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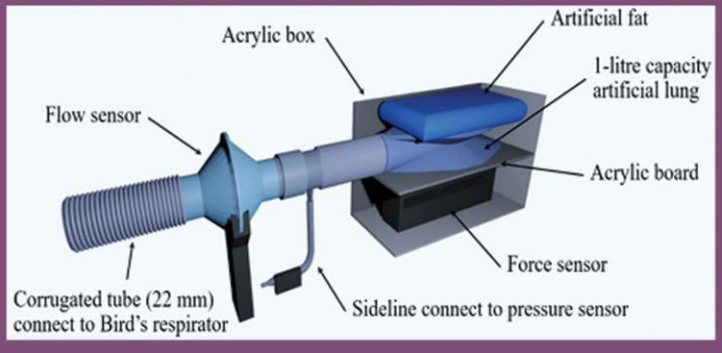


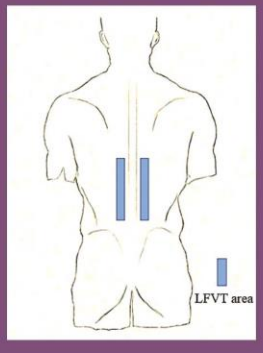


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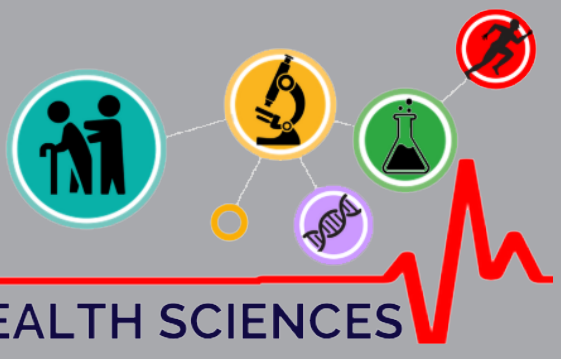

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ORIGINAL ARTICLE

Arch AHS

Archives of Allied Health Sciences 2023; 35(1): 1-11.

# Thermoregulatory and cardiovascular changes after cold water immersion as pre-cooling in amateur young adult mini-marathon runners

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**KEYWORDS**
Thermoregulation; Cardiovascular response; Cryotherapy; Young-adult; Long-distance running.

**ABSTRACT**

Long distance running causes an increase in heat production typically exceeding the heat loss capacity resulting in body core temperature elevation that induces muscle fatigue and decrease of running performance. A strategy to prevent fatigue due to thermoregulation pressure caused by strenuous activity by lowering the increase body core temperature with cold water immersion (CWI) before running is essential. This study aimed to investigate the effect of CWI application as pre-cooling on thermoregulation and cardiovascular changes in amateur young-adult mini-marathon runners. Thirty young adult mini marathon runners aged 22.2 ± 3.1 years old, who had moderate to vigorous physical activity lifestyle were recruited to the study. They were divided into two groups by simple random sampling; non-CWI group (n = 15) performed 5-minutes dynamic stretching and CWI group (n = 15) were applied by 8-10°C cold water immersion for 5 minutes. Paired sample t-test was used to compare changes within groups between baseline and after receiving interventions and independent sample t-test was used to compare measured outcome between both groups. Significant changes were found in heart rate (HR), before and after intervention within both group (non-CWI: 82.5 to 110.1 vs 92.9 to 106.5; CWI: 84.2 to 104.7 vs 84.1 to 105.2, *p*-value < 0.01); body temperature (BT) (non-CWI: 37.1 to 36.6 vs 37.1 to 36.7; CWI: 37.2 to 36.7 vs 37.1 to 36.5, *p*-value < 0.05); and rating of perceived exertion (RPE) (non-CWI: 9.2 to 14.0 vs 7.9 to 13.5; CWI: 8.4 to 12.9 vs 7.9 to 12.4, *p*-value < 0.05). There was no significant difference between both groups in all outcomes (*p*-value > 0.05). These findings indicate that CWI and dynamic stretching application in controlled temperature produced nearly similar results, though CWI appeared to be slightly superior in terms of providing a positive impact on some physiological factors that might be associated with running performance improvement.

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## Introduction

Mini marathon is a long-distance race that covers distance of 10.5 km[1]. It has been witnessing a largest increase in the number of participants. Mini-marathon runners establish their physiological characteristics that enable them to complete long distances races. Body temperature rises during prolonged exercise because heat is generated on the cellular level by metabolism; when the body is unable to dissipate the metabolic heat generated during exercise, body temperature rises further. Hyperthermia can occur as a result of an increase in body temperature[2]. Reaching a higher body core temperature was a symptom of exhaustion development until the individual was knocked down[3]. Long distance running causes an increase in heat production, which exceeds the heat loss capacity[4]. Surprisingly, high body temperature may directly or indirectly affect endurance running performance while exercising under increasing thermoregulation pressure[3]. To improve or maintain their running performances, long distance runners needed a strategy to prevent fatigue and the increase in body temperature while running[5].

Cooling techniques can help increase the heat storage capacity if used prior to exercise, also known as pre-cooling. Several reviews and meta-analyses on cooling interventions have been published in the last decade, with early reviews focusing primarily on the effects of pre-cooling on exercise performance. Many pre-cooling techniques have been shown to be effective, with cold-water immersion (CWI) being the most popular[4]. Water has a higher specific heat than most other substances as immersion. A conduction process transfers heat from the body tissue to the cold modality during cold immersion. CWI application may result in a decrease in body core temperature that lasts throughout exercise[6]. Previous meta-analysis study reported that environmental temperature has a very large influence on the effectiveness of a cooling technique. Previous systematic reviews compared effects of environmental temperatures < 30°C and cooling degrees < 15°C, and found that hot ambient temperature increased thermoregulatory challenge and cardiovascular stress[7-9]. Several studies have investigated physiological data in athletes at various stages of training[10]. Furthermore, it is critical to investigate the effects of pre-cooling on thermoregulation and cardiovascular changes during running performance in controlled temperature. So, the purpose of this study was to investigate how the CWI application before running affected heart rate, blood pressure, body temperature, and rating of perceived exertion in amateur young-adult mini-marathon runners. It was hypothesized that 5-minutes cold water immersion in controlled temperature would be more beneficial on physiological changes than dynamic stretching in order to thermoregulatory and cardiovascular control.

## Materials and methods

### *Study design and participants*

This study was a randomized controlled trial, which used two groups (experimental and control group, using simple random sampling with a lottery method) with pre-test and post-test design. The inclusion criteria consisted of young adult amateur mini-marathon runners (16 males, 14 females) aged 19-35 years old (22.2 ± 3.1 years), who had moderate to vigorous physically active lifestyle (30 minutes/day, 3 days/week for 3 months) and classified as normal weight (18.5-24.9 kg/m$^2$), meanwhile, smokers, those with a history of cold allergies, and those with cardiovascular/pulmonary disease were excluded[11-15]. Thirty subjects of sample size were estimated by using the G*Power 3.1.9.7 software with a 2-group 2-tailed t-test, the effect size of 1.4, α error probability of 0.05, power (1-β error probability) of 0.95, a sample size of participants in each group was 15, the total was 30 participants[13].

All subjects were objectively measured their health status screening at resting condition by evaluating The Physical Activity Readiness Questionnaire (PAR-Q), and measuring blood pressure (BP), heart rate (HR), body temperature (BT) *prior to* the *experimental study*. The recruitment of each subject was carried out in a month in different time and day for each subject, whoever came first, then did health status

screening and if they passed, they were randomly allocated into 2 groups (CWI and non-CWI group). During the recruitment, all participants were instructed to avoid an strenuous exercise and they should prepare whatever they needed to bring for the study protocol (running clothes and shoes, change of clothes for subjects in the CWI group to wear after cold immersion, towels and drinking water was provided). When the subject arrived the laboratory, they changed their clothes to sportswear. Before doing the main study, all participants were asked to complete their health status screening by PAR-Q, and evaluated their HR, BP, and body and skin temperature at the rest condition again. Each subject was asked to sign the consent form and the experimental procedures were verbally explained by researchers. The study protocols have been reviewed and approved by Center for Ethics in Human Research, Khon Kaen University, Thailand (Reference No. HE642206).

***Research protocols***

Each participant did the protocol on the day of experiment. The first outcome measurement was measured before the main study was started. After that, every participant in both groups did the same warm-up protocol (dynamic stretching for five minutes dynamically to full active range of motion at moderate speed and running on a treadmill for three minutes). All participants have been asked their best experienced running speed with in last three months on their running devices such as smart watch or running smartphone application. Then, they did the first running session by running on treadmill for 16 minutes on their own best running speed (km/h) on treadmill (Treadmill Bolzen EX, Australia) at a constant speed with the RPE being monitored continuously. According to Wan et al[17], more longer-duration muscle contractions (~17 min) causes fatigue, which can lead to a decrease in muscle membrane excitability. After each subject finished their first running trial, they all performed a cooling down protocol which was the same as the warm up. Then they were asked to take a rest for approximately 30 minutes or until their HR and BP had returned to a normal status[18].

Before the subjects started their second running session, they repeated the same warm up protocol as before. The intervention was applied before the second running session. The CWI group immersed in 8-10°C cold water for five minutes, meanwhile, non-CWI group performed dynamic stretching exercise for average duration of five minutes. After that they did the same running protocol for 16 minutes and cooled down. The second outcome measurement after running session was measured. All sessions were investigated in a controlled room temperature of 25°C.

If the subjects experienced upper-body discomfort, lightheadedness, nausea, faintness, shortness of breath, joint pain, or unspecified pain during the running sessions, they could stop at any time and the researcher would ask them for another additional appointment at a suitable location and time.

***Interventions***

*Intervention group (CWI group)*

Every subject in CWI group was immersed in a plastic tub with dimension diameter100 : x 80 cm, depth60 : cm at the hip level immersion in a long-sitting position. The subject was immersed at 2 different temperatures of cold water: the first three minutes was applied as familiarization (15-20 °C), and the next was the primary CWI protocol (8-10 °C) for five minutes. A glass thermometer was used to continually monitor the temperature of the cold water. The water was changed for every new subject.

*Control group (Non-CWI group)*

The subjects in the control group (non-CWI group) performed 5-mins dynamic stretching of 5 target muscles; hip extensors and flexors, leg extensors and flexors, and plantar flexors. The dynamic stretching protocol was as follows: A (hip extensors :the subjects lean forward and raise their foot from the floor with their hip and knee joint slightly in flexion .Then, the subject contract their hip joint extensors and extend their hip joint so that their leg was extended to posterior aspect of their body; B (hip flexors :the subject contract their hip joint flexors with their knee joint flexion and then flex their hip joint so

that their thigh come up to their chest; C (leg extensors: the subject contract their hamstrings and flex their knee joint so that their heel kick their buttock) Gluteal; D (leg flexors :the subject contract their hip joint flexors and flex their hip joint, raising their thigh parallel to the ground with their knee joint flexion at about 90°) . Then, the subject contract their quadriceps with the height of their thigh maintained and then extend their knee joint so that their leg extends to the anterior aspect of their body; and E (plantar flexors :the subject raises 1 foot from the floor and fully extend the knee joint .Then, the subject contract their dorsiflexors and dorsiflexion their ankle joint so that their toes were raised[16].

***Outcome measurements***

All outcome measurements, such as HR, BP, BT, and RPE, were taken prior to the main protocol or before the interventions were applied, and after each running session.

*Heart rate (HR)*

The HR (bpm) measurement was measured using HR monitor and sensor chest strap (Polar H7 HR Monitor, Polar Electro Inc./Polar Electro Oy, Finland). These instruments were directly contacted to the skin of participants. It was worn under the chest muscles comfortably (under clothing).

*Blood pressure (BP)*

Systolic (SBP) and diastolic (DBP) blood pressure were measured using digital blood pressure monitor (Omron HEM7361-T, OMRON HEALTHCARE Co., Ltd., Japan) by placing the cuff onto the subject's arm (along the brachial artery location), 2 cm above the antecubital fossa. BP was measured in units of millimeters of mercury (mmHg).

*Body temperature (BT)*

The BT (°C) was measured using an infrared thermometer before and after all subjects running in both sessions. The thermometer was brought to a distance of 2–2.5 cm from the forehead after being turned on perpendicular to the forehead. The measurement was then started by pressing the appropriate button and the result was displayed on the screen[19].

*Rating of perceived exertion (RPE)*

The RPE scale was recorded using the 6-20 points Borg's Scale[20], that was monitored before and after both running sessions and during participants' ran.

***Statistical analysis***

The measured outcomes were expressed as mean ± standard deviations. All statistical analyses were performed using the Statistical Package for the Social Sciences (SPSS) version 28.0 that is licensed by Khon Kaen University. The Shapiro-Wilk test was used to assess the normality of all outcomes. Paired sample t-test was used to compare measured outcome between before and after interventions within CWI and non-CWI group, and independent sample t-test was used to compare measured outcomes between CWI and non-CWI group with the level of significance set of $p$-value < 0.05.

## Results

***Participants' characteristics***

Details of participants' characteristic are presented in table 1. They consisted of 14 females and 16 males. The average mean age of CWI group was 22.5 ± 4.0 years, body weight 60.6 ± 15.0 kg, body height 168.8 ± 10.7 cm, BMI 20.9 ± 2.7 kg/m$^2$, running speed 7.1 ± 1.0 km/h, resting heart rate (RHR) 84.2 ± 15.1 bpm, resting systolic blood pressure (RSBP) 118.6 ± 15.2 mmHg, resting diastolic blood pressure (RDBP) 75.9 ± 12.6 mmHg, BT0.5 ± 37.2°C. Meanwhile, the mean age of non-CWI group was 21.9 ± 2.1 years, body weight 53.9 8.2 ± kg, body height 164.1 ± 9.3 cm, BMI 19.9 ± 1.4 kg/m$^2$, running speed 6.3 ± 1.0 km/h, RHR 82.5 ± 11.7 bpm, RSBP 117.1 ± 15.3 mmHg, RDBP 71.6 ± 10.8 mmHg, BT0.5 ± 37.1°C. There were no significant differences between non-CWI and CWI groups in all characteristics ($p$-value > 0.05).

**Table 1** Demographic characteristics of participants (n = 30), expressed as mean (SD)

| **Characteristics** | **CWI (n = 15) Male = 9, female = 6** | **Non-CWI (n = 15) Male = 7, female = 8** | ***p*-value** | **Total (n = 30)** |
|---|---|---|---|---|
| Age (years) | 22.5 (4.0) | 21.9 (2.1) | 0.65 | 22.2 (3.1) |
| Weight (kg) | 60.6 (15.0) | 53.9 (8.2) | 0.14 | 57.2 (12.4) |
| Height (cm) | 168.8 (10.7) | 164.1 (9.3) | 0.21 | 166.5 (10.1) |
| BMI (kg/m$^2$) | 20.9 (2.7) | 19.9 (1.4) | 0.20 | 20.4 (2.4) |
| Running speed (km/h) | 7.1 (1.0) | 6.3 (1.0) | 0.05 | 6.7 (1.0) |
| RHR (bpm) | 84.2 (15.1) | 82.5 (11.7) | 0.73 | 83.3 (13.3) |
| RSBP (mmHg) | 118.6 (15.2) | 117.1 (15.3) | 0.79 | 117.8 (15.0) |
| RDBP (mmHg) | 75.9 (12.6) | 71.6 (10.8) | 0.33 | 73.7 (11.8) |
| BT (°C) | 37.2 (0.5) | 37.1 (0.5) | 0.59 | 37.2 (0.5) |

**Note:** Independent sample t-test was used to analyze the differences characteristics between groups. RHR, resting heart rate; RSBP, resting systolic blood pressure; RDBP, resting diastolic blood pressure; BT, body temperature.

Table 2 and 3 presented the data of HR, SBP, DBP, BT and RPE scales that were recorded before and after of the first and second running sessions. The HR results showed statistically significant changes in both groups in both running sessions. In non-CWI group HR results after applying dynamic stretching was found to be higher than those before the intervention, from 82.5 ± 11.7 to 110.1 ± 12.3 bpm vs from 92.9 ± 13.5 to 106.5 ± 14.7 bpm (*p*-value < 0.001). Whereas, a slight increase of HR in CWI group was shown after 5-minute cold immersion from 84.2 ± 15.1 to 104.7 ± 19.3 bpm vs 84.1 ± 17.5 to 105.2 ± 14.5 bpm (*p*-value < 0.001).

Likewise, BT results showed statistically significant changes between before and after interventions in both groups, although it was only a slight decrease (*p*-value < 0.05). Meanwhile, the RPE results found significant change differences between before and after interventions in both groups, but after CWI application in CWI group showed a lower RPE scale compare to non-CWI group after performed dynamic stretching (*p*-value < 0.001).

The SBP and DBP results shown no statistically significant changes after interventions in both groups (*p*-value > 0.05). However, the levels of BP showed trend of decrement after the interventions, and the BP in non-CWI and CWI groups showed a small change after second running session or after interventions.

**Table 2** Comparison between pre- and post- test of the first running session (before intervention) on heart rate, systolic blood pressure, diastolic blood pressure, body temperature, rating of perceived exertion, expressed as mean (SD)

| Variable | Group | Pre-Run 1 | Post-Run 1 | Mean Diff. | % diff | *T* | *p*-value | 95% CI |
|---|---|---|---|---|---|---|---|---|
| HR (bpm) | Non-CWI | 82.5 (11.7) | 110.1 (12.3) | -27.7 (11.4) | 25% | -6.29 | < 0.001** | -19.3 to -9.5 |
| | CWI | 84.2 (15.1) | 104.7 (19.3) | -20.5 (16.0) | 19% | -5.63 | < 0.001** | -22.2 to -9.9 |
| SBP (mmHg) | Non-CWI | 117.1 (15.3) | 121.1 (14.4) | -4.0 (10.3) | 3% | -1.50 | 0.15 | -9.7 to 1.7 |
| | CWI | 118.6 (15.2) | 124.1 (13.0) | -5.5 (15.1) | 4% | -1.40 | 0.18 | -13.8 to 2.9 |
| DBP (mmHg) | Non-CWI | 71.6 (10.8) | 77.0 (16.7) | -5.4 (14.0) | 7% | -1.49 | 0.15 | -13.2 to 2.3 |
| | CWI | 75.9 (12.6) | 81.4 (11.4) | -5.5 (11.6) | 6% | -1.84 | 0.08 | -11.9 to 0.8 |
| BT (°C) | Non-CWI | 37.1 (0.5) | 36.6 (0.4) | 0.5 (0.5) | 1% | 4.22 | < 0.001** | 0.2 to 0.7 |
| | CWI | 37.2 (0.5) | 36.7 (0.4) | 0.5 (0.6) | 1% | 3.26 | 0.006* | 0.1 to 0.8 |
| RPE | Non-CWI | 9.2 (1.5) | 14.0 (2.8) | -4.8 (2.4) | 34% | -7.8 | < 0.001** | -6.1 to -3.5 |
| | CWI | 8.4 (1.4) | 12.9 (3.2) | -4.5 (2.1) | 34% | -8.1 | < 0.001** | -5.6 to -3.3 |

**Note:** Paired sample t-test was used to compare HR, SBP, DBP, BT and RPE between before and after first running session within groups, * *p*-value < 0.05, ** *p*-value < 0.001. CI, confidence interval; HR, heart rate; SBP, systolic blood pressure; DBP, diastolic blood pressure; BT, body temperature; RPE, rating of perceived exertion.

**Table 3** Comparison between pre- and post- test of the second running session (after intervention) on heart rate, systolic blood pressure, diastolic blood pressure, body temperature, rating of perceived exertion, expressed as mean (SD)

| Variable | Group | Pre-Run 2 | Post-Run 2 | Mean Diff. | % diff | *T* | *p*-value | 95% CI |
|---|---|---|---|---|---|---|---|---|
| HR (bpm) | Non-CWI | 92.9 (13.5) | 106.5 (14.7) | -13.7 (14.0) | 12% | -5.87 | < 0.001** | -11.7 to -5.8 |
| | CWI | 84.1 (17.5) | 105.2 (14.5) | -21.1 (17.8) | 20% | -5.44 | < 0.001** | -24.5 to -10.6 |
| SBP (mmHg) | Non-CWI | 112.7 (13.5) | 113.6 (11.7) | -0.9 (10.1) | 0.7% | -0.35 | 0.72 | -6.5 to 4.6 |
| | CWI | 118.5 (13.0) | 119.5 (11.0) | -1.0 (12.8) | 0.8% | -0.30 | 0.76 | -8.1 to 6.0 |
| DBP (mmHg) | Non-CWI | 70.1 (7.6) | 71.3 (10.3) | -1.2 (10.2) | 1% | -0.45 | 0.65 | -6.8 to 4.4 |
| | CWI | 76.4 (9.8) | 75.8 (9.8) | 0.6 (10.7) | 0.7% | 0.21 | 0.83 | -5.3 to 6.5 |
| BT (°C) | Non-CWI | 37.1 (0.4) | 36.7 (0.6) | 0.5 (0.8) | 1% | 2.40 | 0.03* | 0.05 to 0.8 |
| | CWI | 37.1 (0.6) | 36.5 (0.5) | 0.6 (0.5) | 1% | 4.69 | < 0.001** | 0.3 to 0.9 |
| RPE | Non-CWI | 7.9 (1.0) | 13.5 (3.5) | -5.6 (3.1) | 41% | -7.1 | < 0.001** | -7.3 to -3.9 |
| | CWI | 7.9 (1.0) | 12.4 (2.6) | -4.5 (2.1) | 36% | -8.5 | < 0.001** | -5.7 to -3.4 |

**Note:** Paired sample t-test was used to compare HR, SBP, DBP, BT and RPE between before and after second running session within groups, * *p*-value < 0.05, ** *p*-value < 0.001. CI, confidence interval; HR, heart rate; SBP, systolic blood pressure; DBP, diastolic blood pressure; BT, body temperature; RPE, rating of perceived exertion.

