National Institute for Health Research

FAMILY MEMBER/CARER INFORMATION SHEET, PHASE 2

Understanding shared decision making about major surgery

Version 1.2, 13 December 2018

We'd like to invite you to take part in our research study. Before you decide, it is important that you understand why the research is being done and what it would involve for you. Please take time to read this information, and discuss it with others if you wish. If there is anything that is not clear, or if you *would like more information, please ask us.*

What is the purpose of the study?

We are a research team from the University of Oxford, studying the process of shared decision making for patients contemplating major surgery who may be considered 'higher risk' due to age and / or other medical conditions e.g. heart, kidney, lung problems. This study is the first part of a much larger research programme, funded by the National Institute of Health Research, to develop ways of optimising shared decision making for major surgery. The reason for the research is that we do not yet know enough about what happens in shared decision making discussions, which makes it hard to know what could be improved or how we should do this.

Our research team aims to understand: (a) the reasons people choose or decline major surgery, including perceptions of the potential positive and negative outcomes, and to see how these change over time; (b) what shared decision making really means for patients, families and clinical teams; (c) the information patients and doctors exchange before and after surgery, and (d) how this shapes shared decision making. By doing this research we are seeking to develop potentially new and better ways of ensuring patients and doctors engage in shared decision making when considering major surgery.

To achieve our research aims we are looking to talk to doctors and patients about their experiences of making a decision about major surgery.

Why have I been invited?

Someone close to you has been offered (and possibly, but not necessarily undergone) surgery in the last 12 months and has asked that you support them to participate in this research. Alternatively, you might have seen a poster or similar information about the research and have chosen to get in touch with the research team.

Do I have to take part?

No, taking part is entirely voluntary and you can withdraw at any time if you later change your mind, without giving a reason. Withdrawal will not affect the current or future clinical care of the person close to you (or you) in any way, as the research team is separate from their medical team.

What will happen to me if I decide to take part?

At this stage you got in touch with the research team directly. The researcher will tell you more about the study and what participating in a focus group would involve, ask if you have questions and if you are ready to make a decision about whether or not you want to take part. If you decline to take part then we will not contact you again. If you confirm that you would like to take part in the research then the researcher will send you a consent form and ask you to sign and return that to confirm that you agree to take part.

The researcher will invite you to a focus group, which will take place up to 6 weeks later. The focus group will involve up to 10 people all of whom, like yourself, have cared for someone who has been offered surgery in the past 12 months or have been offered major surgery themselves in the previous 12 months. The researcher will guide discussion amongst the group about people's experience of illness and their decision making about surgery. They will bring several decision making scenarios about surgery along to the group that the team will have developed from previous phases of the research and ask everyone for their views on those. With permission, the researcher would like to tape (audio) record the focus group discussion. The focus group will be held locally, for instance at your local hospital or community centre. It will last no more than 1.5 hours.

What should I consider?

The main thing to consider is whether you are comfortable with researchers asking you questions and discussing your views in a group; also whether you are comfortable with the discussion being audio-recorded.

Are there any possible disadvantages or risks from taking part?

The main disadvantage of the focus group is that we are asking you to commit some time, and we will ask you to share your experiences of supporting someone who has been offered surgery with the other members of the group. Also, whilst the research team can assure confidentiality, we can only encourage and advise others in the group to do the same.

What are the possible benefits of taking part?

The main benefit of taking part is the research is an opportunity for you to contribute to a programme of research that focuses on improving shared decision making for other people.

Will my taking part in the study be kept confidential?

Yes. All data from the study will be made anonymous. They will be kept on a secure part of the server at the University of Oxford and only accessible by the research team. In those stored data, you will be referred to only by a code name ('pseudonym'). We will keep a separate paper record in a locked cabinet of participants' real names and corresponding code names. Audio recordings may be processed by a transcriber with a contractual agreement with the University. Transcribers are subject to the same requirements of confidentiality as researchers. They will have no other identifying information about you, and will not retain the audio recordings.

Responsible members of the University of Oxford and the relevant NHS Trust(s) may be given access to data for monitoring and/or audit of the study to ensure that the research is complying with applicable regulations.

At the start of each focus group, the researcher will ask that all participants treat discussions as confidential. However, the research team are unable to guarantee that other focus group participants will treat any information you give in this way.

Will I be reimbursed for taking part?

Yes, we will refund reasonable travel expenses (on production of receipts or millage allowance). We will also offer a £10 Amazon voucher to those attending focus groups in recognition of the time and effort taken to participate.

What will happen to my data?

Data protection regulation requires that we state the legal basis for processing information about you. In the case of research, this is 'a task in the public interest.' The University of Oxford is the data controller and is responsible for looking after your information and using it properly.

We will be using information from focus groups and will use the minimum personally-identifiable information possible. We will store research data (anonymised), audio recordings, and any research documents with personal information (such as consent forms) securely at the University of Oxford for up to six years after the end of the study.

Data protection regulation provides you with control over your personal data and how it is used. When you agree to your information being used in research, however, some of those rights may be limited in order for the research to be reliable and accurate. Further information about your rights with respect to your personal data is available at http://www.admin.ox.ac.uk/councilsec/compliance/gdpr/individualrights/]

You can find out more about how we use your information by contacting Sara Shaw, Chief Investigator for the study, using the contact details at the bottom of this Information Sheet.

What will happen if I don't want to carry on with the study?

You can stop at any time. Participation is voluntary and even if you originally said yes, you may change your mind at a later stage. If you withdraw from the study any material that has been collected whilst you have been in the study will be used for research as detailed in this participant information sheet.

Withdrawal from the study will NOT affect the care you or your family member/close friend receive from the NHS now or in the future.

What will happen at the end of the study?

We will analyse the data and write some papers and reports, including a 'lay summary'. We will provide you with a summary of the findings if you would like us to. You will not be identified from any report or publication placed in the public domain as we will anonymise any quotes that we use from focus groups.

Some of the research being undertaken may also contribute to the fulfilment of an educational requirement such as a doctoral thesis.

What if there is a problem?

The University of Oxford, as Sponsor, has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your participation in this study.

If you wish to complain about any aspect of the way in which you have been approached or treated during the course of this study, you should contact Professor Sara Shaw whose details are given below, or Professor Trisha Greenhalgh (Professor Shaw's line manager, same address). Alternatively, you may contact the University of Oxford Clinical Trials and Research Governance (CTRG) office on 01865 616480, or the head of CTRG, email ctrg@admin.ox.ac.uk.

How have patients and the public been involved in this study?

People with experience of having to make decisions about surgery were involved in helping design this study and have also checked this information sheet and consent form.

Who is organising and funding the study?

The study is funded by National Institute of Health Research (NIHR). It is part of the *Optimising Shared decision-makIng for high RIsk major Surgery* (OSIRIS) research programme. The study team is led by Professor Sara Shaw, who works at the University of Oxford; she is also custodian of the study information.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect participants' interests. This study has been reviewed and given favourable opinion by [INSERT NAME OF RESEARCH ETHICS COMMITTEE]. The reference number is [INSERT].

Further information and contact details:

Please contact the following individual if you would like further information.

Professor Sara Shaw (Chief Investigator)
Nuffield Department of Primary Care Health Sciences
University of Oxford
Radcliffe Observatory Quarter
Woodstock Road
Oxford OX2 6GG

T: 01865 617830
E: charlotte.thompson-grant@phc.ox.ac.uk

Thank you for considering taking part.