

After screening and receiving patients' informed consent, the patients were randomized into 2 groups (1:1 ratio) by blocked randomization via computer-generated numbers. The concealed envelopes with serial numbers and group assignments were prepared by research assistant.

### Intervention

One researcher, a physiatrist/rehabilitation physician, examined the patients to find active MTrP in neck and upper back areas and administered injections following their assigned group. An injected syringe was covered with opaque paper to blind the patient's treatment medication. Before starting the study, two other general practitioners, assigned as an assessor and were blinded of the treatment assigned.

In the treatment group (B group), MTrP was injected with 0.2 ml of vitamin B complex (1 ml consisted with B1 100 mg, B2 0.5 mg, B3 100 mg, B6 1 mg) plus 0.2 ml of 1% lidocaine without adrenaline, with a total of 0.4 ml (1:1 ratio) at each MTrP. In the control group, MTrP was injected with 0.2 ml of 1% lidocaine without adrenaline at each MTrP. Both groups were injected on the beginning day of the study.

The patients in both groups were instructed to do a self-stretching home exercise program of neck, upper trapezius and infraspinatus muscles, 10 times of each muscle per day, and avoid other physical modalities and Thai-massage during the study period. Analgesic medication was allowed to take and had to report the assessor.

### Outcome measurements

Primary outcome was pain on neck and/or upper back rated by the patients using numeric rating scale (NRS) which ranged from 0 of no pain to 10 of the most severe pain, at

baseline before treatment and at the end of the 1<sup>st</sup>, 2<sup>nd</sup>, and 4<sup>th</sup> week. Those with the symptoms on both sides had to rate the pain NRS at each side separately. The minimal clinically important change (MCIC) of NRS in patients with neck pain was 2.5 points.<sup>13</sup>

Secondary outcomes were the neck disability index (NDI) Thai-version. The NDI Thai-version consisted of 10 items concerning neck pain affecting activities of daily living including personal care, lifting, reading, headache, concentration, work status, driving, sleeping, and recreation. It is a self-report questionnaires and each item has 5 choices scored ranging from 0, no disability to 5, complete disability, and a total score of 50 being the worst.<sup>14</sup> The internal consistency of Thai-version NDI was 0.835<sup>14</sup> and MCIC of NDI was 3.5 points.<sup>13</sup> The patients completed the NDI Thai-version questionnaire at baseline and at the end of the 1<sup>st</sup>, 2<sup>nd</sup>, and 4<sup>th</sup> week. Those with the symptoms on both sides had to complete the NDI Thai-version based on the most symptomatic side.

### Statistical methods

The estimated required number of symptomatic sides in each group was 29 following Viechtbauer et al.<sup>15</sup>

The analysis was performed according to intention to treat principle. Categorical data were presented as frequency and percentages. Continuous data were presented as mean, median, standard deviation (SD), and interquartile range (IQR), depending on the nature of the data. To compare demographic and baseline characteristic data among groups, the researchers used Fisher's exact test for categorical data and t-test or rank-sum test for continuous data. Correlation between observed data, such as symptomatic sides in the same patient and repeated measurement of NRS in each symptomatic side, were analyzed by using a linear mixed-effect model for analysis of treatment efficacy within and among groups. Adverse events comparing between the two groups were analyzed using Fisher's exact test. Statistical significance was accepted at *p*-value less than 0.05. The data were analyzed using Stata version 12.1.

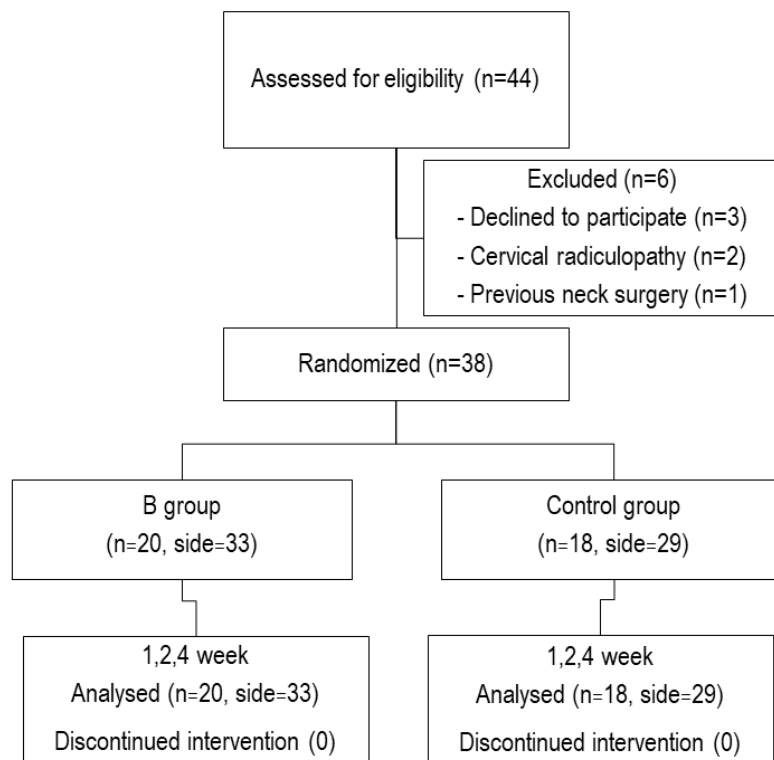
## Results

Flow of the study is shown in Fig. 1. No patient was lost to follow-up. Demographic and baseline characteristics of the patients did not have statistically significant differences (Table 1).

The NRS was assessed and analyzed based on symptomatic sides, 33 in the B group and 29 in the control group whereas NDI was assessed and analyzed based on number of patients, 20 in the B group and 18 in the control group.

The NRS scores were significantly reduced in the first, second, and fourth week in both groups compared with the baseline. In the 1<sup>st</sup> week post-injection, the mean NRS score notably decreased from 5.8 to 3.3 points (mean difference = 2.5 points) in the B group and 5.4 to 3.8 points (mean difference = 1.6 points) in the control group. NRS scores of the B group





**Figure 1.** Participant flow chart

**Table 1.** Demographic and baseline characteristics of the patients

Parameters	Vitamin B group (n = 20, side = 33)	Control group (n = 18, side = 29)	p-value
Age (years) <sup>1</sup>	42.3 (11.0)	46.9 (12.7)	0.241 <sup>a</sup>
Gender <sup>2</sup>			1.000 <sup>b</sup>
Male	4 (20.0)	3 (16.7)	
Female	16 (80.0)	15 (83.3)	
Occupation <sup>2</sup>			0.782 <sup>b</sup>
Office worker	11 (55.0)	9 (50.0)	
Housekeeper	3 (15.0)	4 (22.2)	
Factory worker	0	1 (5.6)	
Other	6 (30.0)	4 (22.2)	
Handed <sup>2</sup>			0.232 <sup>b</sup>
Right	17 (85.0)	18 (100)	
Left	3 (15.0)	0	
Duration of symptoms (months) <sup>3</sup>	0.8 (0.2, 3)	1 (1, 3)	0.268 <sup>c</sup>
Side of symptom <sup>2</sup>			0.899 <sup>b</sup>
Right	3 (15.0)	2 (11.1)	
Left	4 (20.0)	5 (27.8)	
Both sides	13 (65.0)	11 (61.1)	
MTrP locations <sup>2</sup>			0.425 <sup>b</sup>
Upper trapezius	20 (60.6)	15 (51.7)	
Infraspinatus	2 (6.1)	1 (3.5)	
Upper trapezius + Infraspinatus	10 (30.3)	8 (27.6)	
Upper trapezius + neck	1 (3.0)	2 (6.9)	
Upper trapezius + infraspinatus + neck	0	3 (10.3)	
NRS <sup>1</sup>	5.8 (1.4)	5.4 (2.4)	0.397 <sup>a</sup>
NDI <sup>3</sup>	13.5 (10.5,18.5)	14.5 (12,20)	0.500 <sup>c</sup>

<sup>1</sup>Mean (SD), <sup>2</sup>number (%), <sup>3</sup>median (Q1, Q3); <sup>a</sup>Independent t-test, <sup>b</sup>Fisher's exact test, <sup>c</sup>Rank-sum test

MTrP, myofascial trigger point; NRS, numeric rating scale; NDI, neck disability index

Treatment solutions: vitamin B group with vitamin B complex plus 1% lidocaine, control group with 1% lidocaine

were reduced in subsequent follow-up periods but did not show a statistically significant difference when compared to the control group (mean difference -0.04, 95% CI -0.35 to 0.27,  $p = 0.802$ ).

The NDI scores were significantly reduced in the first, second, and fourth week in both groups compared with the baseline. However, the reduction of NDI score in the B group was less than in the control group along the 4-week follow-up period but did not show a statistically significant difference between groups (mean difference 1.2, 95% CI -0.1 to 2.6,  $p = 0.072$ ). (Table 2, Fig. 2 and 3.)

Adverse events are shown in Table 3. Post-injection soreness was the most common complaint found in both groups and showed statistically significant difference between the two groups (80% in the B group and 44.4% in the control group,  $p = 0.042$ ). No significant difference between groups in other adverse events such as contusion and dizziness were found. All adverse events recovered spontaneously without treatment.

## Discussion

This study mixed vitamin B complex with 1% lidocaine for MTrP injections to neck and upper back muscles. It revealed that the NRS scores in the B and control groups declined along the 4 weeks without statistically significant difference. The addition of vitamin B to lidocaine did not demonstrate a difference in pain reduction as expected. In theory, vitamin B increases ATP which consequently mitigates the energy crisis within the muscle cells.<sup>2,3</sup> Moreover, the chemical effect of lidocaine injection leads to local anesthesia by prolonged relative refractory period and limited maximum frequency of impulse conduction of the peripheral nerve.<sup>16</sup>

The NRS scores in both groups showed notable decrease at the first week post-injection, this differs from previous studies which showed decreased scores mostly after the second week.<sup>7,8</sup> One of these studies injected 0.2 ml of 0.5% lidocaine at each MTrP,<sup>8</sup> different concentration from this study using 0.2 ml of 1% lidocaine. However, the mean difference of NRS score reached the MCIC of 2.5 points at the first week in the

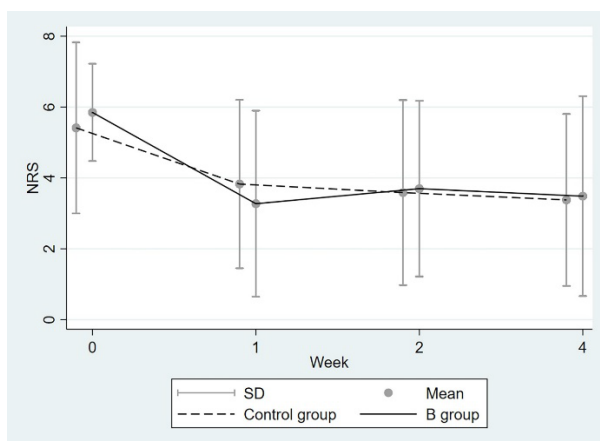
**Table 2.** Comparison of NRS and NDI between baseline and follow-up within group, and between groups

Outcome variable	Vitamin B group (n = 20, side = 33)		Control group (n = 18, side = 29)		Between groups		
	Mean (SD)	p-value	Mean (SD)	p-value	Mean difference	95% CI	p-value
NRS					-0.04	-0.35 to 0.27	0.802
Baseline	5.8 (1.4)		5.4 (2.4)				
1 <sup>st</sup> week	3.3 (2.6)	< 0.001*	3.8 (2.4)	< 0.001*			
2 <sup>nd</sup> week	3.7 (2.5)	< 0.001*	3.6 (2.6)	< 0.001*			
4 <sup>th</sup> week	3.5 (2.8)	< 0.001*	3.4 (2.4)	< 0.001*			
NDI					1.2	-0.1 to 2.6	0.072
Baseline	15.1 (7.7)		15.7 (5.1)				
1 <sup>st</sup> week	8.8 (7.6)	< 0.001*	10.2 (5.8)	< 0.001*			
2 <sup>nd</sup> week	10.9 (7.5)	< 0.001*	9.3 (6.1)	< 0.001*			
4 <sup>th</sup> week	11.1 (9.0)	0.001*	8.0 (5.5)	< 0.001*			

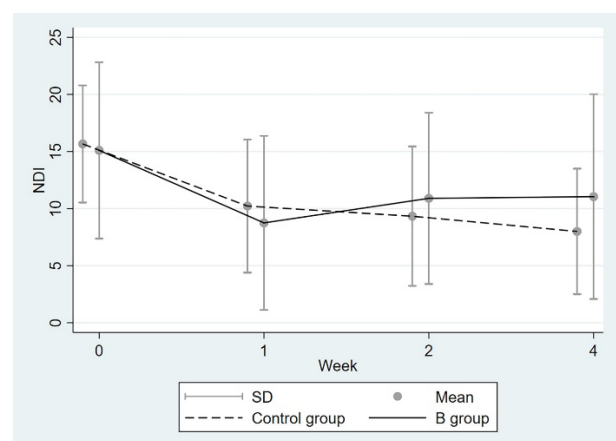
Linear mixed effect model; \* $p < 0.05$

NRS, numeric rating scale; NDI, neck disability index

Injection solutions: vitamin B group with vitamin B complex plus 1% lidocaine, control group with 1% lidocaine



**Figure 2.** Numeric rating scale (NRS) for pain



**Figure 3.** Neck disability index (NDI) scores

**Table 3.** Adverse events

	Vitamin B group (n = 20)	Control group (n = 18)	p-value
Post-injection soreness	16 (80.0)	8 (44.4)	0.042
Contusion			
< 4 cm	3 (15.0)	0	0.232
≥ 4 cm	0	1 (5.6)	0.474
Dizziness	1 (5.0)	1 (5.6)	1.000

B group but not in the control group. This finding could be due to several reasons. First, vitamin B complex (B1, B2, B3, B6) might increase the ATP production via the Krebs' cycle and electron transport chain within the muscle cell.<sup>4</sup> ATP production provides muscle cells the chemical energy needed to break vicious cycle of an energy crisis and stop excess prolonged contraction cycle and reduce pain.<sup>1</sup> Second, the total volumes of injected solution at each MTrP were not equal, 0.4 ml in the B group but 0.2 ml in the control group. A larger volume of the injected solution in the B group may dilute and wash out more sensitive substances in MTrP than the control group does.<sup>5,17</sup>

In addition, in the B group there was an increase in NRS at the end of 2<sup>nd</sup> week but lower than the baseline. This may be due to a short half-life of vitamin B, 1.8 days for B1.<sup>18</sup> Vitamin B complex (B1, B2, B3, B6) has a short half-life and is eliminated via urination.<sup>4</sup> Thus the effect of vitamin B is not sustained for long periods of time.

