Background and rationale

Respiratory muscles generate pressure differences to provide pulmonary ventilation to sustain life. Mechanical Ventilation (MV) is a frequently used potentially life-saving intervention in critically ill patients. Critical illness impairs respiratory musculature in ICU units. During critical illness, patients who are on mechanical ventilation for 96 hours or more are susceptible to ventilator-induced respiratory muscle dysfunction, resulting in loss of strength, endurance and mass, progressing to significant weaning and extubation difficulties that can compromise immediate and long-term recovery. To address RMD, this study compared two methods of respiratory muscle training, and respiratory muscle function was evaluated in prolonged ventilated patients in an acute hospital ICU.

Aims and objectives of this Study

This study aimed to determine the feasibility of an RCT investigating the effect of combined IEMT training in the intervention group and inspiratory muscle training in the control group.

This feasibility study aims to estimate the sample size for a definitive full-scale RCT and offer recommendations regarding research design.

The objectives of this trial were to measure the patient and therapist's willingness to participate, the feasibility of recruitment, adherence to the intervention, the acceptability of the intervention and the possible effect of the implemented interventions for early rehabilitation of respiratory muscles in prolonged ventilated patients based on the selected measurement outcomes in both intervention and usual care groups.

To assess potential effectiveness using muscle function outcome measures in MV patients pre and post-intervention (inspiratory and expiratory training versus inspiratory muscle training). To measure changes in prolonged ventilated patients' respiratory muscle function pre- and post-intervention, the inspiratory muscle function is assessed by MIP, expiratory muscle function by MEP, respiratory muscle endurance by FRI, expiratory muscle thickness by muscle thickness measurement with diagnostic ultrasound, cough score by SCSS and peripheral muscle function by hand dynamometer tests.

Study design

Pragmatic, parallel randomised feasibility trial

The REMDI Study is a single-centre prospective pragmatic parallel randomised feasibility trial. This is a pragmatic RCT (which aims to evaluate the effects of intervention) in this cohort of patients. The random assignment of the participants was to intervention and control arms. The allocation was done on a 1:1 basis. The intervention and control groups were allocated the same number of patients. Simple randomisation was done by a physiotherapist (from another department), who was not involved in the study and had no interaction with trial participants. It is conducted in one of the academic teaching hospitals in an urban area in the Republic of Ireland.

Inclusion Criteria

This study's inclusion criteria include

- Adult patients over 18 years of age admitted to the unit were included
- Able to respond to the verbal commands
- Medically stable
- Five days or more mechanically ventilated (Patients requiring ventilation for more than 96 hours are considered Prolonged Mechanical Ventilation (PMV).
- Richmond Agitation-Sedation Scale (RAAS) score of 0 (patients are alert and calm) on Richmond Agitation-Sedation Scale scores range from +4 to -5, and the scoring typically depends on the patient's response. When patients respond, the score combatively is recorded as (+4); when patients respond highly negatively, the score is recorded as (+3). When patients respond in a mild agitative manner, the score is recorded as +2 . When patients respond restlessly, the score is recorded as +1; when the patients are calm and alert, the score is recorded as 0**;** when patients are drowsy the score is recorded as −1 when patients are on sedation, the score is recorded as −2 , when patients are on light sedation the score is recorded as (-3) when patients are on moderate sedation the score is −4 and when the patients are on deep sedation and are unarousable the patient score is recorded as −5. Patients with zero scores could

follow commands that were best suited for intervention and were included in the study.

Exclusion criteria

- Unable to follow simple commands such as "deep breathe in and out".
- Medically unstable during ICU admission and prolonged ventilation period before training because they would not be able to complete IEMT/IMT training. For example, patients with more than a minimal continuous infusion of inotropic agents were ineligible to participate as the inotropic support is indicated in patients with unstable blood pressure and when their cardiovascular stability is affected.
- Also, patients with severe arrhythmias and acute coronary artery disease were excluded as they had cardiovascular instability. Patients with thoracic dysfunction, including undrained pneumothorax, lung abscess, and flail chest, were excluded as they had a risk of developing thoracic symptoms
- Postoperative patients with acute surgical problems in the immediate period with wound dehiscence or severe postoperative bleeding were excluded during the bleeding period and have been included post-acute period
- Less than five days of mechanical ventilation
- RAAS score greater than 0 or less than 0
- Any patients with any contraindication to disconnect from the mechanical ventilator respiratory muscle training were also excluded.
- Patients who have prior arrangements for transfer to other hospitals when stabilised were excluded as they were unable to continue with the intervention.

Interventions

The proposed study plans to randomise patients into two groups. The study implemented two weeks of high-intensity inspiratory and expiratory muscle training with loads equal to 50% of MIP and MEP for the experimental group (IEMT)(n=12). With loads equal to 50% of MIP

for the control group (IMT group) (n=12). Patients in both groups have undergone four sets of ten breaths twice a day for two weeks duration.

Ethical considerations

Participants were informed about the study in detail using a participant's information leaflet (PIL) that states the purpose of the research, procedure for withdrawal, risks, costs, compensations, as well as the type of data to be obtained and how the data will be used, analysed, stored and reported. Consent was obtained from the participants.

Collected data were analysed with statistical tests, and results will be disseminated.

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