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Research paper

Feasibility, safety, and patient acceptability of electronic inspiratory muscle training in patients who require prolonged mechanical ventilation in the intensive care unit: A dual-centre observational study

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ABSTRACT

Background: Inspiratory muscle training (IMT) is an intervention that can be used to rehabilitate the respiratory muscle deconditioning experienced by patients with critical illness, requiring prolonged mechanical ventilation. Clinicians are currently using mechanical threshold IMT devices that have limited resistance ranges.

Objectives: The objective of this study was to evaluate the safety, feasibility, and acceptability of using an electronic device to facilitate IMT with participants requiring prolonged mechanical ventilation.

Method: A dual-centre observational cohort study, with convenience sampling, was conducted at two tertiary intensive care units. Daily training supervised by intensive care unit physiotherapists was completed with the electronic IMT device. A priori definitions for feasibility, safety, and acceptability were determined. Feasibility was defined as more than 80% of planned sessions completed. Safety was defined as no major adverse events and less than 3% minor adverse event rate, and acceptability was evaluated following the acceptability of intervention framework principles.

Results: Forty participants completed 197 electronic IMT treatment sessions. Electronic IMT was feasible, with 81% of planned sessions completed. There were 10% minor adverse events and no major adverse events. All the minor adverse events were transient without clinical consequences. All the participants who recalled completing electronic IMT sessions reported that the training was acceptable. Acceptability was demonstrated; over 85% of participants reported that electronic IMT was either helpful or beneficial and that electronic IMT assisted their recovery.

Conclusion: Electronic IMT is feasible and acceptable to complete with critically ill participants who require prolonged mechanical ventilation. As all minor adverse events were transient without clinical consequences, electronic IMT can be considered a relatively safe intervention with patients who require prolonged mechanical ventilation.

1. Introduction

Of the 160,000 patients admitted to the intensive care unit (ICU) in Australia and New Zealand every year, more than 50% require invasive mechanical ventilation.[1] In patients ventilated for at least 24 h, the prevalence of inspiratory muscle weakness (63%) is almost double than that of peripheral muscle weakness (34%)[2] and can contribute to ongoing difficulty weaning from mechanical ventilation,[3] hence prolonging the patients' ICU length of stay. Within Australia, each day in the ICU costs approximately AUD$4000.[4] Furthermore, inspiratory muscle weakness often manifests as breathlessness,[5] which may contribute to the poor quality of life

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reported for ICU survivors up to 5 years following ICU discharge.[6,7] These poor outcomes may be improved through targeted strengthening of inspiratory muscles in patients who have required prolonged mechanical ventilation.

Inspiratory muscle training (IMT) in an ICU context requires collaboration between physiotherapists and medical and nursing staff members to minimise sedation and optimise the patient's readiness to participate in training.[3,8] IMT is frequently achieved using a removable spring-loaded device, intermittently applied to the endotracheal tube or tracheostomy, providing a threshold resistance for high-intensity interval training.[8] Previous studies have monitored patients' physiological responses (heart rate [HR], mean arterial pressure [MAP], oxygen saturation [SpO_2], respiratory rate [RR], dyspnoea, pain) and recorded adverse events (airway dislodgement) during IMT.[9–11] The threshold training approach to IMT is safe and feasible in patients who require prolonged mechanical ventilation.[9–11] Two weeks of daily IMT after liberation from mechanical ventilation has been shown to strengthen inspiratory muscles and improve some measures of quality of life.[12,13]

However, spring-loaded IMT devices have a major limitation: the lowest training limit (9 cmH_2O) is usually too challenging for the weakest patients (i.e., those with maximum inspiratory pressure [MIP] less than 18 cmH_2O).[3] Additionally, spring-loaded IMT devices are only able to provide a maximum resistance of 41 cmH_2O. Hence, as participants improve their MIP, spring-loaded IMT devices may not be able to provide sufficient resistance to optimise training outcomes. This may result in participants being unable to achieve an MIP equivalent to the established population norms.[14] New electronic inspiratory muscle trainers have a training range of 5 − 200 cmH_2O, enabling a broader range of training possibilities for patients. Additionally, electronic inspiratory muscle training (eIMT) devices provide tapered-flow, loading resistance throughout inspiration to ensure that the participant generates more work throughout their inspiration.[3] Pilot data indicate that eIMT devices may be feasible for patients admitted to the ICU with respiratory failure, decreased consciousness level, or postoperative complications,[15] and it has been used in patients recently weaned from ventilation due to COVID-19.[16] The feasibility of eIMT in a broader ICU cohort with patients who require prolonged mechanical ventilation has not yet been described. Furthermore, patient acceptability of interventions should be explored during the feasibility phase of clinical trials.[17] To date, the patient-perceived acceptability of eIMT in an ICU context has not been investigated.