The second outcome of this study was the NDI score which assesses the metric of disability among patients with neck pain.<sup>14</sup> The NDI scores at each point in our study did not demonstrate a statistically significant difference between groups. According to a previous study, MCIC of NDI for patients with neck pain is 3.5 points.<sup>13</sup> Our study showed NDI score difference achieved MCIC at 1<sup>st</sup>, 2<sup>nd</sup> and 4<sup>th</sup> week after injection in both groups. Yoon et al. reported the lidocaine injection decreased NDI score at the end of 1<sup>st</sup> and 2<sup>nd</sup> week like the findings of this study.<sup>19</sup> Another finding in the B group in our study was the NDI score declined at the 1<sup>st</sup> week but then increased at the 2<sup>nd</sup> and 4<sup>th</sup> weeks after post-injection whereas in the control group, the NDI scores declined subsequently after injection. In addition, the decreasing trend of the NDI and NRS score seemed similar at each point post-injection at in both groups which supports a highly correlation between the pain score and the NDI score, with correlation coefficient ( $r$ ) = 0.886.<sup>14</sup>

Post-injection soreness was common adverse event. In our study, more patients in the B group reported post-injection soreness than those in the control group 80% and 44.4%, respectively with statistical difference. The percentage in the control group in our study is rather similar with 38.1-57% of patients injected with lidocaine reported in previous studies.<sup>7-9</sup> The high percentage of post-injection soreness in those injected with vitamin B complex may be caused by nicotinamide (vitamin B3) which is hydrolyzed to nicotinic acid in

a physiological pH as 7.35-7.45, and the latter can result in skin irritation and cause a pain sensation.<sup>20,21</sup> An increased ATP caused by vitamin B may activate neural pathways of pain sensation. These two explanations may translate to increased post-injection soreness after vitamin B intramuscular injection. All adverse events spontaneously resolved and did not require treatment. A different form of vitamin B or a different mixture like saline, bicarbonate can be an alternative option in the future trial.<sup>21,22</sup>

This pilot study was feasible in terms of design, setting and participant recruitment. However, an unequally MTrP-injected volumes between the two groups, vitamin B preparation, intergroup different outcomes and post-injection soreness should be considered. Adding an objective outcome as the pain pressure threshold on MTrP by algometer should be measured. The method and outcomes of this pilot study may offer an initial way for future trial planning.

## Conclusions

Adding vitamin B complex to lidocaine for MTrP injection in neck and upper back muscles does not give better outcomes in pain and disability than injection with lidocaine alone. The feasibility and result of pilot study in term of design is useful, although vitamin B complex as an intervention should be reconsidered in preparation and adverse event.

## Disclosure

The authors declare no conflict of interest.

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## Clinical Predictors of Good Functional Outcome in Patients with Acute Stroke

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### ABSTRACT

**Objectives:** To evaluate clinical predictors related to good functional outcomes in acute phase stroke patients.

**Study design:** Prognostic research with prospective cohort design.

**Setting:** Stroke Unit, Maharat Nakhon Ratchasima Hospital, Nakhon Ratchasima Province, Thailand.

**Subjects:** Acute stroke patients age over 18 years who were admitted for conservative treatment

**Methods:** Patients were interviewed face-to-face regarding general information and were physically examined for clinical predictors related to good functional outcome such as premorbid status, diagnosis, comorbid conditions, complications, neurological condition, and bed mobility ability. The Barthel index score was used to determine functional outcome at acute phase admission. The patients were later interviewed by phone to determine their Barthel index score at 2 weeks, 1 and 3 months. Statistical analysis of acute clinical predictors of good functional outcome was conducted using multivariable logistic regression.

**Results:** Two hundred patients were recruited of whom 6.5% were excluded from the study. The average age (SD) was 63.5 (15.2) years and 51.9% were male. At the 3-month follow-up, 82.9% of stroke-survival patients had a good functional outcome (Barthel index > 75). Clinical predictors of a good functional outcome included the ability to change the body position from supine to sitting, independent walking before admission, age less than 65 years and normal consciousness in the acute phase, with adjusted odd ratios (95% CI) of 21.63 (2.13-218.76), 15.80 (2.90-86.11), 4.95 (1.50-16.35) and 3.88 (1.65-9.16), respectively.

**Conclusions:** Among the stroke patients, the ability to change body position from supine to sitting, the ability to walk independently without gait aids before admission, age less than 65 years and normal consciousness in the acute phase were related to good functional outcome.

**Keywords:** Barthel index, functional outcome, clinical predictors, stroke, rehabilitation

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### Introduction

Stroke is a global health burden around the world, including Thailand.<sup>1-5</sup> It is a major cause of disability, functional decline and dependent living that represents a burden to the patient's family and to the social support system. Intensive inpatient rehabilitation has been known to help stroke patients return to their normal life effectively;<sup>6,7</sup> however, over-crowding problems in large hospitals allows only a very short period of admission for both acute treatment and rehabilitation.<sup>8,9</sup> With the limited availability of resources, clinical predictors of good functional outcome in stroke patients that can be identified in the acute phase could help in the selection of the appropriate rehabilitation program for each patient, depending on his/her potential and could help recruit potentiated patients who are at risk of becoming more disabled for early intensive inpatient rehabilitation programs.

A suggestion from a hospital accreditation surveyor is that due to the very short period of acute stroke care available at the stroke unit and the limited number of intensive rehabilitation beds (only 12 beds in Maharat Nakhon Ratchasima Hospital), physicians should develop criteria for effectively identifying the most potentiated patients for the in-patient intensive rehabilitation program. The selection criteria should be simple, require only a short time for assessment at the bedside and should be able to be used even by a non-physiatrist, e.g., asking the patient about premorbid ambulation or asking them to change their body position from supine to sitting without help.<sup>10-12</sup> Previous studies have identified factors associated with a good functional outcome in stroke patients including male gender, younger age, no diabetes mellitus, married status, normal consciousness, good motor power of the weak side, and the ability to transition from supine to sitting independently; however, all those factors were studied during the period after the acute phase.<sup>6,10,11</sup> A study of acute phase predictors at Maharat Nakhon Ratchasima Hospital found that male patients, age younger than 55, with muscle power of the weak side more than grade 2, and normal consciousness were associated

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with a good functional outcome. However, that retrospective study had limitations related to the reliability of medical records covering the acute phase, recall bias on telephone interviews and many patients being lost to follow-up.<sup>13</sup>

The present study was conducted to evaluate acute phase predictors of good functional outcome at the 3-month follow-up of stroke patients using a prospective design that would provide clinicians the opportunity to use predictive factors to recruit potentiated stroke patients for early intensive rehabilitation. Another objective was to study the pattern of stroke recovery covering the acute to the subacute phase using Barthel's index (BI) scores.

## Methods

### Study design

This prognostic research using a prospective cohort design was approved by the Ethics Committee of Maharat Nakhon Ratchasima Hospital, clinical trial registration number 091/2020.

### Participants

From July 2019 to January 2020, acute stroke patients who were admitted to the stroke unit at Maharat Nakhon Ratchasima Hospital and who met the criteria of age 18 years or over with non-surgical treatment were recruited into the study. All patients or an immediate family member were asked for informed consent. Patients who were diagnosed with transient ischemic attack or other diseases, who later had stroke-related surgical treatment, and who could not be followed up, e.g., patients with no known phone number or who were unable to speak, and those who lived without a close caregiver, were excluded. The sample size was estimated using the Peduzzi formula<sup>14</sup>  $N = (10k)/P$ , where N is the sample size to be studied, K is number of independent factors of interest ( $k = 13$ ), and P is the prevalence of good functional outcome (0.79).<sup>13</sup> The calculated sample size for predicting functional outcome was 164 cases plus 10% to cover loss to follow up and an additional 10% to cover exclusion for other reasons. We therefore included 200 cases in the present study.

### Intervention

Data was collected by face-to-face interview and the recruited patients were physically examined by one of two physicians (NI or RS) within 72 hours following the stroke. The data collected consisted of the following: sex, age, premorbid status, length of stay, diagnosis, comorbidities, history of previous stroke, muscle power of the affected side, associated abnormalities (consciousness, speech, swallowing), ability to change position from supine to sitting, in-hospital complications, and admission Barthel index score. Telephone interviews were conducted to re-assess the functional level using the Barthel index at 2 weeks, 1 and 3 months.<sup>15,16</sup>

In the present study, good functional outcome is defined to mean the stroke patient had a Barthel index score of 75 points or more at the 3-month follow-up. Patients with other functional results at the initial examination conducted during the first 72 hours post-stroke, including death due to stroke or stroke-

related complications, were included in the poor functional outcome group. The data analysis was conducted after all of the data collection was completed. The category 'associated abnormalities' was recorded as either normal or abnormal. Abnormal consciousness included inability to follow commands, drowsiness and coma. Abnormal speech included inability to name simple objects such as pen, cup and watch, inability to repeat an eight-word sentence containing 11 syllables, and unclear articulation of speech. Abnormal swallowing means dysphagia. Patients who were endotracheally intubated or who could not follow commands at the time of the examination were marked as "cannot be evaluated for speech and swallowing problems".

The Barthel index is considered a reliable disability scale and is commonly used to determine disability and to follow up the functional recovery of stroke patients. It consists of 10 activities (5 basic activities of daily living, 3 of mobility and 2 continence functions). Each item is scored based on the patient's ability where 0 points means totally dependent and 100 points means totally independent. The Barthel index can be divided into 5 categories by severity of disability: 0 to 20 points = very severe disability, 25-45 points = severe disability, 50-70 points = moderate disability, 75-95 points = mild disability, and 100 points = no disability.<sup>17</sup>

### Outcome measurements

The main purpose of this study was to identify predictors of a good functional outcome within 3 months after a stroke in patients admitted to the stroke unit, in particular, outcomes related to daily activity independence. We considered the outcome at 3 months to be favorable if the Barthel index score was 75 or more. The following independent variables in the acute phase were identified as good clinical predictors: age, sex, premorbid ambulation, type of stroke (ischemic/hemorrhagic), co-morbidities (0-1 vs. 2 or more co-morbidities), a history of previous strokes, complications, level of consciousness, muscle power of the affected side (0-2 vs. 3-5), presence of aphasia or dysphagia, ability to change body position from supine to sitting without help and the admission Barthel index score. The second objective was to study the pattern of stroke recovery from the acute to the subacute phase using Barthel index (BI) scores.

### Statistical methods

Baseline clinical characteristics are reported as percentages, means and standard deviations (SD). The relationship between general clinical characteristics and good functional outcome were assessed using Fisher's exact test. The relationships between clinical predictors and good functional outcome were analyzed by univariable logistic regression and are reported as a crude odds ratio (cOR) and 95% confidence interval (95% CI). All of the independent variables were then analyzed by multivariable logistic regression and are reported as an adjusted odds ratio (AdjOR) and 95% CI. Statistical significance was set at  $p < 0.05$ . Statistical analysis was conducted using Stata version 11.0.

## Results

Two hundred stroke patients admitted to the acute stroke unit at Maharat Nakhon Ratchasima Hospital between July 2020 and January 2021 were recruited into this study, of whom thirteen (6.5%) were excluded: two had a recurrent stroke, three received a craniectomy, one had brain cancer, one was diagnosed with cerebral vasculitis, and six were lost to follow-up leaving 187 patients for analysis (Figure 1). Most (51.9%) were male, the average age was 63.5 years (SD 15.2), the median hospital stay was 3.8 days (IQR 18 hours to 6.4 days, min-max 6 hours and 143 days). Forty-seven (23.5%) died, most (19%) during the acute phase of admission. 81.3% had a current medical disease: the top three were hypertension (63.1%), dyslipidemia (25.7%) and diabetes mellitus (23.1%). Most (83.5%) could walk independently without any gait aid before admission, while only 5.9% could not walk before their stroke attack. Fifty-four patients (28.9%) had complications when they were admitted to the acute stroke unit; the top three were pneumonia (17.1%), acute renal failure (5.3%) and upper gastrointestinal hemorrhage (2.7%). Only 5.8% had good function (BI score 75 or more) when evaluated within the first 72 hours after the stroke; however, at the end of the study (at the 3-month follow-up), 118 patients (62.0%) had a good functional outcome as shown in Table 1.

Table 2 shows the relationship between clinical predictors in the acute phase and functional outcome at the 3-month follow-up using Fisher's exact test. It was determined that the factors of age 65 years old or less, independent pre-morbid ambulation, ischemic stroke, good consciousness, muscle power of the affected side grade 3 or more (useful muscle power), normal swallowing and speech, ability to change posi-

tion from supine to sitting, and no complications at acute admission, were statistically significant predictors of a good functional outcome ( $p < 0.05$ ). The variables associated with a good functional outcome are presented with odds ratios (95% CI) in Table 3. Admission BI scores could not be analyzed because there were no patients who had good function at acute admission which later regressed to poor function at the 3-month follow-up ( $n = 0$ ). Using multivariable logistic regression, the ability to change body position from supine to sitting without help at acute admission, walking independently before admission, age 65 years or less, and normal consciousness were found to be significantly related to good functional outcome at the 3-month follow-up with AdjOR of 21.63 (95%CI 2.13, 218.76), 15.80 (95%CI 2.91, 86.11), 4.95 (95%CI 1.50, 16.35), 3.88 (95%CI 1.65, 9.16), respectively.

Table 4 shows the patterns of stroke recovery and disability level after the acute phase based on 3-month follow-up BI scores. The admission BI scores evaluated at the acute phase (72 hours or less after stroke) were found not to be related to the BI scores at the 3-month follow-up. At the acute phase, 33.7% were dependent stroke patients (very severe disability: BI scores 20 or less) but only 22.1% and 11.6% were dependent stroke patients at the 2-week and 1-month follow-up, respectively. Those numbers are close to the number of dependent stroke patients at the end of study (10%).

## Discussion

The aim of this observational prospective study was to identify acute phase clinical factors that could predict good functional outcome at the 3-month follow-up after an acute stroke. Using multiple logistic regression, only four independent variables were found to be good functional predictors at

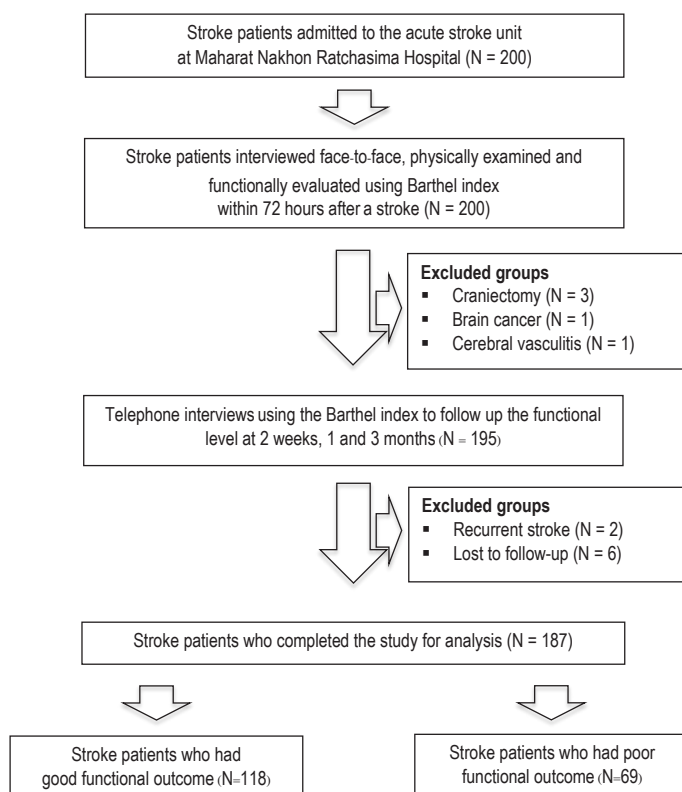


Figure 1. Flow of the study

**Table 1.** Demographic and clinical characteristics of the patients (n = 187)

Characteristics	Value
Average age (years), mean (SD, min-max)	63.5 (15.2, 29-94)
Age (years), n (%)	
Less than 65	99 (52.9)
65-75	45 (24.1)
More than 75	43 (23.0)
Gender: male, n (%)	97 (51.9)
Hospital length of stay (days), median (IQR, min-max)	3.8 (0.75 to 6.4, 0.3-143)
Type of stroke, n (%)	
Ischemic	106 (56.7)
Hemorrhagic	81 (43.3)
Co-morbidities, n (%)	
None	35 (18.7)
Diabetes mellitus	43 (23.0)
Hypertension	118 (63.1)
Dyslipidemia	48 (25.7)
Heart disease	38 (20.3)
Previous stroke	36 (19.3)
Premorbid ambulation status, n (%)	
Independent walking without gait aid	155 (82.9)
Independent walking with gait aid	21 (11.2)
Need assistance to walk or cannot walk	11 (5.9)
Consciousness, n (%)	
Followed command well	129 (69.0)
Drowsiness or coma	58 (31.0)
Muscle power of affected side, n (%)	
Grade 0-2	96 (51.3)
Grade 3-5	91 (48.7)
Swallowing, n (%)	
Normal	90 (48.1)
Abnormal	73 (39.0)
Could not be evaluated	24 (12.8)
Speech, n (%)	
Normal	110 (58.9)
Abnormal	51 (27.3)
Could not be evaluated	26 (13.9)
Able to change body position from supine to sitting, n (%)	73 (39)
Had in-hospital complications, n (%)	54 (28.9)
Received bedside rehabilitation service	51 (27.3)
Functional outcome at admission	
Good (Barthel index 75 or more)	11 (5.9)
Poor (Barthel index less than 75)	176 (94.1)
Functional outcome at the 3-month follow-up	
Good (Barthel index 75 or more)	116 (62.0)
Poor (Barthel index less than 75)	24 (12.8)

the 3-month follow-up: ability to change position from lying to sitting without help [21.63 (95%CI: 2.13-218.76)], independent premorbid ambulation [15.80 (95%CI: 2.91-86.11)], age 65 years or less [4.95 (95%CI: 1.50-16.35)] and normal consciousness [3.88 (95%CI: 1.65-9.16)].

