Original article

# Combined effects of threshold inspiratory muscle training with outpatient phase cardiac rehabilitation after cardiac surgery: Randomized, double-blind, sham-controlled trial

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## Abstract

**Introduction:** The median sternotomy approach in cardiac surgery can lead to a postoperative decrease in respiratory muscle strength, which in turn reduces patients' functional capacity. However, studies investigating the addition of inspiratory muscle training (IMT) to outpatient cardiac rehabilitation (CR) programs are limited. **Objective:** To evaluate the effects of threshold IMT combined with an outpatient CR program on inspiratory muscle strength and submaximal exercise capacity in post-cardiac surgery patients. **Materials and Method:** The present randomized, double-blind, sham-controlled trial included 16 eligible post-cardiac surgery patients with median sternotomy. Participants were randomized into two groups. The IMT group (n=7) received a 12-week program of moderate-intensity aerobic exercise-based cardiac rehabilitation combined with progressive threshold IMT. The sham group (n=9) participated in the same cardiac rehabilitation program but used an IMT device with a fixed, minimal resistance. The resistance settings of the IMT devices were blinded for both groups. The primary outcome, maximal inspiratory pressure (MIP), and the secondary outcome, six-minute walk distance (6MWD) as a measure of submaximal exercise capacity, were assessed at baseline, 6 weeks, and 12 weeks. **Results:** The mean change in MIP from baseline was significantly greater in the IMT group compared with the sham group at both 6 weeks (29.29 vs 6.67 $cmH_2O$; $p$=0.003)

and 12 weeks (37.00 vs 14.78 $cmH_2O$; $p$=0.001). There was no statistically significant difference in the mean change in 6MWD between the two groups at 6 weeks ($p$=0.135) or 12 weeks ($p$=0.629). **Conclusion:** The addition of a 12-week threshold inspiratory muscle training to outpatient cardiac rehabilitation in post-cardiac surgery patients demonstrated a statistically significant increase in inspiratory muscle strength. Nevertheless, no significant enhancement in submaximal exercise capacity is observed when compared with the sham-device control group.

***Keywords*** ● *Inspiratory muscle training* ● *Cardiac rehabilitation* ● *Post-cardiac surgery*

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**นิพนธ์ต้นฉบับ**

# ผลของการฝึกความแข็งแรงของกล้ามเนื้อหายใจเข้าชนิด Threshold ร่วมกับการฟื้นฟูหัวใจ ระยะผู้ป่วยนอกภายหลังการผ่าตัดหัวใจ: การศึกษาเชิงทดลองแบบสุ่มชนิดมีกลุ่มควบคุมด้วยอุปกรณ์ฝึกแบบหลอกและปกปิดสองทาง