Establishing the clinical feasibility of eIMT and ascertaining patient acceptability are crucial prerequisites to robustly determining the efficacy of eIMT in patients who require prolonged mechanical ventilation in a well-powered clinical trial. Thus, the research questions for this study are as follows:

1) Is eIMT safe and feasible for patients who have experienced prolonged mechanical ventilation?
2) Is eIMT acceptable from the perspective of a patient who requires prolonged mechanical ventilation?

2. Methods

2.1. Design and setting

This observational cohort study, with convenience sampling, was conducted at two Australian hospitals (Canberra Hospital and Princess Alexandra Hospital, Brisbane) where both ICUs were tertiary referral centres, with a mixed medical, surgical, and trauma caseload. Both sites' usual practice includes early mobilisation and rehabilitation, including for patients who require prolonged mechanical ventilation.[18,19] Physiotherapy staff at both sites had previous experience with IMT. Before participant recruitment, ethical approval for the study was gained from Metro Health HREC (HREC/2018/QMA/45151) and following administrative review from the University of Canberra HREC 2256 and ACT Health (HREC/2019/STE/00187). The study was prospectively registered on the Australia New Zealand Clinical Trials Registry (ACTRN12619000968178). Participants provided their own informed, written consent (Canberra site), and/or consent was provided through substitute decision-makers (Brisbane site only).

2.2. Participants

Patients were eligible to participate if they had experienced invasive mechanical ventilation via endotracheal tube or tracheostomy for at least 5 days, or had failed a spontaneous breathing trial and could actively participate in the training (Richmond Agitation–Sedation Scale score −1 to +1). Patients were invited to participate if we anticipated that they would remain in the ICU for a further 48 h. Consequently, patients would be likely to be able to complete at least two eIMT sessions while in the ICU.

Patients were excluded if they had any of the following: (i) a new or existing condition impairing the patient's ability to follow commands (e.g., severe neurological injury, intellectual disability); (ii) a new or existing injury likely to result in long-term continuous mechanical ventilation dependence (in the opinion of the treating intensivist); (iii) poor prognosis (e.g., palliation); (iv) displaced fractured ribs including flail rib segments; (v) recent or current pneumothorax; (vi) significant pain from chest trauma, affecting breathing capacity; (vii) the current fraction of inspired oxygen being >0.6, positive end-expiratory pressure being ≥10 cmH_2O, SpO_2 being <90%, an RR of >25 breaths/min; or (viii) the clinician deemed that the patient was medically unstable.

2.3. Intervention

Patients completed the training in high sitting, either in a bed or on a chair. The physiotherapist worked closely with the bedside nurse to minimise sedation and optimise alertness before training. Where a patient was undergoing spontaneous breathing trials, training was timed to be completed immediately before return to the ventilator.

Daily training (Monday–Friday) with the eIMT device (POWERbreathe KH2, POWERbreathe, United Kingdom) was supervised by ICU physiotherapists. This hand-held device was connected to the patient's endotracheal tube or tracheostomy via a filter and a connector (Fig. 1).

The supervising physiotherapist assisted patients to complete five sets of six breaths at the maximum tolerable load each weekday (minimum 50% of maximum inspiratory pressure) as per previously established guidelines.[8] The intensity was increased between sessions to ensure patients were always only just able to complete the sixth breath in each set.[8] Patients were allowed rests on the ventilator between sets as required, with a typical training session of 30 breaths completed in less than 10 min. The IMT sessions ceased when the patient was discharged from the ICU.

