

**THE ISCOMAT STUDY**

**ISCOMAT: Improving Safety and Continuity Of Medicines management At care Transitions**

**Patient Information Sheet**

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How to contact us

If you have any questions about this study, please contact:

Name: <<insert>>
Telephone: <<insert>>
Email: <<insert>>

We would like to invite you to take part in a research study called ISCOMAT

* Your hospital has already agreed to take part.
* Before you decide whether to take part, we would like you to understand what this involves.
* Please read this information carefully and take time to decide whether you would like to take part. Please ask if anything is unclear. You can also discuss it with your relatives or friends if you wish.
* You are free to decide whether or not to take part. If you choose not to it will not affect your care in any way.
* You can keep this information sheet to remind you about the study.
* If you have any questions please contact the nurse who gave you this information sheet, or contact the central study team using the details on this page.

**Thank you for reading this information sheet**

1. Why are we doing this study?

The ISCOMAT study is looking at how people with heart failure can be helped to manage their medicines after they have been in hospital. When a patient leaves hospital sometimes there can be some problems with the way their medicines are managed. This can happen more often in patients who have long-term illnesses and who take a few different medicines. Patients with heart failure often have lots of different medicines to take, and this is why we would like to invite you to take part. We hope to involve around 2100 other patients overall.

This study involves 42 hospitals across the country. Half the hospitals will provide help with managing medicines in a new way, the other half will continue to deliver care as usual. Which hospitals will be delivering this new kind of medicine management has been decided by chance (randomly). This means that neither the hospital, nor the researchers who run the study have chosen which hospitals are in each group. In this way we can compare the two groups at the end of the study.

A group of heart failure patients from different locations have been involved throughout the design of this study, to ensure it is well designed and with patients such as yourself in mind.

1. Why am I being asked to take part?

Your hospital has agreed to take part in this study. We are inviting all patients admitted to your hospital with heart failure to take part.

1. What information will you collect about me?

If you agree to take part, we will:

1. Ask you to complete some short questionnaires
2. Collect information about your care from electronic health records, for example hospital attendances and admissions
3. We may also ask you some questions about your experience and care (following agreement to take part) through discussions with a Researcher.
4. How will you collect this information?

Questionnaires:

If you decide to take part, we will ask you to complete 5 sets of questionnaires over a total of 12 months. The first set would be completed whilst you are in hospital once you have agreed to take part, with the support of a research nurse.

We will contact you again (through the post), 2 weeks and 6 weeks after you’ve left hospital to ask you some questions about your experience in hospital (you may also be asked if you wish to take part in a recorded interview about this, but the recorded interview is an optional part of the study).

We will also contact you again 3 and 12 months after you agreed to take part in the study to ask you to fill in another set of questionnaires about your health, what services you have used and your medications. Again, this contact will be via the post.

If you provide a mobile phone number to the researcher and consent to contact by mobile, we may send you a text message about your questionnaire booklets at 2 weeks and 6 weeks after leaving hospital and at 3 months and 12 months, after you agreed to take part.

Electronic Health Records:

We would also like your permission to obtain information about your medicines, hospital attendances and admissions and your health conditions from your GP and hospital records, community pharmacy, NHS Business Services Authority, and from NHS Digital.

Your medical records are held electronically by your GP practice, your hospital and your community pharmacy. There are different systems that can be used to hold data, dependent upon your care provider.

We are therefore asking for your permission to access all these systems so we can ensure we are able to collect the information we require.

Systems that hold your medical data include;

Hospital records: NHS Digital holds details of all admissions, outpatient appointments and A&E attendances at NHS hospitals in England – this data is known as ‘Hospital Episode Statistics’ or ‘HES’.

Office for National Statistics (ONS) holds information on date and cause of death.

GP records: Most GP practices hold electronic health records (in systems called SystmOne, EMIS Health or VISION) with information about your care provided by your GP and medications.

With your agreement we would like to access your data held in these electronic records to avoid asking you more questions about your recent care. To do this we need to send your identifiable data (for example, your initials, sex, date of birth, NHS number, and postcode) to each system provider to obtain the correct information from these records.

Discussions with you:

If you agree, a Researcher may contact you to discuss your experience of taking part in the study, and the care you have received at a convenient time and place for you. These discussions may be recorded using a voice recorder to help the Researcher so that they do not need to take lots of notes.