From the multivariate analysis in this study, the ability to change body position from supine to sitting in the acute phase (within 72 hours from an acute stroke) and the premorbid ability of independent walking without any gait aid or assistance seem to be the strongest predictors of functional outcome, exceeding the predictive strength of the other two variables. These results are in line with previous studies.<sup>10,11,18</sup> This study helped confirm that the ability to change body position from

supine to sitting is a very simple and useful observational indicator for predicting good functional outcome.<sup>11</sup> Asking a patient who is lying down to sit up requires only a few minutes. If they can do so independently, it indicates that they have a strong probability of a good functional outcome at the 3-month follow-up, 21.6 times greater than patients who cannot do so. Having less difficulty changing body position in bed, i.e., from supine to sitting, may relate to having mild stroke symptoms, but we also found that some patients with useless muscle power (grade 0-2) on the affected side were still able to mobilize in bed with minimal difficulty, indicating that muscle weakness is not a significant predictive factor.

Premorbid walking ability of stroke patients is a significant

**Table 2.** Demographic and clinical characteristics of the patients (n = 187)

Clinical characteristics	Good functional outcome	Poor functional outcome	p-value <sup>a</sup>
Gender, n (%)			
Male	58 (50.0)	39 (54.9)	0.55
Female	58 (50.0)	32 (45.1)	
Age (years), n (%)			
65 or less	76 (65.5)	24 (33.8)	< 0.001
More than 65	40 (34.5)	47 (66.2)	
Premorbid ambulation status, n (%)			
Independent walking without gait aid	105 (90.5)	50 (70.4)	0.001
Need gait aid or assistance or cannot walk	11 (9.5)	21 (29.6)	
Co-morbidities, n (%)			
0-1	22 (19.0)	12 (17.1)	0.846
2 or more	94 (81.0)	58 (82.9)	
Previous stroke, n (%)			
No	96 (82.8)	55 (77.5)	0.445
Yes	20 (17.2)	16 (22.5)	
Diagnosis, n (%)			
Ischemic stroke	73 (63.5)	31 (44.3)	0.014
Hemorrhagic stroke	42 (36.5)	39 (55.7)	
Consciousness, n (%)			
Follow commands well	102 (87.9)	27 (38.0)	< 0.001
Drowsiness or coma	14 (12.1)	44 (62.0)	
Muscle power of affect side, n (%)			
Grade 0 to 2	40 (34.5)	56 (78.9)	< 0.001
Grade 3 to 5	76 (65.5)	15 (21.1)	
Swallowing, n (%)			
Normal	81 (69.8)	9 (12.7)	< 0.001
Abnormal	31 (26.7)	42 (59.1)	
Could not be evaluated	4 (3.5)	20 (28.2)	
Speech, n (%)			
Normal	89 (76.7)	21 (29.6)	< 0.001
Abnormal	22 (19.0)	29 (40.8)	
Could not be evaluated	5 (4.3)	21 (29.6)	
Ability to change body position from supine to sitting, n (%)			
Able	71 (61.2)	69 (97.2)	< 0.001
Unable	45 (38.8)	2 (2.8)	
In-hospital complications, n (%)			
No	93 (80.2)	40 (56.3)	0.001
Yes	23 (19.8)	31 (43.7)	
Admission functional outcome, n (%)			
Good (Barthel index 75 or more)	11 (9.5)	0 (0.0)	0.007
Poor (Barthel index less than 75)	105 (90.5)	71 (100)	

<sup>a</sup>Fisher's exact test,  $p < 0.05$ 

predictor of good functional outcome with an adjusted odds ratio of 15.8, a value which is in line with previous studies,<sup>12,18</sup> although it differs from Yamakuchi's study which showed only a small relationship. However, the Yamakuchi study was conducted in an older age group (average age of 71.7 years)<sup>12</sup> than the present study.

Age is a strong clinical outcome predictor which is related to good functional outcome as reported in many studies.<sup>12,13,18-23</sup> The younger the patient, the higher the probability of having a better functional recovery. Suksatien's study at Maharat Nakhon Ratchasima Hospital found that stroke patients aged 55 or less had a very good long term functional outcome (adjusted odds ratio 11.46)<sup>13</sup> but the mean age of

this study was 62.5, and the mean age in previous studies in Thailand were 62 to 67 years old.<sup>5,8,13,19</sup> To include more stroke patients, we used the age of 65 years or more to evaluate the relationship. The adjusted odds ratio was 4.95. This could allow physiatrists with limited resources to recruit older stroke patients into intensive rehabilitation programs with the expectation of a good functional outcome.

Other independent factors such as a diagnosis of ischemic stroke, no complications at acute admission, useful muscle power of the affected side, normal verbal communication and swallowing, have also been found to be useful as predictors of good functional outcome<sup>12,22</sup> although in this study we did not find them to be good predictors at the 3-month follow-up.

**Table 3.** Clinical predictors related to a good functional outcome

Clinical predictors	Univariable Logistic Regression		Multivariable Logistic Regression	
	cOR (95%CI)	p-value <sup>a</sup>	AdjOR (95%CI)	p-value <sup>b</sup>
Gender: male	0.82 (0.45-1.48)	0.513	0.64 (0.21-1.98)	0.438
Age 65 years or less	3.72 (2.00-6.94)	< 0.001	4.95 (1.50-16.35)	0.009
Independent premorbid ambulation	4.01 (1.80-8.95)	< 0.001	15.80 (2.91-86.11)	0.001
Comorbidities less than 2	1.14 (0.63-2.06)	0.673	0.65 (0.19-2.12)	0.471
No previous stroke	1.40 (0.67-2.92)	0.374	0.63 (0.14-2.88)	0.556
Ischemic stroke	2.18 (1.19-4.01)	0.011	1.31 (0.41-4.16)	0.646
Normal consciousness	7.18 (3.90-13.23)	< 0.001	3.88 (1.65-9.16)	0.002
Muscle power grade 3 or more	7.09 (3.57-14.09)	< 0.001	2.00 (0.58-6.96)	0.275
Normal verbal communication	5.59 (2.69-11.59)	< 0.001	1.80 (0.54-5.98)	0.338
Normal swallowing	12.19 (5.31-27.98)	< 0.001	2.77 (0.74-1.39)	0.132
Ability to change body position from supine to sitting	54.43 (12.71-233.13)	< 0.001	21.63 (2.13-218.76)	0.009
No complications at acute admission	3.13 (1.63-6.03)	0.001	1.62 (0.53-4.75)	0.381

<sup>a</sup>Univariable Logistic Regression,  $p < 0.05$ ; <sup>b</sup>Multivariable Logistic Regression,  $p < 0.05$

cOR, crude Odds Ratio; adjOR, adjusted Odds Ratio; CI, confidential interval

**Table 4.** Pattern of stroke disability from acute phase to 3-month follow-up based on Barthel index (BI) scores (n = 187)

Category of disability by Barthel index	At acute admission n = 187 (%)	Two-week follow-up n = 154 (%)	One-month follow-up n = 147 (%)	Three-month follow-up n = 140 (%)
Very severe disability (BI = 0-20)	63 (33.7)	34 (22.1)	17 (11.6)	14 (10.0)
Severe disability (BI = 25-45)	22 (11.8)	13 (8.4)	8 (5.4)	4 (2.8)
Moderate disability (BI = 50-70)	58 (31.0)	18 (11.7)	15 (10.2)	6 (4.3)
Mild disability (BI = 75-95)	11 (5.9)	40 (26.0)	54 (36.7)	69 (49.3)
No disability (BI = 100)	0 (0.0)	42 (27.3)	46 (31.3)	47 (33.6)
Death at follow-up	33 (17.6)	7 (4.5)	7 (4.8)	0 (0.0)

BI is frequently used around the world to explore the domain of activities and functional outcomes of stroke in both acute care and rehabilitation, especially in stroke care in Thailand. The cut-off level of BI for assessing positive patient outcome varies from 50 to 95 points. In the present study, the authors used the cut-off level of a BI score of 75 or higher as the definition of a satisfactory outcome as relates to the performance of activities of daily living. This measurement has been studied in acute phase patients and this cut-off point has been used as a standard BI score to demonstrate the effectiveness of stroke care in both acute and rehabilitation in Thailand.<sup>16,24,25</sup> There have been many studies of the ability of BI score to act as a predictor of long-term functional outcome<sup>17,23,24,26</sup> including the present study. It can be concluded that a high BI score in the acute phase relates to a good long term functional outcome. However, if the acute stroke patient has a low BI score, that might not be an accurate predictor of poor long term functional outcome because in the acute phase, especially if the BI score is evaluated during the first few days, most patients are effectively bedbound, either by the effect of the active stroke symptoms or as a result of medical treatment. Thus, these patients rarely have the opportunity to engage in activities of daily living by themselves and early intensive rehabilitation may cause more harm than good. A low BI score recorded in the early acute phase may not reflect true functional ability. Most studies have indicated, however, that BI scores evaluated after the first to third weeks can be used as a predictor of long-term functional outcome.<sup>26</sup>

This study found that most of the patients (63.1% of all cases and 82.9% of stroke-survival cases at the 3-months follow-up) had a good functional outcome (BI scores 75 or more) and were able to live their lives independently or with only mild disability, which correlates with our previous study.<sup>12</sup> The mortality rate of acute stroke patients in hospital in this study was 19% which is slightly higher than the average of previous studies (7.5% to 26%).<sup>9,12,17</sup> This could be due to the fact that the present study was conducted in a tertiary or A-level hospital as classified by the Ministry of Public Health where more severe cases are frequently referred to our hospital from community hospitals. The tertiary hospital's resource limitations have resulted in mild cases being transferred out sooner than would be otherwise desired.

A limitation of this study is that it was conducted in a tertiary hospital with inpatient overcrowding problems that resulted in many acute stroke patients having a very short length of hospital stay (the minimum length of hospital stay was only six hours) before being referred to a community hospital. As a result, some patients were not invited to join the study. The patients that remained in hospital may have had more severe symptoms, resulting in the mortality rate of this study (25.3%) being higher than the usual stroke death rate of this hospital (18.2%). Some elements related to functional outcome, e.g., stroke area of brain, normal cognition and perceptual, learning capacity, acute medical care, family and social support, were not included in the present study. Another limitation is that the type of rehabilitation services



which these stroke patients received after discharge from the acute stroke unit, i.e., whether they received intensive or less intensive inpatient rehabilitation, an outpatient rehabilitation or home-based rehabilitation program, were not reported, factors which can affect the functional outcome evaluation at the 3-month follow-up.

## Conclusions

The ability to change body position from supine to sitting, the ability to walk independently without gait aid before admission, age less than 65 years and normal consciousness are good clinical predictors of 3-month functional outcome after an acute stroke. Physiatrists as well as other clinicians working in an acute care ward can easily observe and assess these factors and use that information in planning an appropriate post-acute rehabilitation program.

## Disclosure

The authors declare no conflicts of interest.

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# Functional Outcomes, Effectiveness and Efficiency of Stroke Rehabilitation Services in Ramathibodi Hospital: A Prospective Descriptive Study

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## ABSTRACT

**Objectives:** To study functional outcomes, effectiveness and efficiency of stroke rehabilitation services.

**Study design:** Prospective descriptive study.

**Setting:** Faculty of Medicine Ramathibodi Hospital, Mahidol University, Bangkok, Thailand.

**Subjects:** Seventy-seven acute stroke patients who were consulted to the Rehabilitation Medicine Department from February to May 2016.

**Methods:** The patients' demographic data, Barthel Index (BI), swallowing, communication and cognitive impairments, and the type of rehabilitation services (home-based, outpatient-based and inpatient-based) were recorded and their association with functional recovery was assessed. Rehabilitation effectiveness was measured based on BI gain between the initial and the 12-week follow-up. An inpatient rehabilitation efficiency index was calculated and reported as BI gain per day while in rehabilitation.

**Results:** Eleven of the patients had an initial BI score of 100. Of the 56 patients having an initial BI  $\leq 75$ , a total of 39, 11, and 6 patients had home-based, outpatient-based and inpatient-based rehabilitation programs, respectively. The levels of mean BI gain (SD) at the 12-week follow-up for those programs were 14.7 (18.6), 25.9 (13.0), 39.2 (10.7), respectively. The mean rehabilitation efficiency index was a gain in BI score of 2.1 points per day. Of the 10 patients with BI between 75 and 99, 9 received home-based rehabilitation and 1 had an inpatient-based rehabilitation program; all had a BI score at the 12-week follow-up of  $\geq 95$ . Among those with dysphagia, recovery of the swallowing function at the 12-week follow-up was found in 30.8% of the patients, but no recovery was found in patients with cognitive impairment.

**Conclusions:** In moderately to severely disabled stroke patients (BI  $\leq 75$ ), inpatient-based rehabilitation is more effective based on BI score gains than either outpatient- or home-based rehabilitation. Patients with mild disability (initial BI  $> 75$ ) had BI scores  $\geq 95$  at the 12-week follow-up regardless of the type of rehabilitation provided. The swallowing impairment recovered in one-third of the patients, although cognitive impairment remained.

