University Hospital Southampton
NHS Foundation Trust

Core outcome set of daily monitoring of gastrointestinal function (COSMOGI)

Online Delphi Survey

Participant information sheet for patients/carers
Version 1.3
27th April 2023

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

Background and rationale

Gastrointestinal (GI) dysfunction is a common occurrence in critically ill patients. Research in that field has gained interest over the last decade and the gastrointestinal organ is recognised as an important system in critically ill patients and GI failure has a major impact on patient outcome. Studies that assess gastrointestinal function in critically ill patients currently report different monitoring data using varying definitions and timepoints. Comparison across different studies is made difficult by these variations. Therefore, an agreed list of measures important to patients (and how best to measure them) is needed.

In patients on ICU, we would like to know what the most important things are to measure i.e., the outcomes which are important to patients, in order to assess the effect of different treatments. We are gathering the opinions of people who have experienced intensive care or cared for someone after intensive care: Patients and caregivers are key stakeholder groups for this work.

Who will be Involved in this study?

You are being invited to become part of the patient representative group for this study. We are also inviting intensive care doctors, nurses, physiotherapists, dietitians and researchers who perform clinical trials.

What will I have to do?

The study involves completing four to six questionnaires in two stages. You will receive a link to the questionnaire in your email. Each questionnaire will take around 15 minutes to complete. Completing the online survey implies that you provide your consent to participate. You can contact the primary investigators (Dr Kaspar Bachmann or Bethan Jenkins) via email or phone if you have any queries or difficulties completing any aspect of the online survey. The details are at the end of this information sheet.

First questionnaire, Stage 1

The questionnaires will contain a list of outcomes important to patients that researchers may measure to assess patients who were treated on the ICU. We will ask you to score how important each outcome is on a scale of 1-9, and to complete and return the questionnaire within a week of receiving it via email.

Do I have to take part?

No, you can decide not to complete and return the questionnaire at any time and without providing any reason. You can also take part in the survey but decline to take part in a follow up consensus meeting that is planned as part of this study. You are under no obligation to attend and are free to withdraw from the study at any time (see separate participant information sheet for this part of the study).

If you withdraw your participation after completing the questionnaires then your data will have been anonymised and amalgamated, and therefore cannot be excluded. If you request withdrawal of your contributed data, we will arrange a meeting with you to discuss this and deal with it on a case-by-case basis.

Will my taking part in this study be kept confidential?

In the first questionnaire, we will ask you to provide information about yourself, your name and geographic location. Your name will not be associated with your responses in the questionnaire feedback and will not be attributed to your responses in any report or publication. However, we would like to acknowledge your participation in the study in the final publication. After completing the study, we will send you a thank you letter and ask if you would like to be acknowledged and how your acknowledgement should appear (e.g. name and country). This will appear in an acknowledgement list.

We will give your questionnaire a unique study number. All questionnaires will be stored securely under the Data Protection Act 2018 and as stipulated by the University regulations.

What are the possible risks or disadvantages of taking part?

The only possible disadvantage to taking part in this study is that we will have your name and email contact address. However, this information will be kept separate in a separate folder from all research data generated during the online survey and will be stored securely on the QMUL server.

There is no emotional risk to the individuals as the only topic to be discussed will be the choice of outcome measures and tools to measure these e.g., the use of specific tools to measure quality of life, muscle strength etc. There will be no discussion of individual clinical histories.

What are the possible benefits of taking part?

There is no direct benefit to you from taking part in this study. However, this research project will provide valuable information for critical care researchers and potentially improve the quality of future research studies testing nutritional and metabolic treatments conducted in intensive care settings in the future. The results of this project will also better inform clinicians on the most appropriate information they should be gathering in intensive care after nutritional and metabolic treatments have been delivered to patients. This in turn will benefit future patients in intensive care.

Who is organising and funding the research?

A short version of this study is publicly available at https://www.comet-initiative.org/Studies/Details/1838). This study is being run by a research team from the University of Tartu as well as the University Hospital Southampton NHS Trust. There is no specific additional funding for this study.

What will happen to the results of the research?

We will disseminate our findings in scientific and medical journals and present our findings at national and international multi-disciplinary conferences. We will also liaise with representatives from national and international funding agencies and policy-makers to ensure the core set of outcomes decided on in this study will be adopted by future researchers conducting clinical trials in this area. We will provide lay summaries to relevant patient and carer support groups and organisations.

What if something goes wrong?

If you have any concerns about any aspects of the study, you can contact the Primary Investigators, Dr Kaspar Bachmann (Telephone +41 31 664 15 69) or Bethan Jenkins (bethan.jenkins@uhs.nhs.uk). Should you remain unhappy and wish to make a formal complaint, you can contact:

University Hospital Southampton NHS Trust
Southampton General Hospital
Tremona Road
Southampton
SO16 6YD
Email: researchmanagement@uhs.nhs.uk

Contact for further information

If you have any questions or concerns regarding this study please contact us:

Bethan Jenkins
University Hospital Southampton NHS Trust
Southampton General Hospital
Tremona Road
Southampton
SO16 6YD

Bethan.jenkins@uhs.nhs.uk

Dr Kaspar Bachmann
Junior Lecturer
Department of Anaesthesiology and Intensive Care
University of Tartu, Tartu, Estonia
kaspar.felix.bachmann@ut.ee

This research will be conducted in compliance with data protection legislation. For more information about how we look after your information, how to access your rights and who to contact if you have any queries or concerns about data protection, please visit the University Hospital Southampton clinical research website: https://clinicalresearch.uhs.nhs.uk/take-part/about-clinical-research.

Thank you for your interest in this study and for taking the time to read through this information sheet.