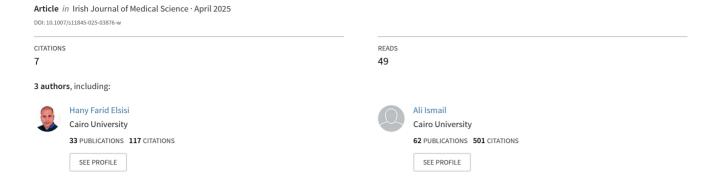
# Functional outcomes of inspiratory muscle training in elderly with intensive care unit-acquired weakness and severe walking disability



# **ORIGINAL ARTICLE**



# Functional outcomes of inspiratory muscle training in elderly with intensive care unit-acquired weakness and severe walking disability

Mushabbab Alahmari<sup>1</sup> · Hany Farid Elsisi<sup>1</sup> · Ali Mohamed Ali Ismail<sup>2</sup>

Received: 9 October 2024 / Accepted: 14 January 2025 / Published online: 3 February 2025 © The Author(s), under exclusive licence to Royal Academy of Medicine in Ireland 2025

#### **Abstract**

**Background** Intensive care unit acquired-weakness syndrome (ICUAWS) leaves several complications in functional movements of patients such as severe walking disability.

**Objective** Assessment of functional outcomes of 1-month inspiratory muscle training (IMT) in elderly with ICUAWS and severe walking disability was our aim.

The design, setting, participants, and intervention.

This study is a randomized controlled trial. ICUAWS patients who complained of severe walking disability on the Modified Functional Ambulatory Category Test (MFACT) were randomly assigned into the IMT group or control group, n = 20 for each group. Both groups received the traditional physical therapy program.

**Results** The results showed that the post-therapy between-group comparison of ICUAWS sufferers/groups' parameters showed a significant improvement toward the IMT group in six-minute walk test, inspiratory and expiratory muscle strength, forced vital capacity, time up and go test, 10-m walk test, forced expiratory volume in the first second, 30-s sit-to-stand test, partial pressure of arterial blood oxygen and carbon dioxide, MFACT, oxygen saturation of arterial blood, physical, and mental summary of short form 36.

**Conclusion** In conclusion, IMT improves functional outcomes in ICUAWS patients with walking disability. **Trial registration number** The clinical trial ID of this ICUAWS trial is NCT06210763.

**Keywords** Elderly · Exercise · Functional outcomes · Inspiratory muscle training · Intensive care unit acquired weakness · Walking

# Introduction

In critically ill patients, the physicians' aim of medical/ pharmacological treatment is directed mainly toward stabilizing the acute life-threatening disease/disorder. Anesthesia, repeated corticosteroid administration, mechanical ventilation, and/or sedatives/neuromuscular blockade are usually used as medical interventions in the intensive care unit (ICU) for sufferers with critical illnesses. Multiple scientific documentations are reporting that these interventions usually induce chronic systemic inflammation, massive catabolic processes, extended periods of immobility, and neurocognitive/neuromuscular insults/disorders including ICU-acquired-weakness syndrome (ICUAWS) [1].

The disorder that is induced by primary myopathy and/or axonal neuropathy in patients hospitalized in ICU due to the presence of critical illness is the definition of ICUAWS. As a complication of ICU stay, the prevalence of ICUAWS is 25–33%. The underlying mechanism of ICUAWS is not fully explained but cumulative microvascular/metabolic changes, electrical/bioenergetic alterations, muscular weakness, and muscular atrophy may be the cause of ICUAWS appearance. ICUAWS is a symmetrical neuromuscular disorder that affects mainly respiratory and proximal limb muscles while facial/ocular muscles are often spared [2].



