# Study title

Is it feasible to conduct a RCT of two different intravenous maintenance fluid volume restrictions in ventilated critically ill children on PICU across the UK?

The MADE Study: **MA**int**E**n**A**nc**E** flui**D** volu**ME** in PICU

# Research Team

Prof Lyvonne Tume (Edge Hill University); Prof Stephen Playfor (Manchester Children’s Hospital PICU); Mr Adam Sutherland (University of Manchester), Dr Julie Menzies (Birmingham Children’s Hospital)

# Invitation

We would like to invite you to take part in a feasibility study exploring IV maintenance fluid restrictions in the PICU. Before you decide whether to take part, it is important that you understand why the research is being done and what it will involve. Take time to read the information that follows carefully and discuss it with others if you wish. Inform the research team if you would like more information or if anything is unclear.

# What is the purpose of the study?

Overall we want to explore if a future trial of differing IV maintenance fluid therapy (IVMFT) restrictions is feasible in the UK, but this part of the study seeks to explore your unit practices around IVMFT restrictions and seeks your views on a future trial.

# Why have I been invited?

You have been invited to take part in the study because you are a healthcare professional working in a PICU in the UK.

# Do I have to take part?

No. It is up to you to decide if you want to take part. Your participation in this study is voluntary. You can change your mind and leave the study at any time without penalty. This survey is anonymous, with only the responding unit identified, to enable us to ensure we have a wide representation from the 29 UK PICUs. You will not be identified. Consent is implied when you submit your responses.

# What will I be asked to do?

The study will involve answering some questions in an online survey about IV MFT in your PICU, it shouldn’t take more than 20 minutes to complete the survey.

# What are the possible benefits or disadvantages of taking part?

***Include any specific benefits/disadvantages or general comments as below***

You may not benefit directly from taking part, however you will have the opportunity to contribute to our understanding of whether it is feasible to conduct a future trial.

# Will my participation be confidential?

Yes. The surveys are anonymous so no personal details will be obtained.

All study data will be stored securely on the University One Drive in a shared folder accessible only by the research team and will be retained for a period of 10 years after which it will be securely deleted. Any personal contact details will be deleted at the end of the study. The procedures for handling, processing, storage and destruction of data from the study are compliant with GDPR and the Data Protection Act (2018).

*At Edge Hill, we are committed to respecting and protecting your personal information. To find ways in which we use your data, please see* [*edgehill.ac.uk/about/legal/privacy*](https://www.edgehill.ac.uk/about/legal/privacy)*.* The University is committed to ensuring compliance with current data protection legislation and confirms that all data collected is used fairly, stored safely, and not disclosed to any other person unlawfully. The University is a data controller and, in some instances, may be a data processor of this data.

# What will happen to the results of the research study?

The results of this study will be presented in the optional feedback webinar, at the annual PCCS-SG meeting in May 2023 and will be published in an academic journal.

# Who has reviewed the study?

The study has been reviewed and approved by Edge Hill University Health-related Research Ethics Committee (REF2223-0018)

# Is there someone independent I can talk to about the research?

If you are unhappy with the research in any way please tell us. We will try to put things right. If you would prefer to talk to someone outside the research team, or if you are not happy with the way we deal with your problem, you can contact the Secretary of the University Research Ethics Sub-Committee on [research@edgehill.acuk](mailto:research@edgehill.acuk)