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A modifying respiratory muscle device: development and pilot testing

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ABSTRACT

Background: A respiratory muscle device was designed in various forms and was available at different price ranging. However, financially disadvantaged users may find it difficult to afford the device.

Objectives: The objective of the study was to develop a device utilizing readily available materials. Subsequently, a pilot study was conducted to evaluate maximal inspiratory pressure (MIP) among healthy adult subjects. Furthermore, feedback and suggestions regarding the device were collected using a questionnaire.

Materials and methods: The device's components were evaluated to ensure safety. Subsequently, laboratory tests were conducted to assess device performance, including measurements of windmill blade rotation and airflow, to determine and prescribe the exercise intensity. Healthy subjects aged 18 to 25 years were then recruited and randomly assigned into either the control group or the exercise group (N=16 per group). Subjects in the exercise group were instructed to use the device daily for four weeks, while those in the control group were asked to continue their usual daily activities. MIP was measured in all participants on a weekly basis throughout the study. Then, subjects in the exercise group were given a questionnaire to evaluate their opinions regarding the device.

Results: The result revealed that all components of the device complied with safety standards. There was no significant difference in MIP between the exercise group and the control group. However, by the third and fourth weeks of the training period, the exercise group exhibited a significant improvement in MIP compared to their values in the first week. Furthermore, user feedback indicated that the device's size, weight, and usability were very satisfactory.

Conclusion: The study concluded that the modified device did not have a significant effect on inspiratory muscle strength, as indicated by MIP, in healthy adult subjects. However, further research is warranted to more thoroughly evaluate the effectiveness of the device and in relevant clinical populations.

Introduction

A respiratory muscle device is frequently recommended for patients with respiratory muscle weakness due to various conditions; its aim is to improve respiratory muscle strength and enhance lung expansion.[1,2] The patient is supposed to inhale or exhale through the device, and its resistance can be adjusted with various methods.[2] For a respiratory muscle device to be classified as a medical device, several phases must be successfully completed, including prototyping, safety testing, and trials in humans. Regarding the latter, three types of trials must be conducted sequentially. The first one involves testing on a small group

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of people to assess safety and side effects. The second one entails a larger group of subjects to evaluate effectiveness and identify possible side effects. The third one involves testing on an even larger group of people to confirm effectiveness and safety, as well as compare the proposed device to existing treatments.[3]

In Thailand, respiratory muscle devices are sold by several companies at different prices. However, the Comptroller General's Department has not included them on the list of nondrug medical supplies.[4] As a result, patients who are advised to use these devices must purchase them themselves. This creates a problem of access for individuals with financial constraints. In addition, the availability of these products may also be limited to certain stores, such as those in urban areas. Therefore, patients who live in remote areas may face further barriers to accessing these devices. Based on these facts, the present study was conducted to develop a modified respiratory muscle device from readily available materials, and its performance was initially assessed in the laboratory. Then, a pilot study was conducted on a small group of healthy subjects to evaluate the device's effectiveness on respiratory muscle strengthening, which was indicated by maximum inspiratory pressure (MIP). The questionnaire also collected feedback regarding the device. The data thus obtained can help researchers enhance the device for optimal performance and inform future trials involving relevant clinical populations.

Materials and methods

The present study was divided into two stages, as illustrated in Figure 1. First, a modified device was developed. Then, the impact of the device on inspiratory muscle strength was evaluated. Furthermore, participants' feedback regarding the device was collected.

