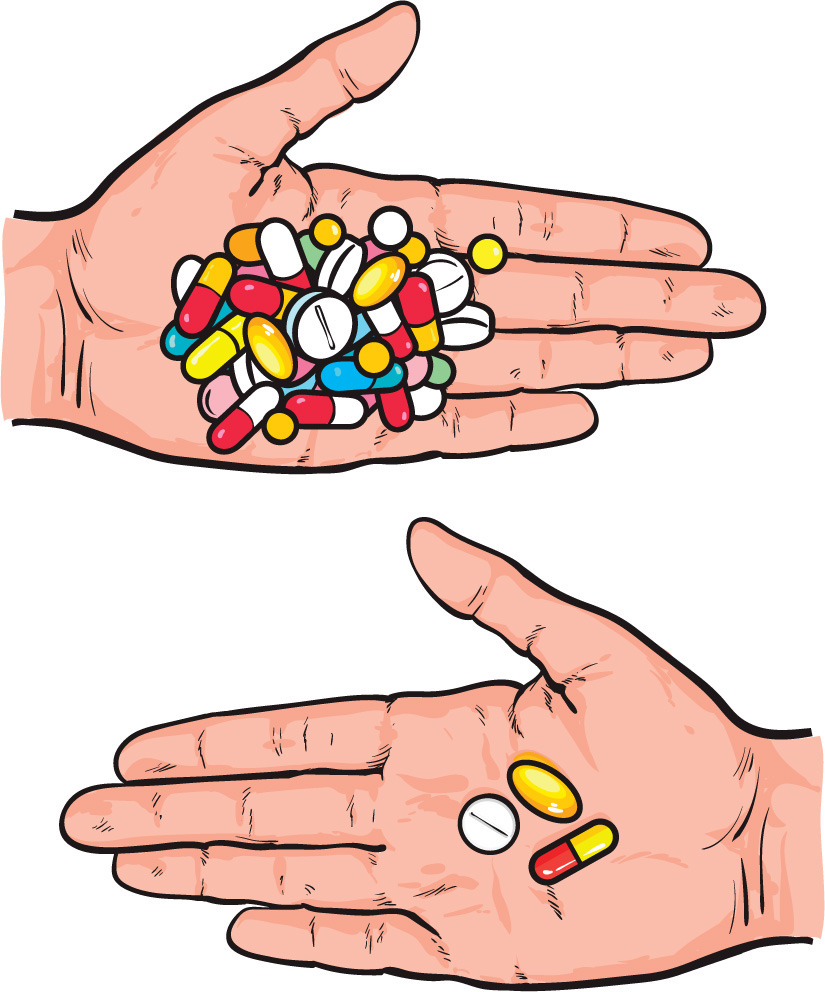
### Participant Information Sheet

**Research study on deprescribing in primary care for people with dementia or mild cognitive impairment**

IRAS number: 325681 Sponsor: University of Southampton (79730)



You are invited to take part in this research study

* Before you decide whether to take part 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. Discuss it with friends and family if you wish.
* You are free to decide whether or not to take part in this study. The medical care that the person you care for gets from their doctor will be the same whether you say yes or no.
* Please ask us if anything is not clear or you would like more information. Our contact details are on the last page.

**What is the study about?**

People living with dementia or mild cognitive impairment often take multiple medications, some of which may be inappropriate. We want to understand how decisions should be made to safely reduce or stop inappropriate medications (deprescribing). We want to find out the views and experiences of both people living with dementia or mild cognitive impairment who take multiple medications and their carers. We want to know how you think different health care professionals could work with people with dementia or mild cognitive impairment and their carers to make decisions together. We will use what we find out to develop an intervention to support health care professionals to do this.

**Why have I been chosen?**

You have been invited to take part because you have been identified as someone who cares for a person with dementia or mild cognitive impairment who is prescribed multiple medications. We would like to include up to 10 people who provide informal care to someone with dementia or mild cognitive impairment in the study.

**Do I have to take part?**

No, it is up to you to decide whether or not to take part. No-one will mind if you say no, or if you say yes and then change your mind. Your decision will not affect your legal rights in any way or the healthcare of the person you care for.

**What will happen to me if I take part?**

You will be visited at your home by a researcher on two occasions. All visits will be arranged at a time suitable for you.

Visit 1: Our researcher will check that you understand the study and what it involves. You will be asked to sign a consent form. Our researcher will then provide you with a camera on loan and you will be asked to use this to take photographs for the research. The researcher will show you how to use the camera and also leave you with written instructions including who to contact if you have any questions. This visit is expected to take 20 to 30 minutes.

Taking photographs: You will be asked to take photographs of things that make you think about how you assist the person you care for to manage their medications on a daily basis. Taking photographs is expected to take around 15 minutes. After about a week our researcher will contact you to see how you are getting on and to arrange a suitable time to collect the camera.

Visit 2: Our researcher will talk to you about the pictures you have taken and your views and experiences of making decisions about reducing or stopping inappropriate medications (deprescribing) for someone with dementia or mild cognitive impairment. The conversation is expected to last around 45 minutes. You can have a break in this time if needed. With your permission, the conversation will be audio recorded to allow us to concentrate on what you are saying. The researcher will also ask you to complete a participant characteristic form during this visit.

**What information about me will be collected and how will you use information about me?**

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

* Name
* Contact details including telephone number, email and/or postal address.

