The MATREX trial
MAnual Therapy for Respiratory EXacerbations

ISRCTN13825248

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MANUAL CHEST THERAPY – TREATMENT PROTOCOL

Trial Recruiter/Assessor: prime responsibilities – patient identification, data collection/management
Physiotherapist: prime responsibilities – therapeutic care, conducting intervention

The content, number and duration of treatments will be at the discretion of the physiotherapist applying the therapy and varied according to clinical need within the bounds set by this protocol.

PERSON	ACTION	REFERENCE/ SOURCE
	1.0 IDENTIFYING & RECRUITING PATIENTS	
Recruiter	1.1 Identify potential participant (checklist) 1.1.1 Liaise with Physiotherapy team	Treatment Protocol Appendix 1
Physio.	1.2 Identify possible risk factors (checklist) 1.2.1 Make clinical judgement as to patient's continued suitability 1.2.2 Confirm eligibility with Trial Recruiter	Treatment Protocol Appendix 2
Recruiter	1.3 Approach patient regarding study 1.3.1 Give Patient Information Sheet 1.3.2 Answer queries, explain RCT principle if necessary 1.3.3 Provide sufficient time for patient to decide * 1.3.4 If patient willing, obtain consent	 Study Protocol Appendix 7 Study Protocol Appendix 8
Recruiter	1.4 Randomise patient to intervention or control arm. 1.4.1 Provide patient with Trial Information Card stipulating arm 1.4.2 Ensure patient's records are marked accordingly 1.4.3 Complete baseline questionnaires 1.4.4 Liaise with Physiotherapy team, stipulate arm, negotiate 1st visit	 Study Protocol Appendix 4
Physio.	1.5 On 1st visit: 1.5.1 Remind patient that physiotherapy visit is part of trial 1.5.2 Implement universal infection control precautions 1.5.3 Observe any additional patient-specific precautions posted 1.5.4 Advise Trial Recruiter where increased risk exists	

*Rapid change in clinical condition is likely in this group. Thus, the recruiter needs to strike a balance between enabling the intervention to occur during the most acute phase of each COPD exacerbation and not **rushing the patient** in their decision

	2.0 INTERVENTION ARM	
Recruiter	2.1 Record baseline oxygen saturation 2.1.1 If receiving, patient to continue on controlled oxygen therapy 2.1.2 If available, obtain continuous oximetry data during intervention 2.1.3 Record additional vital signs physiotherapist deems necessary 2.1.4 Record whether patient is likely to be ambulatory or not	
Physio.	2.2 Auscultate patient 2.2.1 Select 2 most appropriate positions according to clinical findings 2.2.2 Turn patient to position 1 2.2.3 Use pillows to support patient as required 2.2.4 Place light towel (one layer) on area of chest to be percussed 2.2.5 Encourage patient to breath deeply during treatment	Treatment Protocol Appendix 3
Physio.	2.3 **Percuss** thorax with cupped hand(s) directly over the lung segment(s) being drained. 2.3.1 Use both/one hand as deemed necessary 2.3.2 Adapt rate, depth and force of technique to meet individual needs	Definition: Treatment Protocol Appendix 4
Physio.	2.4 **Vibrate** chest over percussed area using two hands 2.4.1 Vibrate on each exhalation 2.4.2 Adapt rate, depth and force of technique to meet individual needs	Definition: Treatment Protocol Appendix 4
Physio.	2.5 Repeat alternate percussion and vibration in short bursts 2.5.1 Encourage **cough** (spontaneous, directed, FET, manual as deemed necessary) after each cycle of percussion/vibration 2.5.2 Collect expectorate 2.5.3 Repeat till 2 consecutive attempts at clearance produce no further expectorate	Definition: Treatment Protocol Appendix 4
Physio.	2.6 Turn patient to position 2 2.6.1 Repeat 2.3 – 2.5.3	
Physio.	2.7 Modify treatment within above parameters depending on assessment of patient's condition/tolerance 2.7.1 Select further position(s) if deemed necessary 2.7.2 After last position, return patient to original/suitable position	
Recruiter	2.8 Record main treatment parameters (i.e. positions & total time) 2.8.1 Record major deviations + brief explanation from Physiotherapist	
Physio.	2.9 Transfer total expectorant to trial-specific sputum pot 2.9.1 Monitor oxygen saturation until return to baseline	
Physio.	2.10 Provide patient with advice sheet on positioning, managing cough and mobilisation 2.10.1 Do not explicitly instigate ACBT or PEP aid 2.10.2 Ask patient to collect further sputum produced post-treatment 2.10.3 Advise patient on next visit (if appropriate)	Study Protocol Appendix 2
Recruiter	2.11 Record wet weight of sputum produced during intervention 2.11.1 Label trial-specific sputum pots with patient details 2.11.2 Ensure patient has sufficient sputum pots for daily use 2.11.3 Liaise with Physiotherapist regarding next visit (if applicable)	
Recruiter	2.12 Independent of physiotherapy visits, on daily basis - 2.12.1 Collect sputum pots and record total wet weight /24 hours 2.12.2 Record oxygen saturation (24 hour average) 2.12.3 Complete Breathlessness, Cough & Sputum Scale	
	3.0 CONTROL ARM	