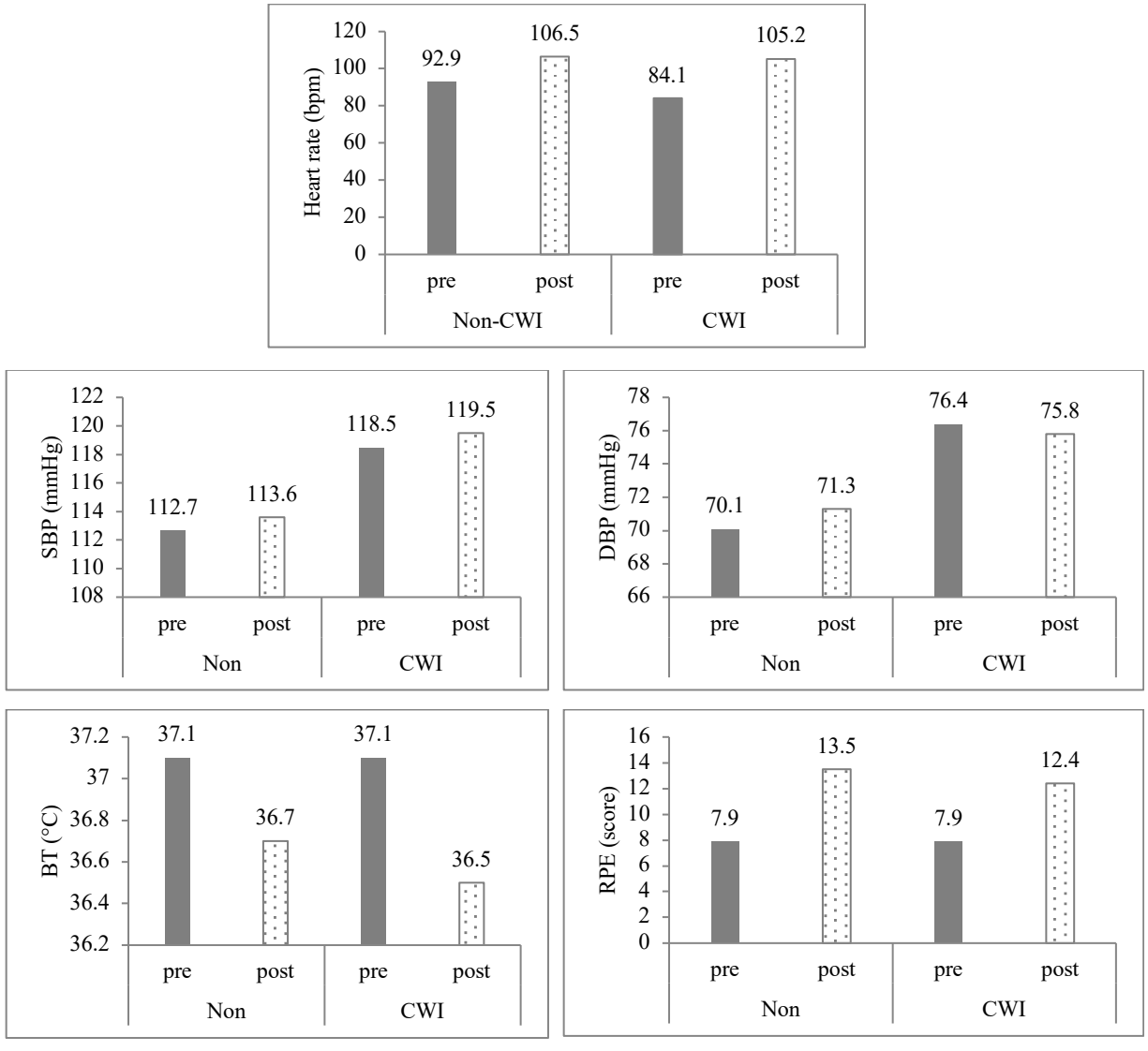


**Figure 1** Comparison of heart rate (HR), systolic blood pressure (SBP), diastolic blood pressure (DBP), body temperature (BT), rating of perceived exertion (RPE) between groups.

**Note:** Independent sample t-test was used to compare HR, SBP, DBP, BT and RPE between both groups, no significant was found ($p$-value > 0.05).

## Discussion

The present study found that CWI affected the increasing heart rate (HR) of the runners, whereby HR after cold immersion increased from 19 to 20%, whereas non-CWI subjects experienced a decrease from 25 to 12% change between before and after intervention. Cold stimulation of the extremities caused a thermoregulatory reflex, which will reduce the heat loss. One of the most noticeable of the findings is a decrease in peripheral blood flow. The HR and contractility are increased due to general sympathetic activation[21]. As a result of the HR, the pattern of cardiovascular reflexes could be seen in this study. (add previous study about HR increase or not increase).

The cold exposure causes peripheral vasoconstriction, which raises systemic vascular resistance, decreases blood flow, decreases respiratory rate, and reduces blood pressure[22]. There was consistent with our present results that a slightly changes in systolic (5.5 mmHg to 1 mmHg, respectively) and diastolic BP (5.5 mmHg to 0.6 mmHg, respectively) between before and after the CWI application. It is likely that cold exposure can be linked to delayed an increasing of blood pressure, in other words, a growing in cardiovascular pressure is better maintained by cold, thus might be enhancing running performance.

Although the BT between before and after both interventions were approximately 1% decrease in both before and after intervention in either CWI or dynamic stretching. However, pre-cooling can be slightly more impact on BT compared to dynamic stretching. A previous study revealed that CWI prior to strenuous exercise may counteract the negative effect of high muscle temperature (> 40°C)[22]. The goal of pre-cooling is understood to be reducing body temperature prior to exercise, thereby attenuating the physiological problem caused by heat strain. This was thought to be caused by the increasing heat storage capacity following CWI application, which prolonged the time required to reach a critical high body and skin temperature[23]. CWI as pre-cooling created a larger heat sink by lowering body temperature further, which increased the body's capacity to store heat while the athletes ran in long distance races[24].

The RPE, ranging from 6 to 20, is a widely used index for assessing fatigue. Hence, the Borg's scale can help the clinician judge the degree of fatigue reached from one test to the next, and correlate the level of fatigue experienced during testing with that experienced during daily activities. In the current study, RPE was significantly lower in both groups (CWI and non-CWI) following both interventions. However, RPE in the CWI group was slightly lower than in the non-CWI group (4.5 vs. 5.6, respectively), it means that CWI has maintain slightly better on the exertion of runners than dynamic stretching. In general, a Borg's scale greater than 18 indicates maximal exercise level of a patient, while values above 15-16 indicates the exceeding anaerobic threshold. However, the runners in our study were only did at an average 12.4-13.5 in both groups or they performed somewhat hard activity (moderate intensity). Therefore, CWI may link to a psychological promotion effect due to lower temperature[25]. Researchers also proposed that perceived exertion influences thermoregulatory behavior prior to a significant change in thermo-physiological parameters during exercise[26].

Nevertheless, there are some notable limitations of the study. Firstly, the results of such laboratory-based experiments are likely to lack ecological validity and mundane realism. Because of the controlled environment in lab experiments, the outcome of the experiment may not yield an accurate reflection of what would be seen in the real world. Secondly, participants were limited to amateur runners who lived in Khon Kaen, Thailand. Lastly, some cooling techniques may result differently with regard to the part of human body. Further study must be conducted to investigate the effects of CWI as pre-cooling including muscle and skin temperature measurement to find the convincing changes, and compare on different cooling techniques, such as cold pack, ice pack, ice massage, coolant sprays. Additionally, it would be worth to find the associations with running performances.

## Conclusion

This study investigated how the CWI application before running affected heart rate, blood pressure, body temperature, and rating of perceived exertion in amateur young-adult mini-marathon runners. According to the findings, CWI application in controlled room temperature produced affectable results, and CWI appeared to be slightly superior in terms of providing a positive impact that can be associated with their running performance compared to non-CWI subjects. As a result, CWI at 8-10°C for 5 minutes can be used as a pre-cooling technique for amateur young adult mini marathon runners.

## Take home messages

CWI application at 8-10°C for 5 minutes has an effect on heart rate, body temperature, blood pressure, and the RPE scale. So, it can be used as a cooling technique before running activity in amateur young adult mini marathon runners to help minimize heat stress during strenuous activity, and might be improve running performances.

## Conflicts of interest

The authors declare no conflict of interest.

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# Effects of low-frequency vibration to the back muscles on recovery-related parameters in college football athletes: a preliminary study

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**KEYWORDS**
Low-frequency vibration; Lower back muscles; Fatigue; Randomized controlled trial.

**ABSTRACT**
Muscle fatigue is commonly found in football athletes due to high training or competitive intensity. Although vibration therapy is one of the popular methods that can transfer mechanical energy into the target muscles, only little evidence on the effects of low-frequency vibration therapy (LFVT) on lower back muscles fatigue was available. Therefore, this study aimed to examine the immediate effects of LFVT on recovery of the lower back muscles after inducing fatigue. Fourteen football athletes of Shaoguan were randomly allocated to receive either a -4min session of the LFVT group or a control group (rested on a bed), after exercise-induced fatigue. Recovery-related parameters including sit-and-reach, pressure pain threshold, visual analog scales, and heart rate variability were obtained before the session of exercise, and immediately after receiving either LFVT or control. Results showed that the LFVT group had no significant difference in the lower back muscles› recovery compared to the control group after the intervention although some parameters did go in the better direction. We conclude that LFVT may have no immediate effects on exercise induced-muscle fatigue.

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## Introduction

In order to get the ideal result in the football game, the players must exercise at high intensity during the training or competition; consequently, fatigue is commonly found during and after exercise and is inevitable. Muscle fatigue is used for describing the declining ability in physical performance for the present[1]. It is a long-standing observation that soccer players are often submitted to high-muscle actions during matches and training sessions. Fatigue after football training or competition is commonly found in football athletes. Besides that, football demands accelerations, decelerations, jumps, changes of direction, and technical and tactical skills to successfully adapt to a rapidly changing environment and achieve optimal performance[2]. Repetitive physical exercises at high intensity could lead to muscle fatigue because of the accumulation of lactic acid or depletion of chemical energy (ATP) in the muscles. It is a kind of stress.

Achieving a good balance between exercise or game stress and recovery is crucial to an athlete's performance; otherwise, it may bring about potential injuries or weakening abilities (poor judgment, reduced endurance, and acceleration) in the athletes[3]. To achieve this balance, many rehabilitation therapies have been used.

Vibration therapy is one of the popular methods that can transfer mechanical energy into the target muscles[4]. Vibration therapy can be divided into two patterns: whole-body vibration therapy and local vibration therapy. There is much less research on the use of local vibration[5,6] compared to whole-body vibration[7-9]. Several measures were involved to assess the effects of low-frequency vibration therapy (LFVT) on the recovery of the lower back muscles. However, the perception of muscle fatigue after exercise measured with the visual analog scale (VAS), and pressure pain threshold (PPT) are important measures to consider when studying the effects on recovery[10]. If the lower back muscles of participants had a poor recovery, they cannot provide good results on the sit-and-reach (SAR) because they cannot lean forward better. Among the tools proposed to assess the athlete's fatigue, the analysis of heart rate variability (HRV) provides an indirect evaluation of the settings of autonomic control of heart activity[11].

However, the effects of vibration therapy on lower back muscle fatigue seldom be explored especially in college football athletes because the back muscles are always used throughout the game as being the core muscles[12]. Therefore, this study aims to measure the effect of LFVT on physical and sensory recovery of back muscles for football players and compare the data within and between the LFVT group and control group.

## Materials and methods

### *Design and setting*

A randomized controlled trial was done in the Physical Therapy Department, Faculty of Physical Education School, Shaoguan University, China. The single-blinded trial was conducted by well-trained assessors. The research proposal of this study was approved by the Khon Kaen University Ethical Committee (HE642185).

### *Participants*

Fourteen participants were enlisted through the notice boards; they were numbered by an independent researcher of this study and placed the number in an opaque sealed envelope, according to the website (http://www.randomization.com), the participants were randomly allocated into the LFVT group (n=7) or control group (n=7) using the random block sizes.

The inclusion criteria were those male football athletes, aged from 18 years old to 27 years old, having a football training history of more than one year. Each of them was excluded if he had one of the following conditions: chronic lower back pain that continues for 12 weeks or longer, a habit of smoking or drinking, a history of surgery in one year, took any medicine one week ago for the data collection[13].

Until now there is no relevant study about LFVT towards lower back muscles through the literature review. Therefore, we conducted this pilot study, using 14 participants as the recommendation for a pilot study (a minimum of 12 participants)[14].

***Procedure***

The 14 participants who met the inclusion criteria in this study were assigned randomly to either the control group or the experiment group (LFVT group).

There were two visits for each participant during the data collection. The first visit was getting familiar with the location, surroundings, and how to work with the assessors. The second visit for the participants was the day next to the first visit. Before the protocol, the participants in the two groups were done the baseline data collection (including height, weight, and age). Moreover, some relevant parameters were also collected including HRV (heart rate variability), PPT (pressure pain threshold), VAS (visual analog scales), and SAR (sit-and-reach). Then the participants in the two groups were induced to fatigue by performing a set of back exercises. They were in a prone position, two arms straightened over the head, then lifted up the arms and feet as high as possible and returned to the original prone position[13] (Figure 2). They received encouragement if their position of hands and feet was lowered to the horizontal level. Fatigue was confirmed when the participants cannot do this anymore or claimed that they were exhausted or discomfort[13]. After the induced fatigue, the participants in the LFVT group received 4-min vibration therapy and at the same time, the participants in the control group lay down quietly under the same circumstances. After the protocol, the participants in the two groups were re-assessed for all variables.

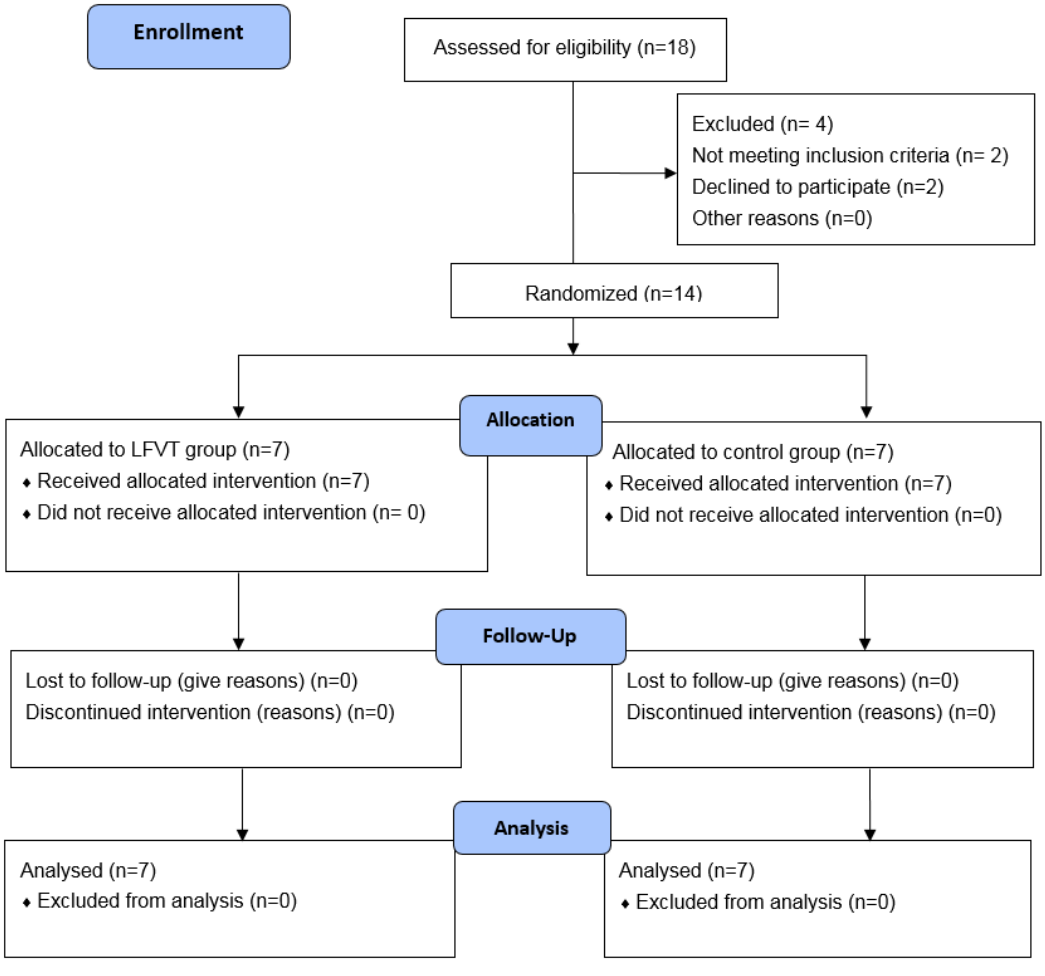


**Figure 1** The participation flowchart.

**Figure 2** The position for induced fatigue in this study.

***Treatment***

*Experiment group (Low vibration group – LFVT group)*

Each participant of the experimental group received the 4-min low-frequency vibration therapy between 16:00 and 18:00 on the data collection day according to the participants' time. The vibration therapy was applied using the vibration stick (TK AMC – 888, Infrared Massager, China), and the chosen frequency of this device was 8 Hz (the frequency was measured by the instrument Biopac, USA) (Figure 3) by a well-trained vibration therapist. The vibration therapy points were on the lower erector spinae muscles of the lower back (Figure 4).

**Figure 3** The treatment instrument of this study.

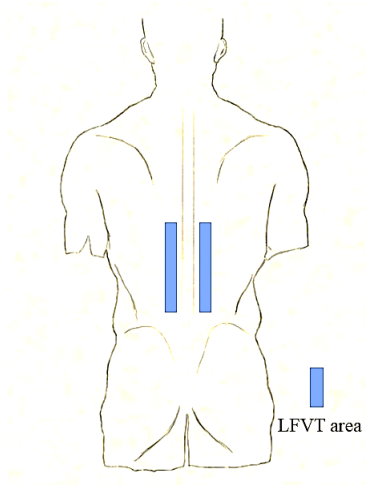


**Figure 4** The treatment area of this study.

*Control group*

The participants in the control group relaxed for four minutes in a prone lying position quietly in the same surroundings as the treatment group.

When all the data collection was done, the participants in the control group were offered to receive the same vibration therapy as the participants in the LFVT group.

***Outcome measures***

All the parameters were collected before and after the programs of each group by four assessors. Every parameter was measured by the same assessor. Details of the assessments are as follows.

*Visual analog scales*

It is a subjective understanding measurement of pain perception. The VAS of this study was recorded on a discrete integer scale, marking categories ranging from 0 to 10 points. Zero means there is no pain whereas 10 represents the most severe pain. The participant draws a line across the given line. Then the distance from zero to the intersection is the pain score of the participant[14]. It is the main outcome of this study.

*Sit-and-reach*

This parameter was measured using a sit-and-reach device (Kedao TZCS-1, China). The participants removed the shoes and sat on a flat surface with legs extended in front of the body and the knee joints must be straight. Then the participants pushed forward the ruler as far as they could, and then the screen showed the maximum number of sit-and-reach in centimeters. The measurement procedure was repeated three times and taken the mean data for the analysis[16].

*Heart rate variability*

The heart rate variability was tested using an HRV device (uBioMacpa version 1.0, Korea). The participants fasted four hours before the data collection. They were not allowed to talk, use a smartphone or fall asleep during the testing protocol. The HRV device was connected to a laptop computer, providing real-time visual results[17].

*Pressure pain threshold*

This parameter was measured by the machine for measuring the PPT (Combo, OE-220, Japan). The number of the screen of the instrument increases as the pressure which is vertical towards the lower back muscle increases. The participant could press the button which was attached to the machine when he felt pain or uncomfortable in the pressing process, then the number of the screen stopped, this point is the pressure pain threshold. It was measured three times and taken the mean data for the analysis[18].

***Statistical analysis***

Data analysis was conducted by IBM SPSS Statistics version 26. Through the Kolmogorov-Smirnov examination, the data group age, height,

and weight showed normal distribution, while the PPT, SAR, VAS, and HRV were non-normal distribution. The baseline comparison between the two groups included age, height, weight, PPT, VAS, and HRV. Using Mann-Whitney U test examined the differences between pre-protocol and post-protocol in the experiment group and control group. The method of independent samples T-Test was used to examine the changes of post-intervention minus before intervention between the two groups. A *p*-value less than 0.05 was regarded as statistically significant.

## Results

### *Baseline characteristics*

The baseline characteristics of the participants are presented in table 1. Fourteen participants were recruited in this study. They were all male athletes (except the goalkeeper) in the university. The baseline of age, height weight, SAR, PPT, VAS, and HRV had no significant difference between the two groups.

**Table 1** Comparison of the baseline characteristics between the groups (Independent T-test)

| | Control | Vibration | *p*-value |
|---|---|---|---|
| Number of participants | 7 | 7 | |
| Age (year); mean (SD) | 20.14 (0.6) | 19.57 (1.1) | 0.103 |
| Height (cm); mean (SD) | 169.85 (5.0) | 72.14 (5.0) | 0.814 |
| Weight (kg); mean (SD) | 56.71 (7.0) | 62.42 (9.4) | 0.493 |
| HRV | | | |
| LF ($ms^2$) | 7.54 (0.67) | 7.70 (0.86) | 0.111 |
| HF ($ms^2$) | 7.02 (1.09) | 6.95 (0.69) | 0.883 |
| LF/HF | 1.05 (0.11) | 1.08 (0.12) | 0.229 |
| Mean BMP(t/m) | 76.48 (16.64) | 78.37 (14.45) | 0.713 |
| SDNN | 52.92 (24.48) | 52.18 (16.37) | 0.887 |
| RMSSD | 50.00 (30.49) | 43.22 (19.60) | 0.657 |
| Other parameters | | | |
| PPT (KG) | 4.69 (1.43) | 4.827 (1.83) | 0.825 |
| VAS(CM) | 4.43 (1.39) | 5.29 (1.11) | 0.948 |
| SAR (CM) | 10.68 (4.949) | 6.17 (4.874) | 0.632 |

**Note:** LF, sympathetic activity; HF, para-sympathetic activity; LF/HF, LF divide HF; Mean BMP, average pulse; SDDN, pulse standard deviation; RMSSD, root mean square standard deviation; PPT, pressure pain threshold; VAS, visual analog scale; SAR, sit-and-reach.