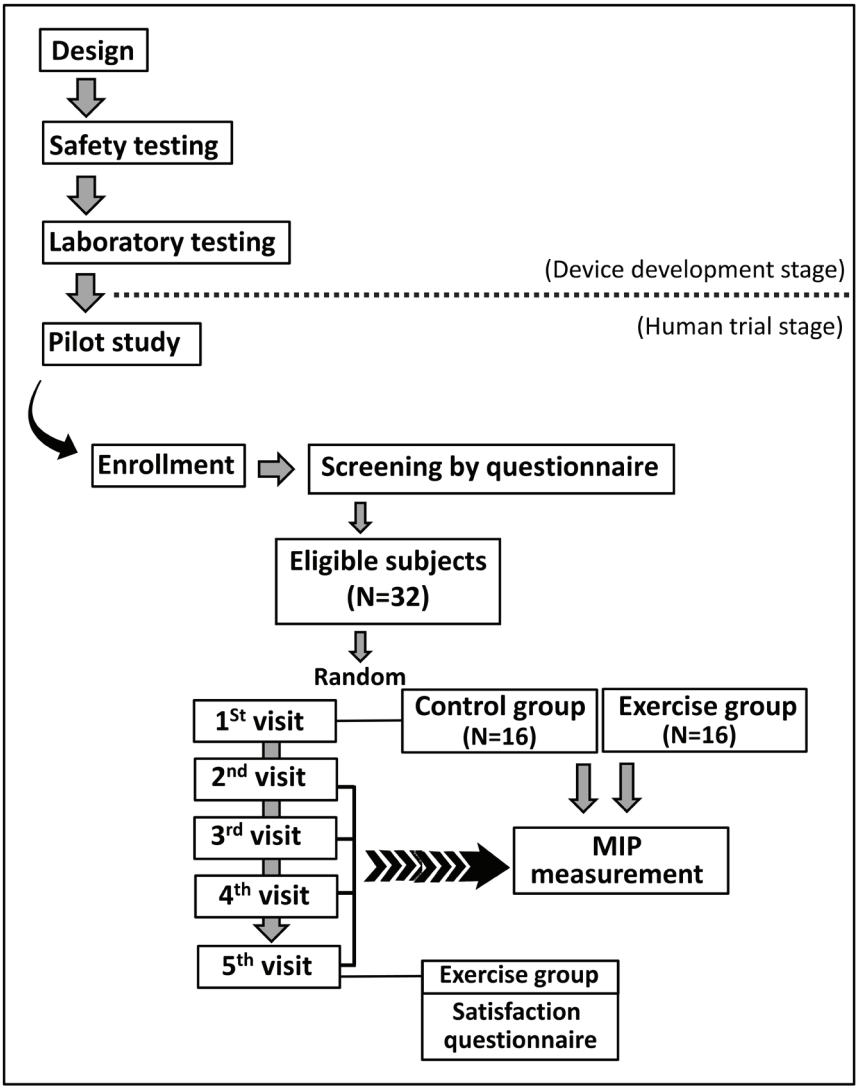


Figure 1. *Consort diagram of the study. MIP: maximum inpiratory pressure.*

Device development

The device was developed by modifying a 22-ounce plastic cup, a plastic cap, and a plastic windmill (Figure 2). Both the cup and the cap were made from food-grade polypropylene plastic, while the windmill was a plastic toy. All the components were submitted for safety-standard testing and assessment of plastic particle release, as detailed in Table 1. The test results demonstrated that the components complied with the relevant safety standards, which confirmed the suitability of the materials used in the device.

The windmill was installed inside the cup and fixed with double-sided adhesive tape (Figure 2A). Then, the cap was placed on the cup (Figure 2B). To let the inhaled air flow, three holes measuring seven millimeters in diameter were made in the bottom of the cup with a soldering iron (Figure 2C). The original diameter of the cap hole was 10 millimeters, which is larger than the typical silicone straw available on the market. Therefore, an eight-millimeter hole was made in the cap to allow the silicone straw, which served as the inhalation tube, to be properly fitted (Figure 2B).

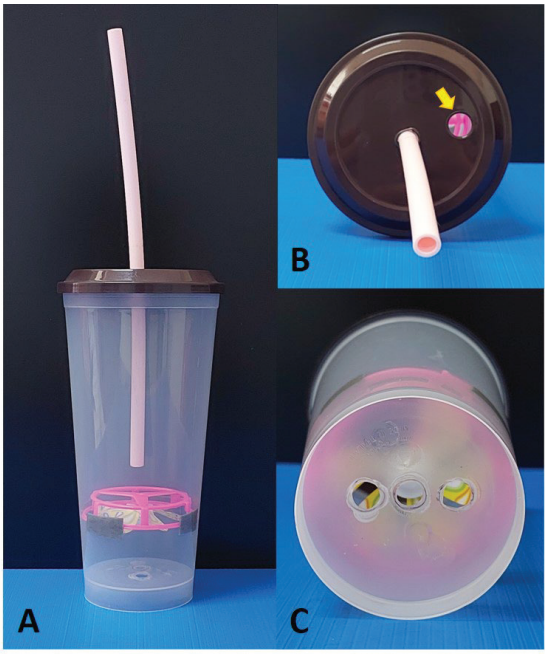


Figure 2. *Components of the modifying device; the ready-to-use device. A: cap with a silicone straw, B: three seven-millimeter diameter holes at the cup bottom, C: arrow indicated the original cap's hole.*

