INVITATION TO JOIN A RESEARCH PROJECT

ISCOMAT: Improving the safety and continuity of medicines management at care transitions

You are being invited to take part in a research study.

Before you decide whether to take part, it is important for you to understand why the research is being done and what is involved. Please take time to read this information carefully and discuss it with friends or relatives if you wish. You are entirely free to decide whether or not to take part in this study.

Your decision about taking part will not affect the standard of care you receive.

If there is anything that is not clear, or if you would like more information, please speak to the research nurse who gave you this information or to the study coordinator – who will be available on the ward to answer your questions. Or you can contact her on 01274 236952

The purpose of this research is to understand more about how patients' medicines are managed after they leave hospital so that patients and healthcare staff can come up with new and better ways of supporting other patients to manage their medicines. In summary, we would like your permission to obtain information about your medicines and your health conditions from your GP, community pharmacy and hospital records and from central organisations that hold information from all hospitals, GP practices and community pharmacies. The data from these sources will be sent to the Clinical Trials Research Unit at the University of Leeds for processing and analysis. All information will be stored securely and only accessed by members of the research team.

Please turn over to find out more about what taking part will involve.

PATIENT INFORMATION

ISCOMAT: Improving the safety and continuity of medicines management at care transitions

We are inviting you to take part in our research study.

- Before you decide we would like you to understand why the research is being done and what it would involve for you. A research nurse will go through the information sheet with you and answer any questions you have. One of the team will return later in the day to ask if you will consent to take part in the study

- Feel free to talk to others about the study if you wish.

- Ask if there is anything that is not clear.

About the study

The purpose of this study is to develop a way of bringing together information about people's health conditions and the medicines they take that is held in different parts of the health system. Your medical records are held electronically by your GP practice and your hospital and your data flows between the different health and social care providers to ensure that professionals involved in your direct care have the most up-to-date information about you. We want to access this routinely collected data which the researchers think is relevant to your heart condition and your discharge from hospital. We want to link the data together and analyse these data so that in the future we will be able to see if changes made to how people are supported with their discharge medicines has an impact on their health and the medicines they are taking.

Why have I been chosen?

You have been in hospital being treated for a heart condition for which a combination of medicines is known to benefit your heart and improve your health and wellbeing.

Do I have to take part?

No, it is up to you to decide to join the study. We will explain the study and go through this information sheet with you. If you agree to take part, we will then ask you to sign a consent form. You are free to change your mind at any time, without giving a reason. This would not affect the standard of care you receive and you will not be treated any differently whether you decide to take part or not.

How do I take part?

If you decide to take part in this study you should complete the consent form and return it to us via the Research Nurse who introduced this study to you. We will post newsletters on the study website to keep you updated on the study (www.bradford.ac.uk/iscomat).

What am I being asked to do?

In order to help us better understand the impact of how your medicines use is supported and how they impact on your health, we would like to link up specific information your GP and community pharmacy store with the information the hospital supplies to national records about treatment and patients' health outcomes.

We would do this using your identifiable data (for example, your NHS number, date of birth, postcode, sex and initials) to make sure that we have the right records.

With your permission, we will write to your GP to tell them you are taking part in this study. We will also inform your community pharmacy that you are taking part in the study.

How will you access my data?

Your medical records are held electronically by your GP practice and your hospital. Different systems are used to hold the data and we would like to obtain certain data from these systems which researchers think is important to your heart condition. Some information may be duplicated in the different systems, but some data may only be on one which is why we need to use the different systems. If we cannot find the data in the electronic systems, a researcher will go directly to the hospital or GP practice to try to obtain the data.

We will share your identifiable data with the following providers:

- *Hospital records:*

The Health and Social Care Information Centre (HSCIC) holds the records of all patients admitted to NHS hospitals in England – this data is known as 'Hospital Episode Statistics' or 'HES' and the National Institute for Cardiovascular Outcomes Research (NICOR) collects clinical information from hospitals across the UK on care received by heart disease patients for the purposes of clinical audit. The HSCIC collects cause of death from the Office of National Statistics (ONS) and we will obtain this information if it becomes available.