**Keywords:** activities of daily living, effectiveness, efficiency, rehabilitation outcome, stroke

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## Introduction

Stroke is a common neurological disorder and a major public health problem. The annual incidence of stroke in Thailand is up to 250,000 cases and the trend is increasing yearly. Additionally, it is the leading cause of death and disability in Thailand.<sup>1</sup> Stroke patients present with variety of impairments other than weakness, such as cognitive, swallowing and communication impairments. These impairments increase morbidity and mortality.<sup>1,2</sup>

Rehabilitation after a stroke is very important to the prevention of complications and permanent disability. Stroke patients who receive early and proper rehabilitation care have an increased level of ability and a better quality of life. According to the Thai Stroke Rehabilitation Registry, stroke patients receiving inpatient-department-based (IPD-based) rehabilitation had significant improvement in physical and mental status as well as quality of life.<sup>3</sup>

The Rehabilitation Medicine Department, Faculty of Medicine Ramathibodi Hospital has operated a stroke rehabilitation outpatient clinic since September 2011 with the goal of improving the quality of care and maximizing function as much as possible so post stroke patients can have more independence, less disability and a better quality of life. These stroke rehabilitation services are delivered as home-based, outpatient-based and inpatient-based.

Our rehabilitation team had previously studied functional outcomes of upper and lower extremities of subacute stroke patients receiving outpatient-based rehabilitation.<sup>4</sup> That study found that patients had improved functional outcomes of upper and lower extremities as assessed using the Ramathibodi modification of the Box and Block Test (R-BBT), the

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Berg balance scale and gait velocity.<sup>4</sup> However, the overall functionality of activities of daily living and of impairments which are consequences of stroke had not been studied.

The main objective of the present study was to demonstrate the functional outcomes, effectiveness and efficiency of stroke rehabilitation at Faculty of Medicine Ramathibodi Hospital, a university hospital with rehabilitation medicine residency training program, with each of three different types of rehabilitation service: home-based, outpatient-based and inpatient-based rehabilitation programs.

## Methods

### Study design

This prospective descriptive study was approved by the Institutional Review Board, Faculty of Medicine, Ramathibodi Hospital (approval number ID 04-59-04).

### Participants

All acute stroke patients who consulted the Rehabilitation Medicine Department from February through May 2016 were recruited into the study if they were willing to participate in the study and to give written informed consent. Patients were excluded if they declined to participate in the study or if they had passed away. In cases where the stroke patient had cognitive impairment affecting decision making, the patient's authorized family members were invited to complete the consenting process.

### Intervention

Demographic and clinical data, e.g., age, underlying diseases, type of stroke and health care coverage were collected. The type of rehabilitation service received, either home-based, outpatient-based or inpatient-based, was determined by physiatrists, the patient's individual context, criteria for admission and availability of beds in the rehabilitation ward. The determination to provide home-based rehabilitation was made by physiatrists, physical and/or occupational therapists when a patient was discharged from the acute stroke inpatient ward. The rehabilitation program was reviewed and/or revised as needed, at the follow-up in the out-patient clinic every 4-6 weeks. Outpatient- and inpatient-based rehabilitation were hospital-based programs which consisted of conventional physical and occupational therapies provided or supervised by therapists. The frequency of outpatient and inpatient hospital-based rehabilitation services were 1-2 times/week and 5 days/week, respectively.

### Outcome measurements

The primary outcome in this study was the ability to perform activities of daily living using the 100-point Thai-version of the Barthel index (BI).<sup>5</sup> In this study, disability was categorized by BI scores into moderately to severely disabled (BI score  $\leq 75$ ), mildly disabled (BI score more than 75 but less than 100, and no disability (BI = 100).<sup>5</sup> Rehabilitation efficacy

was evaluated using BI gain between the initial assessment and the 12-week follow-up assessment.

The secondary outcomes were impairments in three common areas: swallowing, communication and cognitive functions.<sup>6</sup> Swallowing and communication functions were assessed using the dysphagia screening test and the aphasia screening test which are in the clinical practice guidelines for stroke rehabilitation published by Prasat Neurological Institute, Ministry of Public Health;<sup>5</sup> cognitive function was assessed using the Thai version of the Mini Mental State Evaluation (MMSE-Thai 2002).<sup>7</sup> The results of these tests were used to determine if a patient had dysphagia (swallowing impairment) or aphasia (communication impairment). Cognitive impairment was identified based on the MMSE-Thai 2002 cut-off points for educational levels, with scores of  $\leq 14$ , 17 and 22 indicating illiteracy, primary school and higher education, respectively.<sup>7</sup> If the above-mentioned impairments were detected at the initial but not at the final assessment, it was counted as a recovery.

Both primary and secondary outcomes were assessed by a researcher (SR) who was a rehabilitation resident in training. All patients receiving outpatient-based or home-based rehabilitation programs were assessed twice, initially within 2 weeks of the original diagnosis of stroke after medical and neurological conditions had remained stable for at least 48 hours, and then again 12 weeks later. Those receiving an inpatient-based rehabilitation program had two additional points of assessment, at admission to rehabilitation and at discharge, a total of 4 assessments.

### Statistical analysis

SPSS version 21 was used for data analysis. The demographic data were analyzed using descriptive statistics, i.e., frequency, mean and standard deviation (SD). The normality of data was analyzed using the Shapiro-Wilk test.

Rehabilitation effectiveness, i.e., gain in BI score after rehabilitation,<sup>8</sup> was evaluated by comparing the initial and final (at the 12-week follow-up) BI scores within groups using the paired t-test. In addition, rehabilitation efficiency was also demonstrated by dividing the BI gain by the rehabilitation length of stay (LOS), i.e., a rehabilitation efficiency index.<sup>9</sup>

To demonstrate differences in efficacy among different types of rehabilitation services, the mean BI change/gain was analyzed using the analysis of variance (ANOVA) test with post-hoc analysis. The percentage of moderately to severely disabled patients with recovered swallowing, improved communication and reduced cognitive impairment was compared and analyzed using Fisher's exact test. Statistical significance was set at a  $p < 0.05$ .

## Results

From February through May 2016, 79 stroke patients were consulted to the Rehabilitation Medicine Department. Of those patients, two died from other underlying diseases

and post-operative complications and were excluded from the study. Nine patients lost to follow-up at 12 weeks were assessed by telephone. All patients received an initial rehabilitation assessment by a physiatrist with a mean time (SD) of 8.4 (2.7) hours after the initial consultation request or 2.6 (3.3) days after diagnosis. The mean LOS (SD) at the acute stroke ward was 7.7 (11.1) days.

Demographic characteristics of the 77 patients are shown in Table 1. Most of the patients had a brain infarction; the three most common comorbid conditions were hypertension, dyslipidemia and diabetes mellitus. Based on initial BI scores, 11 patients (14.3%) were not disabled; 10 patients (13.0%) were mildly disabled and 56 patients (72.7%) were moderately to severely disabled. Of the 77 patients, 76.6% received home-based, 14.3% outpatient-based and 9.1% inpatient-based programs. All patients with BI = 100 received a home-based program.

Among the 56 patients classified as moderately to severely disabled (BI ≤ 75), 39 patients (69.6 %) received home-based, 11 (19.6 %) outpatient-based and 6 (10.7 %) inpatient-based rehabilitation programs (Table 2). Most of the patient characteristics were comparable among the three different programs. Two differences are that almost all patients receiving an inpatient-based program were female, had an ischemic stroke, and right hemiparesis and that patients receiving the home-based program had a higher percentage with communication and cognitive impairments.

At the 12-week follow-up, the moderately to severely disabled patients in each of the 3 types of rehabilitation programs had a statistically significant increase in BI score (Table 3), with the greatest increase in the inpatient-based group and lowest increase in the home-based group. Only the inpatient-based group showed a statistically significant difference in the mean ΔBI compared to home-based rehabilitation, whereas the mean ΔBI of the outpatient-based program was not statistically significant different from the other programs.

**Table 1.** Demographic and clinical data (n = 77)

Characteristics	
Age (years) <sup>1</sup>	66.3 (13.6)
Sex (male : female) <sup>2</sup>	32 (41.6) : 45 (58.4)
Etiology of stroke (ischemic : hemorrhagic) <sup>2</sup>	70 (90.9) : 7 (9.1)
Hemiparesis <sup>2</sup>	
Right : Left	36 (46.8) : 37 (48.0)
Bilateral	4 (5.2)
Underlying disease <sup>2</sup>	
Hypertension	50 (64.9)
Dyslipidemia	31 (40.3)
Diabetes mellitus	29 (37.7)
Cardiovascular	25 (32.5)
Recurrent stroke	15 (19.5)
Pulmonary	10 (13.0)
Renal	10 (13.0)
Gastrointestinal	10 (13.0)
Hematological	8 (10.4)
Other neurological	5 (6.5)
Psychiatric	2 (2.6)
Initial Barthel index score <sup>1</sup>	
Inpatient-based (n = 7)	52.9 (25.3)
Outpatient-based (n = 11)	47.3 (13.3)
Home-based (n = 59)	60.3 (31.3)
Health care coverage <sup>2</sup>	
Civil servant medical welfare	40 (51.9)
National health security scheme (NHSS)	15 (19.5)
Self-pay	12 (15.6)
State enterprise officer	5 (6.5)
Social security scheme (SSS)	3 (3.9)
Disability scheme under NHSS or SSS	2 (2.6)

<sup>1</sup>Mean (standard deviation, SD), <sup>2</sup>number (%)

The 6 moderately to severely disabled patients with (BI ≤ 75) received inpatient-based rehabilitation. The mean waiting time (SD) from the initial assessment to admission to rehabilitation was 31.3 (26.9) days. During the waiting period, the patients received a home-based program. The mean rehabili-

**Table 2.** Demographic data of moderately to severely disabled stroke patients categorized by type of rehabilitation program received (n = 56)

Characteristics	Home-based (n = 39)	Outpatient-based (n = 11)	Inpatient-based (n = 6)
Age (years) <sup>1</sup>	69.2 (14.5)	64.0 (11.4)	61.3 (10.3)
Sex (male : female) <sup>2</sup>	17 (43.6) : 22 (56.4)	4 (36.4) : 7 (63.6)	1 (16.7) : 5 (83.3)
Etiology of stroke <sup>2</sup> (ischemic : hemorrhagic)	35 (89.7) : 4 (10.3)	9 (81.8) : 2 (18.2)	6 (100.0) : 0 (0.0)
Hemiparesis <sup>2</sup>			
Right : left	16 (41.0) : 22 (56.4)	5 (45.5) : 5 (45.5)	4 (66.7) : 1 (16.7)
Bilateral	1 (2.6)	1 (9.1)	1 (16.7)
Stroke onset (hours) <sup>1</sup>	18.3 (29.7)	26.4 (35.2)	20.5 (26.2)
Initial Barthel index score <sup>1</sup>	42.4 (22.4)	47.3 (13.3)	47.5 (23.0)
Swallowing impairment, yes <sup>2</sup>	19 (48.7)	4 (36.4)	3 (50.0)
Communication impairment, yes <sup>2</sup>	22 (56.4)	3 (27.3)	2 (33.3)
Cognitive impairment, yes <sup>2</sup>	27 (69.2)	3 (27.3)	2 (33.3)

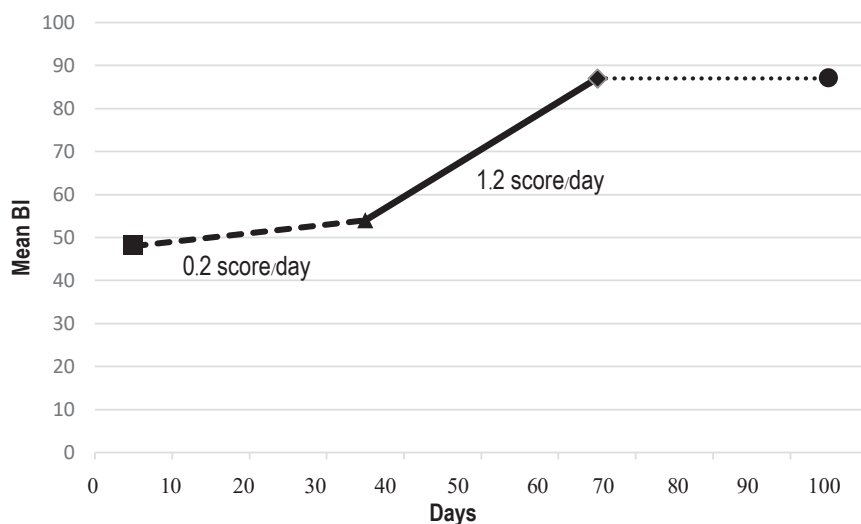
<sup>1</sup>Mean (standard deviation, SD), <sup>2</sup>number (%)

Initial BI, Barthel index before starting rehabilitation programs; stroke onset, time before admission to hospital



**Table 3.** Gain in Barthel index (BI) score according to disability and types of rehabilitation programs

Disability	Rehab	N	Barthel index (BI) <sup>1</sup>		$\Delta$ BI <sup>1</sup>	p-value
			Initial	12-week FU		
BI $\leq$ 75	Home	39	42.4 (22.4)	57.2 (34.4) <sup>a</sup>	14.7 (18.6)	< 0.01 <sup>b</sup> 0.02 <sup>c</sup> 0.08 <sup>d</sup> < 0.01 <sup>e</sup>
	Outpatient	11	47.3 (13.3)	73.2 (20.8) <sup>a</sup>	25.9 (13.0)	
	Inpatient	6	47.5 (23.0)	86.7 (25.6) <sup>a</sup>	39.2 (10.7)	
75 < BI < 100	Home	9	89.4 (5.8)	99.4 (1.7) <sup>a</sup>	10.0 (5.0)	
	Inpatient	1	85.0 (0.0)	95.0 (0.0)	10.0 (0.0)	
BI = 100	Home	11	100.0 (0.0)	100.0 (0.0)	0.0 (0.0)	
Total		77	57.8 (29.0)	73.3 (32.1) <sup>a</sup>	15.5 (17.5)	

<sup>1</sup>Mean (standard deviation, SD)Rehab, types of rehabilitation programs; n, number of patients; FU, follow-up;  $\Delta$ BI, BI change/gain<sup>a</sup>Comparison of initial and 12-week FU BI within group using paired t-test, and  $p < 0.01$ <sup>b</sup>Comparison of mean BI change among 3 rehabilitation programs in BI  $\leq$  75 group using analysis of variance test<sup>c</sup>Comparison of mean BI change between home- and outpatient-based programs using post-hoc analysis<sup>d</sup>Comparison of mean BI change between outpatient- and inpatient-based programs, using post-hoc analysis<sup>e</sup>Comparison of mean BI change between inpatient- and home-based programs using post-hoc analysisThe statistical significance level was set at a  $p < 0.05$ **Figure 1.** The rate of improvement measured as the daily change in the mean Barthel index (BI) in moderately to severely disabled patients (BI  $\leq$  75) who received inpatient-based rehabilitation (N = 6).

The square symbol (■) represents the initial assessment, the triangle symbol (▲) rehabilitation admission, the diamond symbol (◆) discharge from rehabilitation, and the circle symbol (●) the 12-week follow-up.

The dashed line shows the improvement rate (mean BI change/day = 0.2 score/day) during the waiting period (home-based); the solid line shows the rate during inpatient-based rehabilitation (1.2 score/day); and the dotted line, maintenance of mean BI after discharge.

tation length of stay (SD) was 28.9 (7.9) days. In this subgroup, the mean BI scores (SD) recorded at the initial assessment, at rehabilitation admission, at discharge and at the 12-week follow-up were 47.5 (23.0), 54.2 (22.7), 87.0 (26.0) and 86.7 (23.4), respectively.