Ali Mohamed Ali Ismail ali-mohamed@cu.edu.eg

Department of Respiratory Therapy, College of Applied Medical Sciences, University of Bisha, Bisha, Saudi Arabia

Department of Physical Therapy for Cardiovascular/Respiratory Disorder and Geriatrics, Faculty of Physical Therapy, Cairo University, Cairo, Egypt

High morbidity is frequently reported in ICUAWS patients. Beyond the hospitalization period, recent documentations report ICUAWS-associated long-term post-intensive care syndrome (PICS, a syndrome of mental/cognitive and physical dysfunctions). PICS negatively impact daily activities, physical functions, walking, and quality of life among ICUAWS survivors [3].

ICUAWS-induced respiratory manifestations/complications are very common. These complications are rapid/shallow breathing, accumulated/sticky secretions in airways, increased use of accessory respiratory muscles, increased risk of atelectasis/aspiration, diaphragmatic weakness (suggested by during-inspiration paradoxical abdominal movement), during-talking dyspnea/breathlessness, and ineffective cough mechanism [4]. The ICUAWS-induced decrease/loss of respiratory muscular strength causes impairments in the execution of functional/physical activities (routine daily activities and walking) and high energy expenditure/loss during the performance of simple routine activities (dressing, eating, and bathing) [5].

Different pulmonary rehabilitation techniques (breathing exercises, aerobic training, active and resisted range of motion exercises of joints of upper and lower limbs, and nutritional/ psychological counselling) documented improved respiratory muscle strength/endurance, enhanced ventilator function tests, decreased exercise intolerance, increased performance of physical activities, and improved quality of life. Inspiratory muscle training (IMT) devices are relatively new devices that are routinely used during pulmonary rehabilitation programs in patients with chronic respiratory disorders [6]. Breathing against within IMT device external load is the definition of an inspiratory muscle trainer device. There are great reported advantages of IMT devices. Improved exercise capacity/tolerance, diaphragmatic thickness/mobility, cardiovascular autonomic balance/control, quality of life, and walking abilities after rehabilitation programs in healthy, older, and ill subjects are some of IMT devices' reported advantages in literature [7].

The rehabilitation of walking/ambulation appears to be a great aim of rehabilitation programs for ICUAWS sufferers because walking is the main physical activity that is strongly needed to perform patients' basic daily activities and to prevent patient dependence and poor quality of life. To our knowledge, in the context/field of ICUAWS trials, no previous randomized-controlled rehabilitation trial has been discussed/investigated the 4-week effect of IMT on functional outcomes in patients with ICUAWS and severe walking disability, so this trail was built for this mentioned aim.

#### Methods

#### Design

A randomized-controlled post-acute ICU-discharge rehabilitation study.

# **Settings**

The settings of this ICUAWS trial were in a local hospital (general hospital/facility). The rehabilitation of the ICUAWS participants was from 2 August 2023 to 30 March 2024 (clinical trial ID: NCT06210763).

#### **Ethics**

Helsinki rules for applying/performing clinical trials/ research are considered. The unique code of local ethical Cairo-university approval was P.T.REC/012/004624.

# **Criteria of included ICUAWS patients**

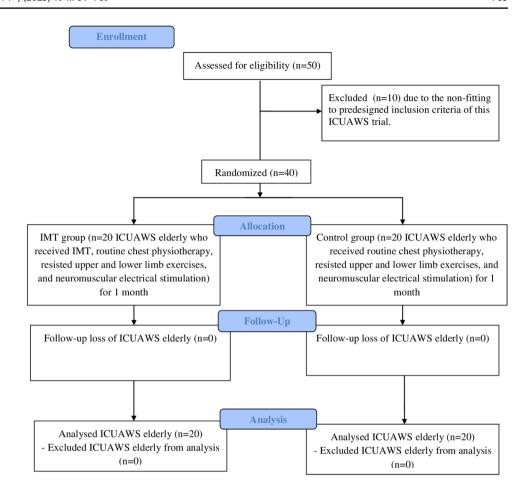
The included elderly were diagnosed as ICUAWS according to the presence of by-physician clinical interpretations of results of electrophysiological studies (nerve conduction studies and electromyography) and/or the presence of a total score of Medical Research Council (MRC) that defines ICUAWS was < 48. To be noted, MRC is a tool designed to assess bilateral strength of twelve muscle groups (wrist extensors, shoulder abductors, elbow flexors, knee extensors, dorsiflexors, and hip flexors) with a score appointed between zero (to muscle that did not contract at all) to five (to muscle that shows normal strength), while the total MRC score ranged from 0 to 60 [2]. The included patients were recently received mechanical ventilation weaning procedures and/or discharged from the ICU unit. The included ICUAWS sufferers complained of severe walking disability (i.e., having a score  $\leq 4$  on the modified functional ambulatory category test) and they had active preserved movement in muscles of the upper and lower limbs. The included patients were free from any neurological, orthopedic, or limb amputation problems.

