Conservative Management in Traumatic Pneumothoraces in the Emergency Department (CoMiTED): A Randomised Controlled Trial

SUMMARY PARTICIPANT INFORMATION SHEET

You (the patient) are being invited to take part in a research study. It is important for you to understand why the research is being done and what it will involve. You are welcome to ask us any questions. Thank you for taking the time to read this information.

We are looking for 750 participants (aged 16 years or older) who have been admitted to Accident and Emergency department (A&E), with a collapsed lung due to injury, to take part in our research.

- A collapsed lung (also known as a 'pneumothorax') can occur following trauma such as falls, road traffic accidents or knife injuries. We are doing a study to compare different treatment options for a collapsed lung.
- Currently, doctors treat this condition by inserting a tube (chest drain) through the chest wall, to help the lung re-inflate. **We think that more patients with a collapsed lung could be safely treated without a chest drain**, but there is currently no good research evidence one way or the other.
- Both treatments for a collapsed lung (treatment with or without a chest drain) have advantages and disadvantages, but we do not know if one is better than the other. **This research will help us find out which treatment is better and whether doctors should change their practice and treat fewer patients with a chest drain.**
- **If you join the study**: you will be asked to complete a consent form confirming you agree to take part. You will be put into one of two groups. One group will have treatment with a chest drain (current usual care) and the other group will be treated without a chest drain to start with.

GROUP 1 - TREATMENT WITH CHEST DRAIN (CURRENT USUAL CARE): you will have a chest drain inserted in A&E. The details of this procedure will be discussed with you by your clinician. After the procedure, you will be admitted to a suitable hospital ward and carefully monitored for ongoing treatment needs.

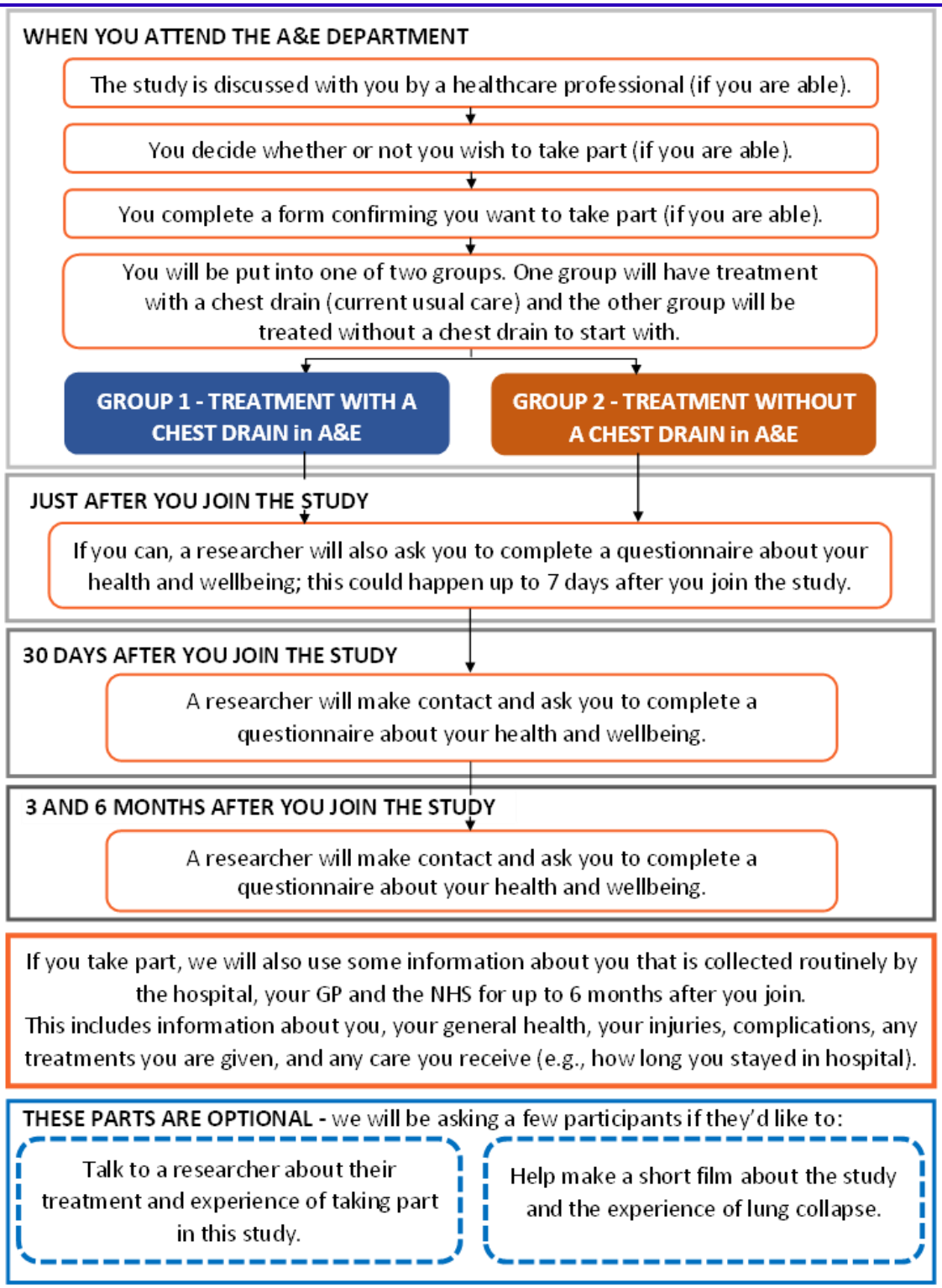
GROUP 2 - TREATMENT WITHOUT CHEST DRAIN: you will be treated without having a chest drain inserted in A&E. You will be admitted to a suitable hospital ward and be carefully monitored by your medical team who will offer appropriate treatment for your injury, which may include a chest drain at a later stage.

