



The MATREX trial
MANual Therapy for
Respiratory EXacerbations

ISRCTN13825248

Dr S.W. Watkin
Consultant Physician
Department of Respiratory Medicine
Norfolk & Norwich University Hospital
Norwich NR4 7UY Tel: 01603 289644

Invitation to participate in a research project

Is Manual Chest Therapy a beneficial and cost-effective treatment for people hospitalised with Chronic Obstructive Pulmonary Disease (COPD)?

You are being invited to take part in a research project. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

Thank you for reading this.

What is the purpose of the study?

Manual Chest Therapy is a technique used by physiotherapists to help people 'clear their chests' when their condition causes them to produce a lot of phlegm (sputum). The physiotherapist places the patient in various positions and 'claps' their back to loosen the build up of phlegm and help them cough it up. Although the technique is used quite often, clinicians are uncertain whether people with COPD benefit from this treatment. It may be that letting people clear their chests themselves is just as effective. We want to see if giving Manual Chest Therapy in hospital makes any difference to people's speed of recovery and whether there are any noticeable longer term benefits once they get back home.

Why have I been chosen?

You have been invited to take part in this research because you have been diagnosed with COPD and needed to come in to hospital to stabilise your symptoms. We will be running this project in several hospitals across East Anglia. In all, we are looking for 550 people to take part.

Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part, you will be given this information sheet to keep and be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. A decision to withdraw at any time, or a decision not to take part, will not affect the standard of care you receive.

What will happen to me if I take part?

Because we do not know which way to treat patients is best, we need to make comparisons. Everyone taking part in this project will be put into one of two groups at random (as if “by the toss of a coin”). Half will be in **Group 1** and half in **Group 2**.

If you are selected to be in Group 1:

A physiotherapist will come and see you whilst you are in hospital. The number of times they come will depend on how troublesome your phlegm is. They will give you Manual Chest Therapy and measure the amount of phlegm you cough up. Once the treatment is finished, the physiotherapist will give you advice on the best way to continue clearing your chest.

If you are selected to be in Group 2:

A physiotherapist will come and see you whilst you are in hospital and give you advice on the best way to clear your chest. If at any time, the physiotherapist becomes concerned you are not able to clear your chest on your own, they may decide to change the group you are in and give you Manual Chest Therapy until your condition stabilises.

Whichever group you are in:

Whilst you are in hospital - before anything else happens, a researcher will talk to you about the study and then ask you some questions about your general use of health services and your quality of life. In all, this should take about 45 minutes. She will then give you 2 questionnaires. One asks questions about how you are managing generally and how COPD affects your life. The other asks questions about how breathless you feel. You can fill these out on your own, or the researcher can help you if you wish. In all, these questionnaires should take about 30 minutes to complete. You will then be asked to collect the phlegm you cough up during the day in special measuring pots. Each day, the researcher will visit you to collect the pots and ask you to fill in a short questionnaire on how you are feeling that day.

When you have gone home - 6 weeks after you have been discharged, a researcher will send you a number of questionnaires asking questions about your health and your quality of life. In all, these questionnaires should take about 40 minutes to complete and you can fill them out with the help of a friend or relative if you wish. We will send a stamped addressed envelope at the same time so you can return them easily. One questionnaire asks questions about how much you have needed to use particular health services. With your permission, a researcher will check this against information held at your GP Practice. The researcher will write to you again at 6 and 12 months, asking you to complete the same questionnaires. At one of your routine checkups at the hospital, you may also be asked to do a ‘walking test’ where we measure how far you can comfortably walk in 6 minutes.

What is the treatment being tested?

The treatment being tested is Manual Chest Therapy. This involves a physiotherapist placing the patient in a number of positions to help drain the phlegm from their lungs. The physiotherapist then ‘claps’ the patient on the chest and ‘vibrates’ the area with their hands to help dislodge phlegm. The physiotherapist then helps the patient cough up the dislodged phlegm. The treatment takes between 5 and 20 minutes depending on how much phlegm the patient is producing.

What are the alternatives?

When patients produce a lot of phlegm, the physiotherapist can give them advice on how best to cough it up. This includes information on the best positions to lie in and the various techniques that can be used for effective breathing and coughing.

What are the side effects and risks of the treatment being tested?

Some people find Manual Chest Therapy uncomfortable. The physiotherapist tries to minimise discomfort by adapting the positions used and the force of the 'clapping' to suit each patient individually. Sometimes the treatment can make people more breathless than usual. If this happens, the physiotherapist monitors the patient carefully until this increased breathlessness eases off.

Rarely, coughing up a large amount of phlegm can make people sick. If this happens, the physiotherapist makes sure the patient can clear their airway and helps them to feel more comfortable. Very occasionally, the physical nature of Manual Chest Therapy can provoke underlying medical conditions such as high blood pressure, heart problems and airway spasms. In the unlikely event any of these things happen, the physiotherapist follows a set course of action to help the patient.

What are the possible disadvantages of taking part?

If you are put in the group that does not receive Manual Chest Therapy, you may feel you are 'missing out' on a treatment that could help you. However, because clinicians are unsure of its benefits, Manual Chest Therapy is not routinely given to every patient hospitalised with COPD. This means that if you chose not to participate in this project, there is still no guarantee you will receive this treatment.

What are the possible benefits of taking part?

Whichever group you are in, the physiotherapist is there to help you. The information we get from this study may help us to treat future patients hospitalised with COPD more effectively.

What if something goes wrong?

If you are harmed by taking part in this research project, there are no special compensation arrangements. If you are harmed due to someone's negligence, then you may have grounds for a legal action but you may have to pay for it. Regardless of this, if you wish to complain or have any concerns about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service complaints mechanisms will be available to you.

Will my taking part in this project be kept confidential?

All information which is collected about you during the course of the research will be kept strictly confidential. We will need to consult your medical records to collect information on your condition and the results of tests routinely carried out as part of your hospital treatment. All the information we obtain relating to you will be treated in the strictest confidence and stored in line with the Data Protection Act (1998). Only investigators from our team (who have formal legal duties of confidentiality) will have access to this information. Any information about you which leaves the hospital will have your name and address removed so that you cannot be recognised from it. With your agreement, we will write to your GP to let them know you are participating in this trial.

What will happen to the results of the research?

We aim to publish the results of this project both locally and nationally. These reports will not include names or other personal details that would allow individual participants to be identified. If you wish, we will send you a copy of the final summary report.

Who is organising and funding the research?

This research is being organised by the University of East Anglia in collaboration with hospitals across East Anglia. The research is being funded by the Department of Health through the NHS Health Technology Assessment (HTA) research funding scheme.

Who has reviewed the study?

The scientific aspects of this project have been reviewed by specialists in the NHS Research & Development funding programme. The Norwich Research Ethics Committee has reviewed the project to make sure this research is ethical and patients' rights are protected. The East Norfolk and Waveney Research Governance Committee has reviewed its suitability to be run in NHS hospitals.

Contact for Further Information

If you need any more information or would like to discuss this project further, you can talk to the researcher who gave you this information sheet, any member of the hospital physiotherapist team or the consultant responsible for your care. If you do decide to take part, whilst you are in hospital you can talk to any of these people about the project.

Once you are back home, if you have any queries or concerns about the project, you can telephone the research team based at the University of East Anglia.

Their telephone number is: **01603 591675**

If you decide to take part, thank you for participating.