#### Randomization

The included ICUAWS elderly (n = 40) were randomly and equally assigned into the IMT group (n = 20 ICUAWS) patients who received IMT, routine chest physiotherapy, resisted upper and lower limb exercises, neuromuscular electrical stimulation) or control group (n = 20 ICUAWS) patients who received the same intervention of the other



**Fig. 1** Flow chart of ICUAWS elderly



group except IMT) (Fig. 1) (sessions were performed via a well-trained physical therapist with the assistance and the supervision of third author). A physical therapy assistant was displaced by authors from participation in this rehabilitation study performed the randomization which was done via the closed envelope technique.

#### Interventions

# Upper limb resistance exercises (nearly 15 min)

Free weights (sandbags) were used for the exercises, and the resistance was set to 50% of the maximum load determined by the maximum repetition test. For the resistance training, three sets of 10 repetitions each of the right and left arm's flexion and abduction movements were done. The right elbow was flexed and extended, followed by the left elbow, in 3 sets of 10 repetitions. The right wrist was flexed and extended, followed by the left wrist, in three sets of ten repetitions. Depending on the patient's tolerance, there was a rest period of 1–2 min between each set of exercises [8].

# Lower limb resistance exercises (nearly 15 min)

With the same idea of training upper limb muscles via resistance training, free weights (sandbags) were used for lower limb resistance exercises, and the resistance was set to 50% of the maximum load determined by the maximum repetition test. For the resistance training, 3 sets of 10 repetitions of each of the right and left hip flexion and abduction movements were done (right hip movements were done first followed by the movements of the left hip. The right knee was flexed and extended, followed by the left knee, in 3 sets of 10 repetitions. The right ankle was dorsiflexed, followed by the left ankle, in 3 sets of 10 repetitions. Depending on the patient's tolerance, there was a rest period of 1–2 min between each set of exercises.

#### **Neuromuscular electrical stimulation**

A 30-min neuromuscular electrical stimulation session was executed daily (5 days/week) on an upper limb (bilateral triceps and wrist extensor muscles) and lower limb (bilateral quadriceps and dorsiflexor muscles). The used intensity levels were directed to induce visible muscular contractions



which were tolerated by the ICUAWS patients. In case of doubt, local palpation confirmed the muscular contraction.

# **Chest physiotherapy**

In patients with ICUAWS, nearly 15-min sessions of traditional chest physiotherapeutic treatment/preventive techniques cough training, vibration and/or shaking, therapeutic percussion, rib springing, and postural drainage positions (used in patients with retained secretions) were applied.

# **IMT** protocol

In a comfortable sitting position on a chair, the ICUAWSgroup patients who were trained via an IMT device (Philips Respironics threshold) were ordered to place the nose clip (delivered to them by the therapist) on their nose. The baseline maximum inspiratory pressure (MIP) of ICUAWS patients was measured to detect the IMT intensity. All ICUAWS patients were trained at the intensity of IMT equal to 40% of their basal MIP. After releasing full relaxed expiration, ICUAWS patients were ordered to put the IMT device's mouthpiece in their mouth during the inspiratory phase of respiration, while they were ordered to strongly and deeply inhale to release the IMT device's valve. For 4-week successive IMT sessions, three sets breathing training (the set contained ten breaths), separated by 1-minute rest [9], were executed two times daily. The IMT sessions were applied five times per week.