### *Immediate effects of low-frequency vibration on heart rate variability*

Table 2 shows the immediate effects after receiving the protocol in the two groups. There was no significant difference in both groups' baseline compared with the post-protocol values respectively, but some values did go towards the better direction (Table 2), for example, the value HF (para-sympathetic activity) (from 6.80 to 6.90), Mean BMP (mean pulse) (from 76.40 to 74.00) and RMSSD (root mean square standard deviation) (from 39.20 to 52.00 in the LFVT group. In the control group, such findings were not shown on the parameters HF (from 7.60 to 6.8). When it comes to the comparison of the changes which were between the baseline and post-test, the parameter LF (sympathetic activity) are slightly better (Table 3).

***Immediate effects of low-frequency vibration on other parameters***

There was no significant difference within and between group comparisons. We found that in the LFVT group, the median value of PPT increased after the vibration therapy, whereas the median value of PPT decreased after the 4-min rest in the control group (Table 2).

**Table 2** Comparison between baseline (pre-test) and post-test in the vibration and control

| Parameters | Control group (n = 7) | | | Vibration group (n = 7) | | |
|---|---|---|---|---|---|---|
| | Baseline Median (IQR) | Post-test Median (IQR) | *p*-value | Baseline Median (IQR) | Post-test Median (IQR) | *p*-value |
| HRV | | | | | | |
| LF ($ms^2$) | 7.3 (1.48) | 7.7 (0.98) | 0.612 | 7.7 (1.3) | 7.7 (1.08) | 0.733 |
| HF ($ms^2$) | 7.6 (6.25) | 6.8 (6.25) | 0.933 | 6.8 (1.1) | 6.9 (1.65) | 0.310 |
| LF/HF | 1.0 (61.7) | 1.1 (61.7) | 0.414 | 1.0 (0.2) | 1.2 (0.20) | 0.914 |
| Mean BMP(t/m) | 75.8 (33.65) | 64.1 (35.3) | 0.063 | 76.4 (17.8) | 74.0 (19.37) | 0.866 |
| SDNN | 45.4 (32.35) | 64.8 (36.95) | 0.499 | 53.0 (27.8) | 53.0 (29.30) | 1.000 |
| RMSSD | 34.0 (28.80) | 59.4 (35.17) | 0.612 | 39.2 (27.9) | 52.0 (33.9) | 0.612 |
| Other parameters | | | | | | |
| PPT (KG) | 4.42 (2.57) | 3.63 (2.66) | 0.091 | 3.91(3.49) | 4.99 (2.98) | 0.600 |
| VAS(CM) | 5.0 (1.93) | 6.0 (1.78) | 0.131 | 6.0 (1.0) | 6.0 (3.00) | 0.705 |
| SAR (CM) | 10.3 (8.93) | 11.4 (7.77) | 0.735 | 3.6 (9.0) | 4.7 (8.88) | 0.753 |

**Note:** LF, sympathetic activity; HF, para-sympathetic activity; LF/HF, LF divide HF; Mean BMP, average pulse; SDDN, pulse standard deviation; RMSSD, root mean square standard deviation; PPT, pressure pain threshold; VAS, visual analog scale; SAR, sit-and-reach.

**Table 3** Comparison of mean about the changes which are post-intervention minus before intervention between the two groups (Independent T-Test)

| Parameters | Control group (n = 7) Post minus before Mean (Standard deviation) | Vibration group (n = 7) Post minus before Mean (Standard deviation) | ES | *p*-value |
|---|---|---|---|---|
| HRV | | | | |
| LF ($ms^2$) | 0.18 (0.95) | -0.20 (1.08) | -0.373 | 0.494 |
| HF ($ms^2$) | -0.04 (0.70) | -0.31 (0.70) | -0.385 | 0.486 |
| LF/HF | 0.02 (0.95) | 0.05 (0.11) | 0.044 | 0.619 |
| Mean BMP(t/m) | -4.71 (5.82) | -0.44 (7.15) | 0.790 | 0.244 |
| SDNN | 12.21 (32.29) | 1.50 (10.78) | -0.444 | 0.421 |
| RMSSD | 4.35 (30.05) | 2.80 (13.75) | -0.066 | 0.903 |
| Other parameters | | | | |
| PPT (KG) | -0.34 (0.46) | -0.28 (1.18) | 0.067 | 0.891 |
| VAS(CM) | 0.85 (1.3) | 0.28 (1.38) | -0.425 | 0.448 |
| SAR (CM) | -0.15 (1.26) | -0.18 (1.82) | -0.019 | 0.973 |

**Note:** LF, sympathetic activity; HF, para-sympathetic activity; LF/HF, LF divide HF; Mean BMP, average pulse; SDDN, pulse standard deviation; RMSSD, root mean square standard deviation; PPT, pressure pain threshold; VAS, visual analog scale; SAR, sit-and-reach; post minus before, the value of post-protocol minus pre-protocol; ES, effect size.

## Discussion

From this experiment, we could not find a significant difference after the protocol in the LFVT group or between the LFVT group and the control group. Considering the safety of the participant, the 8 HZ vibration instrument was used. However, we found in this study that the time duration of intervention and the frequency of vibration did affect the effect of LFVT.

Considering the LFVT, low frequency refers to 0-45 HZ[19]. One previous study showed that vibration therapy at 30 HZ could produce adverse effects on some physiologic systems; some parameters were 7 times higher than what was considered the safe threshold[20].

We used the 8 HZ vibration frequency in the current study because of some reasons. These include safety utilization; favorable experience for the participants when we try LFVT; and confirmation of a study that the low-frequency vibration (15 HZ or lower) after exercise could accelerate cardiovascular autonomic recovery after exercise[21]. In addition, during the study period, the vibration instrument which was lower than 15 HZ we could find in the market was 8 HZ.

Some studies[22-24] showed that LFVT could provide beneficial effects on recovery from fatigue in the longer term. One study found that 15-minute percussive massage therapy (vibration therapy) may improve tissue hardness, skin temperature, and pain intensity[25]. Another study also found that local vibration treatment was effective for male and female volunteers under a session of 15-min intervention[26]. For the longer time duration intervention there were also beneficial effects on the participants. One study

showed that 8-vibration sessions (15 minutes per session) decreased the state of tension anxiety, muscle fatigue, and the perception of pain[27].

There was no significant difference in this study may be because the time duration of intervention was too short to cause a substantial effect. Another possible reason may be because the 8-Hz lower frequency vibration itself provided too low and inadequate energy intervention. Future studies may explore the appropriate frequency for LFVT. For the frequency of vibration therapy, a frequency of 26 Hz vibration therapy precluded the muscle stiffness of the athletes after 10 bouts of 60 seconds of static half squats and it can be suggested to become the potential warm-up exercise and regimen to promote the subsequent performance. A 12 Hz frequency whole body vibration could provide a positive result on the parameter blood lactate[28]. About the whole body vibration therapy, vibration properties of 18 Hz led to significant trunk neuromuscular control improvements for the participants in the experimental group before and after a muscle fatigue protocol[29].

This study has some limitations including being a pilot study with a small sample size, a short period of exposure to the intervention, and no follow-up period. Further study should explore the effects of vibration therapy that apply over a longer period and more sessions. Moreover, a larger sample size with a randomized controlled trial should also be verified.

## Conclusion

After the intervention, although there is no significant difference between the experimental group and the control group or in the experimental group, the PPT parameter had shown a positive result.

### Take home messages

Four minutes of LFVT therapy did not show significant effects on lower back muscle recovery from fatigue in college football athletes based on sit-and-reach, pressure pain threshold, visual analog scales, or heart rate variability.

## Conflicts of interest

The authors declare no conflict of interest.

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# Thai physiotherapists' performance of manual chest wall percussion on an artificial lung: frequency, force, and fatigue perception

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**KEYWORDS**
Manual chest percussion; Physiotherapy; Chest percussion; Chest clapping.

**ABSTRACT**
Manual chest wall percussion (MP) is a conventional chest physical therapy that aims to assist airway clearance. Various frequencies and forces of MP are widely used in current practice. However, MP low frequency, highest frequency, and repeatability have not been explored. Moreover, the relationship between MP force and flow oscillation amplitude (FOA) has not been reported. Our objective is to explore the performance of physiotherapists in performing MP at three frequencies (routine, low, and highest) and repeatability of MP in the artificial lung and explore the relationship between MP force and FOA. Physiotherapists with cardiopulmonary practice experience performed MP at three frequencies: routine, low, and highest. Each physiotherapist performed MP on the artificial lung at each frequency for five minutes, on two different days. We measured the frequency and force of MP, the physiotherapist's fatigue, and the flow and pressure from the artificial lung during percussion. Forty-four participants were recruited for this study. The routine, low, and highest frequencies were 5.4 ± 0.6 Hz, 3.9 ± 0.9 Hz, and 6.5 ± 0.8 Hz, respectively. The force in the dominant hand at the routine, low, and highest frequencies was 5.2 ± 1.2 kg, 4.4 ± 1.4 kg, and 5.9 ± 1.8 kg, respectively. The force in the non-dominant hand at the routine, low, and highest frequencies was 3.8 ± 1.1 kg, 3.3 ± 1.1 kg, and 4.3 ± 1.4 kg, respectively. The average 5-minute upper body fatigue scores for the routine, low, and highest frequencies were 2.5 (range 0.0–5.5), 1.6 (range 0.0–5.6), and 4.1 (range 0.2–8.5), respectively Additionally, the highest and low frequencies show great repeatability (r = 0.90, *p*-value < 0.001, r = 0.86, *p*-value < 0.001, respectively), although the routine frequency only showed moderate repeatability (r = 0.69, *p*-value < 0.001). The positive relationship between dominance and non-dominance in MP force and FOA were met (r = 0.85, *p*-value < 0.001 for the dominant hand and r = 0.76, *p*-value < 0.001 for the non-dominant hand). In conclusion, the possible MP frequency in clinical practices was 3.9 to 6.5 Hz with force 3.3 to 5.2 kg. MP force direct effect on FOA. Based on fatigue perception and repeatability results, we recommend using MP for 3–5 minutes per session.

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## Introduction

Manual chest wall percussion (MP), manual chest wall vibration, shaking, and postural drainage are conventional chest physiotherapist techniques (CPT) that aim to clear secretion, promote ventilation, and prevent lung complications[1]. MP generates mechanical force through the chest wall to manipulate intrathoracic pressure and fluctuate airflow in the bronchial tree[2].

Various chest wall oscillation devices have been developed to replace MP, vibration, and shaking techniques, such as the mechanical vibrator[3], the high-frequency chest wall oscillation machine[4], and the Frequencer®[5]. These instruments can adjust the oscillation frequency, oscillation force, and duration of treatment, thereby reducing the therapist's effort. However, in many places, these tools are not available, and in some cases, therapist's help is required to apply CPT.

MP has three essential components that affect the technique efficacy: oscillation frequency, force, and treatment duration. We found only three studies that have investigated routine MP force and frequency from physiotherapists[2,6,7]. Previous studies have used MP as a treatment intervention with various parameters, such as 3.0–4.5 Hz for 2 minutes[8], 8.3 Hz[9], and 1.6–2.0 Hz for 10 minutes[10]. The textbook recommends an MP frequency of 3.0–6.0 Hz and approximately 2–5 minutes in each position[11-14]. Some studies have used MP as a treatment without reporting the frequency and duration[15,16].

According to various MP parameters, it is possible to cause a mixed result of clearance ability[17-20] and difficulty developing a clear indication of MP. MP is less popular than alternative methods due to the labour involved and the lack of evidence regarding its efficacy[21]. However, MP is still taught in all Thai physiotherapy curricula and is used in many countries, such as Australia, India, and Turkey[22-24]. This technique is easy and has low cost because no equipment is required – nor is the patient's cooperation required, which is especially significant when the patient is a child or an individual in intensive care[22,24].

Reportedly, an oscillation frequency of around 12-13 Hz in mechanical instruments can improve viscoelasticity[25]. If the physiotherapist can do MP, a frequency near this range may improve mucus viscosity. Although the higher frequency is possibly more beneficial, the low frequency was used for children[6]. Some study showed clearance benefits on low frequency chest percussion[20]. Moreover, the therapist's fatigue may be correlated with oscillation frequency, force, treatment duration, and willingness to perform MP.

We still do not know the nature of the current MP techniques, including routine and low frequency, force, and repeatability. Furthermore, the highest frequency at which a physiotherapist can perform MP has not been established. This study investigated physiotherapists' oscillation frequency, force, and fatigue levels when performing MP at three different frequencies (routine, low, and highest) and the repeatability of MP in the artificial lung. Additionally, we aimed to explore the relationship between MP force and flow oscillation amplitude (FOA). We hope that this study would provide essential information for developing standard MP techniques and clear indications under the limits of physiotherapist performance.

## Materials and methods

### *Participants*

We recruited Thai physiotherapists who had a current Thai physical therapy license and one year of experience in the cardiopulmonary field. We excluded individuals who could not perform PM due to musculoskeletal problems, such as wrist, shoulder, or neck pain. This study was approved by the Khon Kaen University Ethics Committee for Human Research (HE632208). All subjects signed an informed consent form prior to the study.

### *Artificial lung*

In this study, we built an artificial lung with an acrylic box (13 × 37 × 10 cm) composed of four layers: (1) artificial fat (icepack gel-filled with sac) in which the sac was fixed with an acrylic board via rope to prevent shifting from the artificial lung, (2) 1-litre capacity artificial lung (Ventiplus™,

Maxtech, Utah, USA), (3) acrylic board, and (4) force sensor (Model SS25LB, Biopac system Inc., California, USA) (Figure 1). Additionally, we used an air compressor (PP-1, PUMA, Bangkok, Thailand) to connect Bird's respirator mark 7 to the artificial lung for continuous air inflation and flow regulation (0.13 ± 0.10 L/sec) via a corrugated tube (22 mm). We set the Bird's respirator at the highest pressure cycle and at the highest inspiratory flow rate for continuous inflation of air in the artificial lung. Before each MP trial, the artificial lung was fully inflated with 25 ± 2 cm $H_2O$ pressure. The artificial fat bag was lifted off the edge of the box.

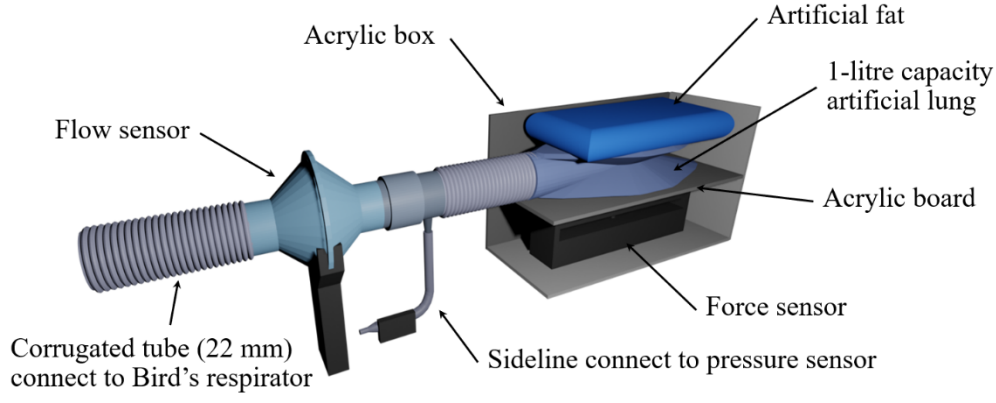


**Figure 1** The artificial lung model component and circuit.

***Manual percussion (MP)***

We directed the physiotherapist to perform percussion at different frequencies for five minutes each: (1) routine frequency ('percuss at a routine frequency that used in daily work'), (2) low frequency ('percuss at a frequency lower than routine frequency'), and (3) highest frequency ('percuss as fast as you can'). This study was conducted for two days: on the first day, the physiotherapists performed percussion at three frequencies; on the second day, they repeated this process. Each subject was directed to start percussion on the artificial lung at routine frequency, followed by low frequency, and then followed by the highest frequency, with 10-minute inter-frequency rests. If the subject could not complete the five minutes of percussion at a given frequency due to fatigue or pain, they could stop.

***Outcome measures***

Subject characteristics were collected using a questionnaire. Airflow, pressure, and force were continuously measured by a flow transducer (Model SS11LA), a pressure transducer (Model SS13L), and a hand dynamometer (Model SS25LB), respectively, that integrated with BIOPAC MP 36 (BIOPAC Systems, Inc., California, USA). The sample rate was set at 500 Hz. We used the last five seconds in every minute for analysis. The flow and pressure were analysed to FOA and pressure oscillation amplitude (POA). Airflow and pressure data were plotted against time, and the flow-time plot was measured to determine the frequency. A numeric rating scale from 0 to 10 was used to evaluate upper body fatigue perception every minute: 0 indicated 'no fatigue', 5 'moderate fatigue', and 10 'extreme fatigue'.

***Statistical analysis***

The sample size was calculated from the estimation mean of the infinite population equation[26]. We set the alpha error at 0.05, the margin of error (d) at 0.297 Hz, and the standard deviation based on the previous study[7], and the total sample size was 44.

All analyses were conducted using STATA 10 software (StataCorp LLC, Texas, USA). This study used descriptive statistics for the analysis. After tracking all data from BIOPAC, the data from the first and second MP at each frequency and each

time point (each trial n = 44) were individual averaged. Below, data is presented as mean and standard deviation for normal distribution continuous data, as median and range for non-parametric continuous data, and as number and percentage for categorical data. The correlation between the first and second trial of frequency and force in each condition were analyzed by Pearson correlation to explore the repeatability of the physiotherapist. The relationship of MP force and FOA were analyzed by Pearson correlation from average first and second trial data.

## Results

Forty-four participants (10 males and 34 females) were recruited for this study. Their characteristics are presented in table 1. All physiotherapists were right-handed.

**Table 1** Characteristics of participants

| Characteristics | Value |
|---|---|
| Gender: n(%) | |
| Male | 10 (22.7) |
| female | 34 (77.3) |
| Age (year) | 37 (26-59) |
| BMI (kg/m$^2$) | 22.2 (17.1-38.9) |
| Experience in the cardiopulmonary field (year) | 12.5 (1-32) |
| Number of cardiopulmonary patients per week (person/week) | 20 (1-75) |
| Frequency of using the percussion per week (time/week) | 10 (1-50) |

**Note:** Data presented in median (min-max) for continuous data and n (%) in categorical data

The distribution of the mean MP frequency (pool data from both trials, n = 88) is illustrated in figure 2. The results showed that MP's average routine and low frequencies were 5.4 ± 0.6 Hz and 3.9 ± 0.9 Hz, respectively. However, the average highest frequency was 6.5 ± 0.8 Hz. The MP frequency range of human performance was 1.9–9.3 Hz or 114–558 times per minute. The highest frequency attained was 9.3 Hz, which occurred during the 3rd minute of the highest frequency MP. The number of physiotherapists who completed MP for five minutes was 42 (95.5%) for routine frequency, 43 (97.7%) for low frequency, and 36 (81.8%) for the highest frequency. The physiotherapists had an average MP force of approximately five kg for the dominant hand and four kg for the non-dominant hand. The frequency and force of percussion were consistent for five minutes (Table 2).

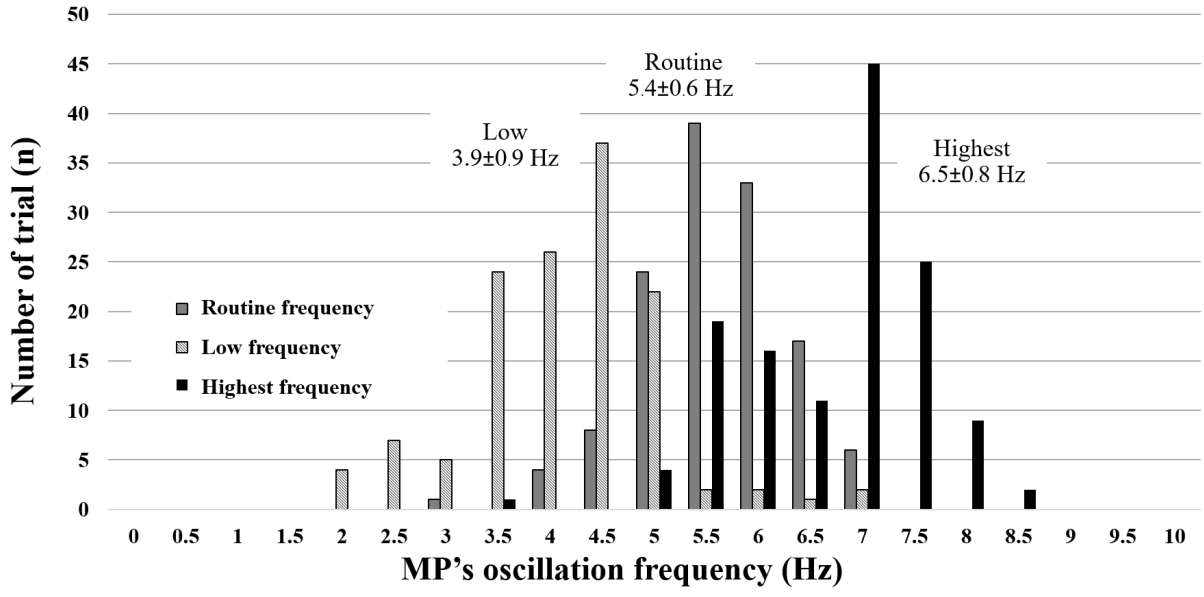


**Figure 2** The distribution of MP frequency (pool data from both trials n = 88). The area of each color represents the number of physiotherapist who performed MP under different conditions.