Table 1. Safety testing results of device components

Parameter (mg/kg)	Cup	Cap	Windmill
Antimony	NT	NT	54.0[B]
Arsenic	NT	NT	ND[B]
Barium	NT	NT	14[B]
Cadmium	ND[A]	ND[A]	ND[B]
Chromium	ND[A]	ND[A]	<1[B]
Copper	0.804[A]	2.079[A]	NT
Lead	ND[A]	ND[A]	ND[B]
Mercury	NT	NT	ND[B]
Selenium	NT	NT	ND[B]
Zinc	4.422[A]	2.324[A]	NT
Diameter sizes of plastic particle (μm)			
>10	ND[C]	ND[C]	ND[C]
>25	ND[C]	ND[C]	ND[C]

Note: Testing method; [A]: In-house method based on EPA 3052, [B]: IEC 62321-5:2013, [C]: Thai industrial standard 531-2558. NT: not tested, ND: not detected.

The next step involved evaluating the device characteristics. First, the device resistance was assessed using a phlegm suction machine (7E-C Yuwell). This assessment included the following steps: 1) marking one of the windmill blades with a magic pen and assembling the device, 2) connecting the silicone straw to the suction tube, 3) mounting a video camera at an angle that enabled the rotation of the marked windmill blade to be observed through the device's bottom holes, 4) opening or closing the bottom holes with transparent adhesive tape, 5) turning the regulator valve for maximum suction pressure, 6) switching on the phlegm suction machine and the video camera for a duration of five seconds, and 7) counting the number of spins of the windmill blades using the iMovie software. This procedure was meant to test the number of spins of the windmill blades under the same suction pressure but with varying conditions (open or closed) for the device's bottom holes. The number of windmill blade spins is shown in Table 2. Second, the Biopac Research MP35 Data Acquisition System was employed to evaluate the airflow measurement, and an offline analysis was conducted using the Biopac Student Lab software (Version 4.1). The results for the mean airflow are presented in Table 2.

Table 2. General characteristics of the modified device based on laboratory testing.

Condition	Number of spinning	Mean airflow (L/sec)	Level of difficulty
7 7 7	11	0.580	Hardest
7 7 0	18	0.619	Moderate
7 0 7	28	0.622	Easy
7 0 0	34	0.625	Easiest

Note: 7: bottom hole of the modified device is open, 0: the hole has been sealed with transparent adhesive tape.

Subjects

As the first human trial of the device, a pilot study was conducted with healthy subjects. The sample size was calculated based on data from the Nepomuceno study.[5] Then, 32 healthy individuals aged 18-25 years were recruited. Next, they were randomly divided into two groups: control (N=16) and exercise (N=16). Personal information was collected through a self-administered questionnaire. No medical or physical conditions affecting respiratory mechanics were present, such as scoliosis or kyphosis. The subjects' BMI values ranged from 18.5 to 22.9 kg/m². Individuals were excluded if they had a history of fainting while taking a deep breath or holding their breath, syncope of unknown origin, or a clavicle, rib, or sternum fracture within the previous six months.

MIP measurement

MIP was measured by a physical therapist. Ten samples at the same age range were included for intra-rater reliability measurement. Test-retest variability was determined by an intraclass correlation coefficient (ICC). The ICC value for MIP assessed by the therapist was 0.996, which indicates high reliability.[6] MIP was measured using the MicroRPM respiratory pressure meter in accordance with its guidelines.[7] The subjects were instructed to perform their maximum inspiratory efforts in a sitting position, with a one-minute break between efforts. Then, the maximum value of three efforts that varied by less than 10% was reported as the MIP value.

Program

The exercise group.

The data presented in Table 2 were used as the basis for classifying the levels of device difficulty. Four levels were determined, ranging from the easiest to the hardest, with the number of windmill blade spins serving as the primary criterion. The duration of four weeks for the training program was chosen to reflect these four levels. All participants in the exercise group began training with the easiest level. Then, each week, they were instructed to increase the difficulty level by one step, thus progressing through all four levels.