# **Outcomes of this ICUAWS trial**

# **Primary outcome**

The net score of the modified functional ambulatory category test (MFACT) was the primary outcome of this ICUAWS trial. The authors of this study utilized the seven-point Likert-scale (I to VII) walking/ambulation test, MFAC, to detect/evaluate gait variations/differences between the patients [10]. Gait/walking testing using MFAC was used to assess the following seven items [11]:

- Item/grade I of MFACT: the tested patient had could not perform the usual gait and needed external manual assistance/help to make a sitting position or the tested patient was unable to perform a 1-min sitting position without back and/or hand support with the bed/plinth height allowing patient's hips, knees, and ankles to be positioned at an angle reached 90 degrees, and both patient's feet were positioned flatly on the floor.
- Item/grade II of MFACT: the tested ICUAWS patient could not perform 1-min sitting without external sup-

- port (back/hand support). The tested ICUAWS patient was able to perform walking with the help of two persons
- Item/grade III of MFACT: Only one person can manually help the tested ICUAWS patient during on-level surfaced ambulation/walking to prevent any form of falling. Continuous and necessary manual help/contact from the assisting person is strongly needed to support during-ambulation ICUAWS patient's balance, body weight, and/or coordination.
- Item/grade IV of MFACT: Only one person can manually help the tested ICUAWS patient during on-level surfaced ambulation/walking to prevent any form of falling. Continuous or intermittent manual help/contact (in the form of light touch) from the assisting person may be needed to support during-ambulation ICUAWS patient's balance and/or coordination.
- Item/grade V of MFACT: During on-level surfaced ambulation/walking, the ICUAWS patient did not receive manual contact/support from an assistant person, but for safety concerns/reasons, the ICUAWS patient required standby verbal cuing or non-physical contact/guarding of one person only.
- Item/grade VI of MFACT: The turning, walking, and transfer activities were done independently by the ICUAWS patient on level ground. Ascending/descending stairs and walking on uneven surfaces or inclines needed negotiations such as therapist's supervision or physical assistance.
- Item/grade VII of MFACT: full ability to perform independent walking/gait on (non)level surfaces/inclines and stairs.

It is to be noted that MFACT did not take into consideration the use of assistive walking aids.

# **Secondary outcomes**

# **Pulmonary functions**

The predicate values of ICUAWS patients' forced vital capacity (FVC) test and the test of the forced expiratory volume (at the first second of ICUAWS patients' expiration) (FEV1) were assessed.

# **Arterial blood gases**

For all included ICUAWS patients in this rehabilitation trial, besides the arterial oxygen saturation (SO<sub>2</sub>), the arterial partial pressure of oxygen, and carbon dioxide (PO<sub>2</sub> and PCO<sub>2</sub>) were assessed.



#### Respiratory muscle strength

According to the published guideline/recommendation of "American Thoracic Society and European Respiratory Society, 2002" [12], utilizing MicroRPM portable/hand-held meter (respiratory pressure meter, CareFusion Micro-Medical, UK), ICUAWS patients' MIP and maximal expiratory pressure (MEP) were assessed/recorded in cm H2O.

# ICUAWS patients' health-associated quality of life (QoL)

The QoL questionnaire, short-form-36 questionnaire (SF-36), is a general/valid patient-reported outcome assessment tool used in measuring ICUAWS patients' life satisfaction associated with their health. In this rehabilitation trial, the 36 SF-36-item questionnaire was eight subscales/subcategories: ICUAWS patient's physical role, ICUAWS patient's vitality, ICUAWS patient's social function, ICUAWS patient's emotional role, bodily discomfort/pain, ICUAWS patient's physical function, and ICUAWS patient's general mental health. Furthermore, the eight scales are combined to create the physical component summary and the mental component summary, and two SF-36-related separated high-order summary scales were constituted from the eight subscales/ subcategories: physical summary (PS) and Mental summary (MS) [13].