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**บทคัดย่อ**

**บทนำ:** การผ่าตัดหัวใจโดยวิธีการเปิดช่องอกตามแนวกึ่งกลางกระดูกสันอกส่งผลให้ความแข็งแรงของกล้ามเนื้อที่ใช้ หายใจลดลงหลังการผ่าตัด ซึ่งนำไปสู่การลดลงของสมรรถภาพของร่างกาย งานวิจัยที่ศึกษาการเพิ่มการฝึกความแข็งแรงของกล้ามเนื้อหายใจเข้าร่วมกับโปรแกรมฟื้นฟูหัวใจระยะผู้ป่วยนอกยังมีจำกัด **วัตถุประสงค์:** เพื่อประเมิน ผลของการฝึกกล้ามเนื้อหายใจเข้าด้วยอุปกรณ์ฝึกแบบมีแรงต้านชนิด Threshold ร่วมกับโปรแกรมฟื้นฟูหัวใจ ระยะผู้ป่วยนอกต่อความแข็งแรงของกล้ามเนื้อหายใจเข้าและความสามารถในการออกกำลังกายในระดับต่ำกว่าสูงสุดในผู้ป่วยหลังการผ่าตัดหัวใจ **วัสดุและวิธีการ:** เป็นการศึกษาเชิงทดลองแบบสุ่มชนิดมีกลุ่มควบคุมด้วยอุปกรณ์ฝึกแบบหลอกและปกปิดสองทาง ในผู้ป่วยหลังการผ่าตัดหัวใจด้วยวิธีการเปิดช่องอกตามแนวกึ่งกลางกระดูก สันอก ที่มีคุณสมบัติตามเกณฑ์จำนวน 16 ราย ผู้เข้าร่วมการศึกษาถูกสุ่มแบ่งเป็นสองกลุ่ม กลุ่มฝึกความแข็งแรงกล้ามเนื้อหายใจเข้าด้วยอุปกรณ์ฝึกชนิด Threshold ซึ่งมีการปรับแรงต้านเพิ่มขึ้นตลอดการฝึก (IMT) ร่วมกับโปรแกรมฟื้นฟูหัวใจที่เน้นการออกกำลังกายแบบแอโรบิกระดับความหนักปานกลางเป็นระยะเวลา 12 สัปดาห์ จำนวน 7 ราย ส่วนกลุ่มควบคุม จำนวน 9 ราย ได้รับโปรแกรมฟื้นฟูหัวใจแบบเดียวกันร่วมกับการฝึกความแข็งแรงกล้ามเนื้อหายใจเข้าด้วยอุปกรณ์ฝึกแบบหลอกที่ตั้งระดับแรงต้านไว้ที่ระดับต่ำสุดคงที่ตลอดการศึกษา (Sham) อุปกรณ์ฝึกของทั้งสองกลุ่มถูกปกปิดไม่ให้เห็นการตั้งค่าแรงต้าน ผลลัพธ์หลัก คือ ค่าแรงดันการหายใจเข้า สูงสุด และผลลัพธ์รอง คือ ระยะทางที่เดินได้จากการทดสอบการเดิน 6 นาที เพื่อประเมินสมรรถภาพ การออกกำลังกายระดับต่ำกว่าสูงสุด โดยทำการวัดที่ก่อนการฝึก สัปดาห์ที่ 6 และสัปดาห์ที่ 12 ของการฝึก **ผลการวิจัย:** ค่าเฉลี่ยการเปลี่ยนแปลงของค่าแรงดันการหายใจเข้าสูงสุด พบว่าในกลุ่ม IMT จริง เพิ่มขึ้นมากกว่าอย่างมีนัยสำคัญทางสถิติ เมื่อเทียบกับกลุ่ม Sham ทั้งที่ 6 สัปดาห์ (29.29 เทียบกับ 6.67 เซนติเมตรน้ำ

*p*=0.003) และที่ 12 สัปดาห์ (37.00 เทียบกับ 14.78 เซนติเมตรน้ำ *p*=0.001) อย่างไรก็ตามไม่พบความ แตกต่างอย่างมีนัยสำคัญทางสถิติของค่าเฉลี่ยการเปลี่ยนแปลงในระยะทางที่เดินได้ใน 6 นาที ระหว่างสองกลุ่ม ทั้งสัปดาห์ที่ 6 (*p*=0.135) และสัปดาห์ที่ 12 (*p*=0.629) **สรุปผล:** การเพิ่มการฝึกความแข็งแรงของกล้ามเนื้อ หายใจเข้าชนิด Threshold เป็นระยะเวลา 12 สัปดาห์ ร่วมกับการฟื้นฟูหัวใจระยะผู้ป่วยนอกภายหลัง การผ่าตัดหัวใจแสดงให้เห็นถึงการเพิ่มขึ้นของความแข็งแรงของกล้ามเนื้อหายใจเข้าอย่างมีนัยสำคัญทางสถิติ แต่ไม่พบความแตกต่างระหว่างกลุ่มในการเพิ่มขึ้นของสมรรถภาพการออกกำลังกายระดับต่ำกว่าสูงสุด