Transparent adhesive tape was used to close the bottom holes in accordance with the difficulty level. It was also used to close the original cap hole, as shown in Figure 2B. Then, the participants were instructed to use the device by taking a slow, deep breath and sustaining a maximal inspiratory effort for three seconds. They were instructed to use the device at home 10 times per set, 3 sets per round, with a 2-minute break between sets, and 2 rounds per day. The training duration was approximately 20 minutes per day.[5] The participants had to keep exercise diaries to record their exercise adherence. They were also monitored by phone twice a week. In addition, they were scheduled to return once a week to have their MIP measured. Then, after completing the training program, they were asked to rate their satisfaction with the device using a questionnaire. This questionnaire elicited responses regarding device structure, usability, cleaning, and storage, as well as overall satisfaction. The participants were asked to rate their satisfaction using a five-point Likert scale: 1 ("very dissatisfied"), 2 ("dissatisfied"), 3 ("neutral"), 4 ("satisfied"), or 5 ("very satisfied"). In the questionnaire, there was also space to provide additional suggestions or comments.

Control group

The control group was asked to carry out various daily routines as usual. They were also scheduled for MIP reassessment once a week throughout the study period.

Statistical analysis

Descriptive information (i.e., the general characteristics of the two groups and the opinions expressed in the questionnaires) is presented in the form of percentages. Data are presented in the mean±SD format. Statistical analysis was performed using Stata (version 18), with a significance level of $p<0.05$. Because the MIP data were not normally distributed, and since the focus was on estimating group-averaged effects of device-based training on the MIP outcome, rather than subject-specific effects, a generalized estimating equation model was used. In addition, the Bonferroni test was utilized to compare MIP at the second, third, and fourth weeks to MIP at the first week in each group.

Results

There were no significant differences between the general characteristics of the two groups, as shown in Table 3. The exercise group had a 100% exercise adherence rate, and no adverse events were reported. There was no significant difference in MIP between the two groups (Table 4). However, in the exercise group, the MIP values in the third and fourth weeks were significantly higher than in the first week (Table 4). Furthermore, when considering the overall effect of training with the device, the MIP value in the exercise group increased by 1.77 centimeters of water compared to the control group, in which this increase was not statistically significant.

The exercise group also provided their opinions. Almost all the respondents (94%) were very satisfied with the device's size and weight; however, regarding the device's material, strength, and configuration, the percentages of very satisfaction were only 69%, 56%, and 50%, respectively. All the participants were very satisfied with the device's usability due to its simplicity. However, the device was difficult to transport, as the following ratings were given concerning ease of transportation: 37.5% satisfied, 19% neutral, and 6% extremely dissatisfied. They were also very satisfied with the device's ease of cleaning (88%) and storage (81%). The rating for overall satisfaction was also considerable (81%). Three participants complained that the windmill blades spun unevenly.

Table 3. General characteristics of the subjects.

Characteristics	Control group (N=16)	Exercise group (N=16)
Male: Female (%)	4:12 (25%:75%)	6:10 (37%:63%)
Age (years)	20.8±1.00 (19-21)	20.6±1.15 (18-22)
Body weight (kg)	56.7±8.48 (47.0-68.9)	55.4±7.21 (47.2-69.3)
Height (cm)	165.5±8.95 (153.0-181.0)	165.1±7.87 (155.0-180.0)
BMI (kg/m^2)	20.6±1.28 (18.2-22.9)	20.2±1.18 (18.6-22.2)
Waist circumference (cm)	70.5±5.93 (63.4-85.0)	69.3±4.85 (60.5-77.0)
Hip circumference (cm)	89.7±7.91 (73.0-101.0)	90.2±6.38 (80.0-98.0)
Waist-to-hip ratio	0.79±0.07 (0.70-0.90)	0.77±0.08 (0.64-0.90)

Note: Data presented in mean±SD (min-max).

Table 4. The maximum inspiratory pressure measurement.

	Control group (N=16)	Exercise group (N=16)	Mean difference (95%CI)	*p* value
Overall			1.77 (-6.75, 10.30)	0.684[A]
At first week	102.31±19.51	113.06±19.62	1.77 (-9.09, 12.63)	>0.999[B]
At second week	101.13±24.21	118.63±23.92	8.52 (-2.34, 19.38)	0.200[B]
At third week	104.88±29.25	123.94±23.73[C]	10.08 (-0.78, 20.95)	0.082[B]
At fourth week	104.69±28.10	124.13±25.82[C]	10.46 (-0.40, 21.32)	0.065[B]

Note: Data are presented in centimeters of water as mean ± SD. [A]By generalized estimating equations model adjusted for baseline values measured at the first visit, [B]Comparison of MIP between the control and exercise groups at the first, second, third and fourth week was performed using the Bonferroni test, [C]Comparison of MIP at the second, third, and fourth weeks with the first week within each group was performed using the Bonferroni test, with significance set at p<0.05.