# Timed up-and-go test

Measured in seconds, ICUAWS patients' timed up-and-go test (TUGT) was assessed after recording the time consumed by the ICUAWS participants to do the following successive steps: rise from the test's standard armchair, perform 3-meter walking, make a turn, walk back to the test's chair, and then sit down [14]. Patients who achieved grade I, II, or III using MFACT were given a score of zero in TUGT.

# Six-minute walk test (SMWT)

Measured in meters, ICUAWS patients' walking distance during 6-min walking was assessed. Patients who achieved grade I, II, or III using MFACT were given a score of zero in SMWT.

#### Ten-meter walk test (TMWT)

Measured in seconds, ICUAWS patients' walking time to cover a 10-m walk was assessed. Patients who achieved

grade I, II, or III using MFACT were given a score of zero in TMWT.

# Thirty-second sit-to-stand test (30sSTST)

ICUAWS patients' number of performed sit-to-stand repetitions covered during 30 s were assessed during 30sSTST. Patients who achieved grade I, II, or III using MFACT were given a score of zero in TMWT.

# **Blinding**

The details of physiotherapeutic interventions (IMT, traditional IMT, routine chest physiotherapy, resisted upper and lower limb exercises, neuromuscular electrical stimulation) applied to ICUAWS patients were not informed to outcome assessors.

#### Sample size

The persons of ICUAWS who completed this study were 40 ICUAWS patients. In fact, this number was 36 persons (this was the initial number that was delivered from a pilot power-analysis test on 16 ICUAWS sufferers, effect size 0.93, 80% power), but it was increased by 10% to 40 ICUAWS sufferers to eliminate the effect of patients' discontinuation during the rehabilitation period.

#### Statistical analysis of this ICUAWS trial

Normality test of basic (age, days of mechanical ventilation, age, BMI) and outcome data (PS, PO<sub>2</sub>, TUGT, PCO<sub>2</sub>, FEV1, 30sSTST, FVC, SO<sub>2</sub>, MFACT, SMWT, MIP, TMWT, MEP, and MS) of ICUAWS patients showed normal distribution by Kolmogorov–Smirnov test. Considering that the common/international significant effect of *P* value was < 0.05 for all ICUAWS trial's data, utilizing the SPPS 18, unpaired (for between-group parity/comparison of ICUAWS elderly's basic data) and ANOVA (for within-group or between-group parity/comparison of ICUAWS elderly's outcomes) tests were practiced during data analysis of this ICUAWS trial.

# **Results**

Pre-treatment between-group comparison of ICUAWS patients' basic (age, days of mechanical ventilation, and BMI as pointed in Table 1) and outcome data (PS, PO<sub>2</sub>, TUGT, PCO<sub>2</sub>, FEV1, 30sSTST, FVC, SO<sub>2</sub>, MFACT, SMWT, MIP, TMWT, MEP, and MS as pointed in Table 2) did not show a significant variation.

After ending the rehabilitative procedures in ICUAWS patients, the within-IMT-group comparison of outcome



Table 1 Basic data this inspiratory muscle rehabilitation trial in ICUAWS patients (expressed as percentage, mean ± SD, or numbers)

Data of ICUAWS patients	IMT group	Control group	P value
ICUAWS patients' age [year]	$73.35 \pm 5.24$	$71.60 \pm 4.50$	0.264
ICUAWS patients' MVD (days)	$35.35 \pm 11.82$	$36.45 \pm 9.77$	0.750
ICUAWS patients' body mass index [kg/m <sup>2</sup> ]	$25.55 \pm 2.57$	$24.51 \pm 3.06$	0.251
ICUAWS Males %	50	55	
Number of primary diagnosis in ICU	7	6	
	6	5	
	5	6	
	2	3	

ICU intensive care unit, non-significant P value is considered when the value is > 0.05, MVD mechanical ventilation duration, IMT inspiratory muscle training, ICUAWS intensive-care-unit acquired-weakness syndrome, SD standard deviation

data (PS, PO<sub>2</sub>, TUGT, PCO<sub>2</sub>, FEV1, 30sSTST, FVC, SO<sub>2</sub>, MFACT, SMWT, MIP, TMWT, MEP, and MS) showed a significant improvement. Regarding the within-control-group comparison, only TUGT, 30sSTST, MFACT, SMWT, PS, TMWT, MIP, and MS showed significant improvements (these improvements were lower than the IMT group's improvements as pointed out in Table 2).