***คำสำคัญ*** *● การฝึกความแข็งแรงของกล้ามเนื้อหายใจเข้า ● การฟื้นฟูหัวใจ ● หลังการผ่าตัดหัวใจ*

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## Introduction

Cardiac surgery, including procedures such as coronary artery bypass grafting and valve replacement, is a common treatment for cardiovascular diseases. Data from the Association of Thoracic Surgeons of Thailand show a rising trend, with 7,748 coronary artery bypass surgeries performed in 2023.[1] The standard median sternotomy approach, however, can lead to a postoperative decrease in lung function and respiratory muscle strength, which in turn reduces patients' functional capacity and quality of life.[2]

Inspiratory muscle training (IMT) is a technique designed to increase the strength and endurance of inspiratory muscles using a threshold loading device such as Threshold IMT®, Respironics which provides a flow-independent, pressure-threshold resistance that activates only when the patient generates sufficient inspiratory pressure to overcome a preset load. This mechanism ensures a consistent and measurable training intensity, facilitating progressive strengthening of the inspiratory muscles. It is an established intervention for patients with chronic obstructive pulmonary disease (COPD)[3] and chronic heart failure.[4] Previous studies conducted during inpatient cardiac rehabilitation (CR) have shown that short-term breathing exercises can reduce postoperative complications and increase maximal inspiratory pressure (MIP) and six-minute walk distance (6MWD) compared with standard rehabilitation alone.[5-10]

Despite these findings, there is a limited number of randomized controlled trials evaluating the efficacy of IMT in patients who have undergone median sternotomy and are participating in outpatient (Phase II) CR programs. Therefore, the objective of the present study was to investigate the efficacy of IMT combined with outpatient phase cardiac rehabilitation program in improving inspiratory muscle strength and submaximal exercise capacity in this patient population.

## Materials and methods

### Type of study

This randomized, double-blind, sham-controlled trial was approved by the Institutional Review Board of the Royal Thai Army Medical Department (No. R054h/2560) and registered with the Thai Clinical Trials Registry (TCTR20250818022). Data were collected from July 1, 2017 to September 1, 2018.

**Sample size calculation**

The sample size was calculated based on data from Hermes et al.[11], targeting a final sample of 20 subjects to detect a significant difference in MIP with 80% power, an alpha of 0.05, and accounting for a 20% dropout rate.[12]

**Participants**

Eligible participants were patients aged 18-75 years who had undergone median sternotomy at Phramongkutklao Hospital and were enrolled in the outpatient CR program within four weeks of surgery. All participants provided written informed consent. Exclusion criteria included contraindications to exercise testing as defined by the American College of Sports Medicine (ACSM) guidelines.[13]

**Randomization and Blinding**

Eligible participants were allocated into two groups using block randomization (block size = 4) with sequentially numbered, opaque, sealed envelopes. Both the participants and the outcome assessor were blinded to group assignments. Participants in both groups received a threshold IMT device (Threshold IMT®, Philips Respironics, USA) that had the pressure scale numbers covered with an opaque black Velcro-like plastic strap to conceal the resistance gauge, which could be unwrapped for pressure adjustment **(Figure 1).** The effectiveness of blinding was assessed by asking participants to identify their perceived group allocation at the end of study.

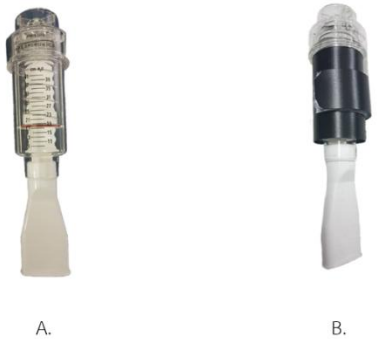


**Figure 1** Respironics® threshold IMT device. A) normal device B) IMT wrapped in opaque black plastic for double blinding

**Intervention**

All participants received standard outpatient CR, which included moderate-intensity aerobic exercise for at least 150 minutes per week. Supervised walking exercise training with ECG telemetry was performed in the outpatient CR clinic. Exercise intensity was prescribed using Borg's rate perceived exertion 11–13, the heart rate = resting plus 20–30 formula,[13] and the talk test for self-monitoring of moderate intensity during at home.

