
PARTICIPANT INFORMATION SHEET FOR CLINICIANS, MANAGERS AND RESEARCHERS

Title: Non-pharmacological management of agitation in the adult intensive care unit – A Delphi study

HREC Reference 15710

Project sponsor Flinders University

Location Online with Danish and Australian participants

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1. Introduction

You are invited to participate in this study because you have had personal experience with patient agitation in the intensive care unit either as a previous patient or a family member. Before you decide, it is important that you understand why this research is being done, and what it will involve. Please take your time to read through this document, and ask questions if there is anything you would like more information about.

2. Why is this study important?

The aim of this study is to develop a practice guideline on non-pharmacological approaches to prevent and minimise patient agitation in the adult intensive care unit. Agitation is characterised by a noticeable rise of behaviours such as restlessness, irritability, distress, confusion, and aggression, and is very common

in the intensive care unit. Agitation can be dangerous for the patient and distressing for both patients, family members and clinicians and therefore must be managed well.

Medication is important when treating underlying causes of agitation and is sometimes essential to keep patients safe. However, medication often has side effects. Therefore, clinicians are encouraged to also consider strategies that do not involve medication, the so-called non-pharmacological strategies.

With advice from a Danish – Australian advisory group and by referring to the existing literature, several tentative recommendations have been identified. We now need input from clinicians, managers, researchers and previous patients and family members to better understand how effective and acceptable these recommendations are.

3. Who is undertaking the project?

Anne Mette Adams is the recipient of an Australian Government Research Training Program Scholarship and is undertaking this study to obtain a Doctor of Philosophy (PhD) at Flinders University. Support is provided by a team of experienced researchers from both Flinders University, South Australia and Aalborg University, Denmark. This project is also supported by a research grant from the Australian College of Critical Care Nurses. Flinders University will own the results of this study.

4. Do I have to take part in this study?

This is a research project and you do not have to be involved. If you do not wish to participate, your employment will not be affected in any way. Also, you may withdraw from the project at any time after you have commenced. You should be aware that data collected up to the time you withdraw will form part of the research project results. Your participation in this study shall not affect any other right to compensation you may have under common law.

5. What is expected from you?

The researchers do not expect the questions to cause any harm or discomfort to you.

If you agree to participate in the research study, you will be asked to:

- Complete three online surveys (known as rounds) over a period of 5 months. You will receive a link to the surveys in an e-mail. Instructions will be provided for each survey. You will be asked to rate and comment on a list of recommendations to be included in the guideline. After each survey, the researcher will collate the information, remove recommendations that reach consensus from the survey and provide material for the next survey. Recommendations that have reached consensus after the third round will be included in the final guideline.
- Spend between 20-40 minutes on each survey round. The time needed to read through and comment on recommendations will vary. It is expected that the first round may require more time.
- Complete each survey within two weeks of receiving the request.

6. Benefits of the study

The sharing of your opinion of the recommendations may not benefit you directly. However, it is predicted that findings from this study will benefit adult patients in the intensive care unit, clinicians, educators, policymakers, and possibly family members of the patients.

7. Expenses and payments

Upon completion of this study, you will be offered a certificate of continuing professional development. There will also be a draw of six random participants who will receive a \$50 gift voucher. Note that during this process participant confidentiality will be maintained.

8. Confidentiality and Privacy

Only researchers listed on this form have access to the individual information provided by you. You will remain anonymous to the other participants throughout this Delphi study. Privacy and confidentiality will be assured at all times. The research outcomes may be presented at conferences, written up for publication or used for other research purposes as described in this information form. You will not be named, and your individual information will not be identifiable in any research products without your explicit consent. No data, including identifiable, non-identifiable or de-identified datasets, will be shared or used in future research projects without your explicit consent.

9. Data Storage

The information collected will be stored securely on a password-protected computer and/or Flinders University server throughout the study. No data will be transferred overseas. All identifiable data will be de-identified for data storage purposes and securely stored at Flinders University for at least five years after publication of the results. Following the required data storage period, all data will be securely destroyed according to university protocols.

10. Will I be able to find out the results of the project?

A summary of the results will be provided to all participants via email. The study findings will also be presented at conferences and published in peer-reviewed journals.

11. Queries and Concerns

This project will be carried out according to the National Statement on Ethical Conduct in Human Research (2007) incorporating all updates. This statement has been developed to protect the interests of people who agree to participate in human research studies

The study has been approved by the Central Adelaide Local Health Network Human Research Ethics Committee. If you wish to speak to someone not directly involved in the study about your rights as a volunteer, or about the conduct of the study, you may also contact the CALHN HREC Chairperson, on 7117 2229 or 8222 6841. The study has also received cross-institutional approval from Flinders University's Ethics committee.

12. If I want to participate, what do I do?

If you accept this invitation, you need to follow the link provided in your Letter of Invitation. This will take you to the first online Survey. At the beginning of every survey, you will be asked to provide your consent to participate.

For further questions or information, you are welcome to contact me or my primary supervisor, Dr Tiffany Conroy. Our contact details are listed above.

Thank you for taking the time to consider this study.

Kind regards,

Anne Mette Adams
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