- *GP records:*

Most GP practices use a system provided by TPP (SystmOne) or EMIS Health.

- *Community pharmacy records:*

Most community pharmacies electronically store limited information about the medicines they dispense to you. They will send this information to the research team.

Will the information I give be kept confidential?

If you decide to participate, the information collected about you will be handled in accordance with the consent that you have given and also the 1998 Data Protection Act. Identifiable information (e.g. initials, date of birth, NHS number, sex, ethnicity, full name and address) will be collected on a paper form and entered by the research nurse or the ISCOMAT research fellow directly onto a secure web-based system hosted by the University of Leeds Clinical Trials Research Unit (CTRU). This information will be shared with the data providers using a Secure File Transfer System to obtain relevant data from your electronic health records and to obtain information about your health status.

Additional data about your heart condition and your stay in hospital will be obtained from your medical notes by the researcher nurse or the ISCOMAT research fellow and will be collected on paper forms and will be sent to the CTRU by standard post. You will be allocated a study number, which will be used along with your date of birth and initials to identify you on each paper form. Every effort will be made to ensure that any further information about you that leaves the hospital will have your name and address removed so that you cannot be recognised from it; this information will usually be removed by a member of the study team at your hospital, but may also be removed by the CTRU upon receipt.

Data you give us will be processed by a study data manager and study statisticians at the University of Leeds CTRU and securely entered and stored on CTRU systems. Identifiable

data sent to us will not be accessed by or shared with any third parties outside the ISCOMAT Research team. All the data you give us will be stored for up to 5 years after the end of the study and then destroyed.

What are the benefits of taking part?

The information we get from this study will help us to work out how best to collect relevant data on patients with heart condition when they are discharged from hospital. This will be used to develop a future trial which may help the way other patients are supported with their medicines. This may contribute to improving their health through helping them better understand their medicines. It may also improve the way medical professionals work together to offer good standards of care to patients when they leave hospital.

What are the drawbacks of taking part?

Researchers will store information about you, such as the medicines you are taking and your identifiable information, but that information will be kept confidential at all times.

What happens at the end of the study?

The information will be used to develop data collection processes for a future trial. We will also write a report and develop a toolkit for patients and healthcare staff to use to improve the way that medicines are managed after someone with a heart condition has been in hospital. That toolkit will later be tested in the trial. We will also publish the study results in academic journals, but you will not be identified in any published report or journal article.

What if I decide during the research that I don't want to take part any more?

That's ok – just tell us that you don't want to take part any more. You don't have to give a reason. There are several ways in which you can opt out of the study:

- If you are still in hospital you can tell the research nurse who will be available on the ward;
- You can telephone the ISCOMAT team on 01274 236952;
- You can email iscomat@bradford.ac.uk;
- You can write to us at ISCOMAT c/o School Pharmacy, University of Bradford, M24 Richmond Building; Bradford DD7 1DP.

What if I have worries about my medicines?

If you have worries about your medicines whilst you are taking part in the study you should talk to your doctor, nurse or community pharmacist (chemist). It is important that you speak to a qualified person if you are worried about your medicines for any reason.

Study organisation

This study has been funded by the National Institute of Health Research and is being managed by the Universities of Bradford and Leeds (the ISCOMAT research team). The CTRU at the University of Leeds is responsible for data processing, storage and analysis of data from your electronic and paper medical records. The study design has been reviewed and approved by independent NHS Research Ethics Committees.

What if I have questions about the study?

If there's anything you're not sure about, or if you have any questions, you can ask [Researcher Name] who will be available on the ward or by telephone on 01274 236952 or email iscomat@bradford.ac.uk.

What if I have a complaint about the study?

If you want to make a complaint at any point about any aspect of the study you can contact Professor Alison Blenkinsopp (01274 234290) or Professor Gerry Armitage (01274 236474) at the University of Bradford. If you want to complain at any point about any aspect of the study to an independent body you can contact your local Patient Advice Liaison Service (PALS) by telephoning [insert local PALS telephone number].

Thank you for considering taking part.

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