

# Comparison of the effectiveness of two different respiratory exercise training methods in prolonged ventilated patients

<b>Submission date</b> 24/06/2020	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 05/07/2020	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 21/10/2022	<b>Condition category</b> Respiratory	<input type="checkbox"/> Individual participant data

## Plain English summary of protocol

### Background and study aims

Reduced breathing muscle performance contributes to the prolonged duration of mechanical ventilation (external breathing machine support) and makes it difficult to come off from the machine. Reduced breathing muscle function also impacts on non-ventilatory functions of the respiratory system including coughing and swallowing function.

We are planning to conduct a study in prolonged ventilated patients (patients on external breathing machine support) to find out the impact of different types of resistance breathing exercises. These are used in some intensive care units to strengthen breathing muscles worldwide. This study will help us to determine whether this resistance breathing exercises during prolonged ventilation are necessary or not.

### Who can participate?

Patients requiring breathing support with a ventilator (external breathing machine) for more than 5 days who are suitable will be included in the study following a discussion with consultant anaesthetist and clinical nurse manager.

### What does the study involve?

This proposed study plans to monitor and manage breathing muscle dysfunction with multiple tests of strength and endurance and with a dual valve CE marked low-cost device that will be adapted in a novel way to train breathing muscles which help to breathe in and out. Patients will undergo four sets of ten breaths twice a day for two weeks duration with CE marked device. The strength and endurance tests of breathing muscles will be done before and after exercise training.

### What are the possible benefits and risks of participating?

#### Benefits:

The results will help us to determine which exercises help to improve weak respiratory muscle function.

#### Risks:

There are no anticipated risks with this study. Respiratory assessments are commonly used in

physiotherapy. The tests are not invasive. None of the assessments have the potential to cause harm. Different exercises being compared in this study. They are both in line with the intended use of the CE marked device. We will find out from this study if there are any differences between these different exercises in improving respiratory muscle function.

Where is the study run from?

Connolly Hospital Blanchardstown (Ireland)

When is the study starting and how long is it expected to run for?

June 2019 to December 2021

Who is funding the study?

Anglia Ruskin University (UK)

Who is the main contact?

Mr Atchuta Kishore Kothapalli, kishore.kothapalli@hse.ie

## Contact information

**Type(s)**

Scientific

**Contact name**

Mr Atchuta Kishore Kothapalli

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## Additional identifiers

**EudraCT/CTIS number**

Nil known

**IRAS number**

**ClinicalTrials.gov number**

Nil known

**Secondary identifying numbers**

Nil known

# Study information

## Scientific Title

Comparing effectiveness REspiratory Muscle Dysfunction Interventions IMT versus RMT study in prolonged ventilated patients

## Acronym

REMDI

## Study objectives

Can respiratory (inspiratory and expiratory) muscle training be feasible and more effective compared to inspiratory muscle training alone in prolonged ventilated patients?

## Ethics approval required

Old ethics approval format

## Ethics approval(s)

Approved 18/06/2019, Ethics Committee (Connolly Hospital Blanchardstown, Dublin 15, D15 X40D, Republic of Ireland; +353 18213844; nancy.mcguirk@hse.ie), ref: none provided

## Study design

Interventional randomized parallel trial

## Primary study design

Interventional

## Secondary study design

Randomised parallel trial

## Study setting(s)

Hospital

## Study type(s)

Treatment

## Participant information sheet

Not available in web format, please use the contact details below to request a patient information sheet

## Health condition(s) or problem(s) studied

Respiratory muscle dysfunction in prolonged ventilated patients

## Interventions

Participants will either receive:

1. 2 weeks of inspiratory muscle training, or
2. 2 weeks of both expiratory and inspiratory muscle training

The same CE marked device is set at 50% threshold to train either:

1. Maximum inspiratory pressure (MIP), or
2. Both MIP and Maximum Expiratory Pressure (MEP). Both groups will undergo four sets of ten breaths twice a day for two weeks

Randomisation. To minimise selection bias during randomisation the physiotherapist who is not involved in the study and will have no interaction with any of the trial participants will randomise with concealed randomisation and will have no interaction with any of the trial participants.