**Table 2** Frequency, force, and upper limb fatigue of manual percussion on artificial lung model

| Parameters | | Time (min) | | | | | | | | | | Average 5 min | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | 1 | | 2 | | 3 | | 4 | | 5 | | | |
| Number of PT n (%) | R | 44 (100.0) | | 44 (100.0) | | 43 (97.7) | | 42 (95.5) | | 42 (95.5) | | | |
| | L | 44 (100.0) | | 44 (100.0) | | 44 (100.0) | | 43 (97.7) | | 43(97.7) | | | |
| | H | 44 (100.0) | | 43 (97.7) | | 40 (90.9) | | 36 (81.8) | | 36 (81.8) | | | |
| Frequency (Hz) | R | 5.5 ± 0.6 | (3.9 - 6.6) | 5.4 ± 0.6 | (3.8 - 6.5) | 5.4 ± 0.6 | (3.9 - 6.5) | 5.3 ± 0.6 | (4.0 - 6.5) | 5.3 ± 0.6 | (4.0 - 6.5) | 5.4 ± 0.6 | (3.9 - 6.5) |
| | L | 3.8 ± 0.9 | (2.0 - 6.7) | 3.9 ± 0.9 | (1.9 - 6.5) | 3.9 ± 0.9 | (1.9 - 6.6) | 3.9 ± 0.7 | (1.9 - 5.4) | 3.8 ± 1.3 | (1.9 - 5.6) | 3.9 ± 0.9 | (1.9 - 6.6) |
| | H | 6.6 ± 0.8 | (5.1 - 8.0) | 6.5 ± 0.8 | (5.0 - 7.9) | 6.4 ± 0.8 | (2.8 - 9.3) | 6.3 ± 0.9 | (4.8 - 7.9) | 6.4 ± 0.9 | (4.8 - 8.0) | 6.5 ± 0.8 | (5.0 - 7.9) |
| Force D (kg) | R | 5.0 ± 1.2 | (1.6 - 7.2) | 5.1 ± 1.2 | (2.8 - 7.6) | 5.0 ± 1.2 | (2.8 - 7.3) | 5.1 ± 1.3 | (2.8 - 7.9) | 5.1 ± 1.2 | (2.8 - 7.6) | 5.2 ± 1.2 | (2.9 - 7.3) |
| | L | 4.5 ± 1.4 | (2.0 - 8.5) | 4.4 ± 1.4 | (2.4 - 8.2) | 4.4 ± 1.4 | (2.3 - 8.0) | 4.4 ± 1.4 | (2.3 - 7.7) | 4.4 ± 1.3 | (2.3 - 7.9) | 4.4 ± 1.4 | (2.5 - 8.1) |
| | H | 6.0 ± 1.8 | (2.8 - 9.6) | 5.8 ± 1.3 | (3.0 - 9.3) | 5.8 ± 1.7 | (2.8 - 9.3) | 5.7 ± 1.7 | (2.5 - 9.6) | 5.8 ± 1.9 | (2.6 - 10.2) | 5.9 ± 1.8 | (2.7 - 9.6) |
| Force nD (kg) | R | 3.9 ± 1.2 | (1.3 - 7.1) | 3.8 ± 1.1 | (2.1 - 6.1) | 3.8 ± 1.0 | (2.1 - 6.2) | 3.9 ± 1.1 | (2.0 - 6.8) | 3.8 ± 1.2 | (1.9 - 6.8) | 3.8 ± 1.1 | (2.1 - 6.6) |
| | L | 3.5 ± 1.2 | (1.6 - 6.5) | 3.3 ± 1.2 | (1.6 - 6.3) | 3.2 ± 1.1 | (1.7 - 6.3) | 3.3 ± 1.1 | (1.7 - 6.4) | 3.3 ± 1.1 | (1.6 - 6.3) | 3.3 ± 1.1 | (1.7 - 6.3) |
| | H | 4.5 ± 1.4 | (2.5 - 7.8) | 4.2 ± 1.3 | (2.2 - 7.4) | 4.2 ± 1.3 | (2.1 - 7.1) | 4.1 ± 1.4 | (1.9 - 7.2) | 4.2 ± 1.4 | (1.9 - 7.4) | 4.3 ± 1.4 | (2.0 - 7.8) |
| Fatigue score Median (min-max) | R | 0.8 | (0.0 - 3.5) | 1.8 | (0.0 - 6.0) | 3.0 | (0.0 - 7.0) | 3.0 | (0.0 - 6.5) | 3.8 | (0.0 - 8.0) | 2.5 | (0.0 - 5.5) |
| | L | 0.3 | (0.0 - 3.0) | 0.5 | (0.0 - 6.0) | 1.5 | (0.0 - 8.0) | 1.5 | (0.0 - 7.0) | 2.0 | (0.0 - 7.5) | 1.6 | (0.0 - 5.6) |
| | H | 2.0 | (0.0 - 8.5) | 3.0 | (0.0 - 10.0) | 4.3 | (0.0 - 9.5) | 5.0 | (0.5 - 9.0) | 6.0 | (0.5 - 10.0) | 4.1 | (0.2 - 8.5) |

**Note**: Data presented in mean ± SD and (min – max). PT, physiotherapist; R, routine frequency; L, low frequency; H, Highest frequency; D, Dominant hand; nD, non-dominant hand.

The average 5-minute upper body fatigue scores for the routine, low, and highest frequencies were 2.5 (range 0.0 – 5.5), 1.6 (range 0.0 – 5.6), and 4.1 (range 0.2 – 8.5), respectively. Table 2 shows that fatigue scores increased over time. There was very strong repeatability in both low and highest frequency MP (r = 0.86, *p*-value < 0.001, r = 0.90, *p*-value < 0.001, respectively), and moderate repeatability in routine frequency MP (r = 0.69, *p*-value < 0.001). The dominant hand MP force of highest and low frequency was very strong and strong repeatability (r = 0.80, *p*-value < 0.001, r = 0.73, *p*-value < 0.001, respectively), and routine frequency MP showed moderate repeatability (r = 0.57, *p*-value < 0.001). In the same way, the repeatability of non-dominance hand MP force in highest frequency was strong (r = 0.76, *p*-value < 0.001), and the routine and low frequency were moderate (r = 0.57, *p*-value < 0.001, r = 0.61, *p*-value < 0.001, respectively).

The dominant hand's POA values produced by the routine, low, and highest frequencies were 23.8 ± 6.9, 20.4 ± 2.1, and 29.8 ± 10.8 cm $H_2O$, respectively. The non-dominant hand's POA values produced by the routine, low, and highest frequencies were 15.4 ± 5.7, 12.9 ± 5.7, and 18.8 ± 8.0 cm $H_2O$, respectively (Table 3). The FOA values produced by the dominant hand in the routine, low, and highest frequencies were 8.7, 6.9, and 11.7 litres per second, respectively. The FOA values produced by the non-dominant hand in the routine, low, and highest frequencies were 5.1, 4.2, and 6.8 litres per second, respectively. FOA is strongly correlated with MP force of dominance (r = 0.92, *p*-value < 0.001) and non-dominant hand (r = 0.87, *p*-value < 0.001).

**Table 3** Flow and pressure oscillation amplitude of manual percussion on artificial lung model

| Parameters | | Time (min) | | | | | | | | | | Average 5 min | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | | 1 | | 2 | | 3 | | 4 | | 5 | | | |
| Number of PT | R | 44 (100.0) | | 44 (100.0) | | 43 (97.7) | | 42 (95.5) | | 42 (95.5) | | | |
| n (%) | L | 44 (100.0) | | 44 (100.0) | | 44 (100.0) | | 43 (97.7) | | 43(97.7) | | | |
| | H | 44 (100.0) | | 43 (97.7) | | 40 (90.9) | | 36 (81.8) | | 36 (81.8) | | | |
| FOA D | R | 8.5 ± 3.2 | (2.4 - 15.3) | 8.6 ± 3.3 | (3.1 - 19.2) | 8.7 ± 3.4 | (3.6 - 18.2) | 8.8 ± 7.7 | (13.2 - 17.6) | 8.9 ± 3.8 | (3.4 - 19.9) | 8.7 ± 3.4 | (3.4 - 18.6) |
| (l/sec) | L | 7.1 ± 3.6 | (2.4 - 17.0) | 6.9 ± 3.3 | (2.5 - 16.4) | 6.9 ± 3.2 | (2.3 - 16.3) | 6.9 ± 3.2 | (2.4 - 14.6) | 7.0 ± 3.0 | (2.1 - 15.0) | 6.9 ± 3.2 | (2.4 - 15.9) |
| | H | 11.6 ± 5.2 | (4.4 - 24.5) | 11.3 ± 4.9 | (4.0 - 23.9) | 11.7 ± 5.2 | (4.1 - 24.0) | 11.6 ± 5.6 | (4.1 - 23.4) | 11.8 ± 5.9 | (4.3 - 23.8) | 11.7 ± 5.2 | (4.4 - 23.7) |
| FOA nD | R | 5.3 ± 6.4 | (11.6 - 40.4) | 5.1 ± 2.4 | (1.9 - 14.2) | 5.1 ± 2.4 | (2.1 - 13.9) | 5.1 ± 2.4 | (2.2 - 13.0) | 5.2 ± 2.6 | (2.1 - 15.0) | 5.1 ± 2.3 | (2.1 - 13.5) |
| (l/sec) | L | 4.5 ± 2.4 | (1.3 - 11.8) | 4.2 ± 2.2 | (1.3 - 11.0) | 4.0 ±2.1 | (1.3 - 10.6) | 4.2 ± 2.2 | (1.3 - 11.6) | 4.1 ± 2.2 | (1.1 - 11.4) | 4.2 ± 2.1 | (1.3 - 11.1) |
| | H | 7.0 ± 3.5 | (2.9 - 18.0) | 6.4 ± 2.9 | (13.8 - 52.3) | 6.6 ± 3.4 | (2.5 - 17.2) | 6.3 ± 3.0 | (2.2 - 12.1) | 6.5 ± 3.6 | (2.2 - 17.5) | 6.8 ± 3.4 | (2.5 - 15.5) |
| POA D | R | 23.8 ± 6.4 | (11.6 - 40.4) | 23.9 ± 7.4 | (11.7 - 46.3) | 23.8 ± 7.0 | (13.8 - 41.5) | 23.5 ± 7.7 | (13.2 - 47.6) | 24.0 ± 8.0 | (12.2 - 46.6) | 23.8 ± 6.9 | (14.0 - 43.6) |
| (cm $H_2O$) | L | 20.7 ± 8.9 | (6.7 - 46.7) | 20.3 ± 8.6 | (7.8 - 45.1) | 20.6 ± 8.5 | (8.0 - 46.3) | 20.1 ± 7.9 | (7.9 - 39.4) | 20.5 ± 7.8 | (7.4 - 40.6) | 20.4 ± 2.1 | (1.3 - 11.1) |
| | H | 29.9 ± 10.7 | (14.0 - 48.8) | 28.8 ± 10.1 | (13.2 - 52.3) | 29.1 ± 10.3 | (13.8 - 49.8) | 29.0 ± 11.1 | (12.6 - 53.0) | 29.3 ± 12.6 | (12.9 - 60.9) | 29.8 ± 10.8 | (14.3 - 52.9) |
| POA nD | R | 16.2 ± 5.9 | (8.3 - 37.9) | 15.2 ± 5.8 | (1.9 - 14.2) | 15.2 ± 5.8 | (5.4 - 32.9) | 15.4 ± 6.0 | (7.7 - 36.3) | 15.3 ± 6.3 | (7.6 - 36.0) | 15.3 ± 5.7 | (7.8 - 34.5) |
| (cm $H_2O$) | L | 13.8 ± 6.0 | (4.7 - 30.7) | 13.0 ± 5.8 | (4.6 - 28.9) | 12.5 ± 5.7 | (4.4 - 26.6) | 12.9 ± 5.8 | (4.7 - 27.4) | 12.8 ± 6.1 | (3.9 - 30.4) | 12.9 ± 5.7 | (4.5 - 27.8) |
| | H | 19.7 ± 8.4 | (9.5 - 46.3) | 17.9 ± 7.1 | (7.9 - 40.3) | 17.7 ± 7.9 | (8.7 - 49.4) | 17.7 ± 6.8 | (7.7 - 36.5) | 17.7 ± 7.6 | (6.2 - 34.1) | 18.8 ± 8.0 | (8.3 - 41.2) |

**Note**: Data presented in mean ± SD and (min - max). PT, physiotherapist; R, routine frequency; L, low frequency; H, Highest frequency; D, Dominant hand; nD, non-dominant hand; FOA, Flow oscillation amplitude; POA, Pressure oscillation amplitude

## Discussion

Our study investigated the frequency and force of the current routine MP in clinical practice. We expanded the survey in low-frequency MP, which is found in clinical use, and extended measurements to the highest frequencies, which the physiotherapist can achieve. Moreover, this study is the first to report the possible treatment duration based on the fatigue score, the repeatability of frequency and force of MP from two trials, and the association between MP force and FOA.

In this study, we found that Thai physiotherapists' routine frequency and force of MP were 5.4 ± 0.6 Hz and 5.2 ± 1.2 kg, respectively. These results differed from those of Blazey et al[7]. They found that Australian physiotherapists' average MP frequency was 6.60 ± 1.00 Hz[7]. In contrast, our results regarding force of MP are close to 58.1 ± 15.3 Newton (5.93 ± 1.56 kg) from Blezey's study[7]. Wong et al[2] found that physiotherapists used a frequency of 6.2 ± 0.9Hz; however, their study used esophagus pressure to represent the percussion force and, therefore, cannot be compared to the present study. A survey by Flower et al[6] reported that physiotherapist MP was around 250 – 480 beats per minute (4.2 – 8.0 Hz); furthermore, they measured the percussion force around 58 – 65 Newtons (5.92 – 6.63 kg) which is similar to the measurement in this study.

In this study, the average highest MP frequency was around 6.5 ± 0.8 Hz (range 1.9 – 9.3 Hz or 114 – 558 times per minute) for maximum performance. The results showed the highest frequency at 9.3 Hz, which occurred during the 3rd minute of the highest frequency MP (Table 2); this was similar to the highest frequency MP in previous studies, 8.0 Hz[6] and 8.47 Hz[7]. However, the maximum MP frequency (9.3 Hz) from this study is beyond the range in which mucus viscosity is improved (12–13 Hz)[25]. Consequently, FOA, characterized as an expiratory flow bias, may be a possible primary clearance mechanism of MP.

In theory, high frequency should provide more benefits, such as changing viscoelasticity or assisting cilia function. Tomkiewicz et al[25] used mucus gel stimulation in an artificial tube. They applied oscillation airflow using high-frequency chest wall oscillation devices (12–13, 22-23 Hz), and they reported that airflow oscillation could decrease the viscosity and spinnability of mucus[25]. Although the MP frequency in our survey did not reach the theoretical model's viscoelasticity effect, greater frequency of MP appeared to have a better benefit for mucus clearing. King and colleagues[27] showed that 5, 8, and 13 Hz of high-frequency chest wall oscillation could improve tracheal mucus clearance (peak improvement at 13 Hz). However, some physiotherapists performing MP at a higher frequency might provide more forceful percussion. Therefore, if the physiotherapist performed high frequency of MP, we advised that the patient should be constantly monitored and that extra towels should be used to avoid complications from unintentional excessive force of MP.

In clinical practice, physiotherapists perform MP for various durations, depending on each patient's clinical status and each physiotherapist's performance characteristics. Some textbooks recommend using MP for 3 – 5 minutes per area[13,14]. This study found that the upper body fatigue scores increased over time. Physiotherapists applying low or routine frequencies were under moderate fatigue after five minutes, whereas physiotherapists applying the highest frequency sometimes experienced fatigue beyond the moderate level. Our results showed that the physiotherapist could percuss consistently in frequency and force for five minutes (Table 2). Based on the above information, we suggest an MP duration of 3 – 5 minutes per area in the routine, low, and highest frequencies for the comfort of the physiotherapist. Our recommendation concurs with the textbook recommendation[11-14]; however, more evidence is needed to confirm the effectiveness of this duration.

This study demonstrates that low and highest conditions have superior repeatability in frequency and force than the routine condition, which has moderate repeatability at both. This result represents that each physiotherapist routinely performed MP with a variety of frequencies

and forces. Physiotherapists perform more consistently when given a certain condition, such as performing low or highest frequency. It could be referring to the absence of MP protocol standards in current usage.

Oscillation amplitude represents the magnitude of changing a variable (highest peak to lowest peak) in each oscillation during the oscillation system[28]. Our results prove that force of MP is directly related to FOA. In this article, we demonstrate that the dominant hand is able to generate a greater MP force than the non-dominant hand because the dominant hand had a marginally higher muscle strength[29]. Therefore, the dominating hand with more force can provide a larger rate of expiratory flow. However, this result should be interpreted with caution because our artificial lung may lack some force-absorbing factor, such as the musculoskeleton, the distance between the chest wall and lung, or pleura.

The recruitment of participants in our study was limited to Thai physiotherapists. We used MP on an artificial lung that could have a deviation in airflow and pressure from the human subjects. The artificial lung constituted a limitation as it could not replicate a natural breathing pattern (i.e., inhalation and exhalation) because the changing pressure would automatically cycle the inspiration and the lung would rapidly deflate.

## Conclusion

The routine, low, and highest frequencies were 5.40 ± 0.62 Hz, 3.91 ± 0.86 Hz, and 6.49 ± 0.81 Hz, respectively. The force in the dominant hand at the routine, low, and highest frequencies was 5.23 ± 1.18 kg, 4.40 ± 1.35 kg, and 5.88 ± 1.78 kg, respectively. Based on the fatigue scores, we recommend an MP duration of 3 – 5 minutes in the routine, low, and highest frequencies. The physiotherapist routinely applied frequency and force of MP with moderate repeatability, but when they changed to the highest frequency, the repeatability for frequency and force was strong to very strong.

### Take home messages

We report a current routine frequency of 5 – 6 Hz with a percussion force of 3 – 5 kg of manual chest wall percussion. The highest frequency is around 6 – 7 Hz. Based on upper body fatigue scores, it is possible to apply 3 – 5 minutes per session in clinical practice.

## Conflicts of interest

The authors declared no conflict of interest.

## Acknowledgments

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ORIGINAL ARTICLE

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# Effect of a certain designed progressive shoulder exercise after breast cancer surgery on shoulder movement, seroma, pain, and satisfaction: a randomized controlled trial

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**KEYWORDS**
Breast cancer;
Arm function;
Satisfaction;
Seroma;
Shoulder exercise.

**ABSTRACT**

A free shoulder exercise for individuals after breast cancer surgery has been used in a hospital. The exercise has no warm-up and cool-down and research evidence. The exercise should be adjusted to a certain designed progressive shoulder exercise that was expected to use instead of the previous one. The study aimed to compare the effect of the certain designed progressive with the free shoulder exercise on shoulder range of motion, shoulder and arm function, net amount of seroma, pain, and overall satisfaction. Sixty (n = 60) individuals after breast cancer surgery were randomized to the free (n = 30) and certain designed progressive shoulder exercise group (n = 30). Both groups exercised by themselves using booklet and video. The free shoulder exercise group chose and did exercise as they preferred, whereas the certain designed progressive shoulder exercise group followed the exercise as described. Both groups were assessed for active and passive shoulder range of motion in all directions, shoulder and arm function, total seroma excretion, pain, and overall satisfaction. The certain designed progressive shoulder exercise showed similar outcomes to the free shoulder exercise, except less active (*p*-value = 0.014) and passive (*p*-value = 0.012) shoulder flexion range on day 3 after surgery. The certain designed progressive shoulder exercise was inferior to the free shoulder exercise on shoulder flexion range on day 3 after surgery. However, its final effect was comparable to the free shoulder exercise. The certain designed progressive shoulder exercise is suggested to be a shoulder exercise after breast cancer surgery since it demonstrates a particular exercise poses and frequency and no pain after exercise.

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## Introduction

Breast cancer is the most worldwide common cancer found in females[1]. Generally, treatment is surgery probably with lymph nodes dissection[2] that may be associated with short- and long-term unexpected effects in several patients[3]. The complications include hematoma, wound infection, seromas, pain, numbness, shoulder range of motion limitation, and lymphedema[4]. Shoulder exercise can reduce pain, increase shoulder range of motion, decrease activity of daily living impairments, avoid seroma formation, and increase volume of wound drainage[5,6]. There are several shoulder exercise programs; however, the suitable technique and content of programs still need further investigation[6].

Shoulder exercise program can be active or passive exercise[6], or free or restricted amplitude active exercise[7,8]. The free and restricted shoulder range of motion exercise demonstrate similar shoulder range of motion, pain, and upper limb function[8], and prevalence of seroma[7,8]. In 2012 at a university hospital in Thailand a free amplitude active shoulder exercise was designed for individuals after breast cancer surgery and has been continuously used for the patients without supporting evidence by any research. The disadvantage of the exercise is no warm-up and cool-down that can reduce vicious resistance of muscles and joints[9], lactic acid accumulation, pain and muscle soreness[10]. Additionally, subjectively observed individuals with complication after breast cancer surgery such as hematoma and wound pain did less and avoided exercise, and did not use arm (Private Patient Division, Siriraj Hospital, unpublished data, February 2015). Therefore, the program needs improvement. By collaboration between a nurse and a physical therapist, a certain designed progressive active shoulder exercise consisting of warm-up and cool-down, and a main active shoulder exercise was raised and expected to be a choice for individuals after breast cancer surgery. Moreover, individuals after breast cancer surgery still need certain shoulder exercise at home after discharge from hospital to reduce pain and promote shoulder range of motion[11]. Therefore, the objective of the study was to compare a certain designed progressive shoulder exercise with a free active shoulder exercise in individuals after breast cancer surgery on shoulder range of motion, shoulder and arm function, seroma drainage, pain, and satisfaction of the exercise and health professions.