To compare the improvement rate during the period of waiting before admission (home-based) and during admission (inpatient-based), the mean BI change per day (mean  $\Delta$ BI/day), i.e., the rehabilitation efficiency index for each period, was calculated. The mean  $\Delta$ BI/day (SD) was 0.2 (0.3) during the waiting period and 1.2 (0.3) during the admission period, an approximately five-fold increase. Moreover, after dis-

charge from inpatient rehabilitation, all 6 patients maintained their mean BI at the 12-week follow-up (Fig. 1).

Of the 10 patients in the mildly disabled group (75 < BI < 100), 9 received a home-based program and were found to have a statistically significant increase in mean BI score (SD) from 89.4 (5.8) to 99.4 (1.7). Only 1 patient in this group was admitted for inpatient-based rehabilitation; their BI score increased from 85 to 95. All patients in the mildly disabled group had a BI score of 95 or more at the 12-week follow-up.

Of the 11 patients with no disability (BI = 100), all of whom received a home-based program, none had swallowing or communication problems or cognitive impairment. They were



advised on prevention of a recurrent stroke, and all maintained their BI score at 12-week follow-up.

Regarding common impairments among the 77 patients, there were 26 patients (33.8%) with swallowing impairment, 27 patients (35.1%) with communication impairment and 34 patients (44.2%) with cognitive impairment. All were in the moderately to severely disabled group except 2 patients with cognitive impairment who were in the mildly disabled group.

In the moderately to severely disabled group, the percentage of recovery at the 12-week follow-up was highest in patients with swallowing impairment (30.8%), and 71.4% of patients who received hospital-based rehabilitation had recovery in swallowing (Table 4). These percentages were statistically significantly higher than for patients receiving a home-based program (15.8%).

Recovery in communication was found in one patient who received hospital-based rehabilitation and in two patients who received home-based rehabilitation. None of the patients in the moderately to severely disabled or in the mildly disabled groups with cognitive impairment showed recovery regardless of type of rehabilitation (Table 4).

## Discussion

The main objective of our study is to demonstrate the functional outcomes, effectiveness and efficiency of stroke rehabilitation programs provided at Ramathibodi Hospital, a university hospital with a rehabilitation medicine residency training program.

In our study, the mean duration (SD) from stroke diagnosis to initial assessment by a physiatrist was 2.6 (3.3) days, shorter than the 4.5 (3.3) days reported by another university hospital.<sup>10</sup> This might be due to our hospital's policy of early rehabilitation consultation by a neurologist and shorter length of stay (LOS) in the acute stroke ward, an average of 8 days.

Additionally, our hospital has been given a disease-specific certificate in stroke care, and one of the key performance indices (KPI) of the stroke ward is that all stroke patients should receive a rehabilitation program.

In this study, the mean initial BI (SD) before rehabilitation was 57.8 (29.0), higher than the 40.5, 39.5 and 37.4 reported in another university hospital,<sup>10</sup> a community hospital<sup>11</sup> and multicenter study<sup>12</sup> respectively, which includes many levels of hospitals. Higher BI scores reflecting less disability is possibly due to the effectiveness of the stroke fast track system and the availability of an acute stroke ward in our hospital, factors which have been shown to affect stroke outcomes.<sup>1</sup>

After rehabilitation for 12 weeks, the mean  $\Delta$ BI of all 77 stroke patients was 15.5 on the 100 BI scale. The minimum clinically important difference of BI is 9.3 on the 100 BI scale.<sup>13</sup> The mean  $\Delta$ BI in this study was clinically significant for all of different disability levels and types of rehabilitation.

Considering inpatient-based rehabilitation in this study, only 6 patients were admitted for rehabilitation and their LOS (SD) was 28.9 (7.9) days which is comparable to the 29.4 (17.9) days reported in the Kuptniratsaikul study<sup>14</sup>, but longer than the standard LOS for neuromuscular inpatient rehabilitation indicated by National Health Security Office (NHSO) (2011) of 23.5 days, and shorter than the maximum acceptable LOS of 46 days.<sup>15</sup> This suggests revision of the standard LOS for stroke rehabilitation in Thailand may be needed, though more studies focusing on LOS are required to provide more information for the NHSO to revise the LOS standard.

For the moderately to severely disabled group (BI  $\leq$  75), most of the demographic data were comparable among three types of rehabilitation, but comparison among the three types of rehabilitation was not possible due to small number of patients in each group. It should be noted that the home-based rehabilitation group had a higher percentage of patients with communication and cognitive impairments than the other

**Table 4.** Recovery of impairments in moderately to severely disabled stroke patients (Barthel Index score  $\leq$  75) by type of rehabilitation at the initial and 12-week follow-up

Impairment	Initial <sup>1</sup>	12-weeks follow-up <sup>1</sup>	Recovery <sup>2</sup>	p-value <sup>a</sup>
Swallowing (n = 26) <sup>1</sup>				
• Home-based	19	16	3 (15.8)	0.01
• Hospital-based	7	2	5 (71.4)	
• Total	26	18	8 (30.8)	
Communication (n = 27) <sup>1</sup>				
• Home-based	22	20	2 (9.1)	0.47
• Hospital-based	5	4	1 (20)	
• Total	27	24	3 (11.1)	
Cognitive (n = 32) <sup>1</sup>				
• Home-based	27	27	0 (0)	NA
• Hospital-based	5	5	0 (0)	
• Total	32	32	0 (0)	

<sup>1</sup>Number, <sup>2</sup>number (%)

<sup>a</sup>Comparison of percentage of recovery between home- and hospital-based rehabilitation using Fisher's exact test with statistical significance level < 0.05

NA, not assessed

groups. Comparison of mean  $\Delta$ BI with different types of rehabilitation services showed that patients receiving inpatient-based rehabilitation had the best outcomes. This finding is in line with results from Bangklam Hospital, a community hospital in Songkhla Province which provides intermediate care service for stroke rehabilitation. That institution reported that moderately to severely disabled stroke patients who received an inpatient-based program had a significantly greater increased in mean BI compared to non-inpatient programs.<sup>11</sup>

During admission for inpatient-based rehabilitation in our hospital, moderately to severely disabled stroke patients had a mean  $\Delta$ BI of 1.2 per day on the 100-point BI scale which is equivalent to 0.2 on the 20-point BI scale. This result is comparable to that reported by Kuptniratsaikul et al.<sup>14,16</sup> and by Pattanasuwanna<sup>17</sup> of 0.2 on the 20-point BI scale. However, it is less than that reported by Suksathien et al.<sup>18</sup> and by Bangklam Hospital<sup>11</sup> which were 0.6 and 0.4 on the 20-point BI scale, respectively. This difference might have been due to differences in waiting time for admission. The present study and studies by Kuptniratsaikul<sup>14,16</sup> and Pattanasuwanna<sup>17</sup> have reported a mean or median waiting time for rehabilitation admission of 31.3, 24 and 19 days, respectively, whereas stroke patients in Bangklam Hospital<sup>11</sup> received earlier inpatient-based rehabilitation, i.e., immediately after discharge from the acute stroke ward. The early inpatient-based rehabilitation in Bangklam Hospital might be a factor in the greater BI change as shown by previous studies reporting that early inpatient-based rehabilitation within a month post stroke results in better outcomes and quality of life as well as shorter LOS.<sup>19-21</sup>

Interestingly, both Bangklam Hospital<sup>11</sup> and Luangphopern Hospital<sup>17</sup> are among the first hospitals to develop an intermediate care rehabilitation service following the plan of the Ministry of Public Health. However, the mean  $\Delta$ BI per day of those two hospitals differ despite the similar context which is probably due to differences in waiting time for admission. This suggests that moderately to severely disabled stroke patients should receive inpatient-based rehabilitation as early as possible and that stroke rehabilitation services should offer inpatient-based rehabilitation to these patients as soon as they are discharged from the acute setting to increase the effectiveness of stroke rehabilitation.

The National Health Security Office in conjunction with the Thai Rehabilitation Medicine Association has proposed a subacute rehabilitation program and has recommended that all stroke patients with BI < 75 or with BI > 75 and more than one impairment should receive inpatient-based rehabilitation when they are ready for an intensive rehabilitation program.<sup>11</sup> Based on that recommendation, 55 of the patients in our study (71.4%) met the criteria and were rehabilitated as inpatients. However, of those 55 patients only 7, including 1 with mild disability (12.7%), actually entered inpatient-based rehabilitation. There are a number of factors related to that situation, including that there were only 10 beds in the rehabilita-

tion ward as well as strict inpatient admission criteria during the time of this study, e.g., all rehabilitation inpatients were required to provide a 24-hour caregiver, patients' request to refer back to their hospitals according to their health care coverages, which acted as barriers to inpatient rehabilitation.

The results of this study together with previous reports<sup>11,14,16-17,19-20</sup> suggest that moderately to severely disabled patients should be provided inpatient-based rehabilitation as early as possible. This also suggests that less rigid and more flexible inpatient admission criteria which depend on each patient's context should be adopted. For patients who have health coverage at another hospital, establishing an inter-hospital rehabilitation network could help ensure early rehabilitation and continuity of patient care.

Factors such as age, gender, initial BI and cognitive impairment have been shown to influence stroke outcomes.<sup>22,23</sup> The reported effects of most factors were comparable to those included in our study with the exception of gender and cognitive impairment. Male gender and cognitive impairment have been shown to be associated with good and poor functional outcomes, respectively. In our study, more female than male patients were in an inpatient-based program, so gender was not a confounding factor for this type of rehabilitation. More patients with cognitive impairment received home-based rehabilitation which might have resulted in the poorer outcomes irrespective of the type of rehabilitation.

The three common impairments, other than weakness, were also evaluated. In this study, 33.8%, 35.1% and 44.2% of stroke patients had swallowing, communication and cognitive impairments, respectively. Previous studies have reported that 10-45% of stroke patients had swallowing problems, 23-36% had communication difficulties and 12-80% had cognitive impairments.<sup>6,18,24</sup> The prevalence of those impairments in this study was comparable to previous studies, suggesting that the screening techniques for impairment used in this study were also comparable to those used in other studies, in spite of the fact that different techniques were used.

At the 12-week follow-up of the moderately to severely disabled stroke patients, our study found that the recovery percentage of swallowing and communication functions was greater in patients receiving hospital-based programs (including inpatients and outpatients) than in those receiving home-based rehabilitation. The higher rates of recovery of the swallowing function in this study might have been due to the establishment of a swallowing clinic in our department and of a proper swallowing training program provided by well-trained occupational therapists. One recent study reported on the success of a home-based program using tongue palatal resistance exercise to improved swallowing function.<sup>25</sup> Provision of such a home-based swallowing training program for those not having access to hospital-based rehabilitation could be another option.

Our study did find a small increase in recovery of communication function in the hospital-based group, but the difference

between the hospital-based and the home-based groups was not statistically significant. To confirm this finding, more patients should be recruited for analysis. It should also be noted that our hospital is the only institute in Thailand which provides an educational program of speech therapy. The country continues to suffer from a lack of speech therapists, and most rehabilitation teams in hospitals have no access to speech therapists who can provide appropriate training for stroke patients with communication impairment.

Moreover, our results show that the cognitive impairment persists at the 12-week follow-up. That lack of improvement might be due to the nature of cognitive impairment following stroke.<sup>26</sup> Our stroke rehabilitation programs focus primarily on movement functions related to activities of daily living and ambulation, but lack a proper cognitive training program, either in a hospital- or home-based setting. Developing a cognitive training program in our department is challenging as it requires experienced personnel such as a neuropsychologist or a well-trained or skillful therapist to provide the training.<sup>27</sup>

Although this was a prospective study, there are some limitations. Statistical analyses of small samples generally cannot provide strong evidence to support the effectiveness of an inpatient-based rehabilitation program. We therefore plan to continue gathering information on additional patients to increase the power of the tests and to provide stronger evidence. The next limitation was the short duration of the follow-up period. The intermediate care plan for rehabilitation proposed by the Ministry of Public Health recommends a 6-month follow-up re-assessment of functional outcomes.<sup>11</sup> This 6-month follow-up seems necessary, especially for those with moderate to severe disability or for patients having additional impairments such as dysphagia, aphasia and impaired cognitive function as these impairments require a longer period for recovery.<sup>24,28-29</sup> In addition, our study did not evaluate psychosocial problems and quality of life of the stroke patients and their caregivers. Caregivers, in particular, are frequently affected when a moderate to severe disability persists. Value-based healthcare and health economics may provide national policy makers with supportive data for considering stroke rehabilitation services in Thailand.

## Conclusions

The findings of this study demonstrate the effectiveness and efficiency of stroke rehabilitation programs, especially with moderately to severely disabled stroke patients (BI  $\leq$  75) treated in a university hospital with a rehabilitation medicine residency training program. The average increase in the rehabilitation efficacy index during inpatient rehabilitation is about 1.2 BI points/day based on BI gain per length of stay. Inpatient-based rehabilitation also results in greater improvement in activities of daily living than either outpatient- or home-based programs. However, all stroke patients with mild disability achieved functional recovery to near normal levels

by the 12-week follow-up regardless of the type of rehabilitation provided. Among swallowing, communication and cognitive impairments, moderately to severely disabled stroke patients with swallowing problems who received hospital-based rehabilitation achieved the greatest levels of recovery at the 12-week follow-up.

## Disclosure

The authors have nothing to declare.

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## Rate and Outcomes of Re-Admission for Rehabilitation in the Thai Red Cross Rehabilitation Center: A Retrospective Study

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### ABSTRACT

**Objectives:** To study the rate of re-admission and functional outcomes in re-admitted patients of the Thai Red Cross Rehabilitation Center during the period 2015-2019.

**Study design:** Retrospective study.

**Setting:** The Thai Red Cross Rehabilitation Center, Samut Prakan Province, Thailand..

**Subjects:** All admitted patients who were re-admitted during the period 2015-2019. Pediatric patients and Thai Red Cross Patrons admitted primarily to provide relief of the burden on caregivers were excluded from the functional outcome analysis.

**Methods:** Rates of re-admission were calculated from all admitted and re-admitted patients during the study period. After excluding pediatric patients and Thai Red Cross patrons, medical records of the remaining patients were extracted and their demographic characteristics, clinical data and functional outcomes from the first and the last admissions were reviewed and analyzed.

**Results:** During the study period, 1,438 patients were admitted of whom 460 patients (32.0%) were later re-admitted. After excluding 271 patients who did not meet the study criteria, 48.2% of the remaining 189 patients had been re-admitted only once. The most common diagnosis at initial admission was stroke (48.2%). Both duration from onset to the last re-admission and diagnostic categories were significantly associated with the number of re-admissions ( $p < 0.001$ ). At the last re-admission, some patients showed improvement in ambulation (29.1%), in disability level based on the modified Barthel Index (23.8%), in dynamic sitting balance (16.9%) and in static sitting balance (15.3%).

**Conclusion:** The re-admission rate at the Thai Red Cross Rehabilitation Center during the 2015-2019 period was 32.0%. Stroke patients had the highest rate of re-admission. At the last rehabilitation re-admission, some patients had gained functional improvement and nearly 30% had improvement in ambulation.

