



ICONIC* Study: Participant information sheet

We are inviting you to take part in a research study. Before you decide whether you would like to take part or not, we would like you to understand what the study involves, and why we are doing it. Take time to think about it and ask the researcher any questions you may have. Feel free to talk to others about the study if you wish. You can request a copy of this information sheet to keep.

Please ask if anything is unclear – there are contact details for the research team at the end of this document.

What is the purpose of this study?

Lots of adults have a long-term condition, such as asthma, high blood-pressure, chronic pain, arthritis or diabetes. About one-in-five people in Scotland have more than one long-term condition. Because we are living longer than ever before, the number of people who have more than one long-term condition is likely to increase.

When people have multiple long-term conditions, they are often expected to do lots of tasks to stay healthy. This includes taking lots of medicines, going to the hospital or GP frequently, or monitoring themselves for changes in symptoms. This can feel like 'work' for someone with multiple conditions. The term used to describe this work is 'treatment burden'.

People who experience high levels of treatment burden may be less likely to do tasks to stay healthy, and their health can suffer as a result.

In this study we want to find out whether there are ways of identifying people who are at risk of experiencing high levels of treatment burden using healthcare data already held by the NHS.

Why have I been invited to take part in this study?

We are inviting you to take part in the study because we believe you meet the following criteria:

- **You are registered with the Scottish Health and Research Register (SHARE).** If you don't think you are on the SHARE register or want to speak to SHARE, contact them on at enquiries@registerforshare.org or by calling 01382 383 471.
- **You have two or more long-term health conditions.** If you believe this to be incorrect, please still consider taking part. This will help us improve our methods of identifying different conditions.
- **You are aged 18 or older.**
- **You are able to read and speak English.** If you have a visual or hearing impairment which makes communication difficult, please contact SHARE **[INSERT SHARE CONTACT DETAILS]** who will pass your message on to the research team. We will do our best to meet your needs.

Do I have to take part in this study?

No. We are looking for volunteers, you do not need to take part if you do not want to. If you do decide to take part, you can change your mind and withdraw by simply not completing the survey. You do not have to give a reason for withdrawing. Your medical care or legal rights will not be affected.

What will happen to me if I take part?

You will be asked to complete a short survey. The survey only takes around ten minutes, and can be done on any electronic device, such as a smartphone, a laptop, a tablet device or a desktop computer. People who have multiple long-term conditions have been involved in testing the survey, to make sure it is as quick and easy as possible to complete. If you want to get help from a carer or other trusted person to complete the survey, please feel free to do so.

The survey firstly asks you for some general information (such as your ethnicity, relationship status, employment status, how far you are from your GP/ local hospital) and about any long-term conditions you have (such as high blood pressure, diabetes, depression, or a previous heart attack) from a list of 29 conditions. It then asks you to rate how much difficulty you have (if any) with thirteen health-related

activities, such as taking lots of medications, seeing lots of different healthcare professionals, or making recommended lifestyle changes (e.g. diet and exercise).

The 29 health conditions on the list have been selected because we are testing how accurately we can identify these specific conditions using people's health records.

We understand that you may have other conditions which are not on the list.

If you want to complete the survey in more than one session, you can save it and come back to it later.

Are there any benefits to taking part?

There are no direct benefits in taking part. However, in our previous research with people who have multiple long-term conditions, some have found that thinking about treatment burden has helped them understand their health and the work involved in staying healthy. We hope that the information you provide will help us identify people who are at risk of experiencing high levels of treatment burden, so we can plan better care in future.

Are there any risks or disadvantages to taking part?

You shouldn't experience any new risks or disadvantages from taking part in the survey. If you find the process of thinking about treatment burden to be upsetting or distressing, please contact a member of the research team who can direct you to services or other agencies who can help.

What if there is a problem?

If you have a concern about any aspect of this study please contact SHARE in the first instance **[INSERT SHARE CONTACT DETAILS]**. If you want to speak with the research team directly, contact Chris McParland (chris.mcparland@glasgow.ac.uk or 0141 330 6813). Chris is the principal investigator for this study and will do his best to answer your questions.

In the unlikely event that something goes wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against the University of Glasgow, but you may have to pay your legal costs.

What will you do with the survey data?

We will collect the survey responses and link them with your routine healthcare data, which the researchers have access to in a pseudonymised format through SHARE and the University of Dundee. By 'pseudonymised' we mean the study team will not be able to tell who you are by examining the data (see '**What about privacy and confidentiality?**' for more information). We will then perform statistical tests, to see what things (like long-term conditions, age, sex, ethnicity etc) are associated with high levels of treatment burden. We hope this data will help us develop a tool to identify people who are at risk of experiencing high levels of treatment burden, so that we can plan better care which is more manageable.

What happens when the study is finished?

At the end of the study the researchers will publish the findings in a scientific journal and present the findings at one or more academic conferences. We would also like to share our findings with you, but we will ask your permission to do this first. You will not be identifiable in any reports or materials we produce.