2.4. Outcome measures

The primary outcomes were the feasibility and safety of the intervention. Feasibility was defined a priori as more than 80% of planned sessions were completed.[11,12] The intervention was considered safe if there were no major adverse events, and we anticipated that minor events would occur on less than 3% of occasions, which is the approximate percentage of minor adverse

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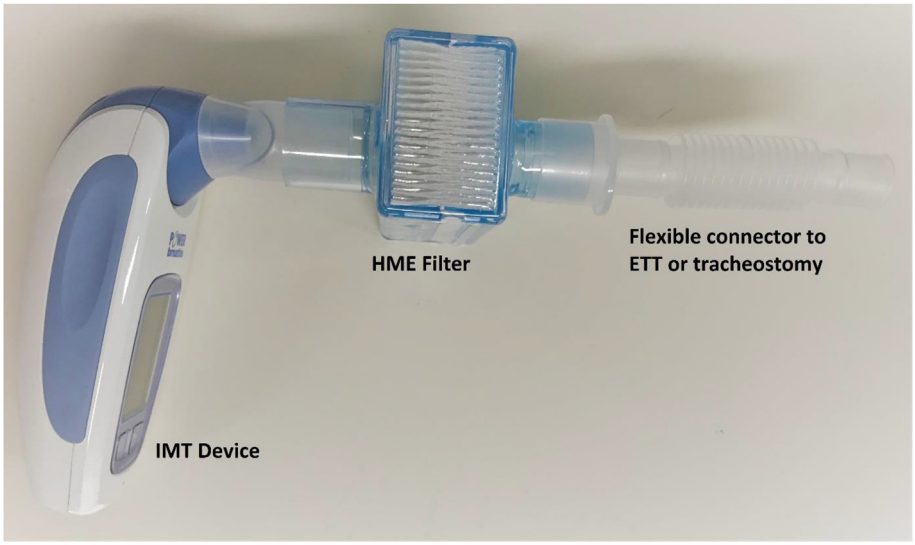

Fig. 1. Electronic inspiratory muscle training device with filter connection. ETT, endotracheal tube; HME, heat moisture exchange; IMT, inspiratory muscle training.

events associated with ICU rehabilitation interventions.[20] Predefined major adverse events were unplanned airway removal or a clinically significant deterioration requiring a medical review and an escalation in care. Minor adverse events were defined as transient events that did not require an escalation in the care plan. Examples of potential minor adverse events included haemodynamic instability (new arrhythmias, alteration in mean MAP requiring an alteration in vasoactive medication, change in systolic blood pressure (SBP) more than 20 mmHg, change in HR more than 20 beats/min, persistent increased RR more than 10 breaths/min above the baseline for 5 min, increase in respiratory support (increase in fraction of inspired oxygen or positive end-expiratory pressure), and increased patient agitation requiring pharmacological or physical intervention.

Secondary feasibility outcomes included (i) training intensity achieved (cmH_2O); (ii) change in inspiratory muscle strength (measured as maximum inspiratory pressure, using the POWERbreathe KH2 IMT device) before the initial session and final session before ICU discharge; (iii) physiological stability (measured as HR, RR, SBP, MAP, SpO_2 before, during, and after each training session by the treating physiotherapist); (iv) breathlessness (Modified Borg Dyspnoea Scale 0–10) before and after each training session; (v) time breathing on the ventilator (days); (vi) and the total time to wean from mechanical ventilation (days). Participants were encouraged to complete the IMT at an intensity that was likely to result in slight to moderate breathlessness (i.e., 4–5 on the Modified Borg Dyspnoea Scale).

At one of the sites, following the final treatment session, patient acceptability was measured using a purpose-designed questionnaire based on the principles of acceptability described by Sekhon et al.[21,22] (Supplementary material 1, Fig. S1). The eIMT acceptability questionnaire was modified to suit the intervention from a previously developed in-bed cycling acceptability questionnaire that was developed following a Delphi process.[23] The theoretical framework of acceptability domains that were assessed by the eIMT questionnaire consisted of burden, perceived effectiveness, and general acceptability.

2.5. Analysis

A convenience sample of 40 participants (20 per site) was chosen a priori. A similar previous study described 195 sessions in 10 patients,[24] but the larger sample size was expected to allow a more detailed description of feasibility and acceptability across a broader cohort. Descriptive statistics were used to summarise the characteristics of the participants and safety and feasibility data, pooling data from both sites. Mean and standard deviation (SD) were calculated for approximately normally distributed data, and median and interquartile range (IQR) were calculated for data with large skewness or time-based measurements. Paired t-tests were used to compare physiological variables (RR, HR, SpO2, and MAP) and perceived breathlessness (Modified Borg Dyspnoea Scale 0–10) before and after each treatment session. Statistical significance was set as $p < 0.05$. All analyses were completed using IBM SPSS Statistics for Windows Version 27 (IBM Corp: Armonk, NY).

