PARTICIPANT INFORMATION SHEET

Optimising Management of Patients with Heart Failure with Preserved Ejection Fraction in Primary Care

We would like to invite you to take part in a research study. It is important that you understand why the project is being carried out and what will be involved. This information sheet will help you decide whether to take part. Please discuss it with your family or carers if you wish. If you have any questions, please contact us using the details provided at the end of this sheet. You can also view a brief video introducing the study. This can be found at https://www.optimisehfpef.phpc.cam.ac.uk/videos/ or the practice may be able to show you the video. Your participation is entirely voluntary.

1. What is the purpose of the study?

- Heart failure is a condition in which the heart does not work as well as it once did to pump blood around the body. About half of all people with heart failure have a type called "Heart Failure with Preserved Ejection Fraction" (HFpEF) in which the heart is very stiff. This type is more common in older people with a history of high blood pressure, obesity and diabetes, but it can be hard to diagnose and is less well understood. Patients often experience shortness of breath, swollen ankles and tiredness.
- At the moment, recommendations for managing this type of heart failure focus on controlling blood pressure, blood sugar, and being active. No specific drugs have been found to help it, except for diuretics or 'water pills'. Most patients are looked after in general practice sometimes in collaboration with specialists.
- In this study we want to assess and follow-up patients with HFpEF for one year. We will assess patients at the start of the study (baseline), and then 6 months and 12 months

later. The assessments will include questionnaires and tests that are described below. They will help us understand more about people with this condition.

- We would also want to check your medical records (at your GP and hospital records) to look at your medications, laboratory tests, and see if you have been admitted to hospital at any time. We will also apply to NHS Digital who collect Hospital Episodic Statistics (information about NHS visits and hospital stays in NHS England) so we can check if you have had any hospitals visits throughout the duration of the study.
- We will use this information to develop a programme of management for people with this type of heart problem that takes into account other conditions, quality of life, symptoms and other needs that people have.

2. Why have I been invited?

We have invited you because your general practice or a heart failure service identified you as potentially having this type of heart condition.

3. Do I have to take part?

No. It is up to you to decide whether or not to take part. If you decide to take part and then change your mind you may withdraw at any time without giving a reason. Your decision about whether to take part will not affect your treatment.

4. What will I need to do at the baseline visit if I take part?

We will ask you to attend up to three visits over 1 year. These will be at:

The Cambridge Clinical Research Centre at Addenbrooke's Hospital

At the first (baseline) visit, we will do the following:

- Measure your height, weight, blood pressure and pulse; check your ankles for swelling and listen to your lungs.
- Do a test to assess your memory
- Do a 12-lead electrocardiogram (ECG) to record your heart rhythm

- Do a transthoracic echocardiogram (echo), which is an ultrasound of your heart. The probe is placed on your chest with some gel to view your heart. At Cambridge following the echo we will measure the stiffness of your arteries (this is called pulse wave velocity), this is done by placing a small pen like device at your neck and your groin.

- Collect a blood sample – approximately 30 ml – about 6 teaspoons. The blood tests will include a blood count (which can detect anaemia for example), chemistry (blood sugar, sodium, potassium levels), and tests that let us know about how your heart is working. At Cambridge, we may also store a small volume of blood for new tests as they emerge.

- Ask you to complete a number of questionnaires about your mood, your quality of life, how you care for yourself, and your symptoms. These are important in order for us to understand your perspective and your experiences.

- We will also ask you to perform a 6-minute walk test. This involves walking between 2 markers at your own pace for 6 minutes. You will be able to stop and rest if you need to and chairs will be placed at either end. We will measure the distance that you can walk in 6 minutes.

- You will be provided with rest breaks during this time if you need them.

- We expect that you will spend 2 ½ - 3 hours in the Clinical Research Facilities to complete these assessments.

- Finally, we will ask you to wear an accelerometer (activity monitor) on your wrist for the next week at home. This will record your activity during the day: sitting, standing, walking or other activities. You will receive an envelope to mail the accelerometer back to us.

Participants coming to the Cambridge Clinical Research Facility will have an Addenbrooke's Hospital Electronic Medical Record created and the research visit will be documented on this system. Blood results collected as part of this study will be available to view via this

Electronic Medical Record by all medical professionals at Addenbrooke's Hospital accessing your records at subsequent times.

It is important to note that at the baseline visit we will do some tests to find out whether you have HFpEF. We expect that some patients will not have HFpEF, and we will let you and your primary care provider know this. If you ***do not*** have HFpEF, we will not repeat the test again. We would like to keep your information from the baseline assessment, as we would like to know how people with and without HFpEF differ. If the results from the baseline visit confirm ***you have*** HFpEF, we will invite you to return for a further two follow-up visits at 6 months and 12 months. The results of your echocardiogram and other tests will be reviewed by a panel of experts who will confirm whether or not you have HFpEF. They will not know your identity. This information will be reported back to your GP, with your permission.

5. What will I need to do at the 6 month and 12 month follow-up visit?

We will arrange for you to come back to the Clinical Research Facility after 6 months and 12 months. The echocardiogram will be done once (at baseline), and the blood tests and ECG will be done at baseline and 12 months. At all 3 visits we will assess your height, weight, blood pressure and pulse, ask you to complete the questionnaires and do the 6 minute walk test, and ask you to wear the accelerometer at home.

6. What are the benefits of taking part in this study?

There is no guarantee that you will benefit personally from taking part. With your permission we would like to share the information from the tests with your general practitioner, particularly the results of your echocardiogram. Possible long term benefits of the research are that it will help to improve the care of patients with heart conditions being cared for in general practice. Your contribution will be valuable in helping us achieve this.