## Materials and methods

The study was approved by the faculty ethic committee (COA No. Si 437/2017) and registered for clinical trial (TCTR20210427001). Participants were informed about the study and signed written informed consent prior to participation.

### *Participants*

The sample size calculation was based on two independent means formula on shoulder abduction at day 3 after breast cancer surgery[12] that the mean difference was 14.4 with a ratio of the two sample sizes = 1, a type II error probability = 0.200, and level of significance = 0.05. A sample size with dropout 15% was 54. Therefore, 27 subjects were in each group. The faculty ethic committee approved to collect 30 subjects in each group, totally 60 participants in the study.

Sixty individuals with breast cancer (n = 60) receiving breast surgery including armpit lymph node removal participated in the study. They were recruited from a Private Patient Division of a university hospital and randomly assigned to the free shoulder exercise (n = 30) and certain designed progressive shoulder exercise group (n = 30). The inclusion criteria were 1) receiving mastectomy or wide excision of breast surgery, 2) removing lymph nodes in the armpit including sentinel lymph node biopsy or axillary lymph node on the same side of breast surgery, 3) able to communicate in Thai, 4) able to move shoulder in all directions before surgery, 5) normal shoulder range of motion before surgery[13], 6) no history of frozen shoulder, and 7) no history of shoulder surgery. The exclusion criteria were 1) diagnosed diabetes mellitus, 2) diagnosed arteriosclerosis, 3) receiving both breast surgery or breast augmentation surgery, 4) receiving radiation after breast surgery, 5) having wound infection after

surgery, and 6) retaining Redovac drain until follow-up.

***Procedures***

The study was single-blind randomized controlled trial using the sealed envelope method. A researcher drew lots for participants that the number 1 was the free shoulder exercise group and the 2 was the certain designed progressive exercise group. On the day of admission, participants received a booklet to read and a compact disc to watch the video that contained the same information of breast cancer and surgery methods and the free or the certain designed progressive shoulder exercise. Nurses on the duty explained surgery methods and its consequences, and the exercises, and also asked participants to perform the exercises to ensure that they did correctly. Participants used the booklet and the compact disc to do exercise by themselves.

Research assistances who were nurses working in the ward were blinded to the data collection. They extracted age, weight, side of breast surgery, dominant hand and the side of breast surgery, surgical method and amount of lymph node dissection, tumor size, and length of hospitalization from medical files. The length of stay in hospital was usually about five days after surgery. Participants could be discharged from hospital if they no longer needed inpatient care and could go home. Therefore, research assistances assessed the following outcomes during participants staying in the hospital and at follow-up (day 14 after surgery). Active and passive shoulder range of motion in flexion, extension, abduction, adduction, and internal and external rotation were examined on day 0 (before surgery), and day 3 and 5, and 14 after surgery by using goniometer[13]. Shoulder and arm function[14] was evaluated before surgery and at follow-up. Total seroma excretion was assessed at 6.00 am every day after surgery during staying in the hospital and at follow-up.

Additionally, participants assessed pain on every session before and after shoulder exercise using numerical rating scale[15] and evaluated satisfaction of exercise program and advice of health professions at follow-up using a developed questionnaire.

***Interventions***

*Free shoulder exercise*

The free shoulder exercise (Figure 1) was a routinely exercise in real situation in a hospital composing of seven shoulder exercises; 1) arm forward lifting, 2) shoulder abduction, 3) wall shoulder side lift, 4) wall shoulder flexion, 5) shoulder extension, 6) shoulder circles, and 7) elbow push back. Participants were free to choose exercise poses and frequency of exercise. The period of exercise was from day 1-14 after surgery. Each exercise was performed 5-10 times, 3-4 sessions/day and done limited by pain. During staying in the hospital and at follow-up nurses asked participants whether they did exercise and how often.

*Progressive shoulder exercise*

The progressive shoulder exercise (Figure 2) consisted of 2 warm-up and cool-down and main exercises. The warm-up and cool-down exercises were shoulder shrugs and shoulder circles. The three main exercises on day 1-3 after surgery were 1) shoulder flexion and abduction with elbow flexion, 2) elbow pushback, and 3) body twist with shoulder abduction. On the first day after surgery the flexion and abduction of the shoulder were limited at maximum 90 degrees[8]. On day 2 and 3 after surgery the range of motion were gradually increased and limited by pain. From day 4 after surgery until follow-up, participants still performed those three exercises together with the other three main exercises limited by pain that were 1) wall shoulder flexion, 2) wall shoulder abduction, and 3) towel shoulder internal rotation. Participants started the exercises on day 1 after surgery until follow-up, 5 times/exercise, 3 sessions/day. They could contact physical therapist if they requested. Participants received a logbook to record exercise and submitted to nurses on the follow-up day.

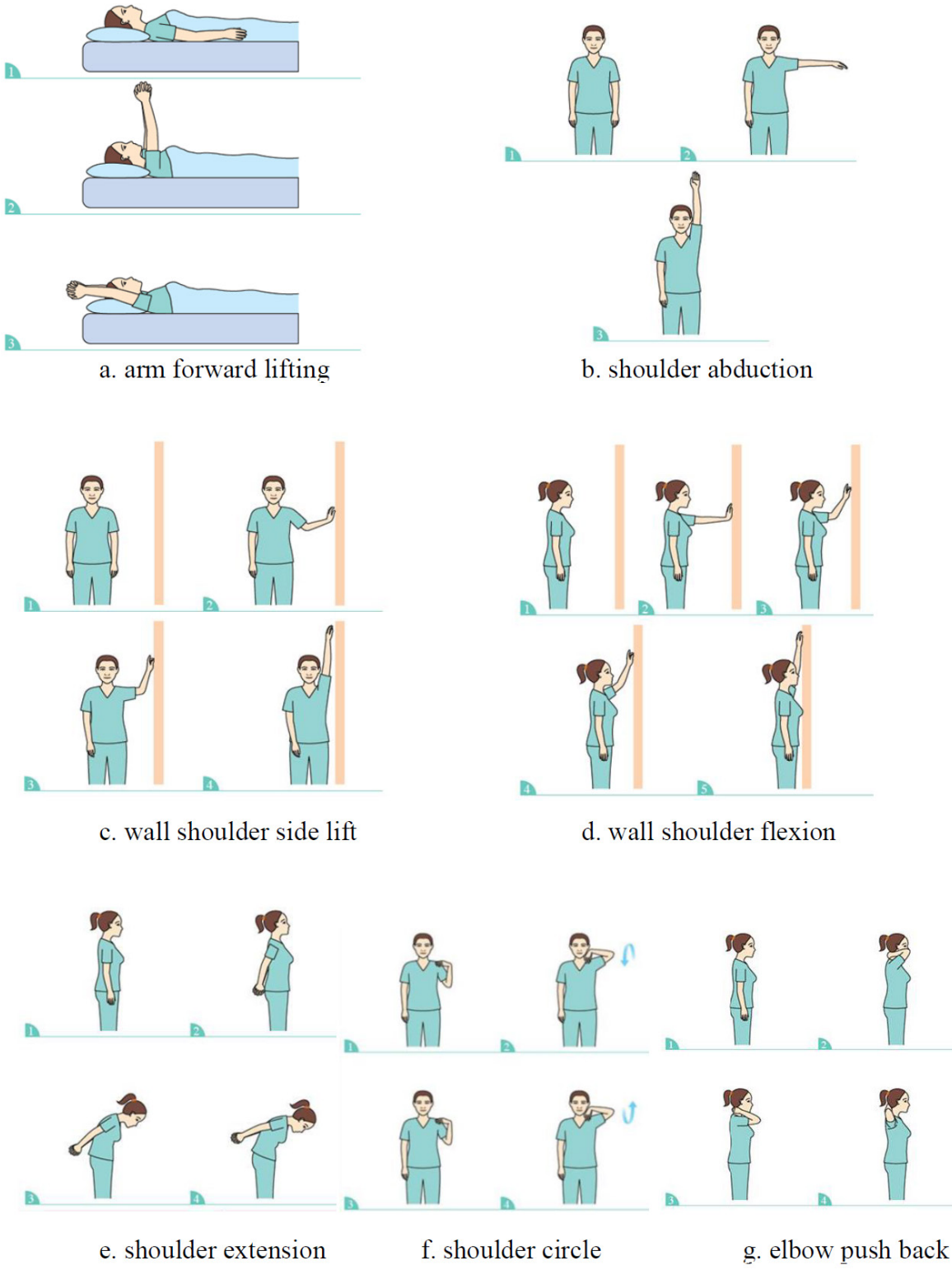


**Figure 1** Free shoulder exercise: a. arm forward lifting, b. shoulder abduction, c. wall shoulder side lift, d. wall shoulder flexion, e. shoulder extension, f. shoulder circle, g. elbow push back


a. booklet b. video

**Figure 2** A certain designed progressive shoulder exercise. Please scan QR code: a. booklet, b. video

***Outcome measures***

*Shoulder range of motion*

Active and passive shoulder range of motion in flexion, extension, abduction, adduction, and internal and external rotation was assessed by a universal goniometer[13]. A physical therapist trained research assistances to use universal goniometer. The inter-and intra-rater reliability were good and excellent[16]. The inter-rater reliability was 0.721 (95%CI = -0.379 – 1.000), 0.700 (95%CI = -0.647 – 1.000), 0.816 (95%CI = 0.005 – 1.000) 0.833 (95%CI = 0.151 – 1.000), 0.764 (95%CI = -0.378 – 1.000), 0.866 (95%CI = 0.383 – 1.000) for shoulder flexion, extension, abduction, adduction, and internal and external rotation, respectively. The intra-rater reliability was 0.989 (95%CI = -0.949 – 0.997), 0.857 (95%CI = -0.366 – 0.968), 0.919 (95%CI = 0.640 – 0.982), 0.865 (95%CI=0.399 – 0.969), 0.981 (95%CI = -0.914 – 0.996), 0.977 (95%CI = 0.896 – 0.995) for shoulder flexion, extension, abduction, adduction, and internal and external rotation, respectively.

*Shoulder and arm function*

Shoulder and arm function[14] was rated on 5-point scale; 0 = unable to perform, 1 = severe difficulty, 2 = moderate difficulty, 3 = mild difficulty, and 4 = no difficulty. The activities were 1) brush and comb hair on the same side of the breast operation, 2) pull a T-shirt/blouse that does not unbutton or tight necked sweater over your head, 3) put on a pair of pants or pantyhose and pull them up, 4) close a back-fastening bra, 5) completely zip up a dress with a back-fastening zipper, 6) wash the upper part of your back on the same side of the breast surgery, 7) wash the upper part of your back on the opposite side of the breast surgery, 8) reach into a cupboard over your head on the same side of the operation, 9) make a double bed, 10) carry an approximately 2-kg grocery bag on the same side of the operation. Each item score was summed to the total score.

*Total seroma excretion*

During staying in the hospital, the seroma excretion in milliliter (ml) was read and recorded from a vacuum drain bottle every morning at 6.00am. At follow-up a needle with syringe was used to draw the seroma. The amount of liquid was read from the syringe and recorded in ml. The total seroma was the summation of the seroma excretion during in the hospital and at the follow-up.

*Pain*

Numerical rating scale[15] ranged from 0 (no pain) to 10 (the worst pain) was rated by

participants before and after exercise session. The score of before as well as after exercise session was averaged. The pain score difference was calculated by the score at before minus after the exercise.

*Satisfaction of exercise program, nurses, and physical therapists*

A questionnaire of satisfaction was developed by a researcher using 5-point scale; 1 = very dissatisfied, 2 = dissatisfied, 3 = neither satisfied nor dissatisfied, 4 = satisfied, and 5 = very satisfied. The questions were 1) easy program to recognize, understand and can follow immediately, 2) clear pictures and contents, 3) able to ask questions and interact with nurses, 4) able to ask questions and interact with physical therapists, 5) good advice and information from nurses, 6) good advice and information from physical therapists, 7) friendly and supportive nurses, 8) friendly and supportive physical therapists, and 9) overall, satisfaction with the exercise program.

***Statistical analysis***

The SPSS version 23 was used for statistical analyses. Kolmogorov–Smirnov test determined data normal distribution. Two-way mixed model ANOVA adjusted with day 0, dominant hand on the side of breast surgery, surgical methods, and lymph node dissection was conducted to analyze shoulder range of motion on day 0, and day 3, 5, and 14 after surgery between groups. Independent t-test or Mann-Whitney U test, as appropriately, was conducted to compare demographic data, shoulder and arm function, total seroma excretion, pain, and satisfaction between groups. No intention-to-treat was done in statistical analysis. The significance value was set at less than 0.05.

## Results

***Participants***

Sixty participants (n = 60) were recruited and randomized to the free (n = 30) and certain designed progressive shoulder exercise groups (n = 30). On day 4 after surgery 17 participants in the free shoulder exercise group and 20 in the certain designed progressive group were discharged from the hospital. Thus, on day 5 after surgery there were 13 in the free and 10 in the certain designed progressive group. All participants came to follow-up (Figure 3). The characteristics of participants are shown in table 1.

***Shoulder range of motion***

There was no difference in active or passive shoulder range of motion in flexion, extension, abduction, adduction, and internal and external rotation before, day 3, 5, and 14 after surgery between groups, except active and passive shoulder flexion on day 3 after surgery (Table 2). No difference between before, day 3, 5, and 14 after surgery within groups was observed in all shoulder directions.

***Shoulder and arm function***

There was no difference in shoulder and arm function between groups before surgery and follow-up (Table 3).

***Total seroma excretion***

No difference in the total seroma [median (Q1, Q3) (min-max)] between the free [220 (143, 428) (0-710)] and certain designed progressive [220 (143, 428) (0-3800] shoulder exercise group was observed (*p*-value = 0.734). A participant in the certain designed progressive shoulder exercise group drained the highest amount of seroma that was 3,800 ml.

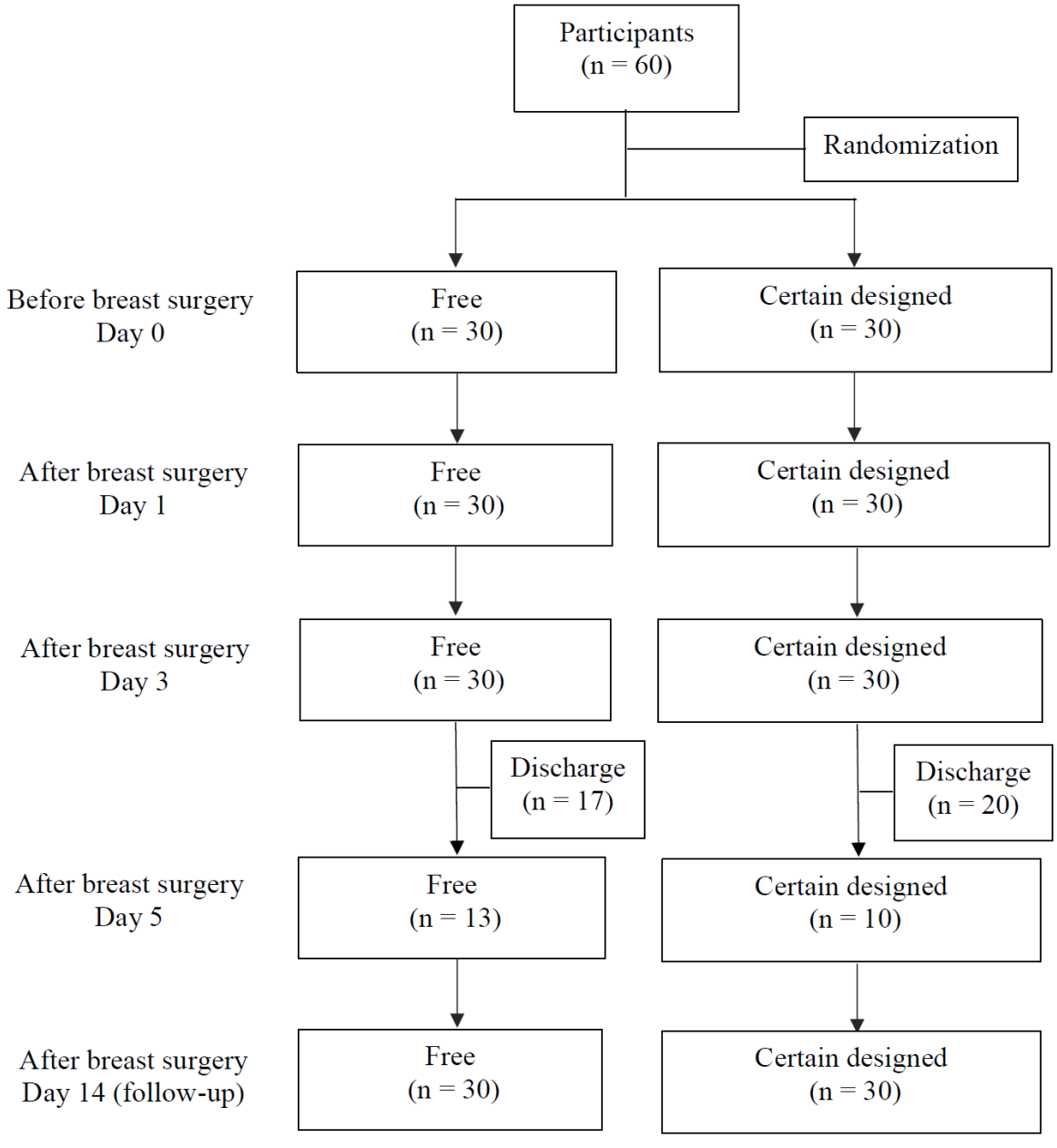


**Figure 3** Number of participants in the free and certain designed progressive shoulder exercise groups.

**Table 1** Characteristics of participants in the free and certain designed progressive shoulder exercise groups

| | Shoulder exercise | | *p*-value |
|---|---|---|---|
| | **Free (n = 30)** | **Certain designed (n = 30)** | |
| **Age (years)** [mean ± SD (min – max)] | 54.3 ± 10.5 (34 – 75) | 54.9 ± 9.1 (37 – 69) | 0.803 |
| **Body mass index (kg/m²)** [mean ± SD (min – max)] | 23.7 ± 4.3 (17.0 – 34.2) | 23.2 ± 3.7 (18.1 – 31.3) | 0.614 |
| **Side of breast surgery [n, (%)]** | | | |
| Left | 18 (60.0) | 16 (53.3) | 0.602 |
| Right | 12 (40.0) | 14 (46.7) | |
| **Dominant hand on the side of breast surgery [n, (%)]** | | | |
| Same side | 10 (33.3) | 16 (53.3) | |
| Opposite side | 20 (66.7) | 14 (46.7) | 0.118 |
| **Surgical method [n, (%)]** | | | |
| Total mastectomy | 24 (80.0) | 22 (73.3) | 0.076 |
| Modified radical mastectomy | 3 (10.0) | 8 (26.7) | |
| Wide excision | 3 (10.0) | 0 (0.0) | |
| **Lymph node dissection [n, (%)]** | | | |
| Sentinel lymph node biopsy | 17 (56.7) | 17 (56.7) | 0.953 |
| Axillary lymph node dissection | 6 (20.0) | 7 (23.3) | |
| Both | 7 (23.3) | 6 (20.0) | |
| **Total lymph node dissection (lymph nodes)** [median (Q1, Q3)] (min – max) | 4 (2, 12) (0 – 23) | 4 (2, 12) (1 – 30) | 0.893 |
| **Tumor size (cm)** [median (Q1, Q3)] (min – max) | 2.3 (1.7, 3.1) (0.5 – 6.0) | 2.1 (1.2, 4.0) (0.5 – 9.5) | 0.807 |
| **Length hospitalization (day)** [median (Q1, Q3)] (min – max) | 5.0 (4.0, 6.0) (2 – 9) | 5.0 (3.8, 5.3) (3 – 7) | 0.677 |

**Table 2** Active and passive shoulder range of motion in flexion, extension, abduction, adduction, and internal and external rotation in the free and certain designed progressive shoulder exercise groups before surgery (both groups; n = 30) and on day 3 (both groups; n = 30), 5 (free shoulder exercise; n = 30, certain designed progressive shoulder exercise; n = 10) and 14 after surgery (both groups; n = 30).

