[insert site logo]
Participant Information Sheet
Patient

Non-Interventional Study - *Adult providing own consent*

[Insert site name]

Title	Phase II (pilot) cluster randomised controlled trial of a multicomponent non-pharmacological intervention to prevent delirium for hospitalised people with advanced cancer
Short Title	The PRESERVE pilot study (**Pr**event delirium through **E**ating and drinking, **S**leep, **E**xercise, **R**eorientation, **V**ision and hearing, and **E**nabling family)
Protocol Number	1.0
Project Sponsor	Palliative Care Clinical Studies Collaborative
Coordinating Principal Investigator/ Principal Investigator	Professor Meera Agar Dr Annmarie Hosie Professor Jane Phillips
Associate Investigator (s) *(if required by institution)*	*[Associate Investigator(s)]*
Location *(where CPI/PI will recruit)*	*[Location]*

Part 1 What does my participation involve?

1 Introduction

You are invited to take part in a sub-study within a research project, the PRESERVE pilot study. The research project is examining the feasibility and acceptability of a multicomponent delirium prevention intervention in people with advanced cancer in an oncology or palliative care unit.

You are invited to participate in this research because you are a patient receiving care in a unit taking part in the PRESERVE pilot study.

This Participant Information Sheet/Consent Form explains the study and what is involved. Knowing what is involved will help you decide if you want to take part.

Please read this information carefully. Ask questions about anything that you don't understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or your doctor.

Participation in this research is voluntary. If you don't wish to take part, you don't have to. You will receive the best possible care whether or not you take part.

If you decide you want to take part in the study, you will be asked to sign the consent section. By signing it you are telling us that you:

- Understand what you have read
- Consent to take part in the study
- Consent to the research that is described
- Consent to the use of your personal and health information as described.

You will be given a copy of this Participant Information Sheet to keep.

2 What is the purpose of this research?

The purpose of this study is to obtain patients' perspectives about the feasibility and acceptability of a multi-component non-pharmacological delirium prevention intervention.

Delirium occurs when illnesses, injury, surgery and/or medicines cause a sudden decline in a person's mental function. The result is reduced ability to concentrate, think and communicate, and sleepiness and/or agitation. Some people have hallucinations or delusions. Delirium usually lasts for hours to days, but may last for weeks or months. Delirium is distressing to experience and witness.

Older people, especially those with dementia, are at highest risk, but it can affect any ill person. Delirium affects up to one in two people with advanced cancer in hospital.

Delirium is a serious medical complication. Even a brief episode can lead to worse outcomes, such as longer hospital stays, loss of independence, longer-term physical and mental decline, admission to a nursing home, and increased risk of death.

There is no approved or proven medication to prevent or treat delirium. Preventing delirium is possible for many people through non-pharmacological strategies to meet essential human needs, such as physical and mental activity, sleep, hydration, vision and hearing. When provided together as a 'multi-component intervention', these strategies reduced the rate of delirium in older hospitalised patients in a number of studies, to the order of 1 in 3 episodes of delirium prevented.

There is potential for a multi-component non-pharmacological intervention to reduce the risk of delirium, or its severity or duration, for people with advanced cancer. In order to inform ongoing research into the effectiveness of the intervention, we first need to determine whether these strategies (individually and as a combined intervention) are feasible and acceptable for people with advanced cancer and how the intervention can be best delivered in oncology and palliative care units.

3 What does participation in this research involve?

By giving verbal consent, you will give permission to take part in a brief interview (approximately 20-30 minutes' duration) about whether you think the delirium prevention strategies provided to you during your admission are feasible and acceptable. We are interested in hearing about the care that helped you to sleep, hear and see, drink, communicate, concentrate and be aware of your surroundings, move, and inform you and your family about delirium and how to prevent it.

If any of the clinical team asked you questions to assess your thinking while you have been a patient in the unit, we will ask about your perceptions of these questions. We will also ask if you have any suggestions about how any of these aspects of care could be better provided.

We will ask you information about yourself: your age, gender, availability of a caregiver, country of birth, preferred language, Aboriginal or Torres Strait Islander status, and diagnosis; and/or we will obtain this information from your medical records.

