The Newcastle upon Tyne Hospitals

NHS Foundation Trust

Decision-making about implantable defibrillators (ICDs)

We are conducting a study to better understand how people make decisions about implantable cardioverter defibrillator (ICD) therapy. We would like to invite 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. Please feel free to talk to other people about the study if you wish and please ask us if there is anything that is not clear or if you would like further information. At the end of this information leaflet you will find details on how to contact us and what you can do if you have any concerns.

What is the purpose of the study?

Implantable cardioverter defibrillators (ICDs) are complex devices with both benefits and risks. We are conducting this study to better understand the information and support needs of those people thinking about having a device and for others who are living with an ICD. The study is led by Professor Richard Thomson and Dr Catherine Exley at Newcastle University.

Why have you been chosen and do you have to take part?

You have been asked to take part because you were identified as someone who may be eligible for an ICD. Participation in the study is entirely voluntary and it is up to you to decide whether or not to take part. You are free to withdraw from the study at any time, without giving a reason. Refusal to take part in the study will not affect the care you receive or your legal rights.

What will I have to do?

If you think you want to take part in the study, a researcher, Holly Standing, will be in touch with you by phone to ask if you are still interested in participating in the study and to arrange a convenient time to conduct the interview. At this point you can ask any questions that you might have and discuss particular aspects of the study further.

The interview will take place at a location most convenient for you (e.g. your home) or by telephone if you prefer. The researcher will introduce herself, answer any additional questions and ask you to sign a consent form. With your permission we will record the interview. The interview will last about 60 minutes, depending on how you feel and how much you have to say.

During the interview you will be asked questions about your views of the decision making process for an ICD. If at any time during the interview you feel uncomfortable about any of the topics raised, you may choose not to answer a particular question or to end the interview and if necessary withdraw from the study.

With your permission we will record your contact details for the purpose of getting in touch in the future to share the findings of the study and to offer you the opportunity to take part in a workshop to help to design a decision support tool.

What are the possible risks of taking part?

Every effort will be made to ensure your comfort and well-being, although it is possible that taking part in an interview may make you feel tired. If this happens you can take a break or you can stop the interview if you wish. There is a possibility that some topics raised during the interview may be difficult or upsetting. You do not have to talk about those topics if you do not want to. If you would like to discuss any distressing or upsetting issues further we can, with your permission, inform a member of the clinical team who is responsible for your care. Please remember that you are free to stop taking part in the study at any time, and this will not affect your current (or future) care or legal rights.

What are the possible benefits of taking part?

We cannot promise the study will help you as an individual but the information we get from this study may help to improve information and decision support for other

people considering (or living with) an ICD and their families. This may in turn deliver benefits for future ICD recipients and their families.

Will my taking part in the study be kept confidential?

YES - We will follow ethical and legal practice and all information about your participation will be confidential. More detail on how we will ensure confidentiality can be found in Part 2 of this information leaflet.

This completes Part 1 of this information leaflet. If the information in part 1 has interested you, and you are considering participation, please read Part 2 before making a decision.

Part 2: Detailed information about the conduct of this study

What will happen if I change my mind about taking part?

If you agree to participate in an interview but later decide that you no longer wish to take part in this study, please contact a member of the research team using the contact details at the end of this leaflet (quoting your unique identification number that is printed on the consent form).

You are also free to stop the interview at any time, without giving a reason and without your medical care or legal rights being affected. At this point we can also destroy any information you have provided in the interview, but we will ask for your permission to continue to use the information that we have collected up until this point.

Will my taking part in the study be kept confidential?

YES. We will not share details of your participation in the study with anyone outside the research team. However, should anything come to light that would suggest malpractice or misconduct, or suggest that any individual was in danger of harm we would have to report this to the appropriate personnel.

Your name or any other information that could identify you will not appear in any reports, publications or presentations based on findings from the study. We may want

to use direct quotes from participants, but these would only be quoted as coming from "a participant" or a participant with a certain label, like "one patient said."
In accordance with Newcastle University's policy on data protection and storage, the typed-up information in note books and transcripts of the interviews will have all names and other identifiers removed, and will be kept in a locked filing cabinet. This information will also be securely stored on password protected computers in the Institute of Health and Society at Newcastle University.

What if there is a problem?

In the unlikely event that you should lose capacity during the interview and are no longer able to participate in the study, any data collected with consent up until that point will be retained and used in the study.

Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed. If you have a concern about any aspect of this study, you should ask to speak to the study lead, Professor Richard Thomson (0191 222 7832), who will do his best to answer your questions. If you remain unhappy and wish to complain formally, you can do this by contacting the hospital's Patient Advice and Liaison Service (0800 032 0202).

What will happen to the results of the study?

We intend to publish the findings in a report, scientific journals and to present the findings at scientific meetings. Any information that could identify you will not be included in any report or publication. We will also hold a dissemination event where we will share the findings of the study with participants; you will have the opportunity to attend this event if you wish. With your permission we would also like to use the information collected in this study for future research projects and educational purposes. It will not be possible to identify you from this information and no further contact will be made with me.

Who is organising and funding the research?

The sponsor of the research is Newcastle upon Tyne Hospitals NHS Foundation Trust and Newcastle University. The study is funded by the National Institute for Health Research (NIHR) Health Services and Delivery Research Programme.

Who has reviewed the study?

The study has been reviewed by the Sunderland Research Ethics Committee and a favourable opinion was given.

What happens next?

A member of the research team, Holly Standing, will contact you, by phone, to explain the study further and to answer any questions you may have. If you are still willing to take part then a convenient time and place to conduct the interview will be arranged. If you prefer the option of a telephone interview you will be asked to complete the consent form in the study information pack and to return it to the University in the prepaid envelope supplied. If you would prefer to conduct the interview face to face then you do not have to complete and return the consent form in advance.

How to contact us

If you have any questions about the study, or would like more information, please contact:

You can also contact the Patient Advice and Liaison Service (PALS) if have any questions or concerns about this study:

North of Tyne PALS Freepost: RLTC-SGHH-EGXJ

The Old Stables, Grey's Yard, Morpeth, NE61 1QD

Freephone: 0800 0320202

Fax: 01670 511260

Text: 01670 511098

Email: northoftynepals@nhct.nhs.uk

Additional information and support is also available at:

Arrhythmia Alliance

24hr HELPLINE: 01789450787

PO Box 3697,Stratford-Upon-Avon,Warwickshire, CV37 8YL

info@heartrhythmcharity.org.uk

Thank you for reading this information sheet