Participant Information Sheet and Consent Form

Study title: Development of a test of thinking and memory in hospice patients

We'd like to invite you to take part in our research study. Joining the study is entirely up to you. Before you decide, we would like you to understand why the research is being done and what it would involve for you.

One of our research team will go through this information sheet with you, to help you decide whether or not you would like to take part and answer any questions you may have. Please feel free to talk to others about the study, if you wish. Take as much time as you need to decide.

Thank you for reading this.

What is the purpose of the study?

People who are in hospices can develop short-term problems with thinking and memory, or become drowsy as a result of their condition. This problem is called 'delirium'. Delirium can be very distressing. However, delirium often goes unrecognised, because of the lack of quick and simple ways for staff to detect it.

The '4AT' is a short and simple bedside test of memory and thinking. The test is routinely used in this hospice, as well as in many hospitals.

The aim of this study is to assess how accurate it is in detecting delirium in patients admitted to a hospice. If delirium is detected earlier or more accurately, it may result in better care and treatment of patients with delirium.

Why have I been invited?

We are asking you to take part because you are a patient who has recently been admitted to the hospice.
We are inviting all patients to take part in the study, not just patients with delirium.

Do I have to take part?

No, it is up to you to decide whether not you take part in the research. If you decide to take part, you will be given this information sheet to keep and be asked to sign a consent form.

You are still free to change your mind at any time and without a reason. Deciding not to take part or withdrawing from the study will not affect the healthcare that you receive or your legal rights.

What will happen if I take part?

Two sets of tests of thinking and memory will be done by your bedside, by two different healthcare professionals (a nurse or a doctor). **One set of tests lasts around 2 minutes (the 4AT), and the other set lasts 15-20 minutes.**

We will examine your medical notes. We may also ask your hospice nurse or doctor about your symptoms, or ask someone who knows you well.

It may be that you become drowsy or develop problems with your memory and thinking between now and when the assessments are done. If that happens, you may not remember everything about the study at that time. It is important that we are able to complete the tests, and so we ask now if you consent to taking part in the study.

What are the possible benefits of taking part?

With your permission, we will inform your hospice team about the results of your tests. It may help your care if they have this information.

We hope the results of this study will help doctors and nurses decide if they should use the 4AT test in a hospice setting. It may lead to better detection of delirium, resulting in improved treatment and care for affected patients.

What are the possible disadvantages and risks of taking part?

The only disadvantage is that you might find the test questions irritating. However, you can choose to stop at any point if you wish. There are no significant risks in this study.

What if there is a problem?

If you have a concern about any aspect of this study, please contact Dr XXXXX, who will do her best to answer your questions (Tel 0131 470 2201 or email XXXXX).
In the unlikely event that something goes wrong and you are harmed during the research, and this is due to someone's negligence, then you may have grounds for a legal action for compensation against Marie Curie, but you may have to pay your legal costs. The normal Marie Curie complaints mechanisms will still be available to you (if appropriate).

What will happen if I don't want to carry on with the study?

If you don't want to continue with the study at any point, the tests will not proceed.

Will my taking part be kept confidential?

All the information we collect during the research will be kept confidential, and there are strict laws which safeguard your privacy at every stage. For details on what data will be held about you and who will hold and store this information, please refer to the Data Protection Information sheet.

You will not be identifiable in any stored data, publications or presentations resulting from this study.

As stated above, with your permission, we will inform the hospice team responsible for your care about the results of your tests.

What happens when the study is finished

We plan to publish information from the study in a medical journal and/or present at a conference.

To request a copy of the published results, please contact:

Dr XXXXX
Marie Curie Hospice
45 Frogston Road West
Edinburgh
EH10 7DR
Tel 0131 470 2201
Email: XXXXX

Anonymised data will be stored securely for 3 years. You will not be identifiable from any stored data, publications or presentations from this study.

Who is organising the research?

This study has been organised and funded by Marie Curie, and sponsored by the University of Edinburgh and NHS Lothian.

Who has reviewed the study?

The study proposal has been approved by Marie Curie. Patient representatives have also been involved in review of the study.

All research is looked at by an independent group of people called a Research Ethics Committee. A favourable ethical opinion has been obtained from Scottish Research Ethics Committee A.

Researcher Contact

If you have any further questions about the study, please contact Dr XXXXX (Tel 0131 470 2201 or email XXXXX

Independent Contact

If you would like to discuss this study with someone independent of the study, please contact:

Dr XXXXX
Usher Institute
University of Edinburgh
Old Medical School
Teviot Place
Edinburgh
EH8 9AG
Email: XXXXXXX

Complaints

If you wish to make a complaint about the study please contact:

XXXXXX
Hospice Manager
Marie Curie Hospice
45 Frogston Road West
Edinburgh
EH10 7DR
Tel 0131 470 2201
Email: XXXXXXX

The sponsor University of Edinburgh will be notified of any complaints.

Thank you for taking the time to read this information sheet

CONSENT FORM

Development of a test of thinking and memory in hospice patients

Participant ID: ☐

Person taking consent: _____

Please **initial** box

1. I confirm that I have read and understand the information sheet (version 4, 14.08.2019) and the Data Protection Information Sheet (version 5, 01/07/2019) for the above study. I have had the opportunity to consider the information, ask questions and have had these questions answered satisfactorily. ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason and without my medical care and/or legal rights being affected. ☐
3. I understand that relevant sections of my medical notes and data collected during the study may be looked at by individuals from Marie Curie, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my data and/or medical records. ☐
4. I understand that relevant sections of my medical notes and data collected during the study may be looked at by individuals from the Sponsor (University of Edinburgh) and regulatory authorities, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my data and/or medical records. ☐
5. I give permission for my personal information (including name, date of birth, clinical information and consent form) to be passed to Marie Curie and the University of Edinburgh for administration of the study. ☐
6. I agree to the hospice healthcare team looking after me being informed of my participation in this study and being given a summary of my test results. ☐
7. I agree to take part in the above study. ☐

Name of Participant	Signature	Date

Name of Person taking Consent	Signature	Date

Name of Witness (if applicable)	Signature	Date

1x original – into Site File; 1x copy – to patient; 1x copy – into medical record