

Developing a new approach to help people with memory problems after a fall

Diary sub-study

Consultee Information Sheet

You are being invited to consider your relative or friend taking part in a research study, as we feel your relative/friend is unable to decide for himself/herself. We'd like to ask your opinion as to whether or not they would want to be involved, considering what you know of their wishes and any advance decisions they may have made about participating in research. This information sheet explains why the research is being done and what taking part will involve. Please take time to read the following information carefully and discuss it with relatives and friends if you wish. You can also ask us if there is anything that is not clear or if you would like more information.

If you decide your relative/friend would have no objection to taking part we will ask you to read and sign the consultee declaration form. We'll then give you a copy to keep.

Thank you for reading this.

What is the purpose of the study?

We are hoping to learn from existing services how best to support people with fall-related injuries who may have problems with their memory and thinking. One way in which we are looking at this is to ask people to complete diaries.

How can I help?

You have been given this leaflet because your friend/relative has suffered a fall. We would like you both to make a note of all the help you receive in a diary. We will use this information to help us develop a new approach for people with memory problem with fall-related injuries.

What's involved?

If you agree to consider your relative/friend taking part:

- A member of the research team will contact you to arrange a convenient time to visit you and your relative/friend at home (or at hospital, if they are an inpatient at the time).
- They will discuss the study in more detail with you, answer any questions, and ask you to complete a Consultee Declaration Form if you are happy to proceed.
- They will explain how they would like you to help your relative or friend to complete a diary for 12 weeks, keeping a note of the services they have been in contact with or used during this time.
- They will ask your relative/friend to complete a short test of their memory. It does not matter if they cannot answer the questions in this test.
- The diaries are returned to the research team by post, using pre-paid envelopes that we will supply.
- We will inform your relative/friend's GP that they are in the study
- If you/they record that they have seen a health care professional, we may look at their medical notes to see what happened.

We may invite you to take part in an interview to explore your views of the help and support your relative/friend has received. After the interview, you may be consulted as to whether your relative/friend would object to one of their appointments with a healthcare professional being observed. This is a separate part of the study and you would be given further information and the opportunity to discuss this prior to making a decision.

What difference will it make?

It is unlikely that taking part will help you directly, however the information you provide within the diary may help us create a better approach to helping people with memory problems who fall in the future.

Are there any possible disadvantages to taking part?

We are aware that discussing your possible involvement in the study may involve talking about potentially sensitive issues. The researchers will be aware of this possibility and will draw on their experience to avoid causing any distress. All efforts will be made to ensure the wellbeing of both yourself and your relative/friend, and you can ask that the researcher stop or suspend the discussion at any point.

Does my relative/friend have to take part?

No. It is entirely up to you to decide whether or not your relative or friend takes part. If you want to find out more about taking part in research, you can contact the NHS Patient Advisory Liaison Service (PALS) <insert local number>. You do not have to give a reason if you do not want to be involved. Whatever you decide will have no effect on the care your family member or friend receives now or in the future. If you change your mind, you can leave the study at any time without giving a reason.

How will my information be kept confidential?

Any information you give us will be kept confidential. Your personal details will only be used if we need to contact you.

The Research and Development department oversee research taking place in The Newcastle upon Tyne Hospitals NHS Trust. They may look at data collected during the study to make sure that the research is being conducted properly.

What will happen to the results of this study?

The results will be presented at research meetings, and published on the National Institute for Health Research Health Technology Assessment programme website and in scientific journals. You and your relative/friend will not be identified in any report or publication.

We will also present our findings at local Patient and Public Involvement groups, and will send a newsletter to all our participants to keep them informed of how the study is progressing.

Who is organising and funding this study?

This study will be organised by a team at Newcastle University. It is sponsored within the NHS by The Newcastle upon Tyne Hospitals NHS Foundation Trust.

The study is funded by the NHS through the National Institute for Health Research (NIHR) Health Technology Assessment programme.

How have patients and the public been involved in this study?

We have already shared our plans for this study with the Patient and Public Involvement organisation, Voice North. Members of this group will also be invited to give their views as the study progresses.

The management group that will oversee the running of the study will also include a patient and an informal carer. Patients will also be invited to contribute to the other parts of this study.

What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak to the researchers first who will do their best to answer your questions (their contact number is 0191 208 1314). If you remain unhappy and wish to complain formally, you can do this through the National Health Service complaints procedure. Details can be obtained from the Patient Advice and Liaison Service (PALS <http://www.pals.nhs.uk/>) at your local hospital. Their contact number is *<insert local PALS contact>*.

Who has reviewed this study?

This study has been approved by the Research and Development Department of *<insert site name>*. The study has also been approved by the National Research Ethics Service Committee Newcastle and North Tyneside 2.

Further information and contact details

If, at any time, you need to get in touch with the research team you can contact them via Beth Edgar, the project secretary:

Beth Edgar  (0191) 208 1314

Email: beth.edgar@ncl.ac.uk

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