- **IMT Group:** In addition to standard care, this group used the threshold-loading IMT device (Threshold IMT®, Philips Respironics, USA) at home at an initial supervised training intensity set at 30% of the baseline MIP. The protocol consisted of breathing through the device for 2-minute cycles at a rate of 6-10 breaths/minute, with a 1-minute rest between cycles, for 5-7 cycles per session, once daily, seven days a week. The resistance was increased by 5-10% of the initial MIP every 2-3 weeks, reaching 60-70% of the initial MIP by the end of the 12-week program.
- **Sham Group:** This group followed the same training schedule but used a device with the resistance fixed at the lowest setting (7 $cmH_2O$). This level of resistance has been shown to be insufficient to elicit a significant training effect on MIP.[14] The resistance was not adjusted during the study.

**Outcome Measurements**

Outcomes were measured at baseline, 6 weeks, and 12 weeks.

- **Primary Outcome:** The primary outcome was MIP, measured in $cmH_2O$ using a MicroRPM device (Micro Medical/Carefusion, Kent, UK) **(Figure 2).** The measurement was performed with the participant seated. The best of three maximal inspiratory efforts, with values within 10% of each other, was recorded.[15-17]
- **Secondary Outcome:** The secondary outcome was submaximal exercise capacity, measured by the six-minute walk distance (6MWD) in meters, following the American Thoracic Society guidelines[18,19] and training related adverse effects.


**Figure 2** MIP measurement device with single-use cylindrical paper mouthpiece

**Statistical Analysis**

Data were analyzed using SPSS version 23.0. The Shapiro-Wilk test was used to assess the normality of data distribution. Within-group changes in MIP and 6MWD over time were analyzed using one-way repeated measures ANOVA with Bonferroni correction. Between-group differences in the mean changes from baseline were compared using an independent t-test. A *p*-value < 0.05 was considered statistically significant.

**Results**

Of the 38 patients assessed for eligibility, 16 completed the 12-week study protocol (7 in the IMT group and 9 in the sham group). The reasons for exclusion or dropout are detailed in the CONSORT diagram **(Figure 3).** There were no significant differences in baseline demographic or clinical characteristics between the two groups **(Table 1).**