7. Are there any risks?

We do not believe you will be harmed in any way by this research although you may find it tiring, and the blood test can result in bruising and discomfort. This study does not involve

testing a drug or medical procedure. If you decide to meet one of our researchers you are welcome to have a family member, carer or friend accompany you if you wish.

8. How will the findings be used?

The results will be used to develop new ways of managing people with heart failure in general practice. The research will be reported in a way that is confidential and your participation will not be identified in any way. The results may be published on the study website and in healthcare journals, presented at conferences and to patient support groups. If you would like to be kept informed of the results please tell the researcher or contact the study team using the details on the last page.

9. What will happen to the information I provide?

All information that is collected is strictly confidential. We will hold your contact information for arranging the study visits separately and securely in a password protected file. Any information that is stored for the project will have your name and address removed so the risk of being identified in reduces and data will be identified by an identification (ID) number only. Your information from your assessment and echocardiogram will be reviewed by an expert panel to determine if you do have heart failure with a preserved ejection fraction. This information will not have any identifying information on it, only your ID number. Only members of the research team will have access to the information. Data will be held in secure storage and destroyed after ten years. Any information that you give will be used for research purposes only and you may ask to see your personal information at any time. To collect information on your hospital visits from NHS Digital, we will share some identifiable information with them (your NHS Number and Date of Birth), this is so they can identify the records we need. NHS Digital have robust information governance policies and IT systems that ensure the way we share data with them, and them with us, is secure and in accordance with good information governance practices.

10. What will happen to the blood samples I provide?

The blood samples you provide will be analysed at:

Blood samples will be disposed of in accordance with the regulations of the Human Tissue Act. At Cambridge, blood samples may be stored for future tests, bloods that are stored will be identified by your study ID only and kept for a maximum period of 10 years; before being destroyed in accordance with the Human Tissue Act.

11. Can I withdraw from the project?

Yes. You may withdraw from the study at any time without giving a reason. This will not affect your treatment or care. If you withdraw we will only retain and use any personal information you have provided up to that point if you give us permission to do so. We will remind you of your right to withdraw at regular intervals and will provide withdrawal options should you decide you no longer wish to take part. Details of withdrawal options will also be included on the study website. If you become unwell during the study to the extent that you are no longer able to provide consent, we will withdraw you from the study and retain and use the information you have provided up to that point.

12. What if there is a problem or I want to make a complaint?

If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions. If you wish to speak to somebody who is independent you can contact Cambridge University Hospital's Patient Advice and Liaison Service (PALS):

Address	Box 53, Cambridge University Hospitals, Cambridge Biomedical Campus, Hills Road, Cambridge, CB2 0QQ
Phone	01223 216756 (Monday to Friday: 9am to 4pm)
Email	pals@addenbrookes.nhs.uk

13. Who has organised the research?

The Chief Investigator for the study is Professor Christi Deaton, Department of Public Health & Primary Care, University of Cambridge, who is working with researchers from the Nuffield Department of Primary Care Health Sciences, University of Oxford. The sponsors for the research are Cambridge University Hospitals NHS Foundation Trust and the University of Cambridge.

14. How has this study been reviewed?

Before funding for the study was awarded, it was reviewed twice by external researchers and a patient representative, and the investigators made changes to improve the study. The study and all documents have also undergone ethical review by London-Surrey Research Ethics Committee (REC reference 17/LO/2136). This is necessary before any study can be conducted.

15. How has this study been funded?

The research is funded by the National Institute for Health Research as part of its School of Primary Care Research programme (award #384).

16. Further information and contact details

If you would like more information please contact:

Patients in the East of England		
Faye Forsyth	01223 762561	OptimiseHFpEF@medschl.cam.ac.uk

17. General Data Protection Regulations Transparency Information

Cambridge University Hospitals NHS Foundation Trust and University of Cambridge is the joint sponsor for this study based in England. We will be using information from you and your medical records in order to undertake this 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. Cambridge University Hospitals NHS Foundation Trust and University of Cambridge will keep identifiable information about you for 10 years after the study has finished. Your rights to access, change or move your information are 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 by emailing research@addenbrookes.nhs.uk

When you agree to take part in a research study, the information about your health and care may be provided to researchers running other research studies in this organisation and in other organisations. These organisations may be universities, NHS organisations or companies involved in health and care research in this country or abroad. Your information will only be used by organisations and researchers to conduct research in accordance with the UK Policy Framework for Health and Social Care Research. Your information could be used for research in any aspect of health or care, and could be combined with information about you from other sources held by researchers, the NHS or government. Where this information could identify you, the information will be held securely with strict arrangements about who can access the information. The information will only be used for the purpose of health and care research, or to contact you about future opportunities to participate in research. It will not be used to make decisions about future services available to you, such as insurance. Where there is a risk that you can be identified your data will only be used in research that has been independently reviewed by an ethics committee.

Cambridge Specific Information

Cambridge University Hospitals NHS Foundation Trust and University of Cambridge will use your name, NHS number or medical record number and contact details to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Individuals from Cambridge University Hospitals NHS Foundation Trust and University of Cambridge and regulatory organisations may look at your medical and research records to check the accuracy of the research study. The only people in Cambridge University Hospitals NHS Foundation Trust and University of Cambridge who will have access to information that identifies you will be people who need to contact you to audit the data collection process. The people who analyse the information will not be able to identify you and will not be able to find out your name, NHS number or medical record number or contact details. Cambridge University Hospitals NHS Foundation Trust and University of Cambridge will keep identifiable information about you from this study for 10 years after the study has finished.