Trial registration: ACTRN12619000968178, https://www.anzctr.org.au/Trial/Registration/TrialReview.aspx?id=377694&isClinicalTrial=False

3. Results

3.1. Participants

The characteristics of the 40 participants recruited for the study are described in Table 1. Four participants were indigenous (10%), and 13 were female (33%). The mean (SD) APACHE III score for the cohort was 70 (22).

3.2. Feasibility

A total of 197 of the planned 242 (81%) eIMT treatment sessions were completed across the cohort and included in the analysis. Participants completed a median (IQR) of 4 (2, 6) sessions. Of the 40 participants, 19 completed 100% of planned sessions. Only two participants completed <50% of planned sessions (Table 2).

The main reasons for noncompletion of a training session were patients declining due to fatigue (34%), patients declining due to reasons other than fatigue (14%), delirium and/or unable to follow commands (14%), technical problems with the device, e.g., battery not charged (11%), medical complication unrelated to training (e.g., vomiting, bleeding, hypotension, unstable blood pressure) (11%), and drowsiness or sedation (6%).

Participants commenced IMT after a median (IQR) of 14 (8, 27) days of mechanical ventilation. Electronic IMT resistance used

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Table 1
Demographic clinical characteristics and outcomes.

Variable	Cohort, n = 40
Age in years, mean (SD)	59 (15)
Females, n (%)	13 (33%)
Indigenous, n (%)	4 (10%)
APACHE III score, mean (SD)	70 (22)
BMI kg/m^2, mean (SD)	29 (6)
Total length of MV, days, median (IQR)	17 (11, 41)
ICU length of stay, days, median (IQR)	20 (11, 46)
Acute hospital length of stay, days, median (IQR)	51 (34, 92)
Primary diagnosis on ICU admission	
Medical	15 (37.5%)
Sepsis	11 (27.5%)
Surgery	6 (15%)
Neurological	4 (10%)
Trauma	3 (7.5%)
Maternity	1 (2.5%)

n, number; SD, standard deviation; APACHE III, Acute Physiology and Chronic Health Evaluation III severity of illness score (0–299); BMI, body mass index; ICU, intensive care unit; IMT, inspiratory muscle training; IQR, interquartile range; MV, mechanical ventilation.

during the training sessions varied widely from 5 to 35 cmH_2O. Of note, 16 participants (40%) commenced training at a level lower than 9 cmH_2O, which is less than the lowest resistance available on spring-loaded IMT devices. The median (SD) starting resistance was 11 cmH_2O (5). Participants were able to complete subsequent sessions with a higher training load with the mean (SD) resistance on the last session being 17 (7). Participants increased their MIP from a median of 22 (11) to 35 (12) by their final assessment (Table 2) (Supplementary Material, Fig. S2).

Table 2
Inspiratory muscle training data.

Parameter	Cohort, n = 40
Total number of sessions planned, n	242
Total number of sessions completed, n, (% of planned)	197 (81%)
Length of MV prior to commencing IMT, days, median (IQR)	14 (8, 27)
Number of sessions per participant, median (IQR)	4 (2, 6)
Initial MIP, cmH_2O, mean (SD)	22 (11)
Final MIP, cmH_2O, mean (SD)	35 (12)
Change in MIP, cmH_2O, mean (SD)	13 (11)
Starting resistance, cmH_2O, mean (SD)	11 (5)
Last session resistance, cmH_2O, mean (SD)	17 (7)
Change in resistance, cmH_2O, mean (SD)	6 (6)
Breathlessness[a] prior to eIMT, mean (SD)	3 (2)
Breathlessness immediately post to eIMT, mean (SD)	4 (2)
Breathlessness immediately 5 min post to eIMT, mean (SD)	2 (2)

IQR, interquartile range; MIP, maximum inspiratory pressure; MV, mechanical ventilation; n, number; RPB, rate of perceived breathlessness; SD, standard deviation.
[a] Breathlessness measured by the Modified Borg Dyspnoea Scale.

