

Participant Information Sheet & Consent Form – Dialyse@Home: A Mixed Methods Pilot Study of Home Haemodialysis

Interviews

You are being invited to take part in a research project. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part. Thank you for reading this.

1. What is the project's purpose?

This study aims to explore the impact of home haemodialysis on patient and carer experience, and wider support needs. It will also explore which factors influence the interest that patients might have in dialyzing at home, and the best ways to help people to feel supported when they are dialyzing at home.

2. Why have I been chosen?

You have been invited to take part because you are being treated with home haemodialysis or you have a close relationship with somebody who is being treated (informal carer). All home haemodialysis patients at the dialysis centre, and their informal carers, are being asked whether they would like to participate.

We are keen to talk to people being treated with home haemodialysis to understand their views and experiences of different ways of providing their care. We are also keen to talk to informal carers to understand their views and experiences.

3. Do I have to take part?

It is up to you to decide whether or not to take part. If you do decide to take part you will be given this information sheet to keep (and sign a specific consent form).

You can withdraw at any time prior to the conclusion of the interview or workshop. You do not have to give a reason, and a decision not to take part or to stop will not affect any care being received. If you decide to stop participating in the research you will be asked if you would like any data already recorded to be destroyed, providing it has not already been analysed.

4. What will happen to me if I take part?

A single interview will be held at a location that is convenient for you or by phone and take about 45-60 minutes. This will be audio recorded, so that we can make accurate notes.

The researcher will have some broad topics to follow, but will be interested in finding out about your experiences and opinions about dialysis. Whilst efforts will be taken to minimise the need for additional travel, where this is necessary you will be reimbursed for any travel expenses incurred.

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5. What do I have to do?

First of all you will need to contact the research team, to let them know that you are willing to take part. You can telephone, email or use the enclosed contact form/s.

Before the interview or workshop session you will be asked to read this information sheet. If you agree to take part you will need to read and sign a copy of the consent form prior to taking part. In the case of telephone interviews, the evaluation team will need to receive consent forms by post, before the interview.

6. What are the possible disadvantages and risks of taking part?

The only anticipated possible disadvantage of taking part is the potential for slight inconvenience due to the time and effort of taking part. This will be minimised by arranging a time that is most convenient for you, and keeping the session as short as possible.

7. What are the possible benefits of taking part?

Whilst there are no immediate benefits for people participating in the project, it is hoped that it will help you to think about the ways that dialysis services are organised and the impact of any recent changes, which you might find useful. Involvement in the evaluation will help to ensure that your views are taken into consideration.

8. What if something goes wrong?

If you wish to raise a complaint about the study, please contact the Principal Investigator or Lead Evaluator. However, should you feel your complaint has not been handled to your satisfaction you can contact the Dean of the School of Health and Related Research at the University of Sheffield (all contact details are at the end of this information sheet).

9. Will my taking part in this project be kept confidential?

All the information that we collect about you during the course of the research will be kept confidential. You will not be able to be identified by others in any reports or publications. If it is considered likely that information might allow others to identify you we will ask for your permission before using it. Whilst it is extremely unlikely, in extreme cases the researcher might need to break confidentiality if the safety of staff or service-users is directly at risk.

10. What will happen to the results of the research project?

The findings will be used with other data to describe the way that your service currently works and what effect any recent changes have had. Sections of transcripts might be used in reports, presentations or publications. Anonymous findings will be shared with organisations and groups involved in dialysis services.

With your permission, the data collected during the course of the project may be used for additional or subsequent research and evaluation.

11. Will I be recorded, and what will happen to these recordings?

The recordings will be digitally transferred to a password protected/encrypted hard drive and the original recordings deleted from the recording machine as soon as possible. The recordings will be destroyed once they have been transcribed. These anonymised transcriptions will not contain any identifiable information, and will be used only for analysis and for illustration in written reports,

To be printed on hospital headed note paper articles, conference presentations and lectures. No other use will be made of them without your written permission, and no one outside the project will be allowed access to the original recordings.

12. Who is organising and funding the research?

The research is being led by Sheffield Teaching Hospitals NHS Foundation Trust in association with the University of Sheffield. It is being commissioned by a charity organisation called The Health Foundation.

13. Who has ethically reviewed the project?

This project has been ethically reviewed via the Health Research Authority approval process for NHS Research Ethics Reviews.

14. Contact for further information

| | |
|---|---|
| Lead Evaluator Dr Steven Ariss Senior Research Fellow Innovation Centre SchARR University of Sheffield S1 4DP Tel: (0114) 222 5426 email: s.ariss@sheffield.ac.uk | Principal Investigator Prof. Martin Wilkie Consultant Nephrologist Sheffield Kidney Institute Sheffield Teaching Hospital NHS Foundation Trust Herries Road Sheffield S5 7AU Tel: (0114) 271 5148 email: Martin.Wilkie@sth.nhs.uk |
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15. What if I am worried?

If you have any questions or want to report any problems with this study, please contact:

Dialysis Unit Staff Member:

Name: _____ Telephone: _____

Study local investigator

Name: _____ Telephone: _____

If you want independent advice, please contact the Patient Advice and Liaison Service (PALS):

Name: _____ Telephone: _____

Study Chief Investigator

Professor Martin Wilkie, Sheffield Teaching Hospitals NHS Foundation Trust. Tel 01142715326

**You will be given a copy of the information sheet and, a signed consent form to keep.
Thank you for considering taking part in the project.**



SCHOOL OF
 HEALTH AND
 RELATED
 RESEARCH

Dialyse@Home: A Mixed Methods Pilot Study of Home Haemodialysis
Interviews

We are carrying out interviews and workshops with people who have home haemodialysis and their close family/informal carers, to get a better understanding of people’s experiences and views. If you agree to being contacted about this research, please either contact the investigator by phone or email, or complete and return this form in the enclosed self-addressed envelope.

| | |
|--|--|
| I am a Home Haemodialysis patient (please sign here) | |
|--|--|

NAME: _____

EMAIL: _____

TELEPHONE: _____

POSTAL ADDRESS: _____

| | |
|--|--|
| I also agree to the participation of the person who is known to me below | Please tick box <input type="checkbox"/> |
|--|--|

| | |
|--|-------|
| I know someone who is a Haemodialysis patient (please sign here) | |
|--|-------|

NAME: _____

EMAIL: _____

TELEPHONE: _____

POSTAL ADDRESS: _____

Researcher contact details: Steven Ariss. Email: s.ariss@sheffield.ac.uk
 Telephone: 0114 2225426

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CONSENT FORM

Dialyse@Home: Interview

Name of Researcher:

Participant Number:

| If you agree with each sentence below, please initial the box. | | Initials |
|--|---|----------|
| 1 | I confirm that I have read the information sheet dated 06-MAR-18 (version 1.0) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. | |
| 2 | I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected. | |
| 3 | I understand that, if I choose to withdraw, I can ask for my data to be destroyed, providing it has not been analysed. | |
| 4 | I understand that what I say will be audio recorded, and these recordings will be destroyed once transcribed. | |
| 5 | I understand that the anonymized transcription of the recording will be used to support other research in the future, and may be shared anonymously with other researchers. | |
| 6 | I agree that a copy of my consent form with my name and signature can be kept by the University of Sheffield during the study period and for five years after the study has ended. | |
| 7 | I agree to take part in the above study. | |

(Name of Participant)

(Signature)

(Date)

(Name of Person taking consent)

(Signature)

(Date)

Time of consent (24 hour clock) _____:

1 copy for the patient, 1 copy for the study team.