| | Active range of motion (degree, mean ± SD) | | *p*-value | Estimate ± SE | Passive range of motion (degree, mean ± SD) | | *p*-value | Estimate ± SE |
|---|---|---|---|---|---|---|---|---|
| | Free | Certain designed | | | Free | Certain designed | | |
| **Flexion (degree)** | | | | | | | | |
| Before surgery | 177.3 ± 3.9 | 179.3 ± 2.5 | 0.080 | 0.003 ± 0.45 | 180.0 ± 0.0 | 180.0 ± 0.0 | 1.000 | NA |
| Day 3 | 159.2 ± 12.1 | 146.0 ± 26.2* | 0.014 | 13.7 ± 5.10 | 166.3 ± 11.1 | 153.5 ± 26.1* | 0.012 | 13.5 ± 4.90 |
| Day 5 | 165.8 ± 10.8 | 163.5 ± 17.3 | 0.505 | 4.32 ± 6.36 | 171.5 ± 9.4 | 170.5 ± 11.7 | 0.590 | 3.27 ± 5.98 |
| Day 14 | 167.3 ± 9.7 | 164.8 ± 15.8 | 0.422 | 3.02 ± 3.69 | 174.0 ± 8.0 | 170.3 ± 15.1 | 0.206 | 4.30 ± 3.30 |
| **Extension (degree)** | | | | | | | | |
| Before surgery | 50.0 ± 0.0 | 50.0 ± 0.0 | 1.000 | NA | 50.0 ± 0.0 | 50.0 ± 0.0 | 1.000 | NA |
| Day 3 | 49.7 ± 1.8 | 48.8 ± 3.1 | 0.322 | 0.70 ± 0.70 | 50.0 ± 0.0 | 49.2 ± 2.7 | 0.050 | 0.85 ± 0.43 |
| Day 5 | 50.0 ± 0.0 | 49.7 ± 1.8 | 0.829 | 0.21 ± 0.95 | 50.0 ± 0.0 | 49.4 ± 2.5 | 0.245 | 0.63 ± 0.54 |
| Day 14 | 50.0 ± 0.0 | 48.8 ± 4.1 | 0.145 | 1.04 ± 0.70 | 50.0 ± 0.0 | 49.5 ± 2.0 | 0.231 | 0.52 ± 0.43 |
| **Abduction (degree)** | | | | | | | | |
| Before surgery | 175.5 ± 11.1 | 179.2 ± 2.7 | 0.087 | 0.37 ± 0.40 | 178.0 ± 8.1 | 180.0 ± 0.0 | 1.154 | 0.33 ± 0.51 |
| Day 3 | 137.1 ± 28.0 | 126.6 ± 31.5 | 0.187 | 11.1 ± 8.15 | 145.9 ± 27.1 | 134.3 ± 30.7 | 0.136 | 12.1 ± 7.83 |
| Day 5 | 142.3 ± 32.2 | 154.0 ± 39.5 | 0.661 | -5.26 ± 11.8 | 148.1 ± 29.0 | 158.5 ± 34.2 | 0.675 | -4.75 ± 11.2 |
| Day 14 | 158.2 ± 25.6 | 156.3 ± 27.5 | 0.752 | 2.50 ± 7.79 | 164.8 ± 23.5 | 163.5 ± 24.1 | 0.786 | 1.91 ± 6.93 |
| **Adduction (degree)** | | | | | | | | |
| Before surgery | 39.7 ± 1.8 | 39.7 ± 1.3 | 0.584 | 0.41 ± 0.18 | 40.0 ± 0.0 | 40.0 ± 0.0 | 1.000 | NA |
| Day 3 | 37.7 ± 6.8 | 37.0 ± 6.9 | 0.670 | 0.72 ± 1.85 | 38.0 ± 6.6 | 37.8 ± 6.1 | 0.865 | 0.28 ± 1.61 |
| Day 5 | 37.7 ± 8.3 | 38.0 ± 6.3 | 0.472 | 1.62 ± 2.21 | 38.1 ± 6.9 | 39.5 ± 1.6 | 0.731 | 0.53 ± 1.83 |
| Day 14 | 39.2 ± 3.2 | 39.7 ± 1.8 | 0.548 | -0.44 ± 0.72 | 39.8 ± 1.7 | 39.7 ± 1.8 | 0.829 | 0.11 ± 0.51 |
| **Internal rotation (degree)** | | | | | | | | |
| Before surgery | 88.5 ± 7.3 | 88.5 ± 4.5 | 1.000 | 0.72 ± 0.02 | 89.0 ± 5.5 | 89.0 ± 5.5 | 1.000 | 0.90 ± 0.05 |
| Day 3 | 87.7 ± 6.3 | 87.2 ± 6.9 | 0.617 | 0.66 ± 1.31 | 88.3 ± 5.9 | 88.2 ± 4.6 | 0.757 | 0.28 ± 0.90 |
| Day 5 | 89.6 ± 1.4 | 89.0 ± 3.2 | 0.776 | -0.47 ± 1.63 | 89.8 ± 1.2 | 90.0 ± 0.0 | 0.282 | -1.38 ± 1.27 |
| Day 14 | 89.0 ± 5.5 | 89.3 ± 2.5 | 0.769 | -0.17 ± 0.57 | 89.0 ± 5.5 | 90.0 ± 0.0 | 0.324 | -0.90 ± 0.90 |
| **External rotation (degree)** | | | | | | | | |
| Before surgery | 89.5 ± 2.0 | 87.7 ± 6.8 | 0.349 | 0.33 ± 0.30 | 90.0 ± 0.0 | 88.3 ± 5.9 | 0.078 | -0.09 ± 0.29 |
| Day 3 | 79.5 ± 15.3 | 80.3 ± 15.4 | 0.947 | 0.27 ± 4.05 | 81.8 ± 13.9 | 83.2 ± 13.6 | 0.963 | 0.17 ± 3.59 |
| Day 5 | 82.7 ± 12.4 | 83.0 ± 18.9 | 0.923 | -0.45 ± 4.54 | 86.5 ± 6.9 | 85.0 ± 15.8 | 0.885 | 0.64 ± 4.39 |
| Day 14 | 83.8 ± 14.5 | 82.8 ± 12.8 | 0.769 | 1.10 ± 3.71 | 85.3 ± 12.2 | 83.9 ± 9.6 | 0.622 | 1.50 ± 2.94 |

**Note:** *Significantly (*p*-value < 0.05) lower than the free shoulder exercise; NA, not applicable.

**Table 3** Shoulder and arm function before surgery and follow-up in the free and certain designed progressive shoulder exercise groups

| Shoulder and arm function | Before surgery Median (Q1, Q3) (min - max) (n) | | *p*-value | Follow-up Median (Q1, Q3) (min - max) (n) | | *p*-value |
|---|---|---|---|---|---|---|
| | Free | Certain designed | | Free | Certain designed | |
| **Brush and comb your hair on the same side of the operation** | | | | | | |
| | 4 (4,4) (3 – 4) (n = 30) | 4 (4,4) (4 – 4) (n = 30) | 0.129 | 4 (4,4) (3 – 4) (n = 30) | 4 (4,4) (3 – 4) (n = 30) | 0.220 |
| **Pull a T-shirt, blouse that does not unbutton or tight necked sweater over your head** | | | | | | |
| | 4 (4,4) (3 – 4) (n = 30) | 4 (4,4) (4 – 4) (n = 30) | 0.129 | 4 (4,4) (2 – 4) (n = 27) | 4 (4,4) (3 – 4) (n = 29) | 0.384 |
| **Put on a pair of pants or pantyhose and pull them up** | | | | | | |
| | 4 (4,4) (3 – 4) (n = 30) | 4 (4,4) (4 – 4) (n = 30) | 0.129 | 4 (4,4) (3 – 4) (n = 30) | 4 (4,4) (4 – 4) (n = 30) | 0.181 |
| **Close a back-fastening bra** | | | | | | |
| | 4 (4,4) (0 – 4) (n = 27) | 4 (4,4) (4 – 4) (n = 30) | 0.544 | 4 (4,4) (0 – 4) (n = 22) | 4 (4,4) (3 – 4) (n = 25) | 0.832 |
| **Completely zip up a dress with a back-fastening zipper** | | | | | | |
| | 4 (4,4) (3 – 4) (n = 30) | 4 (4,4) (4 – 4) (n = 30) | 0.181 | 4 (4,4) (0 – 4) (n = 30) | 4 (4,4) (3 – 4) (n = 23) | 0.654 |
| **Wash the upper part of your back, i.e., shoulder-blade area on the same side of the operation (ipsilateral scapula)** | | | | | | |
| | 4 (4,4) (3 – 4) (n = 30) | 4 (4,4) (3 – 4) (n = 30) | 0.181 | 4 (4,4) (1 – 4) (n = 28) | 4 (4,4) (3 – 4) (n = 25) | 0.467 |
| **Wash the upper part of your back, i.e., shoulder-blade area, on the opposite side of the operation (contralateral scapula)** | | | | | | |
| | 4 (4,4) (1 – 4) (n = 30) | 4 (4,4) (4 – 4) (n = 30) | 0.490 | 4 (4,4) (1 – 4) (n = 28) | 4 (4,4) (3 – 4) (n = 28) | 0.738 |
| **Reach into a cupboard over your head, on the same side of the operation** | | | | | | |
| | 4 (4,4) (3 – 4) (n = 30) | 4 (4,4) (3 – 4) (n = 30) | 0.181 | 4 (4,4) (3 – 4) (n = 29) | 4 (4,4) (1 – 4) (n = 30) | 0.589 |

**Table 3** Shoulder and arm function before surgery and follow-up in the free and certain designed progressive shoulder exercise groups (cont.)

| Shoulder and arm function | Before surgery Median (Q1, Q3) (min - max) (n) | | *p*-value | Follow-up Median (Q1, Q3) (min - max) (n) | | *p*-value |
|---|---|---|---|---|---|---|
| | Free | Certain designed | | Free | Certain designed | |
| **Make a double bed** | | | | | | |
| | 4 (4,4) (3 - 4) (n = 30) | 4 (4,4) (4 - 4) (n = 30) | 0.129 | 4 (4,4) (3 - 4) (n = 25) | 4 (4,4) (1 - 4) (n = 27) | 0.404 |
| **Carry a grocery bag that weighs approximately 2 kg, on the same side of the operation** | | | | | | |
| | 4 (4,4) (3 - 4) (n = 30) | 4 (4,4) (3 - 4) (n = 30) | 0.181 | 4 (4,4) (3 - 4) (n = 24) | 4 (4,4) (2 - 4) (n = 28) | 0.538 |

**Note:** The number (n) was less than 30 since participants did not do that function.

***Pain***

There was no difference in pain score before and after exercise between the free and certain designed progressive shoulder exercise groups. The difference in pain score between before and after exercise was not different between groups (Table 4).

**Table 4** Pain score before and after exercise session and its difference between the free and curtain designed progressive shoulder exercise group

| Exercise session | Pain score [median (Q1, Q3) (min - max)] | | *p*-value |
|---|---|---|---|
| | Shoulder exercise group | | |
| | Free (n = 30) | Certain designed (n = 30) | |
| Before | 0 (0, 0) (0, 0) | 0 (0, 0) (0, 0) | 0.214 |
| After | 0 (0, 0) (0, 1) | 0 (0, 0) (0, 1) | 0.215 |
| Difference between before and after | 0 (0, 0) (0, 0) | 0 (0, 0) (0, 1) | 0.091 |

***Satisfaction of exercise program, nurses, and physical therapists***

No difference was shown in satisfaction of the exercise program, nurses, and physical therapists between groups (Table 5). In the certain designed progressive shoulder exercise participants did not request physical therapists to advice the exercises.

**Table 5** Satisfaction of exercise program, nurses, and physical therapists in the free and certain designed progressive shoulder exercise groups

| Questions | Satisfaction scores Median (Q1, Q3) (min-max) | | *p*-value |
|---|---|---|---|
| | Free (n = 30) | Certain designed (n = 30) | |
| Program is easy to recognize, understand and can be followed immediately. | 5 (4,5) (3 – 5) | 5 (4,5) (3 – 5) | 0.555 |
| Pictures and contents are clear and corresponded. | 5 (4,5) (3 – 5) | 5 (4,5) (3 – 5) | 0.551 |
| You can ask questions and interact with nurses. | 5 (4,5) (3 – 5) | 5 (4,5) (4 – 5) | 0.497 |
| You can ask questions and interact with physical therapists. | NA | - | - |
| Nurses give good advice and information. | 5 (4,5) (4 – 5) | 5 (4,5) (4 – 5) | 0.403 |
| Physical therapists give good advice and information. | NA | - | - |
| Nurses are friendly and supportive. | 5 (4,5) (4 – 5) | 5 (4,5) (4 – 5) | 0.376 |
| Physical therapists are friendly and supportive. | NA | - | - |
| Overall, you are satisfied with the exercise program. | 5 (4,5) (4 – 5) | 5 (4,5) (4 – 5) | 0.439 |

**Note:** NA; not applicable, -; no data for analysis.

## Discussion

The study compared a certain designed progressive shoulder exercise with a free active shoulder exercise for individuals after breast cancer surgery on shoulder range of motion, shoulder and arm function, seroma drainage, pain, and satisfaction of the exercise and health professions in individuals after breast cancer surgery. The certain designed progressive shoulder exercise showed similar outcomes to the free shoulder exercise, except less active and passive shoulder flexion on day 3 after surgery than the free exercise.

The active and passive shoulder flexion range of motion in the certain designed progressive shoulder exercise group was less than the free shoulder exercise group. It may be due to the restriction at 90° of shoulder flexion and abduction in the first day after surgery and gradually increased the range of motion, limited by pain, in the consecutive day. Both groups had no pain before each exercise session. Thus, participants in the certain designed progressive shoulder exercise may perform less shoulder range of motion than those in the free shoulder exercise group because of instruction. Additionally, the certain designed progressive shoulder program designed a particular number of exercises, 5 times/exercise, 3 sessions/day, whereas the free shoulder exercise was suggested in a range, 5-10 times/exercise, 3-4 sessions/day. By communication with nurses on duty, participants in the free shoulder exercise groups did 3 exercises, 10 times/exercise, and 3 sessions/day. Therefore, participants in the free shoulder exercise group seemed to do a greater number of exercise than those in the certain designed progressive shoulder exercise group. Those in the free shoulder exercise did 90 times/day, whereas those in the certain designed progressive shoulder exercise did 45 times/day. However, the active and passive shoulder flexion on days 5 and 14 after surgery was similar in both groups. It may be that the 3 main exercises on the first 3 days together with the other 3 exercises increased the number of exercises in the certain designed progressive shoulder exercise group. Furthermore, the 3 main exercise on the first 3 days was a combination of shoulder external rotation with the movement of flexion and abduction. Shoulder external

rotation is a component of shoulder flexion and abduction[17,18] and is an important factor for the effectiveness of shoulder range of motion exercise[19,20]. It also stretches anterior upper trunk tightness and upper limb dysfunction after breast surgery[21]. Therefore, finally, the certain designed progressive shoulder exercise produced the similar shoulder flexion range of motion to the free shoulder exercise.

The shoulder and arm function, total seroma, and pain of the certain designed progressive shoulder exercise was similar to the free shoulder exercise. It may be due to shoulder exercises starting on the first day after surgery and similar shoulder range of motion in all directions in both groups. After breast cancer surgery, the pain decreases as the shoulder range of motion increases [22]. In the present study, participants had no pain before and after shoulder exercise in each session. Hence, shoulder range of motion was improved, then promoted shoulder and arm function[12] and seroma excretion in individuals with breast surgery[5].

Good satisfaction in the program, nurses, and physical therapists was demonstrated in both the free and certain designed progressive shoulder exercise. No participants in the certain designed progressive shoulder exercise requested to consult physical therapists for exercise. It may be because of clear instruction and ease to follow the exercises from the booklet and video. Moreover, they did not make decision on pose and frequency of exercise, or were worried about pain if they did a lot. Furthermore, they did not have any complications after surgery. Therefore, the exercise booklet and video may be useful for shoulder exercise in individuals after breast cancer surgery who did not have any complication.

There were few limitations in the study. Since the free shoulder exercise group was done routinely in a real situation, the amount, poses, and frequency of exercise in individuals was not recorded. The effect of the free and the certain designed progressive shoulder exercise after surgery was observed in a short duration. The long-term effect of both exercises is suggested in future study.

## Conclusion

The certain designed progressive shoulder exercise may be inferior to the free shoulder exercise on shoulder flexion range of motion on day 3 after surgery, but finally produced similar effects.

## Take home messages

The certain designed progressive shoulder exercise consisting of warm-up, cool-down, and a particular poses and frequency that is easy to perform could be a shoulder exercise for individuals after breast cancer surgery to increase shoulder range of motion and function without pain after exercise.

## Conflicts of interest

The authors declare no conflict of interest.

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ORIGINAL ARTICLE

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# Effect of yoga on premenstrual symptoms, flexibility, and quality of life in university students with premenstrual syndrome: a pilot study

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**KEYWORDS**
Yoga;
Menstruation;
Menstrual disorders;
Exercise;
Quality of life.

**ABSTRACT**

The common symptoms of premenstrual syndrome (PMS) include stomach discomfort, headache, back pain, exhaustion, anxiety, and lack of attention; hence PMS negatively impacts health and quality of life. Non-pharmacological methods, such as yoga, are often favored in the treatments of PMS because they are safe and have minimal adverse effects. However, evidence supporting yoga's effectiveness to relieve the symptoms of PMS is limited. Therefore, the objective of this study was to investigate the effect of yoga on premenstrual symptoms, flexibility, and health-related quality of life in female adolescents with moderate to severe PMS. This study was conducted as a pilot study among 10 university students with premenstrual syndrome. The participants performed yoga at a duration of 20 minutes per session, 3 times a week for 8 weeks. All of the variables were assessed at baseline and at the end of the study. There was a significant increase in flexibility measured by sit-and-reach test after the training (p-value < 0.05). Premenstrual symptoms measured by premenstrual symptoms screening tool (PSST) showed a significant decrease in the domains of mental symptoms, physical symptoms, impacts of the disease, and PSST total score (p-value < 0.05). Moreover, health-related quality of life measured by SF-36 revealed a significant increase in the domains of bodily pain, vitality, social functioning, mental health, and SF-36 total score (p-value < 0.05). Although additional research is required for further investigation, this pilot study indicates the yoga program may be used as an alternative treatment option for young females who suffer from PMS.

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## Introduction

Epidemiological surveys estimate that up to 80% of women of reproductive age suffer from premenstrual syndrome (PMS)[1]. PMS is characterized by a spectrum of physical, behavioral, and emotional symptoms that manifest during the luteal phase of the menstrual cycle[2]. PMS has a negative impact on women's quality of life, as well as their economic and social performance[3-5]. According to Victor et al[6], 49.9% of university students enrolled in health-related courses had PMS. In addition, PMS was found to affect the students' quality of life in all domains, including physical, mental, social relationships, and environmental domain. PMS can be treated using pharmacological and non-pharmacological methods[7]. Nonpharmacological methods such as diet therapy, acupressure, aerobic exercise, and yoga are often favored in the treatment of PMS because they are safer and have less adverse effects[8-11]. In addition, yoga has been demonstrated to alleviate premenstrual symptoms more effectively than aerobic exercise and acupressure[12,13].

Little is known regarding the effect of yoga on premenstrual symptoms in Thai university students with PMS. Recent study by Yonglitthipagon et al[14] determined the effects of 12-week home-based yoga program in young adolescents with PMS aged 18-22 years. The participants showed improvements in the areas of premenstrual symptoms, back and leg muscle strength, and flexibility. However, this study was restricted by the absence of a standardized instrument for assessing premenstrual symptoms, the absence of a health-related quality of life assessment, and the ambiguity of PMS severity. In addition, the effect of an 8-week home-based yoga program on premenstrual symptoms, flexibility, and health-related quality of life in university students with moderate to severe PMS has not been investigated. Therefore, the objective of this study was to investigate the effect of an 8-week home-based yoga program on premenstrual symptoms, flexibility, and health-related quality of life in university students with moderate to severe PMS.

## Materials and methods

### *Study design and participants*

This pilot study was approved by the Ethics Committee of Center for Ethics in Human Research, Khon Kaen University (HE622292). All participants provided their informed consent prior to participation. The recruitment began in May 2020 and continued until January 2021, when the final participant completed the research. Finally, 10 female students with moderate to severe PMS from Khon Kaen University participated in the research voluntarily. A flowchart of the study enrollment is presented in figure 1. The inclusion criteria for this pilot study were as follows: (1) female students aged 18 to 22 years, (2) experience of moderate to severe PMS[15], (3) body mass index (BMI) of 18.5-29.9 kg/m$^2$, and (4) the ability to comprehend and adhere to research protocols. The exclusion criteria were as follows: (1) being pregnant, (2) having neurological, cardiovascular, or musculoskeletal diseases; (3) having routinely exercised (moderate intensity training, more than one hour per week) within three months before the recruitment, and (4) taking oral contraceptives.