3.3. Safety

Across the cohort, there were no major adverse events. There were 19 minor adverse events (10%) experienced by 11 participants. The minor adverse events were primarily cardiovascular events with a transient rise in SBP >20 mmHg (14 events) and a variation in heart rate of >20 beats per min (two events). Of note, eight (42%) of these minor adverse events were attributed to one patient, where blood pressure lability was a feature of their presenting condition. Eight participants experienced minor haemodynamic adverse events that self-corrected within 5 min of cessation of training. There were four episodes of sustained increase in SBP experienced by three participants. One participant experienced two minor adverse events, and nine other participants experienced only a single minor adverse event. There were three respiratory events of persistent tachypnoea, with an increase in the RR > 10 breaths/min for 5 min. There were no ongoing sequelae arising from any of these transient minor adverse events.

3.4. Physiological outcomes

There were small but statistically significant increases observed in the HR, BP, and RR within the treatment sessions (Table 3). However, none of these physiological changes were clinically significant (e.g., HR change of 98–99).

3.5. Acceptability

Thirteen (65%) out of 20 participants at one of the sites completed the acceptability questionnaire. Seven (35%) participants had no memory of participating in eIMT while in the ICU and therefore did not complete the questionnaire. Of those who did remember eIMT, the majority felt that eIMT assisted their recovery, improved their feelings of well-being, and reported that it was helpful to know their changes in breathing strength. All but one participant who recalled completing eIMT sessions (92%) perceived that eIMT was beneficial (Fig. 2A). During eIMT, participants had increased breathlessness, experienced no change, or reported that the training improved their breathlessness. Regarding the perception of breathlessness following eIMT, 69% of participants perceived that breathlessness was improved, whereas 31% perceived no difference (Fig. 2B). A large majority (85%) of participants reported that eIMT assisted their recovery. The optional free-text comments were “The beep needs to be louder”; “I like the electronic IMT better …. The fancy one gives you stats”; “it has really helped me a lot”; and “definitely worthwhile doing”. The only neutral comment was “breathing has remained constant.” There were no negative comments.

Table 3
Physiological training parameters within each session across the cohort.

Parameter	Pre training	Post training	Mean difference	95% Confidence interval
Heart rate (bpm)	98 (15)	99 (16)	1	0.33 to 2.21[a]
Respiratory rate (breaths/minute)	23 (7)	24 (8)	1	0.19 to 1.62[a]
Blood pressure (MAP)	84 (13)	87 (14)	3	1.36 to 3.72[a]
Oxygen saturation (SpO2)	97 (2)	97 (3)	0	−0.03 to 0.55
RPE Borg score	3 (2)	4 (2)	1	1.01 to 1.74[a]

Values expressed as mean (standard deviation).
bpm, beats per minute; MAP, mean arterial pressure; SpO_2, oxygen saturations.
[a] Statistically significant $p < 0.05$.