**Keywords:** rehabilitation, inpatient, re-admission, functional outcomes, ambulation

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### Introduction

Muscle weakness, altered sensations, reduced balance and coordination, impaired speech and communication, dysphagia, and bowel and bladder incontinence are common consequences of neurological diseases/disorders and injuries. After the acute phase, patients who have significant impairment and disability need medical rehabilitation. After completing a post-acute rehabilitation program, they are reminded to perform self-care activities and hand skills training by themselves, and to continue home exercise programs to preserve range of motion and muscle strength.<sup>1</sup> The available evidence showed some patients are unable to maintain their functional level after discharge and need rehabilitation re-admission.<sup>2</sup> In a meta-analysis of patients after acute stroke, the pooled 1-year hospital re-admission rate was 42.5%, and the three major causes of re-admission were recurrent stroke (19.4%), infection (19.3%) and coronary artery disease (16.3%).<sup>3</sup> One study found that a lower functional status on rehabilitation admission was a predictor of an unplanned re-admission to acute care after discharge from inpatient traumatic brain injury (TBI) rehabilitation.<sup>4</sup> Another study of spinal cord injury (SCI) reported a re-admission rate of 18.4% within 5 years after discharge from a private rehabilitation facility; secondary health conditions were the main causes of re-admission.<sup>5</sup>

The Thai Red Cross Rehabilitation Center is governed by the Thai Red Cross Society. Its mission is to alleviate human suffering and to improve the quality of life for all, especially the most vulnerable.<sup>6</sup> The Center, located in Samut Prakan province, includes a 60-bed in-patient hospital and provides multidisciplinary rehabilitation services. The criteria for entering post-acute inpatient rehabilitation programs at the Center are as follows: stable vital signs for at least 48 hours; having functional problems in least two of the following five areas: ambulation, activities of daily living, communication, bowel and bladder control, and swallowing, being able to understand and follow verbal or nonverbal commands, and showing

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a willingness and ability to cooperate with rehabilitation.<sup>7</sup> Those who could successfully participate in 3 hours per day of physical and/or occupational therapy would receive an intensive rehabilitation program.<sup>8</sup> When the goals are achieved or when there is no further functional improvement with a stable Barthel Index score for two consecutive weeks, the patient is discharged and an outpatient rehabilitation program and/or follow-up appointments are scheduled.<sup>9</sup> If the patients' functions decline, a physiatrist will re-assess the need for re-admission for a rehabilitation or reconditioning program. Informal observations suggest rehabilitation re-admission seems to be common at the Center, but there has been no study on re-admission rates or on indications for and benefits from re-admission. The objectives of this study were to report the rates of re-admission and the functional outcomes of patients re-admitted to the Center for use in designing future rehabilitation management improvements.

## Methods

This retrospective study of re-admitted patients at the Thai Red Cross Rehabilitation Center was conducted after receiving approval from the Committee on Ethics in Human Research, Faculty of Medicine, Chulalongkorn University (No. 638/63).

The re-admission rate of patients admitted at the Center between 2015-2019 was calculated based on the ratio of the number of re-admitted patients to the total number of in-patients admitted during that period.

For analysis of functional outcomes, pediatric patients under 18 years old, those more than 80 years old and Thai Red Cross patrons who were re-admitted to relieve the burden on caregivers, were excluded. The included re-admitted patients' demographics, diagnosis, frequency and causes of re-admission, training programs/therapies and functional outcomes were extracted from their medical records.

Diagnostic categories were defined as follows: (1) stroke, (2) TBI, (3) traumatic SCI (TSCI), (4) degenerative diseases of the central nervous system (CNS) e.g., Alzheimer disease, dementia, multiple sclerosis, and transverse myelitis, (5) orthopedic disorders e.g., spondylosis, spinal stenosis, osteoporosis, amputation.

Four functional outcomes, static sitting balance, dynamic sitting balance, activities of daily living (ADL), and ambulation at initial admission, at discharge after the first rehabilitation admission and at the last re-admission were analyzed.

Static sitting balance is defined by a scale of 0 = poor, unable to maintain balance, requires maximal support; 1 = fair, able to sit unsupported without balance loss; and 2 = good, able to maintain balance against resistance. Dynamic sitting balance is defined by a scale of 0 = poor, able to sit unsupported and can reach ipsilateral/front, but unable to reach across midline; 1 = fair, able to sit unsupported, minimal weight shift and can reach ipsilaterally to the front, difficulty reaching across the midline; 2 = good, able to sit unsupported,

can shift weight and can reach across midline.<sup>10</sup>

ADL was assessed using the modified Barthel Index (MBI). The total score represents the level of disability: very severely disabled (0-4), severely disabled (5-9), moderately disabled (10-14), mildly disabled (15-19), and independent or not disabled (20).<sup>11</sup>

Ambulation was determined using the Functional Ambulation Categories (FAC) which is a 6-point functional walking assessment of how much support a patient requires when walking: 0 = non-functional ambulatory, 1 = an ambulator who requires continuous manual contact to support body weight and is reliant on physical assistance, 2 = an ambulator who requires intermittent or continuous light contact for assistance, 3 = an ambulator who requires supervision, 4 = an ambulator who is independent only on a level surface, and 5 = an independent ambulator.<sup>12</sup>

## Statistical analysis

Descriptive statistics, including number, percentage, mean and standard deviation (SD), were used to summarize data. Associations between diagnosis categories and number of re-admissions and between duration from onset to the last re-admission and number of re-admissions were analyzed using the Chi square test. The paired t-test was used to compare MBI scores at admission and at discharge following the first and the last admissions. The Wilcoxon signed rank test was used for comparison between the sitting balance gradings and the FAC levels at initial admission and discharge after the first and the last admissions. The number of patients in each category according to grading of functional outcomes at admission and discharge of the last admission were compared using McNemar's Chi-square test. The level of statistical significance was set at  $p < 0.05$ . IBM SPSS for Windows version 22 was used for data analysis.

## Results

There were 1,438 patients admitted at the Center in this five-year study period, of whom 460 were re-admitted, a re-admission rate of 32.0%. The yearly re-admission rates ranged from 23.3% to 41.4%, as shown in Table 1. After excluding 271 pediatric patients under 18 years old, patients older than 80 years and TRC patron re-admissions, a total of 189 re-admitted patients were recruited for the functional outcome analysis. The patient demographic data are presented in Table 2. The majority were male, unemployed, lived in an urban area, were under Thailand's Universal Coverage Scheme for healthcare, lived with family, and had a family member as a main caregiver. The mean age of the patients was 55.2 years (SD 16.9). The diagnoses of the re-admitted patients were as follows: strokes (48.2%), TSCI (24.3%), TBI (10.6%), orthopedic disorders (9.0%), and degenerative CNS diseases (7.9%).

The number of patient re-admissions ranged between 1 and 12; the majority (48.2%) were re-admitted only once,

**Table 1.** Number and percentage of in-patients and re-admission rates 2015-2019

Year	2015	2016	2017	2018	2019	Total
In-patients, n	290	236	290	292	330	1,438
Re-admitted patients, n (%)	120 (41.4)	72 (30.5)	98 (33.8)	68 (23.3)	102 (30.9)	460 (32.0)

**Table 2.** Demographic characteristics of re-admitted participants (n = 189)

Demographic data	Number (%)
Sex: male	129 (68.3)
Marital status: single/divorced/separated	95 (50.3)
Living place: urban area	144 (76.2)
Educational level: secondary or below	77 (40.7)
Employment: unemployed	131 (69.3)
Health insurance: Universal Coverage Scheme	90 (47.6)
Living with: immediate family	159 (84.1)
Main caregiver: family member	148 (78.3)
Discharge destination: own home	178 (94.2)

23.3% were re-admitted twice, 9% three times, 8.5% four times, 5.3% five times, and 5.8% more than five times (Table 3). Of the 11 patients who were re-admitted more than 5 times, 4 had been diagnosed with SCI. A total of 148 patients (78.3%) had a duration from onset to the last admission of more than one year. The mean rehabilitation length of stay (LOS) of the last re-admission was 39.92 days (SD 20.12). Both the duration from onset of disease/injury to the last re-admission and the diagnostic categories were significantly associated with the number of re-admissions ( $p < 0.001$ ).

The most common rehabilitation programs during re-admissions were exercises to improve muscle strength (35.8%), followed by ambulation re-training (13.9%), bladder and bowel re-training (9.3%), walking with a proper gait aid (8.9%), bed mobility training (7.5%), and ADL re-training (5.2%). In addition, some patients were re-admitted for pain control (6.5%), treatment of spasticity (6.4%), speech therapy (3.6%), swallowing training (1.6%) and sensory re-

education (1.3%).

At the last re-admission, although the majority of patients showed no functional improvement, some did demonstrate improvement of at least one grade in static sitting balance (15.3%) and dynamic sitting balance (16.9%), and at least one level in disability (23.8%) and FAC (29.1%) (Tables 4-6). Figure 1 presents the mean scores of the four functional outcomes, i.e., static and dynamic sitting balance, modified BI scores, and FAC. The means of each functional outcome are significantly different ( $p < 0.001$ ) both between admission and discharge of the first admission and between admission and discharge of the last admission.

## Discussion

The rate of rehabilitation re-admission at the Thai Red Cross Rehabilitation Center during the 5-year period was 32.0%. According to the Center policy, patients with complications have to be admitted elsewhere; however, Thai Red Cross patrons who require a personal care are accepted for a temporary admission to relieve the burden on caregivers, in accordance with a report of a post-stroke rehabilitation multicenter study in Thailand.<sup>13</sup> The high re-admission numbers for continuing personal care and relieving a burden of caregivers, not for rehabilitation, should be a concern. For example, reserving a maximum of 10% of the total beds and allowing 2-3 weeks re-admission for relief of a burden on caregivers to help ensure that there are sufficient beds available for others in need of in-patient rehabilitation in accordance with the Center's aim of alleviating human suffering.

After excluding patients following the exclusion criteria, the rate of re-admission dropped to 16.2%, the majority of

**Table 3.** Association between characteristics of re-admitted patients (N = 189) and number of re-admissions

Characteristics	Number of re-admissions						p-value
	1	2	3	4	5	> 5	
Number (%)	91 (48.2)	44 (23.3)	17 (9.0)	16 (8.5)	10 (5.3)	11 (5.8)	
Time from onset to the last re-admission							
≥ 1 year	54 (28.8)	40 (21.2)	17 (9.0)	16 (8.5)	10 (5.3)	11 (5.8)	< 0.001
< 1 year	37 (19.6)	4 (2.1)					
Diagnosis category							
Stroke	58 (30.7)	12 (6.3)	5 (2.6)	9 (4.8)	4 (2.1)	3 (1.6)	< 0.001
TBI	9 (4.8)	2 (1.1)	5 (2.6)	2 (1.1)	2 (1.1)	0	
TSCI	16 (8.5)	17 (9.0)	3 (1.6)	3 (1.6)	2 (1.1)	5 (2.6)	
Degenerative CNS	6 (3.2)	3 (1.6)	3 (1.6)	2 (1.1)	1 (0.5)	0	
Orthopedic	2 (1.1)	10 (5.3)	1 (0.5)	0	1 (0.5)	3 (1.6)	

Number (%), statistical analysis using Chi-square test

TBI, traumatic brain injury; TSCI, traumatic spinal cord injury; CNS, central nervous system

**Table 4.** Changes in static and dynamic sitting balance at the last re-admission (N = 189)

Static sitting balance	At discharge			p-value
At admission	Poor	Fair	Good	
Poor	23	11	3	< 0.001
Fair	1	33	15	
Good	0	0	103	
Dynamic sitting balance				< 0.001
Poor	42	18	4	
Fair	0	38	10	
Good	0	0	77	

Data are number of patients, comparison using McNemar's Chi-square test

whom were stroke patients who had only one re-admission. The highest percentage of two or more re-admissions was among the stroke patients and the lowest was among orthopedic patients. This finding is in line with a multicenter study in Thailand that reported the most common diagnoses for rehabilitation admission were stroke and SCI.<sup>14</sup> The rates of rehabilitation re-admission in our study cannot be compared with studies that included unplanned re-admission due to recurrent stroke, complications and cardiovascular diseases,<sup>15,16</sup> or admissions due to patient fragility and progression of a chronic disease.<sup>17</sup>

One study reported that poor recovery of the primary condition and inadequate post discharge care are associated

with re-admissions, and that discharge planning and patient education can prevent 12% to 75% of all re-admissions.<sup>17</sup> In stroke rehabilitation, LOS and functional independence have been found to be associated with re-admission after stroke.<sup>18</sup> In our study, we did not analyze the rehabilitation LOS of the first admission, but the average LOS of the last re-admission was 39.9 days. According to a multicenter study of post-acute stroke rehabilitation in Thailand, the average rehabilitation LOS was 29 days.<sup>19</sup> To reduce re-admissions rates, physiatrists in charge of inpatient rehabilitation may have to consider extending rehabilitation LOS, preparing appropriate discharge plans, increasing emphasis on patient education, and/or identifying patients who are fit for intensive rehabilitation programs which require shorter LOS but which achieve higher functional outcomes.<sup>20</sup>

According to a previous study of stroke rehabilitation in Thailand, about one-third of the patients are lost to follow-up. The remainder have functional improvement at 6 months and one year after discharge following the initial rehabilitation.<sup>21</sup> However, in our study, many patients' performance in ADL and ambulation declined after discharge following the first admission as shown in Figure 1, although some had regained function at discharge from the last re-admission as shown in Tables 4, 5 and 6. The decline in functioning after discharge following the first admission might be due to lack of a trained caregiver to provide assistance as nearly 80%

**Table 5.** Changes in static and dynamic sitting balance at the last re-admission (N = 189)

Static sitting balance	At discharge					p-value
At admission	Very severe	Severe	Moderate	Mild	Independent	
Very severe	35	6	1	0	0	< 0.001
Severe	0	17	14	1	0	
Moderate	0	0	30	15	1	
Mild	0	0	0	45	7	
Independent	0	0	0	0	17	

Data are number of patients, using McNemar's Chi-square test

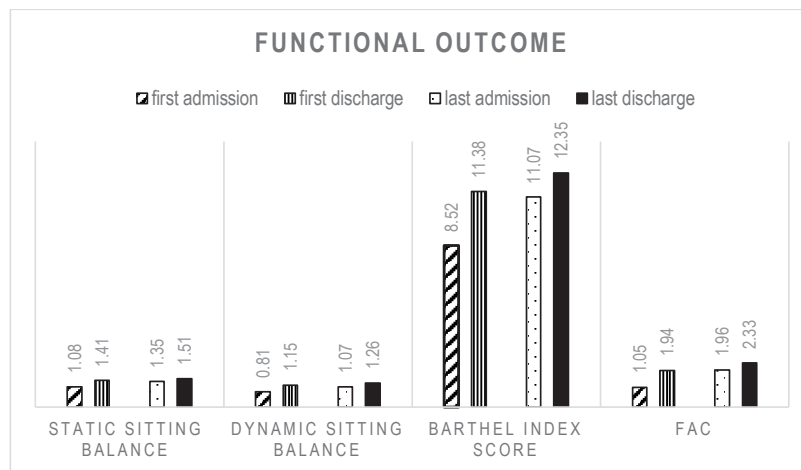
Very severe disability, BI score 0-4; severe disability, BI score 5-9; moderate disability, BI score 10-14; mild disability, BI score 15-19, and independent (no disability), BI score 20

**Table 6.** Change in the functional ambulation category (FAC) level at the last re-admission (N = 189)

FAC levels	At discharge						p-value
At admission	Level 0	Level 1	Level 2	Level 3	Level 4	Level 5	
Level 0	62	6	1	1	1	0	< 0.001
Level 1	0	9	3	7	1	0	
Level 2	1	0	3	6	2	0	
Level 3	0	0	0	16	15	1	
Level 4	0	0	0	0	29	11	
Level 5	0	0	0	0	0	14	

Data are number of patients, using McNemar's Chi-square test

Level 0, nonfunctional ambulator; level 1, an ambulator who is reliant on physical assistance; level 2, as an ambulator who requires light contact for assistance; level 3, an ambulator who requires supervision; level 4, an ambulator who is independent only on a level surface; and level 5 an independent ambulator.<sup>9</sup>



**Figure 1.** Comparison of functional outcomes at admission and at discharge of the first and the last admission  
FAC, functional ambulation categories

of the patients had only a family member as a caregiver. According to one study of Thai stroke survivors, range of motion exercises and balance training, but not ambulation training, were continued at home.<sup>21</sup> These results highlight the need to pay significant attention to educating caregivers, not just the patients. To prevent a decline in functioning after discharge, there should be increased emphasis on teaching both the patients and caregivers about the importance of continuing home rehabilitation programs in reducing unnecessary rehabilitation re-admission.

