PARTICIPANT INFORMATION SHEET

DEVELOPMENT OF A CORE OUTCOME SET FOR TRIALS OF PHYSICAL REHABILITATION AFTER CRITICAL ILLNESS: PART 2

Introduction

You are invited to participate in a research study investigating important outcomes when investigating physical rehabilitation following critical illness.

Muscle wasting and weakness are characteristic problems following critical illness, contributing to significant and long-term physical problems in survivor including impaired physical function, exercise capacity and health related quality of life. Trials of physical rehabilitation to mitigate these complications are challenged by heterogeneity in selection and definition of outcomes used for evaluation. This variability precludes meta-analyses of data and restricts capacity for evidence-based decisions to guide clinical practice.

Establishing a ‘core outcome set’ (COS) is one strategy to address the need for outcome transparency in trials. A COS is set of outcomes that have been agreed by relevant stakeholders as priority to measure in all research studies for a particular condition. Importantly a COS does not preclude researchers from measuring other outcomes of interest relevant to the specific intervention, including the primary outcome. Rather, achieving consensus from key stakeholders on priority outcomes would increase the cumulative value of individual trials for informing evidence-based clinical decision-making.

Our aim is to develop a COS for trials of physical rehabilitation interventions delivered across the continuum of recovery from within the ICU to hospital discharge to the community (‘PRACTICE’; Physical RehAbilitation Core ouTcomes In Critical illNess), involving researcher, clinician and patient/caregiver stakeholder groups.
Before you decide to participate, it is important for you to understand why the study is being done and what it will involve. This summary is designed to explain what will happen if you agree to take part. Please ask if you would like any further information or explanation.

If you decide to take part we will contact you via email, and send you a link to an electronic survey. Instructions will be included for how to complete and return the survey. By completing and submitting the electronic survey, you will be indicating your consent to participate. You are free to withdraw from the study at any time if you wish, and do not have to provide a reason for doing so.

**What is the purpose of this study?**
This study is being carried out to identify a core outcome set for research studies of physical rehabilitation in critical illness. This is required to improve the methodological design of trials investigating physical rehabilitation in critical illness.

**Why have you been invited to take part in the study?**
You are a researcher (identified from involvement in an international clinical trials group or publication of a research study on physical rehabilitation in critical illness) or clinician (identified via a professional organisation relevant to critical care and with a primary role in clinical practice; medical clinicians will be at consultant (or equivalent) level, nursing and allied health professionals will have at least 3 years specialist experience in critical care). Your views as to what outcomes would be important to measure in physical rehabilitation research are valuable for helping us to develop the core outcome set.

**Do I have to take part?**
No. It is up to you to decide whether or not to take part in this study. If you decide to take part, you are free to withdraw at any time and without giving a reason. You will not be paid for your time involved in participation.
What will happen to me if I take part and what study procedures and tests will be involved?
If you decide you to take part in the study, you will take part in a series of surveys. There will be a maximum of six surveys, each taking approximately 20 minutes to complete. The surveys will be completed electronically using an online system and will be each scheduled approximately one month apart. In the first three surveys, you will be presented with a list of outcomes that can be measured in patients receiving physical rehabilitation after critical illness. You will also have the opportunity to suggest any other outcomes you think are important but have not been included in the list. You will be asked to score how important each outcome is to be included in a core outcome set, on a scale of 1-9. On this scale, a score of 1-3 = not important for inclusion; 4-6 = important but not critical; and 7-9 = critical for inclusion. During the survey rounds, you will be provided with feedback on your responses.

In the second three surveys, you will be presented with a list of instruments that are commonly used to measure these outcomes e.g. tests, questionnaires, or scores. We will also give you some explanation of how these instruments work. You will then be asked to score how important each instrument is to measure each outcome. The same scale will be used to score the importance of each instrument.

What happens if I agree to take part?
If you decide to take part we will contact you via email, and send you a link to each electronic survey. Instructions will be included for how to complete and return the survey. By completing and submitting the electronic survey, you will be indicating your consent to participate.

What are the possible disadvantages and risks of taking part?
We do not perceive any major disadvantages or risks of taking part in this study. Some participants may find that the time required for participation (approximately 20mins for a
maximum of 6 surveys) could be a potential disadvantage. However these surveys will not be completed on one occasion but will be separated by 3-4 weeks each time.

**What are the potential benefits of taking part?**

There is no immediate direct benefit for you in taking part in this study. However your participation will assist in developing this core outcome set which we anticipate will improve the design and conduct of future trials of physical rehabilitation in critical illness.

**Will my taking part in this study be kept confidential?**

Information collected during this study will remain strictly confidential at all times. However these may need to be available to others e.g. Ethics Committee members and Regulatory Authorities who monitor research studies such as this. By agreeing to the consent form, you are indicating your agreement to this access for the current study.

We will undertake measures to protect your personal information and will not include your name on any forms, reports or publications unless you provide your permission to do so; instead we would use a number or a code. If you withdraw from the study, we will no longer collect your personal information, but we may need to continue use the information already collected. Sensitive information e.g. date of birth, will be collected but used only for research purposes in relation to this study. To protect your privacy, the information you provide us will be labelled (“coded”) with a subject number, and not your name. Researchers will use this number to monitor information. The only staff who will be able to link your name use your subject number and hence have access to individual research results, will be the research staff involved in this study.

The UK Data Protection Act 1998 will apply to all information gathered in the study and held on password-locked computer files and locked cabinets within King’s College London.

**What will happen to the results of the research study?**
We are happy to provide you with a summary of the results at the end of the study period, at which point your data will be stored securely and anonymously for 5 years, as per recommendations. The results of the study will be presented at international meetings and conferences and we will publish the data in peer-reviewed journals.

**Who has reviewed the study?**
This study has been reviewed and approved by King’s College London Research Ethics Committee.

**Who is organising and funding this research?**
This study is being conducted as part of a Postdoctoral Fellowship to Dr Bronwen Connolly that is funded by the UK National Institute for Health Research (NIHR). Staff will not be receiving personal payment to conduct this study.

**What if there is a problem?**
If you have a concern about any aspect of this study, you should ask to speak to a member of the research team who will do their best to answer your questions. Please contact: Chief Investigator, Dr Bronwen Connolly, Bronwen.connolly@nhs.net, 020 7188 8070.

If this study has harmed you in any way, or if you wish to make a complaint you can contact King’s College London using the details below for further advice and information:

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