[insert site logo]
Participant Information Statement

Interventional Study

SITE LEVEL

[Insert site name]

Title	Phase II (pilot) cluster randomised controlled trial of a multi-component non-pharmacological intervention to prevent delirium for hospitalised people with advanced cancer
Short Title	The PRESERVE pilot study (Prevent delirium through Eating and drinking, Sleep, Exercise, Reorientation, Vision and hearing, and Enabling family)
Protocol Number	1.0
Project Sponsor	Palliative Care Clinical Studies Collaborative
Coordinating Principal Investigators	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 site participation involve?

1 Introduction

Your site is invited to take part in 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 oncology or palliative care units.

You have been invited to participate because you are the person with the required delegation to consent your oncology or palliative care unit which provides inpatient care for people with advanced cancer.

This Participant Information Sheet/Consent Form explains the research project and what is involved. Knowing what is involved will help you decide if your site wants to take part in the research.

Participation in this research is voluntary.

If you decide you want to take part in the research project, 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 information about your site 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 research is to determine if a multi-component non-pharmacological delirium prevention intervention is feasible and acceptable for people with advanced cancer in hospital.

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?

We are recruiting four oncology and palliative care inpatient units in Australia that care for people with advanced cancer.

This study is a phase 2 cluster randomised controlled trial (CRCT). In this design, randomisation is of consented sites, rather than individual patients. Two of the four participating units will be randomised to the intervention arm (delirium screening and diagnosis processes plus immediate implementation of intervention) and two to the control arm (delirium screening and diagnosis processes and waitlist to the modified-intervention).

After the completion of the study the sites that were allocated to the control arm will have the option to receive the intervention, modified if required.

4 What does this site have to do?

If you decide that your site will participate, you, the site investigator and/or other members of the team will be asked to undertake the following:

- **Provide information about the unit**: geographical location; type and level of service provision; number of patient beds; team composition; form of clinical documentation; current process and measures for delirium∗; patient characteristics from sites' most current PCOC report ∗ (age, gender, country of birth, preferred language, Aboriginal or Torres Strait Islander status, primary diagnosis, length of stay, performance status, measured by Australian Karnofsky Performance Status (AKPS) and Resource Utilisation Groups - Activities of Daily Living (RUG-ADL) and palliative care phase), at baseline. Information indicated with a ∗ will be re-collected from PCOC at completion of data collection for the specific time frame of the intervention at each site.
- **Agree to be randomised** to the intervention or waitlist control arm.
- **Support the introduction of delirium screening**. All participating sites will implement routine structured delirium screening, by bedside nurses completing the Nursing Delirium Screening Scale (NuDESC) for all patients at admission and at the end of every shift.
- **Support the introduction of delirium diagnosis**. All participating sites will implement routine structured delirium diagnosis, through the treating physician applying Diagnostic and Statistical Manual of Mental Disorders, Fifth edition (DSM-5) diagnostic criteria for delirium, operationalised by the Delirium Rating Scale-Revised-1998 (DRS-R-98). The DRS-R-98 can be completed by either a physician or nurse trained in its use.
- **Support interdisciplinary implementation of the multicomponent delirium prevention intervention.** The domains of care in the intervention are: Preserve natural sleep; Maintain optimal sensory perception (vision and hearing); Optimise hydration; Promote communication, orientation and cognition; Optimise mobility and function; and Family partnership.
- **Support engagement and relevant training of site staff and volunteers** (if available in your unit) prior to and during the data collection period. Site engagement will require formation of an interdisciplinary working group, to determine site-specific delivery methods for the interventions and promote the intervention to the wider team. Education and training relevant to delirium screening, diagnosis and prevention strategies will be standardised, interdisciplinary, and based on and a workplace educational model.
- **Support data collection** by research nurses for up to 20 patients with advanced cancer for the trial.
- **Support recruitment** by research nurses of up to 20 patients and 20 family caregivers in brief semi-structured interviews; and staff members/volunteers who were involved in the intervention in a brief written or verbal survey during the intervention arm of the research project.
- **Provide access for study investigators and/or project staff to your site** to attend working group meetings; assist with education and training, as described above; promote fidelity to the study; assist in resolving issues that delay implementation of the intervention or threaten its integrity; act as a 'delirium resource person'; and support and encourage clinical and research staff and volunteer participation in the intervention, as required.
- **Provide contact details for confidential counselling services** that can be offered to participating staff, health professionals and family members at the unit in the event they become distressed in interviews or surveys and require this support.
- **Support the site investigator and research nurse/s** in their responsibilities in this study.