After ending the rehabilitative procedures in ICUAWS patients, the between-group comparison of outcome data (PS, PO<sub>2</sub>, TUGT, PCO<sub>2</sub>, FEV1, 30sSTST, FVC, SO<sub>2</sub>, MFACT, SMWT, MIP, TMWT, MEP, and MS) showed a significant improvement toward the IMT group (as pointed in Table 2).

# **Discussion**

This was the first trial that used IMT in the rehabilitation scenario of ICUAWS. Compared with the group of ICUAWS that received a traditional rehabilitation program only, the ICUAWS group that received both IMT and traditional rehabilitation program showed greater significant improvements in PS, PO<sub>2</sub>, TUGT, PCO<sub>2</sub>, FEV1, 30sSTST, FVC, SO<sub>2</sub>, MFACT, SMWT, MIP, TMWT, MEP, and MS.

The explanation of improved respiratory muscle strength (represented as MIP and MEP) after IMT may be a multifactorial mechanisms. Increased proportion/size of type-II respiratory muscle fibers, enhanced diaphragmatic thickness/strength, inhibited respiratory muscles' metaboreflex, and enhanced economical energy expenditure of respiratory muscle contraction are the suggested mechanism of IMT-induced improvement in MIP and MEP. Improved ICUAWS patients' respiratory muscle strength/capacity, by-respiratory-muscle lactate production, respiratory muscle oxygenation, and perception of dyspnea and respiratory muscle fatigue increase functional performance of peripheral muscles (including muscles of locomotion) increases, so the

patients report elevated functional fitness, exercise tolerance, walking abilities, and quality of life [9, 15].

Besides the highly reported improvement in cardiopulmonary fitness that increases the utilization of locomotor muscles in walking and functional performance, exercise protocols of peripheral/limb muscles not only increase respiratory muscles strength/endurance but also add specific training of the respiratory muscles to peripheral muscle training generate more strength in chronic-disease patients' respiratory muscles [16]. So, these explanations may justify the improved gait disabilities after adding IMT to the traditional rehabilitation program of ICUAWS.

Regarding arterial blood gases, the ICUAWS patients' improved PO<sub>2</sub>, PCO<sub>2</sub>, and SO<sub>2</sub> after a 4-week IMT may be related to the consequent reduction of breath workloads, positive changes in ventilator pattern, and improved correction of ICUAWS patients' respiratory pattern/manner from high-energy costing rapid/shallow respiratory pattern to low-energy costing slow/deep respiratory pattern [17].

Consistent with the ICUAWS patients' findings, the COPD patients' PO<sub>2</sub> and PCO<sub>2</sub> significantly responded well to the 2-month IMT training in a study conducted by Aly et al. [17]. In adherence with us, results of hemodialysis patients' SO<sub>2</sub>, PO<sub>2</sub>, SMWT, and PCO<sub>2</sub> significantly responded well to the 2-month IMT (via incentive spirometer) in a study conducted in 2021 [18].

The 8-week IMT protocol for strengthening older women's respiratory muscles significantly improved their MIP and MEP to support us [15]. After 12-week IMT, the atrial fibrillation patients' MEP, FVC, SMWT, FEV1, and MEP significantly improved [19] parallel to our ICUAWS patients' findings. The 6-week trial conducted in 2022 on stroke patients showed a significant improvement in SMWT, MEP, TUGT, and MIP after the IMT protocol to be consistent with our IMT protocol's results [20].