Physio.	3.1 Provide patient with advice sheet on positioning, managing cough and mobilisation 3.1.1 Encourage **cough** (spontaneous, directed, FET, manual as deemed necessary) 3.1.2 Do not explicitly instigate ACBT or PEP aid 3.1.3 Request patient collects sputum produced each day 3.1.4 Advise patient on next visit (if appropriate)	Study Protocol Appendix 2
Recruiter	3.2 Record oxygen saturation 3.2.1 If available, record continuous oximetry data 3.2.2 Record whether patient is likely to be ambulatory or not 3.2.3 Label trial-specific sputum pots with patient details 3.2.4 Ensure patient has sufficient sputum pots for daily use 3.2.5 Liaise with Physiotherapist regarding next visit (if applicable)	
Recruiter	3.3 Independent of physiotherapy visits, on daily basis - 3.3.1 Collect sputum pots and record total wet weight/24 hours 3.3.2 Complete Breathlessness, Cough & Sputum Scale	
	4.0 MOVEMENT BETWEEN ARMS	
Physio.	4.1 Assess the need to move from control to intervention arm when patient's Early Warning Score gives cause for concern and ALL the following apply: 4.1.1 Clinical evidence of sputum retention (e.g. auscultation, chest x ray) 4.1.2 Arterial blood gases: pH less than 7.26 4.1.3 Arterial blood gases: rising CO_2 4.1.4 Already receiving controlled oxygen therapy 4.1.5 Already receiving other supportive treatment(s)	
Physio.	4.2 **At each visit** - use above criteria to assess whether the patient remains in their original or re-ascribed arm	
Recruiter	4.3 Record all movements between arms 4.3.1 Record Physiotherapist's reasons for each re-assignment	

	5.0 ADVERSE EVENTS	OBSERVATION
Physio.	**5.1 If the patient shows signs of increased intracranial pressure** 5.1.1 Stop therapy 5.1.2 Instigate Emergency Medical Procedure as per Trust policy	Disoriented, LOC enlarged pupils, headache, vomiting
Physio.	**5.2 If the patient shows signs of acute hypotension** 5.2.1 Stop therapy 5.2.2 Instigate Emergency Medical Procedure as per Trust policy	Pallor, sweating, ↓ consciousness.
Physio.	**5.3 If the patient suffers a pulmonary haemorrhage** 5.3.1 Stop therapy 5.3.2 Instigate Emergency Medical Procedure as per Trust policy	Visible loss of blood
Physio.	**5.4 If the patient shows signs of dysrhythmia** 5.4.1 Stop therapy 5.4.2 Instigate Emergency Medical Procedure as per Trust policy	Pallor, sweating, chest pain, ↓ consciousness.
Physio.	**5.5 If the patient vomits & aspirates** 5.5.1 Stop therapy and position patient appropriately 5.5.2 Clear airway and suction as needed 5.5.3 Administer oxygen 5.5.4 Maintain airway 5.5.5 Contact appropriate physician *	Visible vomit, harsh breathing, oropharyngeal sounds, prolonged coughing.
Physio.	**5.6 If the patient becomes hypoxic** 5.6.1 Stop therapy 5.6.2 Administer controlled oxygen therapy 5.6.3 Return patient to previous/suitable resting position 5.6.4 Contact appropriate physician * 5.6.5 Ensure adequate ventilation	Falling O_2 sats. tachpnoea, blue lips, tachycardia, confusion
Physio.	**5.7 If the patient shows signs of bronchospasm** 5.7.1 Stop therapy 5.7.2 Return patient to previous/suitable resting position 5.7.3 Consider administering/increasing oxygen delivery 5.7.4 Consider use of broncodilators 5.7.4 Consult appropriate physician *	Tight chest, audible wheeze, abdominal paradox.
Physio.	**5.8 If the patient suffers pain or injury to muscles, ribs, or spine** 5.8.1 Stop therapy associated with pain or problem 5.8.2 Exercise care in moving patient 5.8.3 Consult appropriate physician if deemed necessary	Patient response to treatment.
Recruiter	**5.9 For all adverse events** 5.9.1 Record on Case Report Form 5.9.2 Follow Trial-specific Adverse Event reporting procedure 5.9.3 Follow Trust Policy on Adverse Event/Incident Reporting	

**** apply clinical experience to select appropriately from: HO, SHO, Registrar, Senior Nurse***

Abbreviations:	
RCT – Randomised Controlled Trial	**LOC** – Loss of Consciousness
FET – Forced Expiratory Technique	**EMP –** Emergency Medical Procedure
ABCT – Active Cycle Breathing Technique	**HO** – House Officer
PEP – Positive Expiratory Pressure	**SHO** – Senior House Officer