Two factors were found to be associated with the number of re-admissions in the present study. The first was duration from onset to the last admission: the longer the duration, the higher the number of re-admissions. The second was diagnosis: stroke and TSCI patients had a higher incidence of re-admission than patients with other conditions; this finding is in accord with other studies reporting factors associated with high re-admission rate, e.g., neurological diagnosis.<sup>14</sup> Another predictor reported in a previous study is poorer functional state on admission.<sup>22</sup> In the present study predictors of rehabilitation re-admission were not included as the number of recruited patients was too small for analysis.

Although the re-admitted patients at the Center had moderate to severe disability, re-admission showed benefits including improvement of balance, ADL and ambulation in one-third of the re-admitted patients. The most common indication for rehabilitation re-admission was improving ambulation, a finding which is similar to a study which reported gait rehabilitation to be a common reason for re-training.<sup>5</sup> Our study findings indicate that re-admission training improves functional outcomes; however, that does not mean that re-admission should be encouraged. Exercises, balance and ambulation training can be practiced at home after discharge by the patients themselves as well as with the assistance of caregivers. Physical and occupational therapists should be reminded that skills training in balance, ADL and ambulation can be transferred to caregivers through the active participation of the caregivers during rehabilitation admission. Follow-

ing this strategy may help avoid declines in functioning and reduce rehabilitation re-admissions in the future. The Center also recognizes the need for continuous monitoring in order to help ensure the provision of quality post-discharge rehabilitation via a variety of solutions such as outpatient follow-up, telerehabilitation, and, more recently, an extended community rehabilitation service. Additionally, a high rate of rehabilitation re-admission usually represents a financial burden to the Center as well as to the patients, while a lower re-admission rate is an indication of more effective management.

The present retrospective study which is based on medical record reviews has several limitations. First, it did not include data on secondary health conditions, psychological problems, pain, economic status, or costs of re-admission. Second, the recruited patients were in different diagnostic categories rather than one specific diagnosis. Finally, the number of re-admitted patients was small, not enough for sub-group analysis or for analyzing predictors of rehabilitation re-admission. To address that situation, the authors plan to conduct a cohort study recruiting a larger number of patients, all with a specific diagnosis such as stroke, the most common diagnosis among the patients admitted at the center, which will analyze predictors for re-admission, study the cost-effectiveness of the first rehabilitation admission and of re-admissions to identify potential avenues for improving rehabilitation management at the Center and to provide reference data for other organizations with a similar rehabilitation setting.

## Conclusions

The overall re-admission rate of the Thai Red Cross Rehabilitation Center during the period 2015-2019 was 32%. For patients aged 18-80 years who exhibited potential for rehabilitation at the time of re-admission, the rate was 16%. The number of re-admissions was positively associated with a longer duration after onset and diagnosis and was highest for stroke patients. Some functional outcomes declined after discharge following the first rehabilitation admission, but



there was significant improvement of at least one grade/level in the functional outcomes of static and dynamic sitting balance, ADL and ambulation at the last re-admission. The Center's policies regarding indications for re-admission and rehabilitation management should be reviewed and revised to minimize decline in functional performance after discharge following the first rehabilitation admission and to reduce the incidence of re-admission.

## Disclosure

The authors declare no conflict of interest.

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## Comparison of Walking and Balance Control between Gait and Balance Training on Perturbation Treadmill and Overground in Individuals with Chronic Stroke

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### ABSTRACT

**Objectives:** To study changes in walking and balance control after receiving two different gait and balance training programs in stroke patients.

**Study design:** Assessor-blinded randomized controlled trial.

**Setting:** Sirindhorn National Medical Rehabilitation Institute, Thailand.

**Subjects:** Outpatients with chronic stroke with ability to walk without ambulatory aids for at least 10 meters.

**Methods:** Eligible participants were randomized to experimental group of training on perturbation treadmill and control group of training on overground. Each participant received the assigned training which lasted 30 minutes per session, 3 days per week, for 4 weeks. Before the trainings, both groups received a bench exercise program for 30 minutes. Primary outcome was Timed Up and Go (TUG) test and secondary outcomes was Berg Balance Scale. The outcomes were assessed before and after completion of 12 training sessions.

**Results:** Only 9 participants in each group completed the study. Both groups had a decrease in TUG time and an increased in BBS score but only the latter reached statistical significant level ( $p < 0.05$ ). There were no significant changes in pre-post difference of TUG (experiment 1.10 vs control 1.18,  $p = 0.96$ ) and BBS score (experiment 1.44 vs control 2.89,  $p = 0.17$ ) between the two groups.

**Conclusions:** Due to small sample size, it is inconclusive that 12 sessions of 30-minute gait and balance training on perturbation treadmill improved walking and balance control same as overground training did in individuals with chronic stroke. A further study with adequate sample size should be done.

**Keywords:** stroke, walking, postural balance, perturbation treadmill, gait training

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### Introduction

Stroke is one of the leading public health problems, resulting in a significant number of deaths and disabilities.<sup>1,2</sup> In Thailand, the cumulative national loss of disability-adjusted life years (DALYs) due to stroke confirms that the consequences of stroke are one of the greatest burdens on patients and their families.<sup>2</sup> The Health Data Center (HDC) database from the Thai Ministry of Public Health indicates that there will be more than 250,000 new stroke cases over the age of 50 in 2021.<sup>3</sup> Stroke increases the risk of falls and serious injuries.<sup>4</sup> Stroke survivors living in community have higher risk of fractures than normal population<sup>4</sup> and higher risk of falls than healthy people of the same age.<sup>5</sup>

A systematic review in 2017 showed 3,105 participants from 56 studies, body weight-supported treadmill training (BWSTT) significantly contributes to improved gait speed and endurance in stroke patients who can walk independently<sup>6</sup> but not in those who depended on assistants for walking.<sup>6</sup> Different ways to improve efficacy of gait and balance training after stroke have been suggested, for examples, not using a handrail for support,<sup>7</sup> modifying walking speed during training,<sup>8</sup> altering visual input,<sup>9</sup> and provision of externally generated disturbances that mimic slipping and tripping.<sup>10,11</sup> The latter methods need high cost specialized gait training equipment.

As a specialized rehabilitation institute, we have a special Perturbation treadmill which has been claimed to improve postural balance during walking for those having impaired postural stability and risk of fall, for example, those with Parkinson's disease.<sup>12</sup> However, there has been no previous studies comparing between gait and balance training on Perturbation treadmill and overground in those with chronic stroke. If the gait and balance training on perturbation treadmill shows better outcome than overground training, it may be worth to use this more expensive equipment in practice especially in those whose walking and balance control is not improved by overground training.

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## Methods

### Study design

This randomized controlled trial (RCT) was approved by the Human Research Ethics Committee of Sirindhorn National Medical Rehabilitation Institute, internal no. 3/2561.

### Participants

Outpatients with chronic stroke who were referred to the Physical Therapy Unit, Sirindhorn National Medical Rehabilitation Institute were invited to participate in the study. After receiving informed consent, they were screened for eligibility. Inclusion criteria included demonstrable weakness of one leg, 6 months or longer after a first-ever stroke, age between 18-75 years, and ability to walk without ambulatory aids for at least 10 meters.

Exclusion criteria were having spasticity of the affected legs with modified Ashworth Scale > 2, impaired motor control due to neurological diseases other than stroke, severe balance deficit with static standing balance less than fair grade,<sup>13</sup> Thai-mental status examination (TMSE) score < 25, unilateral neglect, wounds on the feet and arthritis of lower extremities, joint replacement, body weight > 135 kg and receiving robot-assisted gait training.

### Randomization

Eligible participants were randomly assigned to experimental and control groups using computer-assisted mixed block randomization.

### Intervention

Before gait and balance training, all participants received a 30-minute bench exercise program which consisted of passive stretching exercises followed by resistance, active, or assisted hip, knee, and ankle range of motion exercises depending on existing muscle power, muscle tone and motor control. Static, not dynamic, sitting and standing balance exercises were included.

The experimental group received a 30-minute gait and balance training session on perturbation treadmill using BalanceTutor™ (Meditouch Company, Netanya, Israel) controlled by an experienced physical therapist (NS). All participants wore a harness for safety, not for partial body weight support as their body weight support was set to zero. They were then instructed to walk forward on the treadmill, not backward or sideways, at a self-selected and comfortable speed, without holding a side rail, initially without any interference. Later, perturbation generated by moving the treadmill in one of the four directions (forward, backward, left, and right) occurred at random intervals and directions with an average frequency of 6 stimulations per minute. The amplitude of the perturbation was adjusted in 0.5 centimeters increments between 0 and 15 centimeters. The speed of the treadmill and the amplitude of the disturbance were set to the highest possible level that the participants could continue

without losing balance. There was no computer screen for visual feedback.

The control group received a 30-minute session of overground gait and balance training supervised by an experienced physical therapist (OS) without making physical contact unless one appeared to lose balance and needed hands-on correction. This overground gait and balance training consisted of walking forward at a comfortable pace, intentionally walking with a narrower based than normal, sudden stopping and starting to walk when hearing verbal instructions from the supervising therapist, and finally walking in a zig-zag pattern. No other instructions on walking speed, stride length, or cadence were given. Walking backwards and sideways were not part of the training. And, they were not allowed to use a gait aid during training.

During the trainings, the participants in both groups were allowed to rest as often as necessary but all had to complete 30 minutes of walking, and attend the assigned training 3 times per week for 4 weeks, totally 12 training sessions. They also had to report the researchers if any accident such as a fall occurred.

### Outcome measurements

Primary outcome was Timed Up and Go (TUG) test and secondary outcomes was Berg Balance Scale (BBS). Before and after completion of the 12-session training, a blinded physical therapist (MM) assessed all participants of both groups with TUGT and BBS.

The TUGT test is a tool to assess balance when walking by measuring the time to get up from a chair, walk a distance of 3 meters, turn around and come back to sit at a chair.<sup>14</sup> In this study, all participants were asked to walk with the fastest speed and we used a G-Walk (Meditouch Company, Netanya, Israel) equipped with a software to record the TUG time.<sup>15</sup> The test was repeated three times and the times recorded in seconds were averaged for further analysis.

BBS is a tool to assess basic balance required for everyday activities for the elderly and patients with neurological disorders.<sup>16</sup> The test includes 14 activities such as standing up from a seated position, standing still and reaching for objects, and stepping. Each activity is graded on a scale of 0 to 4 (5 levels), with a total score of 56 points, and score less than 45 indicates a greater risk of falling.<sup>16</sup>

Remark: This report is a part of the main project of Effectiveness of perturbation treadmill training and conventional gait training on balance control in stroke patients: a randomized controlled trial, and only some relevant data were reported and analysed.

### Sample size calculation

Our superiority hypothesis was the training on perturbation treadmill resulting in better walking and balance outcomes than the overgroup training did. Based on the mean and standard deviation of TUG times from the study of Jung

et al.<sup>17</sup> and using n4Studies, the calculated sample size in each group was 26. When adding 25% drop out, the total expected number of participants were 66, 33 in each group.

### Statistical methods

Demographic data were described using descriptive statistics. Kolmogorov-Smirnov test was used to test the data distribution. If the data was normally distributed, paired t-test was used to compare the mean values of TUG and BBS of pre- and post-training within group; and independent t-test to compare the pre-post difference between groups. A *p*-value < 0.05 was considered as significant difference by using SPSS.

### Results

From November 2018 to December 2020, only 20 participants were eligible and randomized,<sup>11</sup> were assigned to the experimental group and 9 to the control group. Two in the experimental group could not complete the study and dropped out, one moved to another province and the other had a accidental fall at home with no fracture but needed 18 days of hospitalization. There was no drop out in the control group. The participants' demographic data as well as baseline results of the TUG test and BBS are shown in Table 1 and showed no statistically significant differences between groups.

Compared with the pre-training assessment (see Table 2), the post-training TUG time decreased in both groups but not reached statistically significant level whereas the post-training BBS score increased with statistically significant differences in both groups. However, there were no significant

differences of the pre-post TUG time and BBS score between the two groups.

### Discussion

Due to COVID-19 pandemic we had difficulty in recruiting outpatients to participate in the study. With small sample size, the results assumed as a preliminary report shows that the training on perturbation treadmill was not superior than the overground training as there were no statistically significant differences between groups.

Interestingly, statistically significant improvement in BBS balance score was found in both groups, but not in the TUG time. The improvement in the TUG time in both groups seems minimal and similar. Although randomization was done, the experimental group had older age but shorter duration of stroke than the control group. These factors may affect the TUG time. However, due to the limitation of sample size, relationship between the TUG time and these factors was not analysed.

Moreover, the mean BBS score increased 1.44 points in the experimental group and 2.89 points in the control group. The value of the control group seems comparable with results reported from other studies. For example, a systematic review showed that various kinds of gait training improved the BBS score of patients with chronic stroke by an average of 2.26 points.<sup>18</sup> However, the reference value of the smallest real difference (SRD) for BBS is 6.7 points,<sup>19</sup> and the minimal clinically important difference (MCID) for BBS is 5 points.<sup>20</sup> Therefore, when planning the next study, we have to consider whether more sessions of training will result in more points gained in BBS, and concern of difficulty in recruiting outpatient

**Table 1.** Comparison of participants' demographic and baseline assessment data between groups.

	Experimental group (N = 9)	Control group (N = 9)	<i>p</i> -value
Demographic data			
Gender: male/female <sup>1</sup>	7/2	7/2	1.00 <sup>a</sup>
Age, years <sup>2</sup>	57.11 (10.09)	48.33 (14.31)	0.15 <sup>b</sup>
Lesion: ischemic/hemorrhagic stroke <sup>1</sup>	7/2	7/2	1.00 <sup>a</sup>
Affected side: left/right <sup>1</sup>	8/1	6/3	0.26 <sup>a</sup>
Duration of illness, months <sup>2</sup>	7.78 (1.56)	12.11 (6.25)	0.06 <sup>b</sup>
Baseline assessment			
TUG, seconds <sup>2</sup>	22.43 (6.81)	27.63 (13.19)	0.31 <sup>b</sup>
BBS score <sup>2</sup>	49.55 (2.19)	47.33 (3.46)	0.90 <sup>b</sup>

<sup>1</sup>Number, <sup>2</sup>mean (SD); <sup>a</sup>Pearson Chi-square for clustered data, <sup>b</sup>independent t-test

TUG, Timed Up and Go; BBS, Berg Balance Scale

**Table 2.** Comparison between pre- and post-training TUG time and BBS score within group and between groups.

Variable	Experiment (N = 9)		<i>p</i> -value <sup>a</sup>	Control (N = 9)		<i>p</i> -value <sup>a</sup>	Pre-post difference		<i>p</i> -value <sup>b</sup>
	Pre	Post		Pre	Post		Experiment	Control	
TUG, seconds	22.43 (6.81)	21.33 (7.44)	0.35	27.63 (13.19)	26.45 (12.74)	0.36	1.10 (3.31)	1.18 (3.64)	0.96
BBS Score	49.55 (2.19)	51.00 (2.40)	0.02 <sup>*</sup>	47.33 (3.46)	50.22 (2.05)	0.01 <sup>*</sup>	1.44 (1.51)	2.89 (2.62)	0.17

Mean (SD)

<sup>a</sup>Paired t-test, <sup>\*</sup>statistically significant at *p* < 0.05; <sup>b</sup>independent t-test

TUG, Timed Up and Go; BBS, Berg Balance Scale

participants and drop out rate which seemed to be barriers to complete the trial in the study.