What about privacy and confidentiality?

Your privacy matters to us. All information which is collected about you, or responses that you provide during the study will be kept strictly confidential. Only staff at SHARE will have access to your name and the personal information you have already provided them with when you joined the SHARE Register; this will not be shared with the research team at University of Glasgow. Staff at SHARE and the University of Dundee's Health Informatics Centre will link your survey response with your health records, before providing this to the research teams in a pseudonymised (non-identifiable) format.

Please note that all assurances on confidentiality will be strictly adhered to unless evidence of serious harm, or risk of serious harm, is discovered. In such cases, the research team may be obliged to contact relevant statutory bodies/agencies.

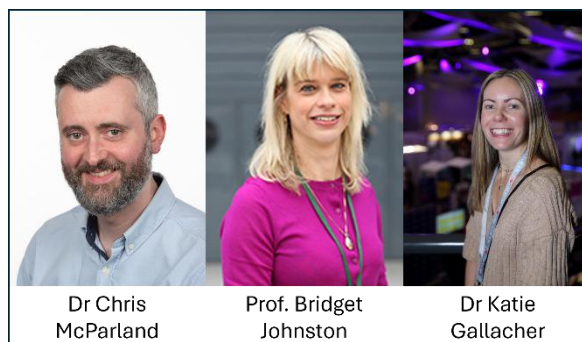
The data will be analysed within the University of Dundee's data safe haven, which is a secure computing environment where researchers can work with routinely-collected healthcare data in a pseudonymised format. Any datasets or results generated during the study will be checked by University of Dundee staff to make

sure you cannot be identified from them, before being shared with the research team. Any research data which is shared with the research team will be stored securely on University of Glasgow servers, and will only be available to the research team, appropriate governance staff, and other researchers who have obtained the necessary approvals to conduct research using the data. See the section '**What will happen to my data?**' for more information.

Who is conducting this study?

This study is being conducted by a research team at the University of Glasgow, made up of nurses and doctors with experience caring for and conducting research with people who have multiple long-term conditions. It has been funded by the NHS Greater Glasgow and Clyde Research Endowment Fund.

The study is led by Dr Chris McParland, a researcher and nurse whose PhD focussed on nursing care for people



with multiple long-term conditions. Chris' current work is mainly directed at identifying and managing treatment burden in this group. Chris is supported by Professor Bridget Johnston and Dr Katie Gallacher, both experienced researchers who have conducted research in this area and several others, including palliative care, stroke care, and the development of interventions to improve the way people are cared for. Contact details for the research team are available at the end of this document.

Who has reviewed the study?

The study has been reviewed by other people who have two or more long-term conditions and has been independently peer reviewed by two researchers at the University of Glasgow who are not associated with the project. All research in the NHS is also looked at by an independent group of people, called a Research Ethics Committee. A favourable ethical opinion has been obtained from **[SPECIFY REC]**.

What will happen to my data?

Any identifiable data you have already provided to SHARE and your routinely-collected healthcare data will be managed in line with SHARE's privacy policy. For

more information (including contact details for SHARE), visit

<https://www.registerforshare.org/privacy-and-security>.

Once this data has been analysed, the University of Glasgow will request a results and a summary dataset from SHARE. This data will be in a pseudonymised (non-identifiable) format.

Your rights to access, change or move the information we store may be limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible. You can find out more about how we use your information from Chris McParland (chris.mcparland@glasgow.ac.uk or 0141 330 5612).

Researchers from the University of Glasgow collect, store and process all personal information in accordance with the General Data Protection Regulation (2018). All study data will be held in accordance with The General Data Protection Regulation (2018). The data will be stored in archiving facilities in line with the University of Glasgow retention policy of up to 10 years. After this period, further retention may be agreed or your data will be securely destroyed in accordance with the relevant standard procedures.

Your identifiable information might be shared with people who check that the study is done properly and, if you agree, in coded form with other organisations or universities to carry out research to improve scientific understanding. Your data will form part of the study results that will be published in expert journals, presentations and on the internet for other researchers to use. Your name will not appear in any publication.

Who can I contact for further information?

If you wish to ask for information about the study without informing the study team, contact SHARE **[INSERT SHARE CONTACT DETAILS]**.

Full details for the study team are also listed here. Please note email is the preferred method of contact.

Dr Chris McParland: (Primary contact)	chris.mcparland@glasgow.ac.uk	0141 330 5612
Prof. Bridget Johnston	bridget.johnston@glasgow.ac.uk	0141 330 3691
Dr Katie Gallacher	katie.gallacher@glasgow.ac.uk	0141 330 8323

If you would like further information or to speak to someone independent of the study, please contact:

Dr Greg Kotronoulas	grigorios.kotronoulas@glasgow.ac.uk	0141 330 6883
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If you would like to make a complaint about the study, you can contact the researcher in the first instance.

The research team would like to offer our sincere thanks for taking the time to read this participant information sheet.

**ICONIC: Identification of a Cohort in Need of Improved Care.*