- After you have been allocated to treatment Group 1 or Group 2, a member of the research team will collect information about your general health, your injuries and medical treatment from your medical records.
- **Within the next 7 days:** if you can, we will ask you to complete a questionnaire about your health and wellbeing.
- **Around 30 days after you join the study:** a researcher will ask you to complete a questionnaire about your health and wellbeing. A researcher will also look at relevant parts of your medical records to see if you required further treatment or had any complications, and record details of your care (e.g., how long you stayed in hospital).
- **Around 3 and 6 months after you join the study:** a researcher will ask you to complete a questionnaire about your health and wellbeing, and any further care you received due to your injuries.
- **At 30 days and 6 months after you join the study:** we will also be asking a *few* study participants if they'd be willing to talk to a researcher about their treatment and experience of taking part in this study. This interview is optional and you don't have to take part; it won't affect your participation in the rest of the study.
- **At the end of the study:** we will be asking a *few* participants if they'd like to help make a short film about the study and the experience of lung collapse - to make sure the results are understood by future patients. This is optional and you don't have to take part; it won't affect your participation in the rest of the study. Patient perspectives and experience are extremely important to this research for additional opportunities to get involved please email comited-trial@bristol.ac.uk.
- The **diagram on the next page summarises what is involved if you take part**. You are welcome to ask us any questions and the doctor or nurse can provide an additional information pack for you to read now or later.
- **Taking part is entirely voluntary.** If you take part, you can leave the study at any time without giving a reason. Your treatment will continue as normal.

Use of personal data

In this research study we will use information from you, your medical records, and/or your GP. We will only use information that we need for the research study. We will let very few people know your name or contact details, and only if they really need it for this study. Everyone involved in this study will keep your data safe and secure. We will also follow all privacy rules. At the end of the study, we will save some of the data in case we need to check it and/or use it for future research. We will make sure no-one can work out who you are from the reports we write. The additional information pack tells you more about this.

Flow diagram for the CoMiTED study



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Please note: *for the purpose of this information sheet, any reference to 'we' means the study Sponsor (North Bristol NHS Trust).*