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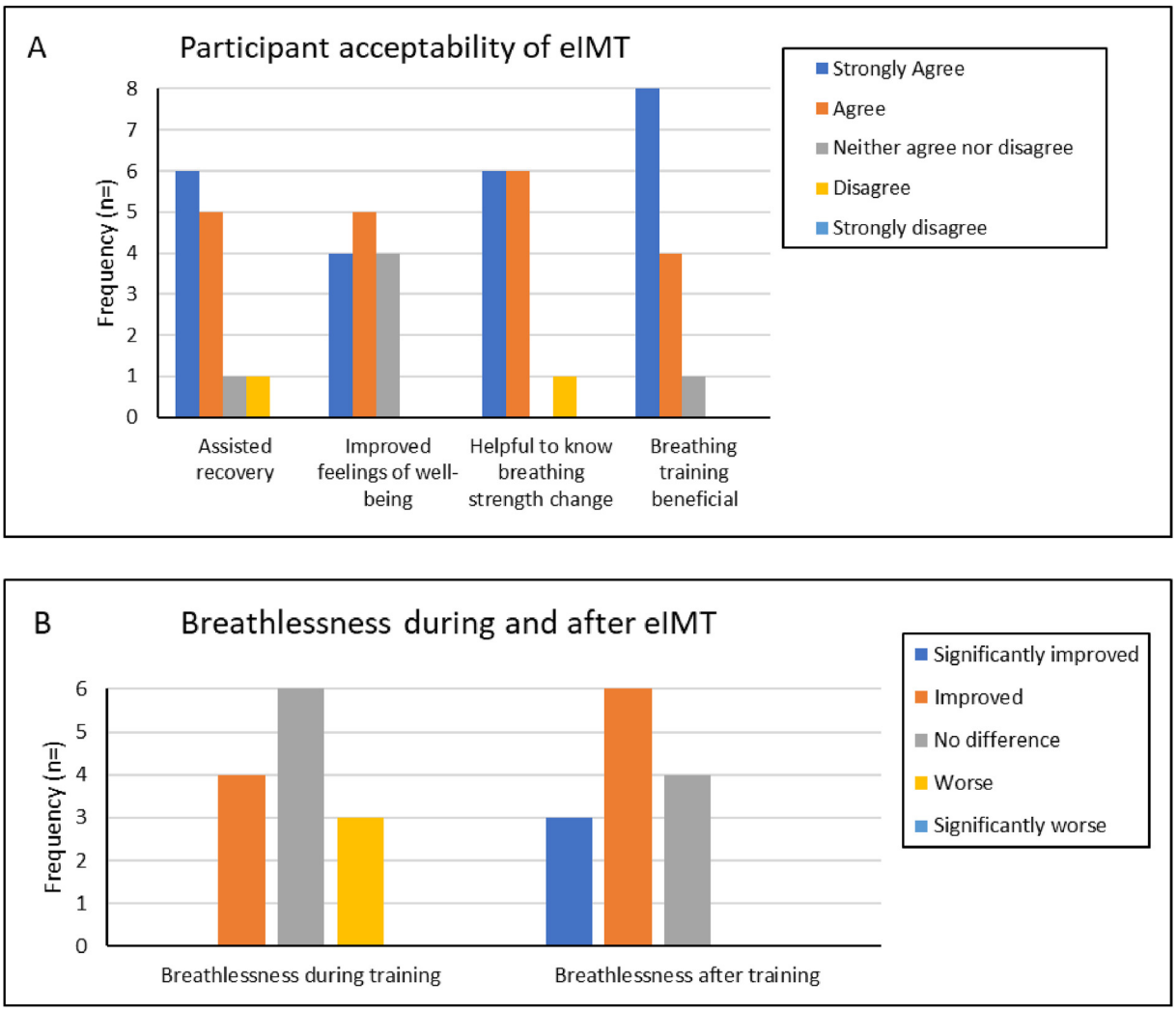

Fig. 2. (A) Participant acceptability of eIMT. (B) Breathlessness during and after eIMT. eIMT, electronic inspiratory muscle training; n, number.

4. Discussion

The main findings of this observational study were that the eMIT is feasible and acceptable, with 81% of the planned sessions completed. Out of the 13 participants at one site who recalled completing eIMT, more than 85% of participants reported that eIMT was either helpful or beneficial and that eIMT assisted their recovery. There were no major adverse events across the 197 training sessions analysed. The rate of minor adverse events was higher than the hypothesised rate (10% vs 3%); however, none of these minor events were clinically significant or required any escalation of care. Almost half of the minor adverse events were attributable to a single patient with known haemodynamic variability.

The magnitude of mean change in inspiratory muscle strength between the first and final training sessions (13 cmH_2O) in this observational study is consistent with other studies and reviews of IMT in patients in the ICU.[15,16,24,25] The finding that more than 40% of the participants in this study commenced training at an intensity lower than 9 cmH_2O highlights that eIMT is more feasible and appropriate than the threshold IMT for a significant proportion of patients who are extremely weak. Clinicians should bear this in mind when selecting their treatment strategy, especially for patients with an initial MIP score of less than 18 cmH_2O.

The other secondary outcomes for this study also indicate that eIMT is well tolerated. The increases in HR, BP, and RR noted after training were statistically significant but not clinically concerning. These increases may reflect a normal exercise response to strength training. Similarly, the increase in breathlessness scores (modified Borg breathlessness scale) immediately after training is to be expected, given the targeted resistance applied to the inspiratory muscles. Immediately following training, the mean rating for breathlessness reflects slight to moderate breathlessness and was the target intensity that participants were encouraged to train at by the physiotherapist conducting the training session. Encouragingly, patients perceived that their breathlessness was reduced within 5 min following the intervention. We observed that SpO_2 did not change with training, without oxygen entrainment, which indicates that oxygen entrainment may be unnecessary for safe eMIT in patients in the ICU, who require prolonged mechanical ventilation (when participants commence IMT according to the session inclusion criteria previously specified).