Discussion

The major result of the present study is the development of a modified respiratory muscle device (a type of medical device). All the components of the device were safe in accordance with the relevant standards. Furthermore, the findings of the pilot study conducted with healthy subjects show no significant differences in respiratory muscle strength, as indicated by MIP.

The modified device in this pilot study is classified as a non-in vitro diagnostic medical device according to the Thailand Medical Device Act.[8] Furthermore, it is comparable to the medical equipment standard number 93/42/EEC, class I medical devices.[9] As a result, all the components were tested to ensure compliance with safety standards before conducting the pilot study. The components were safe to use. Furthermore, the equipment to build the device costs approximately USD 1 per set. The device currently holds a petty patent (No. 23538) in Thailand.

In the pilot study, the effectiveness of the modified device on respiratory muscle strength was assessed using MIP. However, the MIP values in the exercise group did not increase significantly when compared to the control group. Several factors may account for this finding. First, the exercise protocol may have contributed to the lack of significant improvement. According to previous studies, the effective training period for improving respiratory muscle strength is typically 4-8 weeks.[10,11] Moreover, another study suggested that, in healthy individuals, the training intensity should exceed 50% of MIP, with a frequency of 1 to 2 sessions per day, 5 to 7 days per week, to achieve significant adaptation of muscle function within 3 weeks.[12] In the present pilot study, the lack of increase in the MIP values of the exercise group may be due to the fact that the modified device failed to provide sufficient load to elicit a training effect.[13] Second, in the pilot study, all the participants were required to start the exercise at the easiest level, without consideration of individual respiratory muscle strength. This methodological decision might account for the absence of significant changes in MIP. However, this approach allowed the participants to experience all four difficulty levels, which ensured the collection of detailed feedback on the device.

Previous studies conducted in young, healthy individuals have indicated that increases in diaphragm thickness are associated with improvements in MIP.[11, 14] They have suggested that these improvements are attributable not only to diaphragm hypertrophy but also to neural adaptations, including improved coordination of synergistic muscle contractions and an increased capacity to maximize the activation of individual muscles.[11,14] Similarly, in the present pilot study, the exercise group showed significant improvements in MIP at the third and fourth weeks of the training period compared to the first week. This finding may be attributed to enhanced coordination of synergistic muscle contractions through training, which contributed to the observed increases in MIP.

In a previous study, Das *et al.* reported an adaptive device consisting of a sterile surgical glove firmly tied with micropore medical tape to the broad end of a sterile injection syringe barrel, with the piston removed.[15] To exercise, patients were instructed to take as deep a breath as they could and exhale into the device via the free end of the syringe. They were encouraged to inhale enough air to inflate all the glove's fingers. The bulging of the gloves' fingers acted as an incentive. This type of device is simple to assemble and thus readily available. Its reuse was not specified by the authors. Because the device was built with medical-grade materials, which are typically designed for single use and disposal, the overall cost per unit is likely comparable to that of the modified device used in the present pilot study. Additionally, since the device in Das *et al*.'s study was used for expiratory breathing, its training effects on respiratory muscles may differ from those of the modified device in this pilot study, which was employed for inspiratory breathing.

The BreatheMAX device developed by Jones *et al*.[16,17] consists of a sealed water bottle and two tubes, a design that differs from that of other devices available in Thailand. The inlet tube sinks beneath the surface of the water, providing an incentive in the form of bursting bubbles and a bubbling sound. The BreatheMAX has both incentive spirometer (IS) and positive expiratory pressure (PEP) functions that adjust resistance based on the water level in the bottle. Its effectiveness has been studied to aid sputum clearance,[16,17] reduce resting blood pressure in isolated systolic hypertension patients,[18] and increase MIP in patients with COPD.[19] The training program to increase MIP lasted eight weeks at an intensity level of 30% of MIP in COPD patients. The authors found a significant increase (31%) in MIP.[19] This training duration is notably different from the one adopted in the present pilot study. The modified device examined here offers only four adjustable resistance levels; therefore, with a progressive increase in difficulty each week, it could be used for a training period of only four weeks. Furthermore, the BreatheMAX is manufactured using medical-grade plastic, which allows for repeated use. However, its retail price is around USD 23.5 per set, which may create an accessibility barrier for patients with limited financial resources.

