Information for patients about an observation study

You are being invited to take part in a research study. We would be very grateful for your help. This information sheet explains why the research is being done and what it would involve. Please read this information carefully. You may want to discuss it with a family member, friend or healthcare professional to help you decide.

Thank you for reading this.

If you have any questions, please contact our researcher:

Emily Spencer — Telephone: 07502 872305

Queen Mary, University of London — Email: emily.spencer@qmul.ac.uk

This information sheet has two parts:

- **Part 1** provides an overview of the study
- **Part 2** gives more detail about certain aspects of the study

Part 1: Overview of the study

Why are we doing this research?

People with dementia or problems with memory and thinking often prefer to be treated at home instead of in hospital. Hospitals can be distressing for some patients and their family carers.

The National Health Service (NHS) is now investing money in **virtual wards**. Virtual wards provide care, monitoring and treatment for patients who would otherwise be in hospital. This can be through face-to-face treatment, as well as using technology. Through virtual wards, patients can be supported to stay at home.

The benefits of virtual wards include being in a familiar environment, keeping usual routines, and avoiding the need to travel for treatment. This may be particularly helpful for people with dementia or problems with memory and thinking. However, at the moment we don't know whether virtual wards work well for these people.

We would like to know how virtual wards can work best for people with dementia, as well as the family members and friends who are involved in supporting them to stay at home.

Why have you been invited?

We are working with your local virtual ward to see how they care for people with dementia, memory or thinking difficulties. You have been identified as someone who is currently being cared for on the virtual ward, and who may want to take part.

What are we asking you to do?

If you decide to take part:



A researcher will visit you to observe how you are cared for at home as part of a virtual ward. This will include how health and care professionals provide treatment and support, as well as how your family or friends may help you with your care. The researcher will make written notes about what they see, and they may ask you some questions. The researcher will not write down any information that could identify you.

With your agreement, we would like to visit **up to five times over the next year** to see how the support given varies on different days.



We will only visit to observe and make notes if everyone has agreed to take part. This means that any family members, friends, and health or care professionals involved in supporting you would also need to agree.

We hope to use the information that we record to develop **guidance and information** on how professionals can ensure virtual wards work best for all people with dementia and their family carers.



We will ask you to **complete a short questionnaire** with us so that we can collect important information such as your age, gender, ethnicity and living situation. This will take no more than five minutes. This information helps us to understand how people's experiences might differ depending on their background.

We would also like to access your medical notes to see how the virtual ward and your GP have been supporting you recently with your health care.

All of your information, including your medical information and the notes written about your care, will be stored securely and confidentially.

What are the benefits of taking part?

By allowing us to observe your experiences, you will help us understand how virtual wards can best work for people with dementia, memory and thinking difficulties, and their family carers. This will help us to develop guidance and information for the health and care professionals involved in running virtual wards. We hope that this will lead to improved care.

As a thank you for your time, you will also be offered a £20 high street voucher.

What are the risks of taking part?

We do not believe taking part will cause you any harm, and your treatment will not change in any way. However, you may feel slightly self-conscious about being observed by a researcher. If at any stage you feel uncomfortable and wish to stop with the study, you are free to do so.

Do you have to take part?

No. Taking part is your choice. It will not affect your medical care in any way if you decide not to take part.

If you choose to take part, you can change your mind without giving a reason. If you change your mind within 6 weeks of an observation, we will delete the written notes and any other information that we have about you. After 6 weeks, we will start to analyse the notes.

After the observation study, a group of people with dementia, family carers and health and care professionals will help us develop some guidance on running virtual wards. You can tell us whether this is something you might like to help with. **You do not have to take part.**

Part 2: Further information

What happens if I am no longer able to decide for myself during the study?

We understand there may be times when you are not able to tell us whether you would like to join the study or continue taking part. If this happens, we will talk with you about what you would like to do, as long as you are able to let us know your wishes.

If you would like, you can choose a relative or close friend for us to contact should this situation arise. This person would be asked to advise us about what they believe you would want (this is called a "consultee"). Choosing someone is completely optional.

You do not have to take part in the study, you do not have to continue in the study, and you do not have to provide the name of anyone to contact. Whatever you decide will not affect the care or support you receive.

Will information be kept confidential?

Everything that we observe will be kept confidential. However, if you tell us or we observe that a member of staff is doing something wrong (malpractice), someone is being harmed or treated badly, a crime may have been committed, or you are at serious risk of harm, we may need to share this with someone who can help.

How will we use information about you?

We will need to use information from you and your medical records for this research project. This information will include:

- Your name

- Your contact details
- The questionnaire you complete
- The observation notes written by the researcher
- Information from your medical records

People will use this information to do the research or to check your records to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

Queen Mary, University of London (QMUL) is the sponsor of this research. QMUL is responsible for looking after your information. We will not share your information related to this research project with any other organisations.

We will keep all information about you safe and secure by:



- Keeping all your information in a secure location at QMUL.
- Electronic data will be stored on an access-controlled, encrypted network.
- Paper documents will be kept in a locked filing cabinet.

How will we use information about you after the study ends?

Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no one can work out that you took part in the study.

We will keep your study data for a maximum of five years. The study data will then be fully anonymised and securely archived or destroyed.

Your data will not be shared outside of the UK.

What are your choices about how your information is used?

- You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.
- You have the right to ask us to access, remove, change or delete data we hold about you for the purposes of the study. You can also object to our processing of your data. We might not always be able to do this if it means we cannot use your data to do the research. If so, we will tell you why we cannot do this.
- If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study.

Where can you find out more about how your information is used?

You can find out more about how we use your information:

- by looking at the Health Research Authority's leaflet: www.hra.nhs.uk/patientdataandresearch
- by asking one of the research team, or
- by sending an email to data-protection@qmul.ac.uk

Who is organising and funding this study?

This research is funded by the Alzheimer's Society (project grant 667). The study is being led by Professor Nathan Davies.

Has the research been reviewed by an appropriate research ethics committee?

All research in health and social care is looked at by an independent group of people – a Research Ethics Committee – to protect participants' safety, rights, wellbeing and dignity. This research study has been reviewed and approved by the NHS Research Ethics Committee Wales REC7.

What if there is a problem?

If you feel worried about anything to do with the research, please contact the principal investigator, Professor Nathan Davies.

Email: n.davies@qmul.ac.uk

You can also complain formally through the NHS Complaints Procedure. You can contact the NHS Patient Advice and Liaison Service (PALS) on 020 3594 2040 or by emailing bartshealth.familycontact@nhs.net.

What happens now?

You can get in touch with the lead researcher to say whether or not you would like to take part, or to ask for more information:

Researcher: Emily Spencer

Email: emily.spencer@qmul.ac.uk

Telephone: 07502 872305

Thank you for taking the time to read this.