The patient perspective was an important part of our analysis and informs the clinical implications of this study. The most frequent reason patients did not participate in the eIMT sessions was fatigue, and this is consistent with other studies of rehabilitation interventions in the ICU (e.g., mobilisation,[26] in-bed

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cycling[23]). This suggests clinicians should anticipate that patients may be too fatigued to participate in every training session, and this should be respected. Other reasons for nonparticipation, such as technical problems with the device (e.g., battery not sufficiently charged), appear avoidable. The finding that approximately a third of participants had no memory of their eIMT experience in the ICU is somewhat intriguing but aligns with recent evidence about the prevalence of problems with memory and delirium experienced by ICU survivors.[27] Nonetheless, in those who could remember their training, the acceptability of eIMT was consistently favourable, with several patients reporting they enjoyed the training and found it worthwhile. It is possible that the process of breathing independently from the ventilator and completing resistance breathing training could assist patients to build confidence with the knowledge that they are progressively improving their breathing strength.[9] Positive clinician feedback and improvements in breathing strength may assist to enhance patients' feelings of well-being.

Patients in the current study were unable to commence eIMT sessions until a median of 14 days following ICU admission. The most common reason for the delay to commence eIMT was the patient's lack of consciousness either due to sedation or neurological compromise. Patients were meeting safety criteria before this timepoint; however, patients' inability to sufficiently follow commands prohibited participation in eIMT. Intervention feasibility was further demonstrated by the completion of eIMT with existing staffing resources, with the physiotherapists taking approximately 10 min to provide the intervention. This is a similar time to complete usual respiratory care interventions such as manual or ventilator hyperinflation and/or deep breathing exercises.

The strengths of this study include the capture of a broad range of patients from two different ICUs, encompassing a wide range of underlying pathologies and varying durations of mechanical ventilation. The dual-centre approach increases our confidence in the feasibility of eIMT across different environmental contexts. The limitations of this study include the conservative definition of minor adverse events, which could arguably be considered a normal function of strength training, particularly as there were no clinically important sequelae. The findings of this study can only be extrapolated to other units where patient alertness is optimised to facilitate active participation in eIMT. Finally, the observational study design does not allow any conclusions to be drawn about the efficacy of eIMT for improving strength or enhancing ventilator weaning; however, this study suggests that eIMT is feasible, safe, and acceptable to patients in the ICU. On this basis, a fully powered multi-centre, randomised trial of eIMT is warranted in patients who require prolonged mechanical ventilation.

5. Conclusion

eIMT appears feasible and acceptable in patients who require prolonged mechanical ventilation. Clinicians using eIMT with patients who require prolonged mechanical ventilation can anticipate minor transient events in approximately 10% of sessions. eIMT is acceptable to patients who require prolonged mechanical ventilation, and further studies of the efficacy of this intervention are warranted.

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CRediT authorhip contribution statement

Marc Nickels: conceptualisation, methodology, investigation, data collection, resources, writing – original draft, reviewing and editing, project administration, funding acquisition, supervision. **Katie Erwin**: conceptualisation, methodology, data collection, writing - reviewing and editing. **Grant McMurray**: conceptualisation, methodology, writing - reviewing and editing. **Richie Talbot**: investigation, resources, formal analysis, writing - reviewing and editing. **Mark Strong**: conceptualisation, methodology, investigation, data collection, writing - reviewing and editing. **Anand Krishnan**: conceptualisation, methodology, investigation, resources, writing - reviewing and editing. **Frank van Haren**: conceptualisation, methodology investigation, resources, writing - reviewing and editing. **Bernie Bissett**: conceptualisation, methodology, investigation, resources, formal analysis, original draft preparation, writing - reviewing and editing, project administration, funding acquisition, supervision.

Conflict of interest

No conflicts to declare.

Data availability statement

Data available on request due to privacy/ethical restrictions. The data that support the findings of this study are available on request from the corresponding author (MN). The data are not publicly available due to ethical restrictions, e.g., their containing information that could compromise the privacy of research participants.

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Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.aucc.2023.04.008.

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