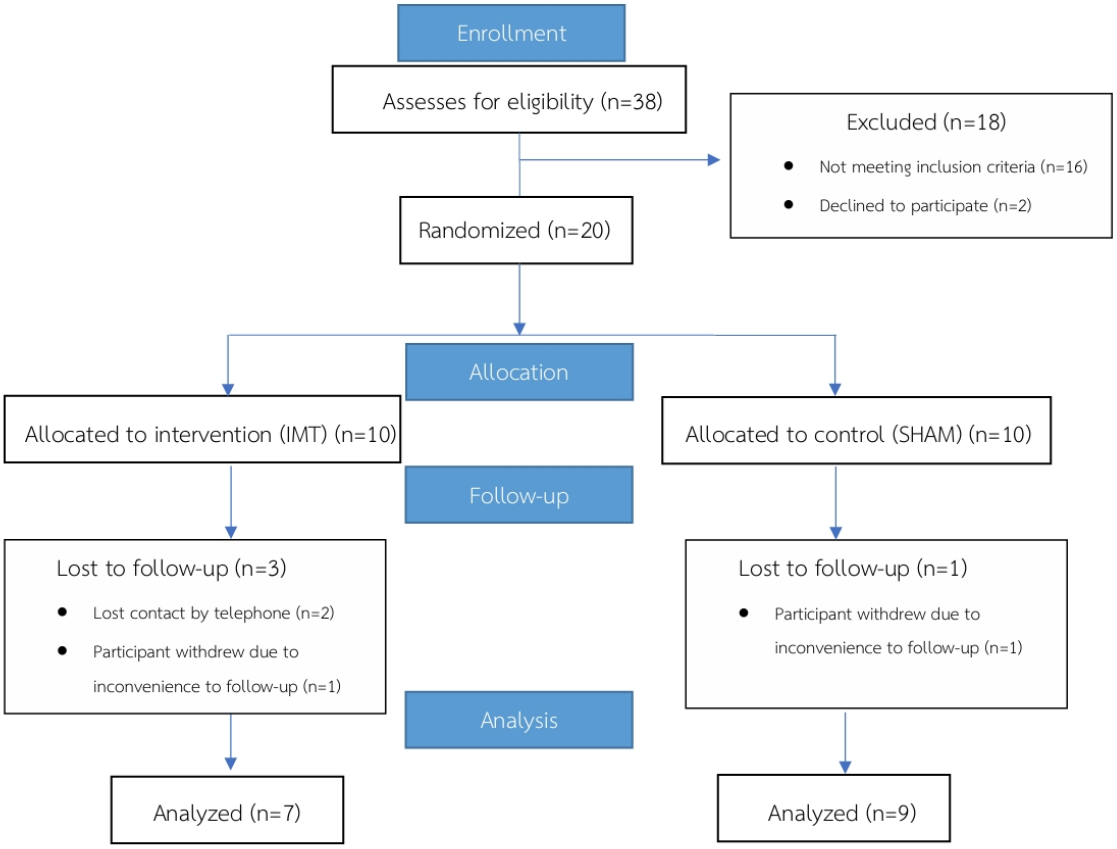


**Figure 3** CONSORT flow diagram

**Table 1** Baseline characteristic of the participants

| | IMT (n=7) | Sham (n=9) |
|---|---|---|
| Age | 54.86±3.53 | 57.33±8.97 |
| Sex n (%) | | |
| male | 6(85.71) | 6(66.67) |
| female | 1(14.29) | 3(33.33) |
| Disease n (%) | | |
| CABG | 5(71.43) | 6(66.67) |
| valvular heart disease | 2(28.57) | 2(22.22) |
| others | - | 1(11.11) |

| | IMT (n=7) | Sham (n=9) |
|---|---|---|
| Risk stratification for cardiac patients n (%) | | |
| low | 3(42.86) | 5(55.56) |
| moderate | - | 2(22.22) |
| high | 4(57.14) | 2(22.22) |
| Ejection fraction | 46.06±19.03 | 60.00±13.15 |
| Height | 1.69±0.05 | 1.64±0.09 |
| Weight | 66.63±10.88 | 63.08±10.20 |
| BMI | 23.15±3.18 | 23.28±2.83 |
| MIP before program | 49.71±14.02 | 49.67±18.93 |
| 6MWD before program | 378.8±116.58 | 343.87±69.02 |

**Maximal Inspiratory Pressure (MIP)**

Within-group analysis showed that MIP increased significantly from baseline in both groups. In the IMT group, MIP increased from 49.71 ± 14.02 $cmH_2O$ at baseline to 79.00 ± 23.59 $cmH_2O$ at 6 weeks (p=0.003) and 86.71 ± 15.87 $cmH_2O$ at 12 weeks (p<0.001). In the sham group, MIP increased from 49.67 ± 18.93 $cmH_2O$ at baseline to 56.33 ± 18.30 $cmH_2O$ at 6 weeks (p=0.041) and 64.44 ± 17.17 $cmH_2O$ at 12 weeks (p=0.020) **(Figure 4).**