Leelarungrayub *et al*. demonstrated a simple prototype device.[20] This was constructed using a PVC plastic water pipe and plastic caps. The main tube consisted of a 10-centimeter-long PVC water pipe with a diameter of 2 centimeters, and it featured a flat, 2-centimeter-wide mouthpiece at one end. Three plastic caps, each with a central hole of different diameters (2, 4, and 6 millimeters), were designed to be placed on the opposite end of the mouthpiece to provide variable resistance.[20] The training period with this simple prototype device lasted for three weeks, during which the aperture size of the device was progressively decreased. Participants began training with a 6-millimeter opening in the first week, progressed to a 4-millimeter opening in the second week, and completed the protocol with a 2-millimeter opening in the third week. Leelarungrayub *et al*. did not provide details regarding the type of plastic used or the cost per set. However, compared to the present pilot study, the study had a shorter training duration, corresponding to the number of plastic caps

designed by the researchers. Still, they found that their device was effective in improving MIP among healthy participants aged 20-23 years.[20]

The following aspect concerns the design modifications of the device used in the present study. The blades spin when air enters the cup through the holes in the bottom, which creates a feedback mechanism that encourages users to take deep breaths. This mechanism is not influenced by gravity, which is required in other respiratory devices, such as the BreatheMAX.[17] Hence, users can perform the exercise in any position with the modified device developed in this study. Furthermore, when comparing the modified device to the adaptive device created by Das *et al*.[15] and the simple prototype by Leelarungrayub *et al*.,[20] the spinning blades may serve to further motivate users to engage in deep breathing exercises or provide visual feedback on sustained MIP. Moreover, as the modified device was adapted from a windmill toy, its colorful blades offer an additional advantage, particularly for use with children. However, parameters such as lung volume and thoracic expansion were not assessed in this pilot study, so further research is needed to investigate these aspects.

The questionnaire results show that almost all the participants were very satisfied with the device's size and weight, as well as its usability. Moreover, the silicone straw can be reused by simply cleaning it with dishwasher detergent and thoroughly drying it. As a result, the participants were very satisfied with the ease of cleaning. However, some of the respondents commented on the uneven spinning of the blades. In response to this feedback, the researcher carefully inspected each windmill before assembling it into the device set. Incorporating suggestions from subjects and the data obtained from this study into future research will likely help confirm the device's efficacy and may also increase opportunities for its application in clinical contexts.

Limitation

This pilot study has several limitations. First, it was conducted exclusively in healthy subjects; therefore, the findings may not be generalizable to other populations. Future trials are needed in relevant clinical populations. Second, a standard protocol for resistance calibration was not available, as the device was modified and adapted from other equipment. Consequently, resistance was assessed using a modified approach, as detailed in the above section on device development. Third, since the cup, cap, and windmill were not made from medical-grade plastic, the ethics committee permitted their use for only one day. As a result, the subjects in the exercise group had to change the device daily, which increased the associated costs and may have caused variability in windmill blade rotation across different sessions. Future scholars should consider improving the device design and manufacturing it from medical-grade plastic to facilitate repeated use. In addition, the tool's validity and consistency of repeated performance for training will be confirmed by the technology acceptance model (TAM) of user experience (UX), and user interface (UI) for the standardized tool will be confirmed. Fourth, because the characteristics of the modified device limited the exercise intensity levels in this pilot study, the study duration could not be extended beyond four weeks. Thus, future study should consider determining exercise intensity based on each participant's MIP to ensure appropriate training loads.

Conclusion

The modified device developed in the present study did not have a significant effect on inspiratory muscle strength, as indicated by MIP, in healthy young subjects. However, further research is warranted to evaluate the effectiveness of the device more thoroughly.

Ethical approval

The study was approved by the Ethics Committee of the Khon Kaen University (HE654036), and all the participants gave written informed consent.

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Conflicts of interest

The authors declare no conflicts of interest.

CRediT authorship contribution

Raoyrin Chanavirut: conceptualization, resources, writing-reviewing and editing; **Rattakarn Yensano**: laboratory testing; **Ponlapat Yonglitthipagon**: statistical analysis; **Saowanee Nakmareong**: methodology; **Lapasrada Chaipattaranun** and **Warisara Jaratpongtakul**: data collection. All authors have read and agreed to the final version of the manuscript.

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