The interview will be recorded and a transcript made.

There are no costs associated with participating in this research project, nor will you be paid. You will not need to travel to participate in this research.

4 What do I have to do?

Participating in the research will not involve any changes to your care, other than the time spent considering your participation and taking part in the interview described in Section 3.

5 Other relevant information about the research project

There will be approximately 20 people participating in this part of the study, with 10 expected to participate from this site. This research will be conducted in four oncology or palliative care units in Australia.

6 Do I have to take part in this research project?

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the research at any stage.

If you do decide to take part, you will be given this Participant Information and Consent Form to sign and given a copy to keep.

Your decision whether to take part or not to take part, or to take part and then withdraw, will not affect your routine treatment, relationship with those treating you, or your relationship with *[Institution]*.

7 What are the alternatives to participation?

You do not have to take part in this study to receive care at this hospital. You will receive the same care regardless of whether or not to take part.

8 What are the possible benefits of taking part?

There will be no clear benefit to you from your participation in this study, other than knowing that you are contributing to research that will inform future studies and clinical care to prevent delirium for people with advanced cancer in hospital.

9 What are the possible risks and disadvantages of taking part?

It is possible that you become upset or distressed as a result of being interviewed about your experience of delirium or clinical care. If this happens, counselling or other appropriate support will be offered, as required. Any counselling or support will be provided by qualified staff who are not members of the research team. This counselling will be provided free of charge.

10 What if I withdraw from this research project?

If you decide to withdraw from this research project, please notify a member of the research team. He or she will explain if there are any special requirements linked to withdrawing.

If you do withdraw your consent during the research project, the researchers will not collect additional information from you, although information already collected will be kept to ensure that results of the research can be measured properly and to comply with law. You should be aware that data collected by the sponsor up to the time you withdraw will form part of the study findings. If you do not want them to do this, you must tell them before you participate.

All patient participants will be followed by their treating clinicians for continuing care irrespective of why or when they exit the study.

11 Could this research project be stopped unexpectedly?

This study may be stopped unexpectedly for a variety of reasons. Reasons may include that the unit you are in decides to withdraw from the research, or that other research answers this study's questions.

12 What happens when the research project ends?

At the end of the project, findings will be reported back to participating sites, published in journal articles, presented at conferences and other forums, and summarised on relevant websites, including that of the National Breast Cancer Foundation.

Part 2 How is the research project being conducted?

13 What will happen to information about me?

By signing the consent form, you will give permission to the relevant research staff to collect and use information about you for the study. Any information obtained in connection with this study that can identify you will remain confidential. All participants will be allocated a unique identification number, only the research team will have access to the code that links your identification number with you.

Your information will only be used for the purpose of this study. It will only be disclosed with your permission, except as required by law. Study investigators will have access to data by identification number only for the purposes of data monitoring and analysis. The Project Officer will have access to all study data for the purposes of data checking, monitoring and preparation for analysis. Study auditors will have access to study files (by identification number only) in order to audit the study. Site research ethics committees will have access to local data for audit purposes.

In accordance with relevant Australian and/or New South Wales privacy and other relevant laws, you have the right to request access to your information collected and stored by the research team. You also have the right to request that any information with which you disagree be corrected. Please contact the research team member named at the end of this document if you would like to access your information. Data will be securely stored for 15 years after the research is completed and will be destroyed at this time.

Information about you may be obtained from your health records held at this health service for the purpose of this study. By signing the consent form, you agree to the research team accessing health records if they are relevant to your participation.

Your health records and any information obtained during the research project are subject to inspection for the purpose of verifying the procedures and data. This review may be done by the relevant authorities and authorised representatives of the sponsor, the Palliative Care Clinical Studies Collaborative (PaCCSC), the institution relevant to this Participant Information Sheet, *[Name of institution]*, or as required by law. By signing the consent form, you authorise release of, or access to, this confidential information to the relevant research personnel and regulatory authorities as noted above.

It is anticipated that the findings of this study will be published and/or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that you cannot be identified, except with your permission.

Information about your participation in this study may be recorded in your health records.