There are two data collection points 1) at baseline and 2) at 2 weeks after exercise

## **Intervention Type**

Behavioural

## **Primary outcome measure**

Maximum Inspiratory Pressure (MIP) measured using CE marked Micro RPM (Respiratory Pressure Monitor) at pre-(baseline) and post-intervention (2 weeks). 3 trials are taken and the highest value will be used.

## **Secondary outcome measures**

Measures will be performed pre-(baseline) and post-intervention (2 weeks):

1. Maximum Expiratory Pressure (MEP) will be measured using a pressure manometer - 3 trials are taken and the highest value will be used
2. Cough strength will be measured using a semi-quantitative cough strength score
3. Fatigue resistance index will be measured using the ratio of MIP, post-training with Inspiratory Muscle Trainer/MIP pre-training.
4. Rectus abdominis muscle thickness assessment will be measured using a diagnostic ultrasound machine
5. Hand dynamometry will be measure peripheral muscle function – 3 trials are taken on the participants dominant hand and the highest value will be used

## **Overall study start date**

18/06/2019

## **Completion date**

31/12/2021

# **Eligibility**

## **Key inclusion criteria**

1. Adult patients 18 years or above admitted to general critical care unit and required mechanical ventilation support for more than five days
2. Patients who can respond to the verbal command and can tolerate breathing exercises such as "deep breath in and out"
3. Richmond Agitation-Sedation Scale score 0

## **Participant type(s)**

Patient

## **Age group**

Adult

**Lower age limit**

18 Years

**Sex**

Both

**Target number of participants**

30

**Key exclusion criteria**

1. Medically unstable during critical care admission and prolonged ventilation period before training
2. Use of more than minimal continuous infusion inotropic agents
3. Contraindication to disconnect the patient from the mechanical ventilator for RMT treatment or IMT treatment
4. Acute coronary artery disease
5. Thoracic contraindications

**Date of first enrolment**

06/09/2019

**Date of final enrolment**

31/12/2021

## **Locations**

**Countries of recruitment**

Ireland

**Study participating centre**

**Connolly Hospital Blanchardstown**

Mill Rd

Abbotstown

Dublin

Ireland

D15 X40D

## **Sponsor information**

**Organisation**

Connolly Hospital Blanchardstown

**Sponsor details**

Mill Rd  
Abbotstown  
Dublin  
Ireland  
D15 X40D  
+353 1 8213844  
therapy.chb@hse.ie

**Sponsor type**

Hospital/treatment centre

**Website**

<https://www.hse.ie/eng/services/list/3/acutehospitals/hospitals/connolly>

**ROR**

<https://ror.org/03h5v7z82>

**Organisation**

Anglia Ruskin University

**Sponsor details**

East Road  
Cambridge  
England  
United Kingdom  
CB11PT  
+44 (0)1223 692362  
frep-fhems@anglia.ac.uk

**Sponsor type**

University/education

**Website**

<http://www.anglia.ac.uk/>

**ROR**

<https://ror.org/0009t4v78>

**Funder(s)**

**Funder type**

University/education

**Funder Name**

Anglia Ruskin University

**Alternative Name(s)****Funding Body Type**

Private sector organisation

**Funding Body Subtype**

Universities (academic only)

**Location**

United Kingdom

## Results and Publications

**Publication and dissemination plan**

Study participants will be offered a summary of the study's results, by post, at the end of the study. The results of this study will be reported via at least one peer-reviewed medical journal. Research findings will also be disseminated at a scientific conference. We will not be naming any organisations (i.e. Hospital) in the report although the principal investigator works at this institution (with is usually named on reports). The hospital ethics committee has given permission to conduct the research.

**Intention to publish date**

31/12/2022

**Individual participant data (IPD) sharing plan**

The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request. Raw data will be available for 5 years from when the results are submitted for publication.

**IPD sharing plan summary**

Other

**Study outputs**

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">Basic results</a>			21/10/2022	No	No
<a href="#">Protocol file</a>			21/10/2022	No	No