This preliminary results demonstrating the lack of a statistical difference in the improvement of the TUG time and BBS score between the two groups. To prove this assumption, more sample size is needed. The data (mean and SD) from this study can be used to calculate the sample size of the future trails. Given the large cost differences between these two gait and balance training programs, future studies are needed to clarify not only the efficacy of the perturbation treadmill in gait rehabilitation of chronic stroke patients but also the cost-effectiveness of the therapy. In addition, fall rate should be included as an outcome parameter.

As the above-mentioned results show better outcome of BBS in the control group, the overground gait and balance training program as described in this study may provide sufficiently intensive and specific gait and balance training because it involves a mixture of sudden acceleration, deceleration (start and stop of gait), and change of direction (zigzag walking), which increases the need for dynamic balance correction (narrow-based walking). Next, perhaps the duration of training (30 minutes of total active training time) is another important factor. The use of telerehabilitation technologies for overground gait and balance training is conceivable. This has the potential to provide a very cost-effective solution for maintaining independence and preventing fall-related injuries in chronic stroke patients and should be a focus of future studies.

## Conclusions

Due to limited sample size, it is inconclusive that 12 sessions of 30-minute gait and balance training on perturbation treadmill gives no better walking and balance than overground training. The results and limitations learned from this study can be used when planning the next proper trials to evaluate the effectiveness of both training programs.

## Disclosure

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## Improvement of Cadres' and Health Care Workers' Knowledge of Diabetic Foot Care and Rehabilitation with Community-Based Rehabilitation Webinar Program in Indonesia

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### ABSTRACT

**Objectives:** To analyse the effect of a community-based rehabilitation (CBR) webinar program on cadres' and health care workers' knowledge of diabetic foot care and rehabilitation.

**Study design:** A quasi-experimental study.

**Setting:** Public Health Center of Kepulauan Seribu, Jakarta, Indonesia.

**Subjects:** Thirty-five Cadres and health care workers who voluntarily registered and attended a 6-session webinar program on diabetic foot care and rehabilitation.

**Methods:** The webinar program consisted of 3 topics: 2 sessions on early detection, 1 session on prevention, and 3 sessions on basic rehabilitative management of diabetic foot care. The participants had to complete a pre-test before each webinar session to assess their basic knowledge of each topic and a post-test to re-assess newly learned knowledge. The scores of the pre- and post-tests were then analyzed using the Wilcoxon-Signed rank test to measure the improvement of the participants' knowledge.

**Results:** The pre-test scores showed that basic knowledge was highest in the early detection topic and least in the basic rehabilitative management. The post-test scores were increased significantly in most of the webinar sessions ( $p$ -value  $< 0.05$ ), except in the 4<sup>th</sup> session ( $p$ -value  $> 0.05$ ).

**Conclusion:** The 6-session CBR webinar program on diabetic foot care improved cadres' and health care workers' knowledge of diabetic foot care and rehabilitation. A subsequent study to evaluate the implementation of the webinar CBR program for patients with diabetic foot in Kepulauan Seribu is needed.

**Keywords:** community-based rehabilitation, diabetic foot, rehabilitation, webinar

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### Introduction

In Indonesia, people over 15 years old suffering from diabetes mellitus was 6.9% among its population of more than 500 million<sup>1</sup> and continued to increase by 2% in 2018 based on the result of the Basic Health Research by the Ministry of Health Data and Information Center.<sup>1,2</sup> Diabetes mellitus is a chronic disease with many complications that impair a patient's quality of life. A diabetic foot ulcer is a common and severe complication of diabetes mellitus with high morbidity and mortality rates.<sup>3</sup> In the first 12 months, diabetic foot ulcers were associated with a 5% mortality rate and increased to 42% in 5 years.<sup>3</sup> A multidisciplinary approach is key to diabetic foot ulcer management. Furthermore, Community-based Rehabilitation (CBR) is a strategy that aims to assist, support, and apply for rehabilitation programs in the community; and to help people with disabilities to improve their quality of life.<sup>4</sup> A good knowledge among cadres and health care workers is an essential marker for the success of the CBR program.

Rehabilitation programs including exercises, proper footwear and shoe modification, and ambulatory aids, can be used to improve the diabetic foot ulcers condition,<sup>5</sup> and can reduce the burden of diabetic foot problems.<sup>6-8</sup> Therefore, the Department of Physical Medicine and Medical Rehabilitation, University of Indonesia, concerned about the serious impact of diabetic foot problems on individuals' functioning and decided to conduct a CBR teaching program on basic diabetic foot care and rehabilitation to improve knowledge of cadres and health workers in Indonesia. The first two sessions of early detection included identification and impact of diabetic foot problems on patient's daily living, assessment

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of the sexual dysfunction related to diabetic foot; the third session was prevention of diabetic foot ulcers; and the last three sessions of basic rehabilitative management consisted of physical exercises for patients with diabetic foot problems, diabetic foot gymnastics and use of a walker.

Previously, CBR educational programs were conducted in a conventional face-to-face classroom. Due to the COVID-19 situation, a webinar was chosen as a new online distance teaching-learning method.<sup>9,10</sup> Participants and facilitators living in distant areas can communicate directly by virtual platforms and interact in real-time via voice over IP (Internet Protocol) technology and web camera equipment.<sup>11</sup> As this was the first-time webinar CBR program on the diabetic foot for cadres and health care workers we conducted, the objective of this study was to determine the effectiveness of this program.

## Methods

Cadres and health care workers at the Public Health Center of Kepulauan Seribu were invited to voluntarily register for the webinar CBR program on diabetic foot care and rehabilitation via a google form. The program of 6 sessions delivered by physical medicine and rehabilitation specialists was announced. The first session was conducted on 2<sup>nd</sup> July 2021 and the last session on 17<sup>th</sup> September 2021.

At the beginning of each session, a moderator provided a google form link to a pre-test. All attending participants were asked to complete the pre-test before a speaker started the session, and at the end, they could directly ask the speaker or send a question through a chat column, followed by a google form link for the post-test that they had to be

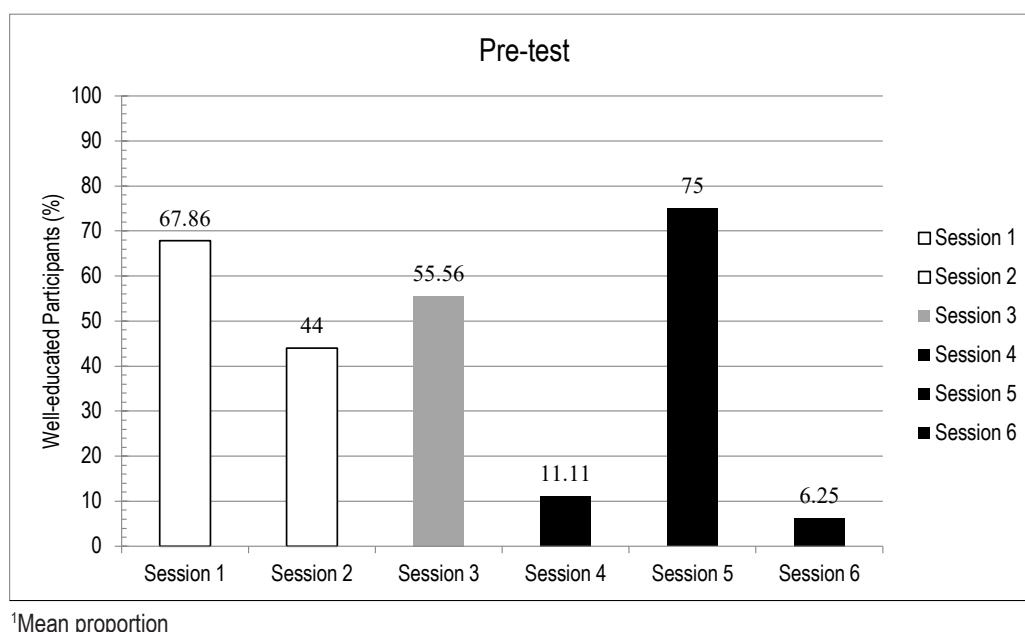
completed within 24 hours. The pre-test and post-test scores ranged from 0 to 100, and were measured after each session. Questions in the pre-test and the post-test of each session were the same.

The pre-test and post-test scores in each session of attending participants were measured. The outcome of this study was the participants' improvement in basic knowledge of diabetic foot care and rehabilitation after attending the program. Any participants were considered well-educated if their pre-test score reached 80 or more. The open-ended or multiple choice or true/false questions? in the pre- and post-test of each session were the same? and related to the topic of the session. The participants were said to have better knowledge if the post-test scores improved significantly than the pre-test scores ( $p < 0.05$ , using the Wilcoxon-Signed rank test).

## Results

There were 35 participants registered. Their average age was 37 (SD 7.8) years old, ranging from 23 to 55 years old; two-thirds of the participants were female; 37.1% of the participants were nurses, 34.3% were medical doctors, and others included housewives (17.1%), civil servants (5.7%), a dentist (2.9%) and a medical administrator (2.9%). The attendance number of participants varied, highest ( $n = 20$ ) in the first two sessions and lowest ( $n = 13$ ) in the 4<sup>th</sup> session, as shown in Table 1.

Not all of the attending participants answered both the pre-test and post-test in each session. The percentage of completing the pre-test and post- tests based on the total attendance of each session was highest (83.3%) in the 5<sup>th</sup> session and the lowest (64.5%) in the 1<sup>st</sup> session. Based on



<sup>1</sup>Mean proportion

**Figure 1.** The percentage of well-educated participants in each session. Sessions 1 and 2 on early detection, session 3 on prevention and sessions 4, 5 and 6 on basic rehabilitative management

occupations, the percentage of the pre-test and post-test completion was highest among the nurses (64.1%), followed by medical doctors (56.9%), housewives (43.1%), dentists (41.7%), medical administrators (25%) and civil servant (20.8%).

The mean pre-test scores were 75.3 (SD 21.2) in the two early detection sessions, 73.3 (SD 16.5) in the diabetic foot prevention session, and 63.3 (SD 9.0) in the three basic rehabilitative management sessions. Figure 1 shows the percentage of well-educated participants based on the pre-test score of 80 points or more in each session, the highest (75%) in the 5th session of prevention of diabetic foot ulcers and the lowest (6.3%) in the last session of use of walkers.

Table 1 shows the pre- and post-test scores in each session of the participants who answered both tests. The median post-test score increased significantly in the 1<sup>st</sup>, 2<sup>nd</sup>, 3<sup>rd</sup>, 5<sup>th</sup>, and 6<sup>th</sup> sessions (Wilcoxon-Signed rank test,  $p$ -value < 0.05). The most improvement was in the 6th post-test score. The pre- and post-test were not significantly different in the 4<sup>th</sup> session scores ( $p$ -value > 0.05).

The participant's feedbacks were that the webinar should be held in the morning instead of in the afternoon and the availability of a good internet connection to increase their participation in each webinar session.

## Discussion

This quasi-experimental study demonstrated the effect of the webinar CBR program, which aimed to improve cadres' and health care workers' knowledge of patients with diabetic feet. Based on the statistical analysis of the pre-test and post-test scores, the knowledge improvement among the participants in most of the sessions reflects that the participants could understand more about early detection of diabetic foot problems and impacts on patient's daily activities, prevention of diabetic foot ulcers, proper rehabilitation programs such as exercises in general and specifically for patients with diabetic foot, and use of ambulation aids. The highest improvement score on the use of ambulatory aids may be due to a lack of initial knowledge in the use and selection of a walker for

patients with diabetes, and the new information provided was easy to understand. The improvement of knowledge in cadres who are the first line educators in the CBR program and in the health care workers who are the medical professionals is hoped to have a massive impact on patients' quality of life.

Moreover, the results showed that before attending the program, they had some basic knowledge based on the pre-test score, the highest in early detection topic, followed by prevention, and the least in basic rehabilitative management. They might have had some knowledge of early detection and prevention of diabetic foot problems as these topics are common in the daily practice of cadres and health care workers or delivered in other seminars. The results also demonstrate that they had little knowledge of the basic rehabilitative management in patients with diabetic foot. Adding the basic rehabilitative management in the CBR webinar program increases the knowledge of the cadres and health care workers and hopefully that they will implement exercises, proper footwear, and the use of ambulatory aids to prevent complications of diabetic foot problems.<sup>12</sup> WHO stated that CBR is community action to ensure that people with disabilities have the same rights and opportunities as the other community members, including equal access to health care, education, skills training, employment, family life, social mobility, and political empowerment.<sup>13</sup>

The post- tests within 24 hours after the session ended gave the real-time measurement of participants' knowledge regarding the information about diabetic foot patients. The weak points of this webinar CBR program were the inconsistent attendance of participants in each session, as seen in Table 1. This variation was due to the webinar being held during the working days. Some participants had to work during the webinar. Some had limitations of internet connection. A more suitable time for the webinar such as in the morning or during the weekend and a good internet connection will ensure better participants' attendance. The pre- and post-tests used in this program should be validated and tested to make the questions more suitable for participants with different educational levels, easy to understand, unambiguous, and unbiased.<sup>14</sup>

**Table 1.** Comparison between the pre- and post-test scores of the participants who answered both tests in each session

Topic	Sessions	Test	N	Median	Min	Max	$p$ -value
Early detection	1	Pre	20	80	10	100	0.010
		Post	20	100	60	100	
	2	Pre	20	70	50	100	
		Post	20	100	70	100	
Prevention	3	Pre	14	80	50	100	0.019
		Post	14	95	60	100	
The basic rehabilitation management	4	Pre	13	60	30	80	0.435
		Post	13	70	10	100	
	5	Pre	15	80	60	100	0.013
		Post	15	100	80	100	
	6	Pre	14	56.3	37.5	100	0.005
		Post	14	93.8	37.5	100	

## Conclusions

The webinar CBR program on diabetic foot increases cadres' and health care workers' knowledge of diabetic foot, especially in basic rehabilitative management. Its main limitation is participants' inconsistency in participating which has to be considered. For improvement, the pre- and post-test questions need to be evaluated for further use and the subsequent study is to evaluate the implementation of the CBR Program for patients with diabetic foot in Kepulauan Seribu

## Disclosure

The authors have nothing to disclose.

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