In accordance with relevant Australian and/or New South Wales privacy and other relevant laws, you have the right to request access to the information collected and stored by the research team about you. You also have the right to request that any information with which you disagree be corrected. Please contact the research team member named at the end of this document if you would like to access your information.

Any information obtained for the purpose of this study that can identify you will be treated as confidential and securely stored. It will be disclosed only with your permission, or as required by law.

14 Complaints and Compensation

If you suffer any problems as a result of this study, you should contact the researchers as soon as possible and you will be assisted with arranging appropriate counselling and/or support. This support will be provided free of charge.

15 Who is organising and funding the research?

This research has been initiated by Professor Meera Agar, Dr Annmarie Hosie and Professor Jane Phillips from the University of Technology Sydney. The research is funded by the National Breast Cancer Foundation through a competitive research grant. The Palliative Care Clinical Studies Collaborative (PaCCSC) is the study sponsor.

No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages).

If knowledge acquired through this research leads to discoveries that are of commercial value to the study investigators or their institutions, there will be no financial benefit to you or your family from these discoveries.

16 Who has reviewed the research project?

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the HREC of South Western Sydney Local Health District. This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

17 Further information and who to contact

The person you may need to contact will depend on the nature of your query. If you want any further information concerning this study or if you have any problems which may be related to your involvement, you can contact any of the following people:

Clinical contact person

Name	*[Name]*
Position	*[Position]*
Telephone	*[Phone number]*
Email	*[Email address]*

For matters relating to research at the site at which you are participating, details of the local site complaints person are:

Name	*[Name]*
Position	*[Position]*
Telephone	*[Phone number]*
Email	*[Email address]*

18. Complaints contact person

This study has been approved by the South Western Sydney Local Health District Human Research Ethics Committee. Any person with concerns or complaints about the conduct of this study should contact the Research and Ethics Office, Locked Bag 7103, LIVERPOOL BC NSW 1871 on 02 8738 8304 / fax 02 8738 8310 / email research.support@sswahs.nsw.gov.au, website: http://www.swslhd.nsw.gov.au/ethics/default.html and quote [*Local project number*].

Thank you for taking the time to consider this study.
If you wish to take part in it, please sign the attached consent form.
This information sheet is for you to keep.

[insert site logo]

[insert site name]

CONSENT FORM

[To be used in conjunction with a Participant Information Sheet]

Title:	Phase II (pilot) cluster randomised controlled trial of a multi-component non-pharmacological Intervention delirium for hospitalised people with advanced cancer.
Short Title:	The PRESERVE pilot study (**Pr**event delirium through **E**ating and drinking, **S**leep, **E**xercise, **R**eorientation, **V**ision and hearing, and **E**nabling family)
Protocol Number:	Version 1.0
Project Sponsor:	Palliative Care Clinical Studies Collaborative
Coordinating Principal Investigator /Principal Investigator	Professor Meera Agar Dr Annmarie Hosie Professor Jane Phillips
Associate Investigator (s) *(if required by institution)*	*[Associate Investigator(s)]*
Location *(where CPI/PI will recruit)*	*[Location]*

Declaration by Participant

1. I, ...of..... ..... agree to participate in the study described in the participant information statement attached to this form.

2. I acknowledge that I have read the participant information statement, which explains why I have been selected, the aims of the study and the nature and the possible risks of the investigation, and the statement has been explained to me to my satisfaction.

3. Before signing this consent form, I have been given the opportunity of asking any questions relating to any possible physical and mental harm I might suffer as a result of my participation and I have received satisfactory answers.

4. I agree that research data gathered from the results of the study may be published, provided that I cannot be identified.

5. I understand that if I have any questions relating to my participation in this research, I may contact Dr .....on telephone....., who will be happy to answer them.

6. I acknowledge receipt of a copy of this Consent Form and the Participant Information Statement.

Name of Participant (please print) _____

Signature_____ Date _____

Name of Witness* to Participant's Signature (please print) _____

Signature_____Date_____

* Witness is not to be the investigator, a member of the study team or their delegate. In the event that an interpreter is used, the interpreter may not act as a witness to the consent process. Witness must be 18 years or older.