Besides MIP improvement, engagement time in physical activity and after-exercise fatigue time was significantly increased after 8-week IMT in moderately active elderly



**Table 2** Outcomes of this inspiratory muscle rehabilitation trial (mean  $\pm$  SD)

Parameters		IMT group	Control group	P value (between IMT and control groups)
FVC (% predicted)	Pre-rehabilitation program	69.90 ± 6.75	67.60 ± 5.78	0.255
	Post-rehabilitation program	$73.55 \pm 6.36$	$68.60 \pm 6.26$	$0.018^{*}$
	P value (within rehabilitation groups)	< 0.001*	0.09	
TUGT (measured in seconds)	Pre-rehabilitation program	$20.35 \pm 5.70$	$24.10 \pm 9.05$	0.125
	Post-rehabilitation program	$10.10 \pm 3.98$	16.90 ± 6.91	< 0.001*
	P value (within rehabilitation groups)	< 0.001*	< 0.001*	
FEV1 (% predicted)	Pre-rehabilitation program	$71.30 \pm 5.91$	$68.85 \pm 7.06$	0.242
	Post-rehabilitation program	$75.75 \pm 5.71$	$69.55 \pm 6.03$	$0.002^{*}$
	P value (within rehabilitation groups)	< 0.001*	0.188	
PO <sub>2</sub> (mmHg)	Pre-rehabilitation program	$93.70 \pm 3.19$	$91.30 \pm 5.22$	0.088
	Post-rehabilitation program	$95.10 \pm 2.55$	$91.50 \pm 6.53$	$0.027^{*}$
	P value (within rehabilitation groups)	0.028*	0.746	
30sSTST (repetitions managed in 30 s)	Pre-rehabilitation program	$15.25 \pm 2.24$	$13.90 \pm 2.10$	0.057
	Post-rehabilitation program	$17.80 \pm 2.09$	$14.95 \pm 2.16$	< 0.0001*
	P value (within rehabilitation groups)	< 0.001*	< 0.001*	
PCO <sub>2</sub> (mmHg)	Pre-rehabilitation program	$41.10 \pm 4.25$	$43.60 \pm 3.71$	0.055
	Post-rehabilitation program	$39.80 \pm 4.40$	$43.35 \pm 6.06$	0.041*
	P value (within rehabilitation groups)	0.044*	0.691	
MFACT	Pre-rehabilitation program	$2.55 \pm 1.09$	$2.65 \pm 1.13$	0.779
	Post-rehabilitation program	$5.65 \pm 1.18$	$3.75 \pm 1.06$	< 0.001*
	P value (within rehabilitation groups)	< 0.001*	<0.001*	
SO <sub>2</sub> (%)	Pre-rehabilitation program	$94.05 \pm 1.60$	$95.15 \pm 2$	0.063
	Post-rehabilitation program	$97.25 \pm 2.44$	$95.25 \pm 2.61$	0.017*
	P value (within rehabilitation groups)	< 0.001*	0.875	
SMWT (measured in meters)	Pre-rehabilitation program	$135.45 \pm 46.45$	$118.30 \pm 35.51$	0.197
	Post-rehabilitation program	$288.40 \pm 55.24$	$250.60 \pm 44.46$	$0.022^{*}$
	P value (within rehabilitation groups)	< 0.001*	<0.001*	
MIP (cm H <sub>2</sub> O)	Pre-rehabilitation program	$34.85 \pm 4.69$	$31.30 \pm 7.10$	0.07
	Post-rehabilitation program	$37.95 \pm 4.18$	$31.55 \pm 6.71$	0.001*
	P value (within rehabilitation groups)	< 0.001*	0.680	
TMWT (measured in seconds)	Pre-rehabilitation program	$14.35 \pm 2.49$	$16.10 \pm 3.22$	0.063
	Post-rehabilitation program	$7.05 \pm 1.63$	$11.75 \pm 3.22$	< 0.001*
	P value (within rehabilitation groups)	< 0.001*	< 0.001*	
PS	Pre-rehabilitation program	$22.35 \pm 6.45$	$26.30 \pm 6.10$	0.054
	Post-rehabilitation program	$25.75 \pm 6$	$29.65 \pm 6.08$	0.048*
	P value (within rehabilitation groups)	< 0.001*	<0.001*	
MEP (cm H <sub>2</sub> O)	Pre-rehabilitation program	$33.50 \pm 6.36$	$29.90 \pm 7.89$	0.121
	Post-rehabilitation program	$38.30 \pm 5.94$	$30.95 \pm 7.82$	0.002*
	P value (within rehabilitation groups)	<0.001*	< 0.001*	
MS	Pre-rehabilitation program	$49.25 \pm 5.28$	$46.40 \pm 4.33$	0.07
	Post-rehabilitation program	$54.35 \pm 5.22$	$47.45 \pm 4.35$	< 0.001*
	P value (within rehabilitation groups)	< 0.001*	0.003*	