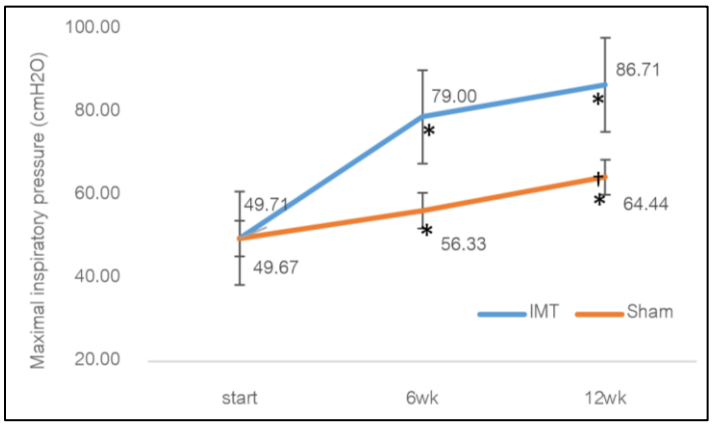


**Figure 4** Maximal inspiratory pressure (MIP) at baseline, 6 weeks, and 12 weeks in the IMT group *$p < 0.05$ compared with baseline; †$p < 0.05$ compared with 6 weeks (within-group comparison)

The between-group comparison, which was the primary analysis, revealed that the mean improvement in MIP from baseline was statistically significantly greater in the IMT group than in the sham group at both 6 weeks (mean difference: 22.62 cmH2O, p=0.003) and 12 weeks (mean difference: 22.22 cmH2O, *p*=0.001) **(Table 2).**

**Table 2** Comparison of mean difference from before program between IMT and Sham group

| | **IMT (Mean±SD)** | **Sham (Mean±SD)** | ***p*-value** |
|---|---|---|---|
| **6MWD** | | | |
| 6wk after training | 61.43±66.88 | 25.14±15.78 | 0.135 |
| 12wk after training | 61.64±61.00 | 49.20±39.65 | 0.629 |
| **MIP** | | | |
| 6wk after training | 29.29±13.00 | 6.67±6.34 | 0.003* |
| 12wk after training | 37.00±9.04 | 14.78±12.18 | 0.001* |

* $p<0.05$

**Six-Minute Walk Distance (6MWD)**

In the IMT group, the 6MWD did not increase significantly from baseline (378.8 ± 116.58 m) to 6 weeks (440.23 ± 68.08 m; *p*=0.153) or 12 weeks (440.23 ± 68.08 m; *p*=0.111). In the sham group, the 6MWD increased significantly from baseline (343.87 ± 69.02 m) to 6 weeks (369.01 ± 72.57 m; *p*=0.004) and 12 weeks (393.07 ± 78.26 m; *p*=0.018) **(Figure 5).**

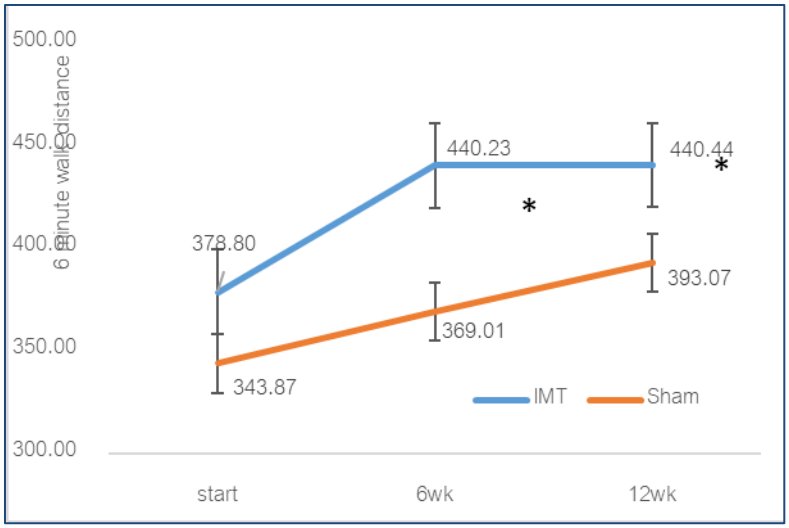


**Figure 5** Six-minute walk distance (6MWD) at baseline, 6 weeks, and 12 weeks in the IMT group. *$p < 0.05$ compared with baseline; †$p < 0.05$ compared with 6 weeks (within-group comparison)

When comparing the change from baseline between groups, there was no statistically significant difference in the improvement of mean change of 6MWD at 6 weeks ($p$=0.135) or 12 weeks ($p$=0.629) **(Table 2).**

## Adverse effects

Nine participants (six in the IMT group, three in the sham group) reported mild, transient chest wall pain during the first 1-2 weeks of using the device. This pain was tolerable, did not require discontinuation of the training or analgesics, and resolved spontaneously. No serious adverse events were reported in either group.