As the purpose of this study is to determine if a multi-component non-pharmacological delirium prevention intervention is feasible and acceptable for people with advanced cancer in hospital, we cannot guarantee benefit through implementing the intervention.

Units randomised to the control arm will be waitlisted to receive the modified intervention, should findings indicate that modification is required.

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

Your decision whether or not to participate will not prejudice your future relationship with the study investigators or the University of Technology Sydney. If you decide to participate, you are free to withdraw your consent and to discontinue participation of the unit at any time without prejudice. Your organisation will be required to sign a funding agreement outlining the requirements of participation and how your site will be remunerated, including the circumstance of withdrawing at various time points during the study. Data collected about your unit prior to withdrawal will not be deleted from the research project database, but no further data will be collected.

6 What if the site withdraws from this research project?

If you decide to withdraw from this research project, please notify a member of the research team before you withdraw. A member of the research team will inform you if there are any special requirements linked to withdrawing.

If you do withdraw your consent during the research project, the relevant study staff will not collect additional information from your site, although information already collected will be retained to ensure that the results of the research project 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 research project results. If you do not want them to do this, you must tell them before you join the research project.

7 What happens when the research project ends?

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

The results of this study will inform a Phase 3 trial to measure efficacy of the intervention in this population. If negative, this pilot study will help in the design of alternative delirium prevention interventions for people with advanced cancer, and inform clinical practice.

Part 2 How is the research project being conducted?

8 What will happen to information collected?

Any information that is obtained in this study and that can be identified with you or your unit will remain confidential and be disclosed only with your permission, except as required by law. If you give us your permission by signing this document, we will include the information you provide in results aimed at informing future research into delirium prevention in people with advanced cancer. These results will be presented at conferences, published in peer-reviewed journals, posted on websites and included in reports to participating sites. In any verbal or written report, results will only be given at a summary level rather than for individuals or units, and will be presented in such a way that your unit cannot be identified.

In accordance with relevant Australian and/or *[name of state/territory]* privacy and other relevant laws, you have the right to request access to the information collected and stored by the research team about your site. 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 information relevant to your site.

9 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 your unit from these discoveries.

10 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.

11 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 project or if you have any problems which may be related to your site's 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 your site, the details of the local site complaints person are:

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

13. 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 your site 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

Site Level

[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 to prevent delirium for hospitalised people with advanced cancer
Short Title	The PRESERVE pilot study (Prevent delirium through Eating and drinking, Sleep, Exercise, Reorientation, Vision and hearing, and Enabling family)
Protocol Number	1.0
Project Sponsor	Palliative Care Clinical Studies Collaborative
Coordinating Principal Investigators	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, the person with the required delegation, of …….. unit have read the information and decided to give consent for this unit to participate in the above research project.

2. I acknowledge that I have read the participant information statement, which explains why this site has 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 this unit's participation and I have received satisfactory answers.

4. I understand that if I have any questions relating to this unit's 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.

Title and name (please print): _____

Position: _____ Organisation: _____

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. Witness must be 18 years or older.

[Insert site logo]

[Insert site name]

REVOCATION OF CONSENT FORM

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 (Prevent delirium through Eating And drinking, Sleep, Exercise, Reorientation, Vision and Hearing, and Enabling family)

Protocol Number: Version 1.0

Project Sponsor: Palliative Care Clinical Studies Collaborative

Coordinating Principal Investigator/Principal Investigator Professor Meera Agar
Dr Annmarie Hosie

Associate Investigator (s) *[Associate Investigator(s)]*
(if required by institution)

Location *[Location]*
(Where CPI/PI will recruit)

Declaration by Participant

I hereby wish to **WITHDRAW** my consent to participate in the research proposal described above and understand that such withdrawal **WILL NOT** jeopardise my relationship with the University of Technology Sydney and Palliative Care Clinical Studies Collaborations.

Name of Participant (please print) _____

Signature_____ Date _____

Please forward the completed Revocation of Consent Form to Dr AnnMarie Hosie at University of Technology Sydney (UTS), Faculty of Health, Building 10, Level 3, 235-253 Jones St, Ultimo, NSW 2007.