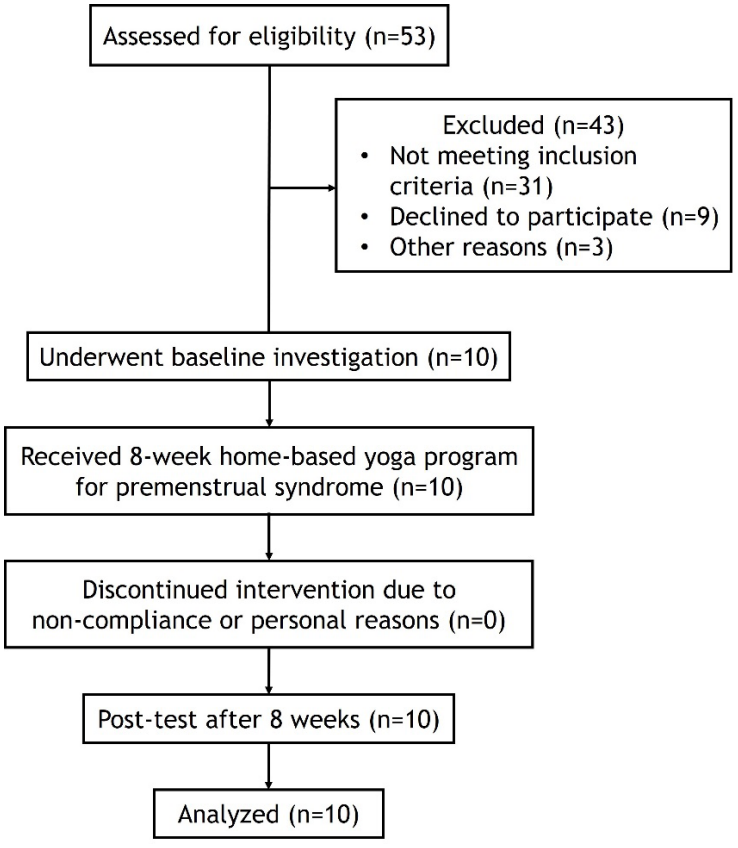
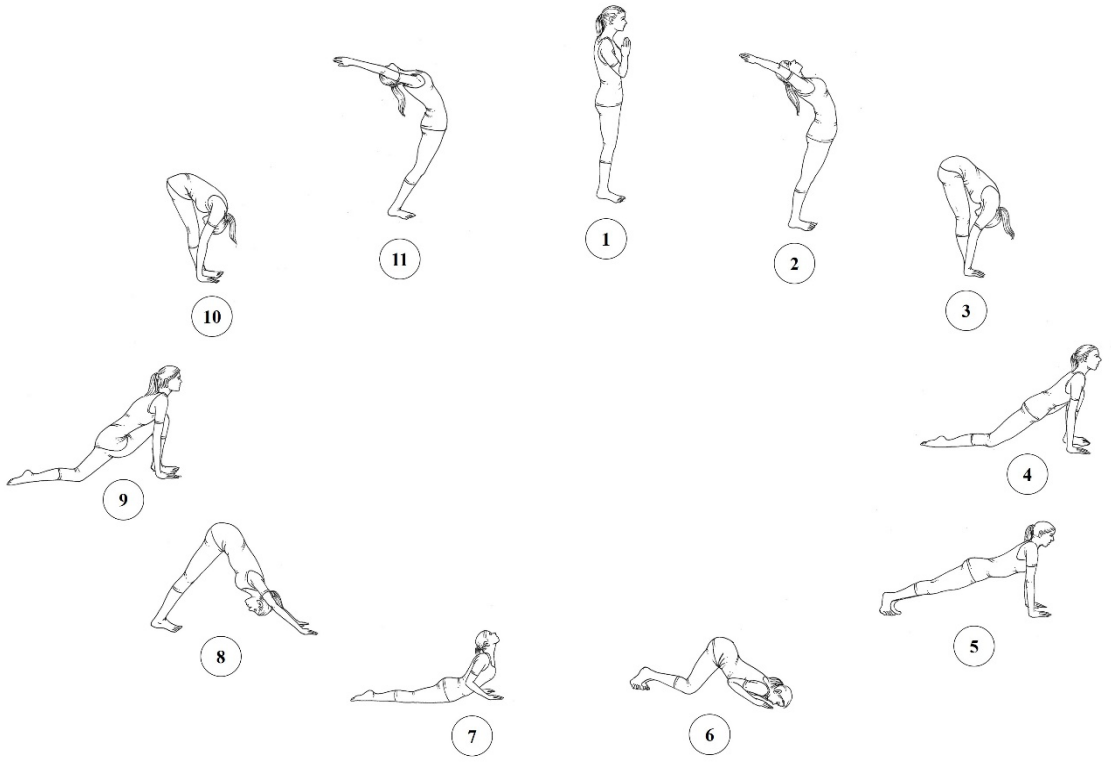


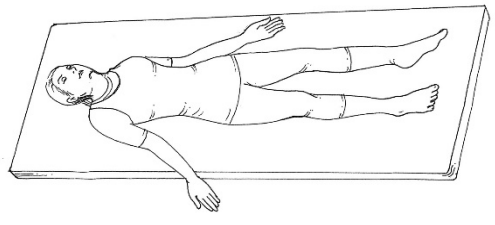

**Figure 1** Study flowchart.

***Intervention***

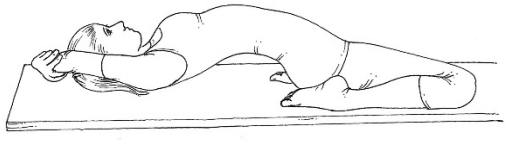
The yoga poses employed in this study were derived from those discovered by Yonglitthipagon et al[14], who found that they could improve premenstrual symptoms, back and leg muscle strength, and flexibility in young women with PMS aged 18-22 years. The yoga poses for 8-week home-based yoga program shown in figure 2 were as follows: Corpse pose or Shavasana (3 minutes), Sun salutation or Surya Namaska (3 sets of this pose for 6 minutes), Diamond pose or Supta Vajarasana (2 minutes), Head-to-knee pose or Janu Sirsasana (3 sets of this pose for 3 minutes), Seated forward bend or Paschimottanasana (3 minutes), and Shavasana (3 minutes), respectively. The participants were instructed for one hour by a yoga instructor who had five years of expertise teaching yoga to women with PMS. After becoming familiar with all poses, they were instructed to practice yoga at home for eight weeks, three times each week for 20 minutes per session. All participants were given the 'Yoga for Premenstrual Syndrome' pamphlet, which was created specifically for this study. Despite the fact that yoga is usually better instructed by a yoga teacher, the selected yoga poses were not too difficult for participants to do at home by following the clear instructions in the pamphlet. Additionally, after an hour of yoga instruction, the participants were able to perform these poses correctly. Exercise diary was used to keep record of exercise participation as well as any adverse events that occurred during the at-home yoga program. During their participation in this program, the participants were advised not to engage in any other forms of physical activity because doing so could affect the outcomes. In order to verify that each participant adhered to the intervention and practiced yoga correctly, the participants received a weekly phone call to provide encouragement and discourage dropout. Each participant included in the final analysis was required to have at least 90% compliance (≥ 20 sessions) with the yoga intervention.



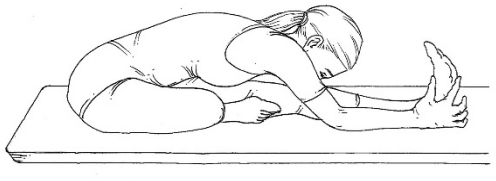

**(a) Surya Namaskar**



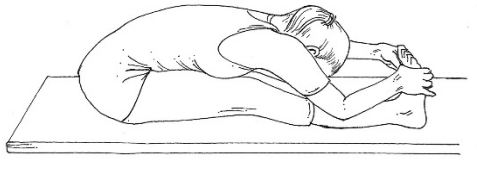
**(b) Shavasana**



**(c) Supta Vajarasana**



**(d) Janu Sirasasana**



**(e) Pashimotanasana**

**Figure 2** Home-based yoga program for adolescent females with premenstrual syndrome.

***Outcome measurements***

*Sit-and-reach test*

The low back and hamstring flexibility was assessed by the sit-and-reach test (SRT)[16]. Participants were asked to sit on the floor with legs fully extended, and the soles of both feet must be placed against the sit-and-reach box. Then they placed both hands together, and reach those hands forward along the measuring line as far as possible. The average of the 3-time reach distances was used for data analysis.

*Premenstrual symptoms screening tool*

Thai version of premenstrual symptoms screening tool (PSST) with high value of internal consistency (Cronbach's alpha > 0.9) was used to determine the severity of PMS in this study[17]. The PSST consists of 19 questions that are divided into three domains including mental symptoms, physical symptoms and impacts of the disease[17]. Each question was scored between 0 and 3 based on the severity of the symptoms. The range of PSST scores was from 0 to 57. In this study, participants with moderate to severe PMS were recruited if they had greater than 20 scores with the following three conditions: 1) at least one moderate or severe symptom reported from questions 1-4 in the questionnaire, 2) at least four moderate or severe symptoms were indicated from question 1-14 in addition to first condition, and 3) at least one moderate or severe symptom was reported from the last five questions in the questionnaire[1,15].

*The 36-Item Short Form Health Survey*

A short form 36 (SF-36) health survey questionnaire (Thai version) was used to evaluate quality of life[18]. It consists of 36 questions across eight domains including physical functioning, role limitation due to physical problems, bodily pain, general health perception, vitality, social functioning, role limitation due to emotional problems, and mental health. The score range is between 0-100, where 0 is the lowest and 100 is the highest state of health[19].

All outcomes were measured at baseline and after 8 weeks of the yoga program.

***Statistical analysis***

IBM SPSS Statistics version 23.0 software (Khon Kaen University licensed) was used for all statistical analyses. The descriptive statistics were applied to explain participants' demographic. The Shapiro-Wilks test was used to determine the normality of the data. Non-parametric statistics were used due to the small sample size and normality violations. The pre- and post-intervention flexibility, PSST, and SF-36 data were compared using Wilcoxon Signed-Rank test. The statistical significance was set at $p$-value < 0.05.

## Results

Ten participants have completed the 8-week of home-based yoga program. During the time that the yoga program was being carried out, the participants did not experience any complications. Table 1 shows the demographic information of the participants in this study.

**Table 1** Baseline characteristics of the participants (n = 10)

| Variable | Median (IQR) |
|---|---|
| Age (year) | 21.00 (2.25) |
| Weight (kg) | 53.00 (7.38) |
| Height (cm) | 161.00 (9.25) |
| BMI (kg/m$^2$) | 19.96 (3.07) |

**Note:** IQR, interquartile range; BMI, body mass index.

Table 2 presents within-group analyses of the sit-and-reach test, PSST, and SF-36. After participating in the yoga program for eight weeks, there was a statistically significant increase in the low back and hamstring flexibility measured by the sit-and-reach test ($p$-value < 0.05). Further, premenstrual symptoms measured by PSST showed a significant reduction in the domains of mental symptoms, physical symptoms, impacts of the disease, and PSST total score ($p$-value < 0.05). Additionally, health-related quality of life measured by the SF-36 revealed a significant increase in the domains of bodily pain, vitality, social functioning, mental health, and SF-36 total score ($p$-value < 0.05).

**Table 2** Within-group analysis for the outcomes of the study

| Variable | Baseline | After 8 weeks | *p*-value |
|---|---|---|---|
| Sit-and-reach test (cm) | 0.40 (13.43) | 5.35 (10.18) | 0.005* |
| PSST (score) | | | |
| - Mental symptoms | 20.00 (2.50) | 6.00 (5.00) | 0.005* |
| - Physical symptoms | 15.00 (4.25) | 5.50 (3.50) | 0.004* |
| - Impacts of the disease | 11.40 (2.50) | 3.40 (1.50) | 0.005* |
| - PSST total score | 45.50 (8.50) | 16.00 (9.50) | 0.005* |
| SF-36 (score) | | | |
| - Physical functioning | 80.00 (13.75) | 85.00 (18.75) | 0.076 |
| - Role - physical | 75.00 (56.25) | 100.00 (50.00) | 0.161 |
| - Bodily pain | 28.25 (37.50) | 67.50 (24.88) | 0.020* |
| - General health | 47.50 (33.75) | 55.20 (20.00) | 0.285 |
| - Vitality | 47.50 (26.25) | 65.00 (10.00) | 0.015* |
| - Social functioning | 62.50 (37.50) | 75.00 (15.63) | 0.046* |
| - Role - emotional | 50.00 (75.00) | 100.00 (33.33) | 0.105 |
| - Mental health | 54.00 (29.00) | 72.00 (11.00) | 0.007* |
| - SF-36 total score | 59.43 (26.54) | 76.07 (13.01) | 0.022* |

**Note:** The values are presented in median (interquartile range) using the Wilcoxon Signed-Rank test for non-parametric data, *significant difference from baseline. PSST, premenstrual symptoms screening tool; SF-36, the 36-item short form health survey.

## Discussion

Our findings suggest that the 8-week home-based yoga program may be used as an alternative treatment option for university students with PMS. When compared with before exercise training, this yoga program could improve premenstrual symptoms, flexibility, and quality of life in university students with PMS (Table 2). Furthermore, no adverse events associated with the yoga training were reported by any participants. The improvements in those 3 outcome measures shown in the current study should result in enhanced physical function in the participants' daily activities[14,20].

Due to the fact that low back pain is a common symptom of PMS[21], it is possible that women with PMS would experience decreased hamstring and low back flexibility[22]. The significant increase in low back and hamstring flexibility seen in the present study may be related to thrice-weekly 20-minute yoga sessions for 8 weeks of forward bending yoga poses such as Surya Namaskar, Janu Sirasasana, and Pashimotanasana that stretch the lower back and hamstring muscles. The results of this study are in line with those of a study by Yonglitthipagon et al[14] and Yonglitthipagon et al[23], who found that twice-weekly 30-minute yoga sessions for 12 weeks can improve the flexibility of young adolescents with premenstrual syndrome and women with primary dysmenorrhea, respectively. It is interesting to note that changes in female hormones, particularly estrogen and progesterone during the menstrual cycle, are the primary cause of increased ligament looseness, which leads to increased flexibility, and decreased neuromuscular performance, which leads to decreased muscle strength[24]. Therefore, the increase in low back and hamstring flexibility observed in our study could be attributed not only to the yoga program but also to hormonal changes during the menstrual cycle.

Further, the current study found a statistically significant improvement in premenstrual symptoms across all PSST domains (emotional, physical, and impacts of the disease) as well as total PSST score (Table 2). PMS is known to induce physical, behavioral, and emotional problems[2]. Previous studies[14,20] have also found that PMS symptoms decreased following the completion of yoga programs. Based on a systematic review and meta-analysis in 2022[25], yoga was beneficial in alleviating premenstrual symptoms. This advantage was observed in all PMS sub-domains except the physical sub-domain. Research is still needed to determine whether yoga has any impact on the pathophysiology of PMS, particularly on the hormonal imbalance. Kanojia et al[26] investigated the effect of yoga in adolescent girls with PMS and found that participants who practiced yoga six days per week for the duration of three menstrual cycles had significant improvements in their weight, resting heart rate, resting blood pressure, frustration, depression, and anxiety level compared to the control group. Tsai et al[20] also reported that twice-weekly 50-minute yoga sessions for 12 weeks significantly decreased the use of analgesics during menstruation and improved premenstrual symptoms as well as health-related quality of life among Taiwanese female employees. In addition, earlier studies have demonstrated that yoga was more effective than acupressure[12] and aerobic exercise[13] in alleviating premenstrual symptoms.

In addition, the current study demonstrated that the health-related quality of life, as evaluated by the SF-36, significantly increased in the domains of bodily pain, vitality, social functioning, mental health, and SF-36 total score. The mechanism by which yoga improves quality of life in people with premenstrual syndrome is unclear. The improvement in quality of life is probably due to the result of a reduction in premenstrual symptoms across all PSST domains (emotional, physical, and impacts of the disease) and also an increase in lower back and hamstring flexibility. Our findings are in line with those of Tsai et al[20], who discovered that a 12-week yoga intervention not only reduced premenstrual symptoms, but also improved quality of life in the domains of physical function and bodily pain in Taiwanese female employees with PMS. According to Wu et al[27], women with PMS who engaged in short-term yoga practice during the luteal phase were able to make themselves feel better and maintain a higher level of concentration by increasing in alpha wave production in the brain. Previous studies have shown that yoga and meditation increase alpha waves by slowing abdominal breathing[28,29]. Kamie et al[30] also revealed that yoga practice led to an increase in alpha wave production and a drop in serum cortisol, the body's stress hormone. Brain waves in the alpha range are attributed to feelings of calm, relaxation, motivation, and better mood[31]

The major limitations of this pilot study were that the study employed an overly simplistic experimental design that compared before and after a single intervention without the use of control group or random assignment. Therefore, additional research for contributing comparison groups or random allocation design is recommended. This will show whether young females with PMS who engage in the yoga program improve their premenstrual symptoms, flexibility, and quality of life as compared to controls. Secondly, the limited sample size and the fact that the participants were sedentary university students aged 18-22 years old may have reduced the impact of our findings, making it less likely that our results can be generalized to all women of reproductive age. Additional research is needed to evaluate if the same improvements in premenstrual symptoms, flexibility, and quality of life observed in this study would be found in other populations (e.g., athlete college students, women of reproductive age a broader age range). Finally, the demographic data of the participants provided few meaningful insights. Demographic data on age of menarche, menstrual characteristics, and personal lifestyle factors such as alcohol consumption, smoking, and exercise habit should be obtained in future studies.

## Conclusion

Although additional research is required with larger participant cohorts to further evaluate efficacy, the results of our study show that the yoga program could be an alternative therapeutic option for university students with PMS.

### Take home messages

When it comes to university females who suffer from premenstrual syndrome, an 8-week home-based yoga program can improve the severity of premenstrual symptoms, as well as lower body flexibility, and health-related quality of life.

## Conflicts of interest

The authors declare no conflict of interest.

## Acknowledgements

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# Effects of strength training combined with task-oriented training on upper extremity recovery and enjoyment of individuals with chronic stroke

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**KEYWORDS**
Cerebrovascular disease; Rehabilitation; Physiotherapy; Arm; Muscle weakness.

**ABSTRACT**
Only little evidence has assessed the impact of strength training combined with task-oriented training (TOT) on the upper extremity function of patients with chronic stroke. This study investigated the effects of adding strength training to TOT on the upper extremity recovery and enjoyment of individuals with chronic stroke. Nineteen chronic stroke patients were randomly allocated to either a strength training combined with TOT program (experimental group, n = 10) or a TOT-only program (control group, n = 9). Both groups received a 70-minute training program, 5 times a week for 4 weeks-with a total of 3,600 repetitions for all tasks in the training. The outcomes were assessed in terms of upper extremity functions, grip strength, upper extremity motor impairment, shoulder flexion active range of motion (AROM), muscle tone, and physical activity enjoyment as assessed using the Physical Activity Enjoyment Scale (PACES) at baseline and post-intervention. The upper extremity function, upper extremity motor impairment and shoulder flexion AROM of the participants in both groups improved significantly ($p$-value < 0.05) post-intervention without increasing spasticity. There were no statistically significant differences between the two groups. Grip muscle strength was improved in the experimental group only ($p$-value < 0.05). The PACES score of the experimental group and the control group were 105.0 (89.0, 118.2) and 91.0 (83.5, 106.0), respectively. The findings suggest benefit of 4-week strength training combined with TOT program on the improvement of upper extremity functions, upper extremity motor impairment and shoulder flexion AROM of the participants similar to the improvement witnessed in the participants of the TOT-only program. However, only the strength training combined with TOT program improved muscle strength. The post-chronic stroke patients seemed to enjoy the strength training combined with TOT program more than the TOT-only program.

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## Introduction

Post-stroke, more than 80% of patients suffer upper extremity functional limitations[1]. Upper extremity function is essential for daily-life activities that consist of reaching for and manipulating objects[2]. Stroke patients unable to restore their hemiparetic upper extremity functional ability may compensate by using their sound side[3]. Consequently, the undertaking of daily life activities and/or social interactions might be decreased since many activities require bilateral movement such as the buttoning up of clothing, driving vehicles, or showering oneself [4]. In addition, complications such as muscle atrophy and contractures could occur following such immobility[5]. Thus, the improvement of the hemiparetic arm function is a core aspect of stroke rehabilitation practice.

Muscle weakness is a predominant cause of post-stroke upper extremity functional activity limitation[5], as is defined as an inability of the muscle to produce the necessary tension to maintain, initiate, or control movement[6]. Several factors can cause muscle weakness post-stroke, including a reduction in the number of motor units being used, a decrease in the firing frequency and/or recruitment order of motor units[6], and adaptive length-associated changes of muscle and muscle disuse[7]. Previous research has demonstrated that restoration of upper extremity muscle strength improves upper extremity functional activity[8,9]. The upper extremity strength training program, which consisted of 36 repetitions of upper extremity movement 3 days per week for 5 weeks, was found to be effective in improving upper extremity muscle strength in chronic stroke patients. Furthermore, the strength training program also had a positive effect on upper extremity functions[10]. This finding is in line with a recent systematic review, which suggested that resistance training may be beneficial in improving upper extremity function post-stroke[11].

Task-oriented training (TOT) is a well-established and evidence-based approach that has been proven to effectively restore functional outcomes post-stroke[12]. This specific, intense, engaging, collaborative, self-directed, and patient-centered training has been found to significantly improve upper extremity function in stroke patients[13]. Combining a strength training program with the TOT program appears to be more beneficial than the TOT-only program for chronic stroke patients. Research has shown that the 360-minute TOT program combined with strength training can improve bilateral upper extremity tasks more effectively than the TOT-only program[14]. However, this research provided fixed tasks of training for individual stroke patients. Notably, allowing stroke patients to take part in goal setting and selecting training of their own training tasks can significantly improve their satisfaction with rehabilitation programs[15]. This suggests that the TOT program may be more effective when patients are given the opportunity to involve in the process.

Limited research has been conducted to assess the impact of strength training combined with TOT on the upper extremity function of patients with chronic stroke. Our research team discovered that a combination of strength training and patient-centered goal-setting TOT program (1,800 repetitions of total tasks training within 2 weeks) significantly improved unilateral upper extremity tasks of stroke patients[16]. Despite our previous research, we have not seen a significant improvement in unilateral upper extremity tasks when strength training and TOT are combined, compared to TOT-only program. The evidence is clear that neural plasticity can be promoted through task training repetitions, with a study of chronic stroke patients showing positive results after 3,150 repetitions of total task training[17]. The aim of this study was to evaluate the impact of strength training combined with TOT (3,600 repetitions of total tasks training over a period of 4 weeks) compared to a TOT-only program. This study further explored the level of enjoyment experienced by chronic stroke patients in each program.

## Materials and methods

### *Study design and participants*

This study employed a matched-pair, randomized, controlled, and single-blinded design

to recruit participants from the community in Mueang District, Phitsanulok Province, Thailand. Eligible participants for this research had experienced a stroke within the 6- to 60-month period prior to the study, were aged between 40 and 70 years old, had a motor recovery score of the upper extremity assessed by the Fugl Meyer Scale between 19 and 58, were able to extend their wrist and fingers, could sit independently for more than 30 minutes, and had the capacity to follow commands. The exclusion criteria for this study were individuals with other neurological conditions and a Modified Ashworth Scale (MAS) score of 3 or greater for shoulder adductors, elbow flexors, wrist flexors, and bilateral hemiplegia. Ethical approval was received from the Naresuan University Institutional Review Board IRB No.0012/62 (COA No.1302019) and Buddhachinaraj Hospital Institutional Review Board IRB No.100/62.

***Sample size***

A sample of 10 patients per group was necessary at a 5% significance level, 80% power, and 20% dropout rate based on a study by Arya et al[18].

