Invitation to continue participating in the CoMiTED study

(Following Consultee advice)

We would like to invite you to continue to take part in a research study. Before you decide, it is important for you to understand why the research is being done, what has happened so far and what the study will involve in the future if you choose to continue to take part. You are welcome to ask any questions you may have. Thank you for taking time to read the supporting information.

Introduction

When you recently attended the Accident and Emergency department (A&E), you were found to have a collapsed lung (also known as a 'pneumothorax') and were included in a research study called CoMiTED, "Conservative Management in Traumatic Pneumothoraces in the Emergency Department: A Randomised Controlled Trial". The aim of CoMiTED is to find out which treatment is better for patients who have a collapsed lung. Doctors currently treat a collapsed lung by inserting a tube (chest drain) through the chest wall to help the lung re-inflate. We think that more patients could be safely treated without a chest drain, but there is currently no good research evidence one way or the other. We want to find out whether doctors should change their practice and treat fewer patients with a chest drain.

Why am I already in this study?

We felt that you were too unwell to make a decision about your involvement in the study when a decision needed to be made. An adult who is either temporarily or permanently unable to make this kind of decision for themselves, is described as 'lacking capacity' under the Mental Capacity Act 2005. This law protects the interests of adults (in England and Wales) who are unable to make their own decisions, including whether to take part in research. This law also allows a Consultee to be appointed to give researchers advice as to the likely feelings and wishes of an adult who lacks capacity about taking part in a research study.

We therefore asked either a Personal Consultee (i.e. your relative, friend, unpaid carer or a court appointee) or, if not available, a Nominated Consultee (i.e. your doctor or lawyer) for their advice. After considering the aims of the research, and what the practicalities, risks and benefits of taking part would be for you, your Consultee advised that you would want to continue to take part in the study.

Now that your condition has improved, it is felt that you are able to make a decision about whether you wish to continue in the study, or not. We would like to let you know what the study is about, why we're doing it and ask whether you would like to continue to take part. Further details about the study are provided in the separate participant information materials; Summary Participant Information Sheet (and/or equivalent video) and Detailed Participant Information Sheet; this is the same information which was provided to your Consultee. If there is anything in the information supplied that you don't understand, please ask someone to explain it to you. The doctors and nurses involved will be happy to answer any questions you may have.

What happens next?

If, after reviewing the separate participant information materials, you wish to continue to take part in the CoMiTED study, a member of the research team will ask you to complete a Participant Informed Consent Form that confirms that you wish to continue to take part in the study. This form will ask whether you agree to complete questionnaires about your health at around 30 days, 3 months and 6 months after your injury. You will also be asked if you would agree to being contacted by a researcher with a view to being interviewed about the treatment you received and your

experiences of taking part in the study and/or with a view to helping us to make a short film about the study and your experience of lung collapse. You do not have to agree to take part in either if you do not wish and this will not affect your taking part in the rest of the study. This information will be documented on the Consent Form, which you will be given a copy of for your records, and your personal and research data will be kept for at least 5 years after the end of the study, held confidentially and securely by the research team. If, at a later date, you decide that you wish to stop taking part in this study, please inform your doctors and you will be withdrawn from the study.

Taking part in the study is voluntary and if, after reviewing the separate participant information materials, you do *not* wish to continue to take part in the CoMiTED study, you will be withdrawn from the study. For us to understand why you have come to this decision, and to help in future research, you may be asked to answer a few questions, if you are willing. However, you do not have to give a reason why and choosing not to continue to take part in the study will not affect the medical care you receive in any way. We will ask you if we have your permission to confidentially keep any information (data) collected up to this point to include in our analysis of the study results.

You can find more details in the supporting Detailed Participant Information Sheet. If there are any parts of the information supplied that you do not understand, you have any questions, or you would like further information, please use the contact details on the Detailed Participant Information Sheet.

THANK YOU FOR READING THIS INFORMATION. PLEASE KEEP A COPY FOR YOUR RECORDS.

Sent on behalf of the CoMiTED Study Team

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Acknowledgements and Disclaimers: *This study is funded by the National Institute for Health Research (NIHR) Health Technology Assessment (HTA) Programme (NIHR132889). The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care. This study was designed and delivered by the Bristol Trials Centre, a UKCRC registered clinical trials unit, which is in receipt of National Institute for Health Research CTU support funding. This study is sponsored by North Bristol NHS Trust.*

FUNDED BY NIHR | National Institute for Health Research