Health Improvement through Weight Management in Atrial Fibrillation (HiWeiMan AF)

Introduction

You are being invited to take part in a research study. The study will explore problems which people who have atrial fibrillation may experience in maintaining a healthy weight. This is entirely voluntary and you can choose whether or not to take part without any impact on your care. Please take time to read this information to help you decide whether you would like to take part or not.

What's it about?

Atrial fibrillation (AF) is a condition where an irregular heartbeat affects the ability of the heart to pump efficiently. It is not dangerous in itself, but people with AF may be aware of palpitations or fluttering in the chest, they may feel lightheaded, breathless or short of energy. About 1.4 million people in the UK have AF.

Because there is no cure for AF at present, treatments focus on preventing stroke and managing symptoms with medications. Once a person has had an episode of AF, they are likely to experience further episodes. These episodes tend to get longer over time.

Recent research studies suggest that people with AF who are overweight can experience significant improvements in their symptoms and the duration of AF episodes by losing weight. There is some evidence that the progression of the condition may be slowed or even reversed by weight loss. However, many people find it difficult to maintain a healthy weight. People with AF may face additional obstacles to healthy weight management because of their symptoms.

This study aims to explore the experiences of people with AF to help identify ways to make weight management services more appropriate, acceptable and accessible.

What would I have to do?

I am a cardiac research nurse. I am inviting you to take part in this study because you have experience of living with AF. I am interested in your views about weight management and healthy lifestyle, and how this has been explained to you by health care providers.

Please take as long as you need to decide whether or not you would like to take part. If you decide to take part, you will be asked to sign a consent form. I will interview you about your experiences and opinions. We can arrange the interview at a convenient time for you.

The interview will include completing two questionnaires about your AF symptoms and your quality of life. There will be questions about how you feel about weight information campaigns, what has helped you in the past or what you find challenging, and how you think weight management services could be improved.

The interview will take place in a private room in the hospital. To avoid unnecessary trips to the hospital in keeping with coronavirus precautions, the interview can be done by telephone or video link if you prefer. It will last about an hour. I will ask to record the interview on a password-protected audio recording device. When not in use the audio recording device will be kept in a locked cupboard in my office in the John Radcliffe Hospital. A password-protected back-up will be kept on the Oxford University Hospitals server in accordance with the OUH Data Protection and Privacy policies, to which only I will have access.

I will phone about a week after the interview to check the key points of your interview with you, add anything further, and confirm you are happy for the anonymised interview to be used. This will be the end of your involvement in the study.

What will happen to my information?

The recorded interview will be transcribed and anonymised so there will be no way to identify you personally. The information you and other participants provide will be analysed and compared to look for common themes and differences in your experiences and opinions, and these will be used to guide service improvement recommendations.

Your Cardiology Consultant and your GP will be informed that you are taking part in a research study.

How will we use information about you?

I will need to use information from you for this research project. Only information you provide in your interview and questionnaires will be used. 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 code number instead.

We will keep all information about you safe and secure.

Once I have finished the study, I will keep some of the data to check the results. I will write my reports in a way that no-one can work out that you took part in the study.

What are your choices about how your information is used?

- You can stop being part of the study at any time, without giving a reason, but I will keep information about you that I already have.
- I need to manage your records in specific ways for the research to be reliable. This means that I won't be able to let you see or change the data I hold about you.
- If you agree to take part in this study, you may have the option to take part in future research using your data saved from this study in the University of Birmingham Research Data Archive.

Where can you find out more about how your information is used?

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- at www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/data-protection-and-information-governance/gdpr-guidance/templates/template-wording-for-generic-information-document/
- our leaflet available from www.hra.nhs.uk/patientdataandresearch
- by asking one of the research team
- by sending an email to dataprotection@contacts.bham.ac.uk
- by ringing us on 0121 414 3916

What are the possible benefits of taking part?

There are no specific benefits to you from taking part. By sharing your experiences and opinions on weight management services and treatments for AF, you may contribute to future improvements.

Because this study aims to gather patients' opinions, I will not be able to give any specific advice about health improvement. However I may be able to answer any questions you have at the end of the interview, or refer you to a clinician or other services who can help with your inquiry. If you wish to be referred to health improvement services, I will be happy to refer you to

the Here For Health service at the John Radcliffe Hospital or the Horton General Hospital, and to inform your Cardiology Consultant and your GP.

What are the possible disadvantages and risks of taking part?

There are no specific risks in taking part. If anything in the interview makes you feel you need additional support or counselling I will arrange this. Your information will be treated in confidence, and your clinical care will not be affected.

Who has funded this study? This is a self-funded academic study.

Will I be offered compensation or reimbursements?

Because this is a self-funded academic research study it will not be possible to reimburse time or travel costs. Interviews will be scheduled at a time which is convenient for you, such as on a day when you already have a hospital appointment.

Who has reviewed and insured the study?

The study is sponsored by the University of Birmingham. The University has in force a Public Liability Policy and Clinical Trials policy which provides cover for claims for "negligent harm" and the activities here are included within that coverage.

This study has been approved by the London - Bromley Research Ethics Committee.

What if I have concerns about the conduct of the study?

If you have any concerns about this study, you can contact Oxford University Hospitals Patients Advice and Liaison Service (PALS) Tel 01865 221 473 or email PALS@ouh.nhs.uk

Alternatively you may contact the study sponsor:

Dr Birgit Whitman
Head of Research Governance and Integrity
Research Support Group
Room 117, Aston Webb Building
The University of Birmingham
Edgbaston, B15 2TT
Email: Researchgovernance@contacts.bham.ac.uk
Phone: 0121 4158011

Further information

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Oxford University Hospitals NHS Foundation Trust

I am a Clinical Research Nurse from Oxford University Hospitals NHS Foundation Trust. I am carrying out this research as part of a Masters Degree at the University of Birmingham.

For further information please contact Rachel Bates (Clinical Research Nurse) on 01865 740 422 or email rachel.bates@ouh.nhs.uk