The data from these sources will be sent via secure methods to the Clinical Trials Research Unit (CTRU) at the University of Leeds (where the study is being centrally coordinated) for processing and analysis.

If you take part in discussions with a Researcher, audio recording of the discussion will be transported securely to the study Research team at the University of Bradford, where the Researchers are based. It will be stored safely in the research office there, and only members of the research team will be able to access it. Recordings will be transcribed into a written format, with any personal identifiers removed –which means they would not identify you in any way. If you agree, anonymous quotes from your discussions with the Researcher may be included when we share the findings of the study, in either written or spoken form.

As well as staff at the CTRU being involved in the study, the team also involves staff from the University of Bradford and Bradford Teaching Hospitals NHS Foundation Trust.

1. What are the advantages and risks of taking part?

We hope that this study could improve care for people diagnosed with heart failure in the future, but we cannot say that you will definitely experience an improvement. The same would be true if you were not part of the study personally.

We do not expect there will be any direct risks or disadvantage to taking part.

1. More information about taking part

**What will happen if I do not want to carry on with the study?**

You are free to withdraw from the study at any time and without giving a reason and without affecting your care in any way. If you did wish to withdraw, you would need to tell us (contact details can be found on the first page of this information sheet). We would then stop collecting information about you. Data already collected would remain on file and will be included in the final study analysis.
 **What if there is a problem?**

If anything about your care, treatment or health worries you, you should speak to your Dr or nurse. If you have a concern about any aspect of this study, you should ask to speak to the research nurse at your hospital, or the study team (contact details on first page) who will do their best to answer your questions. If you remain unhappy, you may wish to contact your local Patient Advice and Liaison Service (PALS Telephone number: <<insert number>>). There are no special compensation arrangements in place for this study.

**Will my taking part be kept confidential?**

The information collected about you will be handled strictly in accordance with the consent that you have given and also the 1998 Data Protection Act.

Most of the information needed for study will be collected on paper forms and sent (usually using standard Royal Mail post but in some cases by email) to the study team at the Clinical Trials Research Unit (CTRU).

The CTRU will hold a copy of the consent form that you sign, which will have your name on it. Your name, address, phone number(s) and email address (if you have one) will also be given to the study team at the CTRU and to the researcher(s) on the study. This is so that they can contact you about the study when they need to. In addition, as mentioned in section 4, your identifiers (for example, your initials, sex, date of birth, NHS number, and postcode) will be provided to the holders of the electronic health records datasets, to ensure we only obtain data in line with consent. These identifiers will be sent securely. This information will not be accessed by anyone else.

Every effort will be made to make sure that any further information about you will have your name and address removed so that you cannot be recognised from it. You will be given a unique study number, which will be used along with your date of birth and initials to identify you on each paper form.

It is possible that the information collected about you might be shared with other research teams to answer new research questions in the future. If this happened, the information would be anonymised so that no-one would be able to identify you from it.

Your data will be entered onto a secure database held at the CTRU. All access to data and databases will be restricted just to the staff who require access to process and analyse the data.

At the end of the study, your information will be securely archived for up to 10 years.

**What happens if new information about the study becomes available?**

We will keep you updated regularly regarding study progress and access to your data via regular newsletters. We will also post any updates on the ISCOMAT website (<https://www.bradford.ac.uk/life-sciences/pharmacy-medical-sciences/morg/iscomat/research/>) If you wanted to speak to anyone in the study team at any point about your participation, please use the contact details on the first page of this information sheet.

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

When the study is complete the results will be published in a medical journal, but no individual participants will be identified.

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

The study is being organised and supervised by the Bradford Teaching Hospitals NHS Foundation Trust. It is funded by the Department of Health. All research is looked at by an independent group of people called a Research Ethics Committee to protect the safety, rights, wellbeing, and dignity of those taking part. This study has been reviewed and approved by Yorkshire & The Humber - Bradford Leeds Research Ethics Committee.

1. Questions?

If you have any questions or would like more information, please contact us using the contact details on page 1 of this information sheet.

If you would like further information about research in general, the UK Clinical Research Collaboration (a partnership of organisations working together on research in the UK) have published a booklet entitled ‘Understanding Clinical Trials’, you can access this here: [www.ukcrc.org](http://www.ukcrc.org).

**Thank you for taking the time to read this information sheet.**