***Randomization***

According to the wide range of inclusion criteria of this study, the matched pair design was employed to reduce confounding factors[19]. Patients were matched based on their upper extremity function and grip strength and stratified by age, gender, post-stroke duration, and upper extremity function to ensure an equal distribution. To ensure concealed allocation, a person not involved in the patient selection process performed the randomization. A computerized program was utilized to randomly assign patients to either the strength training associated with patient-centered goal-setting TOT program (experimental group) or the patient-centered goal-setting TOT-only program (control group). Outcomes were assessed at the beginning of the intervention and again at the fourth-week post-intervention. A blinded physiotherapist assessed all variables, while the participants were unaware of which group they were assigned to. However, due to the nature of the study, the physiotherapists who trained the patients in each group were not blinded.

***Interventions***

All of the participants received a 70-minute session, 5 times per week for 4 weeks at their respective homes. The program for each group was provided by 2 individual physiotherapists with an average of 3 years of neurorehabilitation experience. To ensure consistency, the therapists gave the same instructions and verbal cues for TOT training to all participants in both groups. The TOT activities were designed based on daily-life undertakings and consisted of strength-dependent activities relating to the hemiparetic arm, those bimanual and dexterity of the hemiparetic hand. These activities presented in table 1 were originally published in Thai[16].

**Table 1** Task-oriented training activities

| Task-Oriented Training Activities |
|---|
| **1. Strength-dependent activities of the hemiparetic arm** |
| 1.1 Reaching for and grasping of a glass |
| 1.2 Swiping a table while extending one's elbow |
| 1.3 Pouring water from the a bottle |
| 1.4 Brushing hair |
| 1.5 Lifting a bottle |
| 1.6 Lifting a mobile phone to one's ear |
| **2. Bimanual activities** |
| 2.1 Folding a towel |
| 2.2 Opening drawers |
| 2.3 Twisting a towel |
| 2.4 Lifting a pot |
| 2.5 Swiping a desk |
| 2.6 Picking a ball from a basket |
| **3. Dexterity of the most hemiparetic hand** |
| 3.1 Buttoning up a clothing item |
| 3.2 Tying shoelaces |
| 3.3 Turning a key |
| 3.4 Picking up a pencil |
| 3.5 Lifting a spoon |
| 3.6 Grasping and releasing a small ball |

The participants in both groups selected six training activities from the three categories outlined in table 1, customizing their goals based on their capacity and individual needs. For instance, they practiced lifting a spoon and bringing it close to their lips. The sequence of training was randomized, and both groups received the same frequency and amount of training. The intensity of the training was designed according to previous studies[14,20]. The participants underwent stretching of their hypertonic upper extremity muscle groups both before and after their training session. The training program consisted of 10 sets repeated 3 times, with a 30-second rest interval between each set and a 1-minute rest interval between each activity[10,14,17]. All activities were performed while the participants were seated on a chair with a backrest, with their hips and knees flexed at 90 degrees. A belt was used to restrict the trunk and prevent any compensatory movements during training. The trainer provided verbal cues to offer feedback on the exercise performance, limit compensatory movements, and reinforce positive behaviors. The participants in the experimental group identified their one-Repetition Maximum (1RM) of shoulder flexor by sitting on a chair with a backrest and raising their hemiplegic arm with a sandbag attached to their wrist. The final weight of the sandbag that allowed each participant to raise their arms to the full range of motion was set as their 1RM. Their 1RM was multiplied by 0.06 to be the target weight. At the 3rd-week milestone, the difficulty of all activities was increased in various ways, such as increasing the range of motion, the size of objects used, and the target weight set according to each participant's capacity. The intervention results for both groups are presented in table 2.

**Table 2** Intervention for experiment and control groups

| Program | Control group | Duration | Experimental group | Duration |
|---|---|---|---|---|
| Warm up | Stretching | 5 | Stretching | 5 |
| Training | TOT | 60 | Strength training and TOT | 60 |
| Cool down | Stretching | 5 | Stretching | 5 |

***Outcome measures***

*Primary outcome measures*

The primary outcome measure of this study was the change in upper extremity function over time, as measured by the Streamlined Wolf Motor Function Test for chronic patients (SWMFT-C). This test was streamlined from the widely used 17 items of the Wolf Motor Function Test (WMFT)[21] in order to reduce the burden of administration and provide the most relevant information about recovery potential[22]. The SWMFT-C demonstrated excellent predictive validity, concurrent validity, comparable responsiveness[23], excellent test-retest reliability and internal consistency[24]. The SWMFT-C consists of six tasks; extend elbow weight, hand to box (front), lift can, lift pencil, turn key in lock, and fold towel. These tasks are evaluated in regard to the performance time witnessed and the patient's functional ability scale. The maximum time allowed to complete a task is 120 seconds. There are six levels of functional ability ranging from zero (does not attempt with involved arm) to five points (movement appears to be normal)[22].

*Secondary outcome measures*

The secondary outcome measures included grip strength, upper extremity motor impairment, shoulder flexor range of motion, muscle spasticity of the affected side, and the enjoyment of receiving the program as assessed by a hand grip dynamometer, the Fugl Meyer for Upper Extremity (FMA-UE), a goniometer, the modified Ashworth scale (MAS) and the Physical Activity Enjoyment Scale (PACES)[25], respectively.

The participants were seated in a backrest chair with their shoulder abducted and flexed at 10 degrees and their elbow flexed at 80 degrees in order to assess their grip strength and upper extremity motor impairment. The grip strength was selected as an outcome measure due to its strong correlation with upper extremity function in stroke patients[26]. The hand grip dynamometer was employed to assess grip strength due to its demonstrated excellent concurrent validity, intra-rater reliability, and test-retest reliability[27,28]. Participants were instructed to apply as much grip pressure as possible on the dynamometer for three times, with the highest values recorded[26].

The FMA was used to evaluate motor impairment in stroke patients. It is scored based on direct observation of the patient's performance and has been shown to have good concurrent validity and test-retest reliability[29,30]. The FMA-UE consisted of 33 items, out of 155 items of the FMA, including the reflex activity of the elbow flexor and extensor muscles, upper extremity movements (volitional movement with synergies, and volitional movement mixing synergies, volitional movement with little or no synergy), normal reflex activity, wrist movements, hand movements, and coordination/speed of the index finger as it moves from one's knee to one's nose. Here, reflex activities were scored as 0 (none) and 2 (can be elicited) while movement performances were scored on a 3-point ordinal scale (0 = cannot perform, 1 = performs partially, 2 = performs fully). The scores ranged between 0 and 66 points[31].

The shoulder flexion ROM was measured in a supine position with the knee flexed by the universal goniometer, which demonstrated good concurrent validity and test-retest reliability[29]. The ROM was chosen as an additional outcome measure due to its ability to predict upper extremity function[32]. The normal range of motion (ROM) for shoulder flexion is typically between 160 and 180 degrees. The axis location of the universal goniometer was the middle of the humeral head laterally while the stationary arm was held parallel with the trunk[33].

The muscle tone of the shoulder abductor, the elbow flexor, and the wrist flexor muscles was assessed using the MAS. This scale has been widely used in both clinical and research settings, and has been found to have moderate inter-rater and intra-rater reliability[34]. The MAS score ranged from 0 (no increase in tone) to 4 (extremity rigid in flexion or extension)[34].

The 18-item of PACES was used to assess the participant's enjoyment of their physical activity. The PACES had high internal consistency and had high internal consistency[36]. A 7-point bipolar Likert scale was here employed, as ranged from 1 (I enjoy it) to 7 (I hate it). The scores of the negative items were reversed, and the summed total scores ranged between 18-126, with higher scores indicating higher enjoyment[25].

***Statistical analysis***

The SPSS 17.0 statistical software was used for the data analysis of this research. The groups of data have been expressed by means and standard deviations. The normality of the data has been tested using the Shapiro–Wilk test, as is in accordance with the data's non-normal distribution. Descriptive statistics have been presented by means (standard deviation) for the normally distributed variables and medians (IQR) for the non-normally distributed variables. The Wilcoxon Signed-Rank test and Mann-Whitney U test were used to compare all variables within and between the groups. The significance level was set at $p$-value < 0.05.

## Results

A total of 163 patients were screened for eligibility, with 20 ultimately being matched and randomly assigned to either a strength training program associated with TOT (experimental group) or a TOT-only program (control group). The experimental group completed 4 weeks of training, while unfortunately, one participant in the control group dropped out due to relocation to another city. At the end of the study, 19 participants' data were eligible for analysis. The study flow diagram, which outlines the number of participants in the experimental and control groups, is summarized in figure 1.

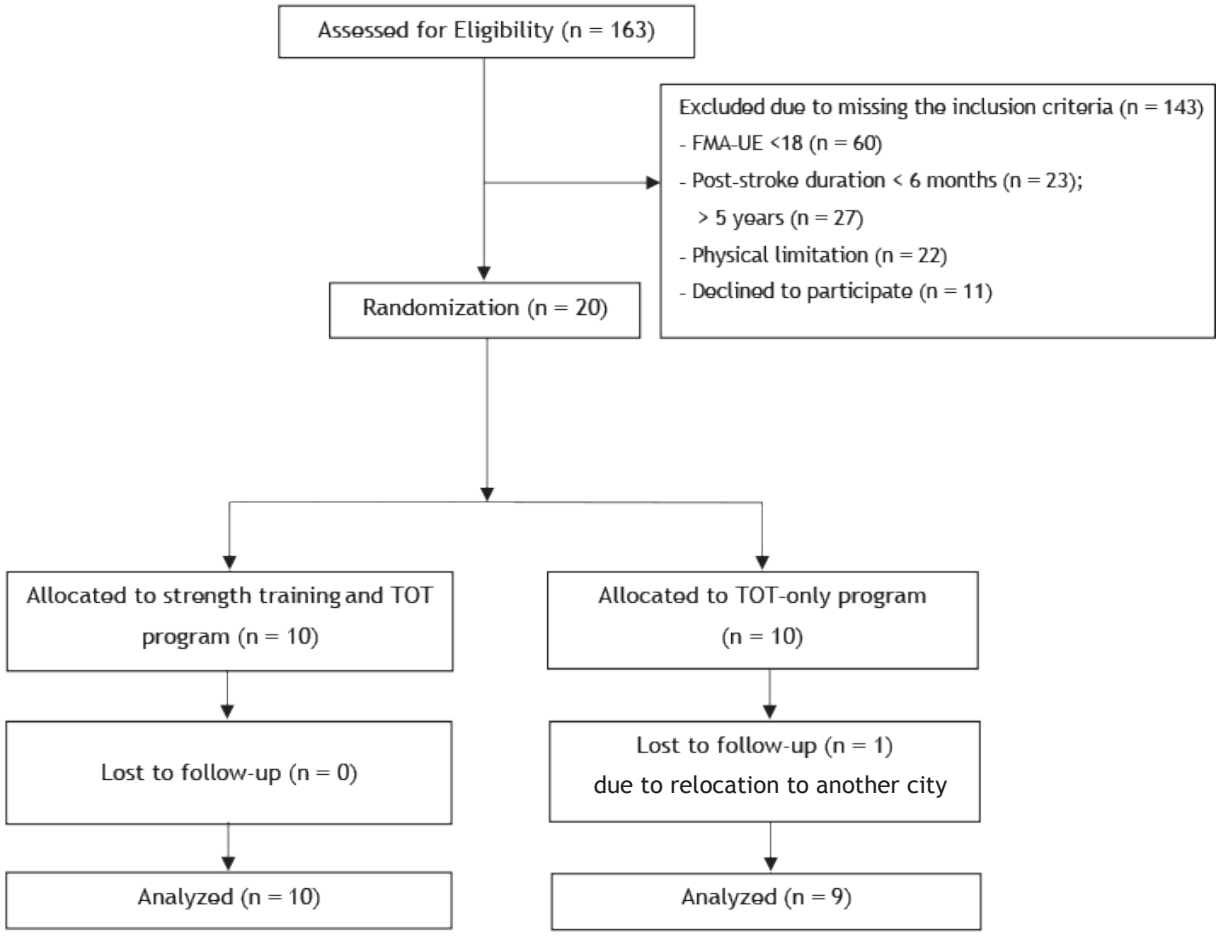


**Figure 1** Study flow diagram showing the number of participants in the experimental and control group

Table 3 details the demographic and clinical characteristics of the participants. At the baseline level, there were no significant differences between the two groups. Furthermore, no significant differences were observed in the SWMFT-C-FAS, SWMFT-C-TIME, muscle spasticity grip strength, FMA-UE, shoulder flexor range of motion, and upper extremity muscle spasticity among the participants in each group.

**Table 3** Participants' demographics

| Variable | Control group (n = 10) | Experimental group (n = 10) | *p*-value |
|---|---|---|---|
| Age (years) | 61.5 ± 8.5 | 59.6 ± 8.5 | 0.47[a] |
| Gender (male/female) | 5/5 | 6/4 | 0.63[b] |
| Hemiparetic side (Right/Left) | 4/6 | 3/7 | 0.63[b] |
| Disease duration (month) | 26.6 ± 13.5 | 23.4 ± 19.4 | 0.14[c] |
| Pathology (Ischemic/Hemorrhagic) | 6/4 | 8/2 | 0.32[b] |
| SWMFT-C-FAS (0-5) | 3.00 (1.0, 3.4) | 2.4 (1.0, 3.3) | 0.70[c] |
| SWMFT-C-TIME (0-120 second) | 7.6 (3.8, 120.0) | 5.6 (3.1, 120.0) | 0.43[c] |
| Grip strength (kg) | 11.6 (5.1, 18.4) | 8.3 (7.4, 18.4) | 0.94[c] |
| FMA-UE (0-66) | 38.0 (22.5, 42.0) | 32.5 (22.7, 39.0) | 0.62[c] |
| Shoulder flexion ROM (degree) | 128.3 (32.5, 145.8) | 132.1 (38.4, 149.8) | 0.77[c] |

**Note:** Values are presented as number, mean ± standard deviation, or median (interquartile range). [a] Compared between the groups using the independent t-test, [b] Compared between the groups using the chi-square test, [c] Compared between the groups using the Mann-Whitney U test. SWMFT-C-FAS, streamlined wolf motor function test-chronic-functional ability scale; FMA-UE, fugl meyer assessment-upper extremity; ROM, range of motion.

Table 4 illustrates the medians (IQR1,3) and statistics recorded across the 19 participants. Significant within-group differences were observed in the SWMFT-C-FAS, SWMFT-C-TIME, FMA-UE, and shoulder flexion ROM ($p$-value < 0.05) for both groups, with the experimental group exhibiting a statistically significant difference in grip strength ($p$-value < 0.05). Neither group experienced an increase in spasticity of the shoulder abductors, elbow flexors, and wrist flexors over time. The experimental group had an enjoyment scale result of 105.0 (89.0, 118.2), while the control group had a result of 91.0 (83.5, 106.0). No statistically significant differences were observed in any of the outcome measurements between the two groups.

**Table 4** Outcome measures across 3 assessment occasions

| Outcome | Control group (n = 9) | Experimental group (n = 10) | *p*-value* |
|---|---|---|---|
| **SWMFT-C-FAS (0-5)** | | | |
| Baseline | 3.00 (1.0, 3.4) | 2.4 (1.0, 3.3) | 0.70 |
| 4th week | 3.33 (1.1, 4.1)* | 3.0 (1.5, 3.9)* | 0.87 |
| **SWMFT-C-TIME (0-120 second)** | | | |
| Baseline | 7.6 (3.8, 120.0) | 5.6 (3.1, 120.0) | 0.43 |
| 4th week | 4.4 (2.7, 100.7)* | 3.3 (2.4, 53.1)* | 0.36 |
| **Grip strength (kg )** | | | |
| Baseline | 11.6 (5.1, 18.4) | 8.3 (7.4, 18.4) | 0.94 |
| 4th week | 11.7 (5.3, 19.1) | 11.4 (8.8, 20.3)* | 0.65 |
| **FMA-UE (0-66)** | | | |
| Baseline | 38.0 (22.5, 42.0) | 32.5 (22.7, 39.0) | 0.62 |
| 4th week | 48.0 (30.5, 57.5)* | 44.0 (30.7, 54.0)* | 0.80 |
| **Shoulder flexion ROM (degree)** | | | |
| Baseline | 128.3 (32.5, 145.8) | 132.1 (38.4, 149.8) | 0.77 |
| 4th week | 145.0 (51.7, 151.9)* | 139.6 (61.2, 156.8)* | 0.68 |
| **Shoulder abductor spasticity (MAS 0-4)** | | | |
| Baseline | 1.0 (0.0, 1.5) | 1.0 (0.0, 2.2) | 0.96 |
| 4th week | 0.0 (0.0, 1.0) | 0.0 (0.0, 1.5) | 0.56 |
| **Elbow flexor spasticity (MAS 0-4)** | | | |
| Baseline | 1.0 (0.0, 2.0) | 1.5 (0.0, 3.0) | 0.51 |
| 4th week | 0.0 (0.0, 1.5) | 1.0 (0.0, 2.0) | 0.10 |
| **Wrist flexor spasticity (MAS 0-4)** | | | |
| Baseline | 1.0 (0.0, 2.0) | 1.0 (0.7, 3.0) | 0.43 |
| 4th week | 1.0 (0.0, 1.5) | 1.0 (0.0, 2.2) | 0.43 |
| **PACES (0-126)** | | | |
| 4th week | 91.0 (83.5.5, 106.0) | 105.0 (89.0, 118.2) | 0.23 |

**Note:** Values are presented as median (interquartile range). *Compared with the baseline within the group using the Wilcoxon Signed-Rank test, *p*-value < 0.05. TOT, task-oriented training; SWMFT-C-FAS, streamlined wolf motor function test-chronic-functional ability scale; FMA-UE, fugl meyer assessment-upper extremity; ROM, range of motion; MAS, modified ashworth scale; PACES, physical activity enjoyment scale.

## Discussion

The results of this study indicate that 4-week strength training associated with TOT program did not yield better outcomes than the TOT-only program for chronic stroke patients with mild to moderate motor recovery. However, the strength training associated with the TOT program did improve grip muscle strength. Additionally, neither training program seemed to stimulate spasticity.

This study provides evidence that TOT is effective in improving upper extremity functions and motor impairment[13,14]. Both groups completed 3,600 training repetitions for each task, which is likely enough to promote neural plasticity, or the capacity to modify, restore, or reorganize structurally and functionally[17]. The randomization of the task training provided in both groups resulted in a faster brain reorganization response than that of block training[37]. This allowed for a more efficient and effective reorganization of the brain. Stroke patients can recover rapidly during the first six months post-stroke, however, neural plasticity can be stimulated at any stage post-stroke[38]. This study determined the intensity and duration of training necessary to induce neural plasticity, based on previous research which found that at least 30 hours[39] or more than 3,000 repetitions of task training[17] were required. This finding was supported by both groups, who showed similar neuromuscular adaptation. This study enabled the participants to customize their training tasks within the TOT program in collaboration with their therapist. Before each training session, the participant identified their training activity and established objectives for each task based on their capabilities and needs. Consequently, all training activities were meaningful in that they are likely to sustain their long-term engagement[40]. Participants enjoyed the training program, as evidenced by the enjoyment scale scores of both groups being higher than 80. The scores among the group that combined strength training with the TOT program were notably higher, likely due to their quicker recovery of upper extremity muscle strength, as observed in our previous study[16].

The TOT program's strength training failed to improve grip muscle strength more than the TOT-only program group, as the only muscles being reinforced were the shoulder, the elbow and the wrist muscles. This was due to the strength training consisting of the participants hanging sandbags from their wrists, which did not target the hand muscles.

The findings of this study contradict a prior research, which has demonstrated that strength training with the TOT program had a more marked effect than TOT-only programs[14]. The divergence between the two studies may be attributed to the different outcome measures employed. Da Sil Va et al[14] investigated the effect of TOT and strength training on upper extremity function using the Test d' Evaluation des MembresSuperieu des PersonnAge´es, which includes 4 bilateral and 4 unilateral tasks. In contrast, this current study utilized the SWMFT-C which consists of only one bilateral task and 5 unilateral tasks that address the hemiparetic side.

The strength training associated with TOT program showed a faster improvement in ULFA and grip strength than the TOT-only program, with results seen after just six 70-minute sessions[16]. This finding supported that upper extremity functions are accompanied by strength training[41]. This finding further supported the evidence which found that upper extremity functions can be improved through strength training[26]. Strength training associated with the TOT program has been demonstrated to effectively improve muscle strength, a major cause of upper extremity functional limitation in stroke patients. This finding suggests that strength training should be incorporated into upper extremity rehabilitation programs for chronic stroke patients with moderate to high motor recovery. Strength training associated with TOT program had no effect on muscle spasticity in stroke patients who had either no or mild spasticity at the start of the program, as evidenced by the findings of other studies[41].

This study has provided data that could be further explored through larger sample size to confirm the effectiveness of strength training combined with TOT. It is noted that this study does have some limitations. Firstly, the results cannot be generalized to post-chronic stroke patients with lower upper extremity function, as only those with moderate to high function were recruited. Secondly, it is unclear whether the participants' social activity participation also increased after their functional improvement, so further investigation is needed in this area. Lastly, the study did not assess the retention of the training or the neural plasticity of the participants, which could be addressed in future research. Further

research should be conducted to explore the effects of strength training associated with TOT, which focuses on resistance exercises for the hands to improve dexterity.

## Conclusion

This study has demonstrated that a 4-week strength training program combined with a TOT program can significantly improve ULFA, upper extremity motor impairment, and shoulder flexion AROM in chronic stroke patients, with similar results to those achieved with the TOT-only program. However, the TOT-only program did not improve upper extremity muscle strength. Furthermore, the participants seemed to prefer the strength training combined with TOT program over the TOT-only program.

### Take home messages

The combination of strength training and the TOT program has been shown to improve upper extremity function, motor impairment, and shoulder flexion in chronic stroke patients to a similar degree as the TOT-only program. However, only the combination of strength training and TOT has been found to improve upper extremity muscle strength.

## Conflicts of interest

The authors declare no conflict of interest.

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