## Discussion

This study demonstrates that a 12-week program of threshold IMT, when added to standard outpatient cardiac rehabilitation, leads to a significantly greater improvement in inspiratory muscle strength compared with aerobic exercise combined with a sham intervention.

This result is consistent with previous research in diverse populations, including patients with COPD[3], chronic heart failure[4], and those in the inpatient phase of post-cardiac surgery

recovery.[5-10] The observed increase in MIP aligns with the overload principle of resistance training, where exercising muscles against a load exceeding their metabolic capacity induces structural and neural adaptations that enhance strength.[20-24] Studies have shown that IMT can increase the proportion of Type I muscle fibers and the size of Type II fibers in the intercostal muscles, leading to greater strength and fatigue resistance.[25]

A notable finding was the statistically significant, albeit smaller, increase in MIP within the sham group. This can be attributed to the natural recovery process following median sternotomy. The procedure is known to cause a sharp decline in MIP due to incisional pain and reduced chest wall compliance.[26, 27] As patients recover and pain subsides in the weeks following surgery, their ability to generate maximal inspiratory force naturally improves, often returning to near-preoperative levels within two months.[28] The standard aerobic exercise in the cardiac rehabilitation program may also have contributed to this improvement. However, the significantly larger gains observed in the IMT group confirm the specific and additional benefit of targeted resistive training.

To the authors' knowledge, this is one of the first randomized controlled trials to investigate the combined effect of IMT on 6MWD in an outpatient post-cardiac surgery population with randomized, double-blind, sham-controlled study design. The results indicate that the addition of IMT did not provide any further improvement in submaximal exercise capacity beyond that achieved through the standard aerobic exercise component of cardiac rehabilitation. Both groups demonstrated an increase in 6MWD over the 12 weeks, which is an expected outcome of a structured exercise program following a period of deconditioning associated with major surgery.[29] The lack of a different effect suggests that in this patient population, submaximal walking performance is likely limited by factors other than inspiratory muscle strength, such as peripheral muscle function, cardiovascular adaptation, and overall conditioning, which are primarily addressed by aerobic exercise.[29] This finding is consistent with

studies in other populations, such as the elderly, where IMT improved muscle strength but did not translate to improved 6MWD.[20]

These findings may be translated into outpatient cardiac rehabilitation practice by incorporating threshold IMT devices for patients recovering from cardiac surgery with sternotomy who are at risk of inspiratory muscle weakness - such as those with COPD or stable congestive heart failure - to enhance clinical outcomes.

**Limitations**

This study has several limitations that should be considered when interpreting the results. Firstly, the final sample size of 16 participants was smaller than the 20 subjects targeted by the initial power calculation. This may have rendered the study underpowered to detect a small but potentially clinically meaningful difference in 6MWD between the groups. Secondly, despite efforts to maintain blinding, 33% of participants in the sham group correctly identified their group allocation, which may have introduced a performance bias. Thirdly, the IMT and aerobic exercise were performed at home without direct supervision or adherence monitoring, which could have introduced variability in the training stimulus. Finally, data on preoperative inspiratory muscle strength were not collected, which would have provided a more complete picture of the postoperative recovery trajectory. Future research should address these limitations by utilizing a larger sample size, exploring alternative sham protocols to improve blinding, and incorporating methods to monitor adherence to home-based exercise.

**Conclusion**

The addition of a 12-week threshold inspiratory muscle training to outpatient aerobic exercise-based cardiac rehabilitation in post-cardiac surgery patients demonstrated a statistically significant increase in inspiratory muscle strength. Nevertheless, no significant enhancement in submaximal exercise capacity is observed when compared with a sham-device control group. Threshold inspiratory muscle training demonstrated a good safety profile for home-based use.

## References


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