We will also collect the following information about you:

* Information about your views and experiences of making decisions about reducing or stopping inappropriate medications (deprescribing) for someone with dementia or mild cognitive impairment.
* The following personal data, so that we gain views from people with a broad range of characteristics:
  + Your age.
  + Your gender.
  + Your ethnicity.
  + Your highest level of educational attainment.
  + Your relationship with the person you provide care for.
  + Whether the diagnosis of the person you care for is dementia or mild cognitive impairment.
  + Whether you live with the person you provide care for.
  + The Index of Multiple Deprivation score for your address. This is a measure of deprivation at small local area level based on seven domains including income and health. This will be identified using your postcode.

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 participant ID number instead.

We will keep all information about you safe and secure.

**Will my taking part in this study be kept confidential?**

Yes, the research team will keep all information which is collected about you during the research strictly confidential. We will be using information from you solely for the purposes of undertaking the study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly.

There are some exceptional situations when your confidentiality may be breached, such as if there is a safeguarding or safety concern, but this will be discussed with you first.

Responsible members of the University of Southampton may be given access to information about you. This could be for monitoring purposes and/or to carry out an audit of the study to ensure that the research meets regulatory requirements. Individuals from regulatory authorities (people who check that we are carrying out the study correctly) may require access to your data. All these people have a duty to keep your information strictly confidential.

We will store your contact details in a separate location to all other information you provide. We will anonymise all other data collected from you. A participant ID will replace your name and we will label your data with this code.

We will store all data in electronic format by scanning any paper records, then shredding the paper copy. Data will be securely stored on university password protected and encrypted computer systems, backed up on secure platforms. Data will be accessible by the research team only.

Audio-recordings will be typed into text (transcribed). We will securely transfer recordings to a third-party, university-approved transcriber. When transcription is complete, any identifying details will be removed, and recordings destroyed. Data will be analysed after any personal information that could directly identify you is removed.

We will destroy your contact details at the earliest opportunity after your interview unless you have provided us with consent to retain these details until the end of the study to send you the study report. With your permission we will also retain your details for up to six months from the end of the study if you would like to provide feedback on the prototype intervention developed using the findings from the study. The University will store your anonymised data for 10 years after the end of the study. This data will then be securely destroyed.

**What are my choices about how my information is used?**

You can stop being part of the study at any time, without giving a reason. However, if you withdraw from the study after the date of the interview it may not be possible to fully withdraw your data. This is because once we have destroyed your name and contact details, your data will be anonymised and will not be identifiable. In this situation, we will keep the data obtained from you for the purposes of achieving the objectives of the study only.

We need to manage your records in specific ways for the research to be reliable. This means that we won’t be able to let you see or change the data we hold about you.

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. With your consent we will place the anonymised transcript of your interview and photographs in the University of Southampton data repository, with all data that could make you identifiable removed. Your data will not be available for non-academic research.

**Are there any benefits of taking part?**

There may not be any direct benefits to you personally. However, what you tell our researcher will help us learn more about the best approach to making decisions about reducing or stopping inappropriate medication (deprescribing) for people with dementia or mild cognitive impairment. The intervention developed could benefit people with dementia or mild cognitive impairment in the future.

**Are there any risks or disadvantages involved with taking part?**

This study is designed with minimal potential risks to all participants. Taking part will mean giving some of your time which is likely to be around 2 hours for most people. The researcher will avoid unnecessary intrusion and asking any sensitive questions. If you do not wish to answer a particular question, you are free to say no. If you feel uncomfortable, we can end the interview early. If you do experience any difficulties, please discuss them with the researcher at any time, who can signpost you to support if required.

**Will I get paid for taking part?**

There is no payment for taking part in this study. However, after the interview you will receive a £40 gift voucher as a thank you. If you need to make arrangements for the person you care for to be looked after so that you can take part in the interview, then we will pay these costs.

**What will happen to the results of the research?**

We will publish the full study report on the ARC Wessex website on completion of the study. We will send you a summary report with the main findings if you wish to receive one. The results of the study will also be published in academic journals and the research team may also present the results at conferences and local meetings and research events. We will write our reports in a way that no-one can work out that you took part in the study. The findings may be supported by quotes taken from your answers, but these will be anonymised.

**Who has reviewed the study?**

Ethical approval was given by the London Central Research Ethics Committee (REC Number: 23/PR/0366) and is sponsored by the University of Southampton.

**Who is organising and funding the research?**

This research is being funded by the National Institute of Health Research (NIHR) Applied Research Collaboration (ARC) Wessex.

**What happens if there is a problem?**

If you have any questions or concerns about any aspect of this study, you should contact one of the research team. Their contact details are at the end of this sheet.

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 (023 8059 5058, [rgoinfo@soton.ac.uk](mailto: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/ls/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 ([data.protection@soton.ac.uk](mailto:data.protection@soton.ac.uk)).

You can also find out more about how your information is used at by asking one of the research team.

**How can I contact the research team?**

Please do not hesitate to contact a member of the research team if you have any questions, concerns or if you want further information after reading this information sheet:

Dr Kinda Ibrahim

Senior Research Fellow in Geriatric Medicine

Faculty of Medicine

University of Southampton

Email: [k.ibrahim@soton.ac.uk](mailto:k.ibrahim@soton.ac.uk)

Dr Nicola Andrews

Research Fellow

School of Health Sciences

University of Southampton

Telephone: 07500 760061

(Monday to Friday, 9 am – 5 pm)

Email: [n.m.andrews@soton.ac.uk](mailto:n.m.andrews@soton.ac.uk)

Or

**Thank you**

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

This information sheet is for you to keep. If you decide to take part, you will be asked to sign a consent form.