Welfare Attorney, Guardian or Nearest Relative Information Sheet and Consent form

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

You are being invited to consider giving your permission for your relative or the person you are consenting for, to take part in a research study. Before you decide, it is important for you to understand why the research is being done and what it will involve.

We would then ask that you put your own views about the research aside, and to consider and take into account, the past and present wishes and feelings of your relative (or person you know), had they been able to consent for themselves.

One of our research team will go through this information sheet with you, to help you decide whether or not you would like your relative (or person you know), to take part. They will 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, and even 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 has your relative been invited to take part?

Your relative has been asked to take part because they are a patient, who has recently been admitted to the hospice. However, they currently lack the mental capacity to make an informed decision about whether they can take part in a research study. We are therefore asking you, as their nearest relative, guardian or welfare attorney, if you will give consent, on their behalf, to take part in this study. This is permissible by law under the Adults with Incapacity (Scotland) Act 2000.

Does my relative have to take part?

No. It is up to you to decide whether they take part in the research or not. If you decide your relative should 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 giving a reason. Deciding not to take part or withdrawing your relative from the study will not affect their healthcare or legal rights.

What will happen to your relative if they take part?

Two sets of tests of thinking and memory will be done by your relative's 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.**

Please note that, even your next of kin is drowsy or not feeling well, we can still gather very useful information by simply observing them at the bedside and asking a small number of questions, if they are able. If they are unable, then the brief observation at the bedside is still very valuable in allowing us to test if the new test is effective.

We will examine their medical notes. We may speak to the hospice doctors or nurses about your relative's symptoms, as well as you or another person who knows the patient well.

If your relative regains capacity at any stage before the tests, they will be asked to give their consent to continue with the study.

What are the possible benefits of taking part?

With your permission, we will inform the hospice team responsible for your relative's care about the results of their tests. It may help your relative's 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 your relative might find the test questions irritating. However, they can choose to stop at any point if they wish, and we will stop the testing if there is any evidence that your relative is finding the process unpleasant or irritating. 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 XXXXXX).

In the unlikely event that something goes wrong and your relative is harmed during the research, and this is due to someone's negligence, then you may have grounds for 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 my relative to carry on with the study?

If you don't want your relative to continue with the study, they will not participate in any further assessments.

Will taking part in the study be kept confidential?

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

Your relative 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 relative's care about the results.

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 any published results please contact:

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

Anonymised data will be stored securely for 3 years. You or your relative will not be identifiable from any stored data, publications or presentations resulting 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 Scotland A Research Ethics Committee.

Researcher Contact Details

If you have any further questions about the study, please contact XXXXXX on 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 XXXXXX
Usher Institute
University of Edinburgh
Old Medical School
Teviot Place
Edinburgh
EH8 9AG
Email: XXXXXX

Complaints

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

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

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

Thank you for taking the time to read this information sheet

CONSENT FORM

Development of a new test of thinking and memory in hospital 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 relative's participation is voluntary and that I am free to withdraw my relative from the study at any time, without giving any reason, and without their medical care and/or legal rights being affected. ☐

3. I understand that relevant sections of my relative's medical notes and data collected during the study may be looked at by individuals from Marie Curie where it is relevant to my relative taking part in this research.
I give permission for these individuals to have access to my relative's data and/or medical records. ☐

4. I understand that relevant sections of my relative's 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 relative taking part in this research.
I give permission for these individuals to have access to my relative's data and/or medical records. ☐

5. I give permission for my consent form and my relative's 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 my relative being informed of their participation in this study and being given a summary of their test results. ☐

7. I confirm that I am the nearest relative for _____ and that no other nearest relative or welfare attorney or guardian exists. ☐

   Relationship to participant _____

8. I confirm I am Welfare Attorney or Guardian for _____ ☐

1x original – into Site File; 1x copy – to relative/guardian/attorney; 1x copy – into medical record

Please **initial** box

9. In my opinion_____would have no objection to taking part in the above study. ☐

10. I agree to my relative taking part in the study. ☐

Name of Person Giving Consent (i.e. Attorney, Guardian, Relative)	Date	Signature
Name of Person taking Consent	Date	Signature

1x original – into Site File; 1x copy – to relative/guardian/attorney; 1x copy – into medical record