

Participant Information Sheet

Study Title: Access to Medicines (ActMed) Study

Researchers: Jakki Birtwistle

ERGO number: 45790

You are being invited to take part in the above research study. To help you decide whether you would like to take part or not, it is important that you understand why the research is being done and what it will involve. Please read the information below carefully and ask questions if anything is not clear or you would like more information before you decide to take part in this research. You may like to discuss it with others but it is up to you to decide whether or not to take part. If you are happy to participate you will be asked to sign a consent form.

What is the research about?

This study is focused on evaluating patient and carer access to medicines during the last year of life, for individuals living at home. We know that medicines are essential for control of symptoms but there is evidence that accessing medicines can be complicated and demanding for patients and their families.

The study is funded via the National Institute for Health Research (HS&DR 16/52/23). It is a collaboration involving three Universities: the University of Southampton, the University of Leeds and the University of Bradford.

Why have I been asked to participate?

You have been approached to participate in a telephone interview, as we would like to understand your experience of facilitating access to medicines for patients and carers during the last year of life. We are interested in the barriers and facilitating factors that enable good practice with respect to medicines access to be sustained and embedded.

We will compare experiences across different types of services that deliver healthcare and provide recommendations for policy and the future delivery of healthcare services. This will enable patients and carers to receive improved access to medicines in the future.

We will look at up to 6 different types of service via case studies. Up to 240 patients will be involved, 40 per service type (with data being collected via interviews, logs and case note analysis). We will include healthcare professionals, such as yourself, who provide care within each of the services, involving up to 50 healthcare professionals per service type via interviews.

What will happen to me if I take part?

If you agree to take part in an interview you will be asked to sign a consent form (a copy of this consent form is attached).

The interview will be via telephone and take place at a day/time convenient to you. It will take up to 45 minutes and will focus on your experiences of facilitating access to medicines for patients and carers during the last year of life. By "medicines access" we mean: prescribing, dispensing, supply and associated information giving about medicines and information about access to medicines. We are interested in the barriers to medicines access and the facilitating factors that enable practice transformation and good practice with respect to medicines access to be sustained and embedded. We are also interested in experiences both in and out of working hours.

We will ask to audio-record the interview so that it can be transcribed and analysed. The audio-recording will be destroyed as soon as the transcripts are produced and checked. All identifiable information will be removed from the interview transcript and the transcript will be given an ID code.

A master file that links ID codes and individual names will be kept on password protected electronic files on secure servers at the University of Southampton and University of Leeds. The file will only be accessed by members of the research team, and will be destroyed on study completion.

Are there any benefits in my taking part?

There may be no direct benefit to you individually in taking part but the information that we collect from you and others will help us improve our understanding of patient and carer experiences of obtaining medicines. This will enable us to provide policy and service recommendations to improve access to medicines for patients and carers in the future.

Are there any risks involved?

We do not foresee any risks to you in taking part.

What data will be collected?

Only interview data will be collected. Your contact details (required for the purposes of arranging interviews) will be stored separately to the data on password protected electronic files on secure servers at the University of Southampton or University of Leeds. The file will only be accessed by the research team and will be destroyed at the end of data collection.

Consent forms will be stored in locked filing cabinets within locked offices at the University of Southampton or University of Leeds.

Will my participation be confidential?

Your participation and the information we collect about you during the course of the research will be kept strictly confidential.

Only members of the research team and responsible members of the University of Southampton may be given access to data about you for monitoring purposes and/or to carry out an audit of the study to ensure that the research is complying with applicable regulations. Individuals from regulatory authorities (people who check that we are carrying out the study correctly) may require access to your data. All of these people have a duty to keep your information, as a research participant, strictly confidential.

Do I have to take part?

No, it is entirely up to you to decide whether or not to take part. If you decide you want to take part, you will need to sign a consent form to show you have agreed to take part. If you would like to take part please contact the study researchers directly via email or phone (contact details below).

What happens if I change my mind?

You have the right to change your mind and withdraw at any time without giving a reason and without your participant rights being affected. If you would like to withdraw please contact the study researchers (contact details below). If you withdraw from the study, we will keep the information about you that we have already obtained for the purposes of achieving the objectives of the study only.

What will happen to the results of the research?

Your personal details will remain strictly confidential. Research findings made available in any reports or publications will not include information that can directly identify you without your specific consent.

We expect ActMed to complete in July 2020, after which point the results will be published formally. Please email actmed@soton.ac.uk if you would like to be added to a list to receive a summary of the research findings.

Where can I get more information?

If you would like any further information, please contact the ActMed study researchers:

Jakki Birtwistle – Email: j.birtwistle@leeds.ac.uk Tel: 0113 343 6907

Kath Black – Research Nurse St Gemma's Hospice Tel: 0113 218 5198

What happens if there is a problem?

If you have a concern about any aspect of this study, you should speak to the researchers who will do their best to answer your questions. If you remain unhappy or have a complaint about any aspect of this study, please contact the University of Southampton Research Integrity and Governance Manager Tel: 023 8059 5058 Email: rgoinfo@soton.ac.uk

Data Protection Privacy Notice

The University of Southampton conducts research to the highest standards of research integrity. As a publicly-funded organisation, the University has to ensure that it is in the public interest when we use personally-identifiable information about people who have agreed to take part in research. This means that when you agree to take part in a research study, we will use information about you in the ways needed, and for the purposes specified, to conduct and complete the research project. Under data protection law, 'Personal data' means any information that relates to and is capable of identifying a living individual. The University's data protection policy governing the use of personal data by the University can be found on its website:

<https://www.southampton.ac.uk/legalservices/what-we-do/data-protection-and-foi.page>

This Participant Information Sheet tells you what data will be collected for this project and whether this includes any personal data. Please ask the research team if you have any questions or are unclear what data is being collected about you.

Our privacy notice for research participants provides more information on how the University of Southampton collects and uses your personal data when you take part in one of our research projects and can be found at:

<http://www.southampton.ac.uk/assets/sharepoint/intranet/Is/Public/Research%20and%20Integrity%20Privacy%20Notice/Privacy%20Notice%20for%20Research%20Participants.pdf>

Any personal data we collect in this study will be used only for the purposes of carrying out our research and will be handled according to the University's policies in line with data protection law. If any personal data is used from which you can be identified directly, it will not be disclosed to anyone else without your consent unless the University of Southampton is required by law to disclose it.

Data protection law requires us to have a valid legal reason ('lawful basis') to process and use your Personal data. The lawful basis for processing personal information in this research study is for the performance of a task carried out in the public interest. Personal data collected for research will not be used for any other purpose.

For the purposes of data protection law, the University of Southampton is the 'Data Controller' for this study, which means that we are responsible for looking after your information and using it properly. The University of Southampton will keep identifiable information about you for 10 years after the study has finished after which time any link between you and your information will be removed.

To safeguard your rights, we will use the minimum personal data necessary to achieve our research study objectives. Your data protection rights – such as to access, change, or transfer such information – may be limited, however, in order for the research output to be reliable and accurate. The University will not do anything with your personal data that you would not reasonably expect.

If you have any questions about how your personal data is used, or wish to exercise any of your rights, please consult the University's data protection webpage:

<https://www.southampton.ac.uk/legalservices/what-we-do/data-protection-and-foi.page> where you can make a request using our online form. If you need further assistance, please contact the University's Data Protection Officer via email at: data.protection@soton.ac.uk

Thank you for taking the time to read this information sheet and considering taking part in this study.