FEV1 forced expiratory volume in the patients' first second of expiration, 30sSTST thirty-second sit-to-stand test, MIP maximal inspiratory pressure, IMT inspiratory muscle training, SMWT six-minute walking test, SD standard deviation,  $SO_2$  oxygen saturation,  $^*P$  value is significant, MS Mental Summary of Short Form 36,  $PO_2$  partial pressure of oxygen, TUGT time up-and-go test,  $PCO_2$  partial pressure of carbon dioxide; MFACT Modified Functional Ambulation Category Test, PS Physical Summary of Short Form 36, MIP maximal inspiratory pressure, FVC forced vital capacity, TMWT ten-meter walking test



[16]. Also, functional capacity and limitations due to physical factors (as two domains of an eight-domain SF-36 QoL questionnaire), MIP, and 30sSTST significantly improved in institutionalized Brazilian elderly after 6-week IMT [21].

The results of 8-week IMT in type diabetics were concurrent with our ICUAWS patients' recorded results because the diabetics showed significant improvements in MIP, TUGT, and SMWT [22]. Outcomes of applying 8-week IMT in multiple sclerosis patients were concurrent with us due to FEV1, MEP, TUGT, FVC, and MIP, all domains of the SF-36 QoL questionnaire [23].

#### Limitations

Despite the well-applied randomization and blinding of this study, tracking changes in PS, PO<sub>2</sub>, TUGT, PCO<sub>2</sub>, FEV1, 30sSTST, FVC, SO<sub>2</sub>, MFACT, SMWT, MIP, TMWT, MEP, and MS after the trial termination was the main limitation. Perspective and randomized future IMT trials in ICUAWS patients should manage/test effect of different types of respiratory muscle trainer devices in ICUAWS patients.

As seen in different settings and circumstances [24–26], examining the efficacy of the unsupervised home sessions [24], tele-rehabilitation [25], or robot-assisted rehabilitation [26] must be examined, but in ICUAWS survivors.

# **Conclusion**

Adding IMT protocol to traditional rehabilitation programs improves ICUAWS patients' PS,  $PO_2$ , TUGT,  $PCO_2$ , FEV1, 30sSTST, FVC,  $SO_2$ , MFACT, SMWT, MIP, TMWT, MEP, and MS.

**Acknowledgements** The authors are thankful to the Deanship of Graduate Studies and Scientific Research at University of Bisha for supporting this work through the Fast-Track Research Support Program.

**Author contribution** AM, EHF, and IA contributed equally in all parts of this study performed on older sufferers with ICUAWS. All three authors of ICUAWS trial authorize the responsibility of the content of this paper.

Data Availability Up on request.

# **Declarations**

**Ethics approval** Helsinki rules for applying/performing clinical trials/ research are considered. The unique code of local ethical Cairo-university approval was P.T.REC/012/004624.

**Consent to participate** All ICUAWS older patients were consented.

**Informed consent** The unique code of local ethical Cairo-university approval that allowed consenting of patients was P.T.REC/012/004624.

Consent for publication Not applicable.



**Competing interests** The authors declare no competing interests.

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