Insert local NHS Trust logo here

Cluster randomised trial on optimising shared decision-making for high-risk major surgery (OSIRIS Trial)

PATIENT INFORMATION SHEET

Version: 2.0 28.03.2023

Principal Investigator: [insert name]

IRAS: 282492

Introduction

You are being invited to take part in a research study, intended to improve shared decision making for patients who have a problem for which they could be offered surgery. Before you decide whether to take part, it is important to understand why this research is being done and what it involves. Please take time to read the following information and decide whether or not you wish to take part. Talk to your friends and family about the study if you wish and ask us if anything is unclear.

What is the purpose of the study?

We are a research team from Queen Mary University of London (QMUL), working with doctors and nurses at [INSERT NAME OF TRUST]. We are studying how patients who might require surgery make decisions together with their doctors. This study is part of a much larger research programme, funded by National Institute of Health Research, to develop ways of understanding and improving the shared decision making process for surgery. Shared decision making ensures that individuals are supported to make decisions that are right for them. It is a collaborative process which brings together the clinician's expertise, such as treatment options and the evidence, risks and benefits of these and what the patient knows best: their preferences, personal circumstances, goals, values and beliefs. Decision support aids support discussions where clinician expertise (and treatments) and patients' expertise (about themselves and their lives) can be effectively brought together.

We have developed the OSIRIS decision aid which is a computer based decision aid intended to support effective shared decision making by helping you understand how surgery might

impact long-term health. The aim is that patients will be able to make a more informed choice about surgery, and its risks and benefits, than has been previously possible.

Why have I been invited?

You have been invited because your surgeon has identified you as someone who may be suitable for our study, in terms of your age and general health, and who might wish to take part.

Do I have to take part?

No. It is up to you to decide whether or not you would like to take part in the study. If you decide to take part, you will be asked to sign a consent form. You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have. If you decide not to take part, or later to withdraw, this will not affect any aspects of the care you receive.

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

In the OSIRIS trial, your hospital will either be in the standard care group or the intervention group. For both groups, an experienced doctor or nurse from our research team will ask you to complete some information about yourself, including how your medical conditions affect your life and their impact on your quality of life. In the standard care group, your doctors will provide details about your condition and possible treatments according to their usual ('standard') practice. If your hospital is in the intervention group, you will be asked to enter additional information about your current health and healthcare priorities into the OSIRIS decision aid. According to the information entered, a summary of the risks of complications and/or other illness that could develop after major surgery specifically for higher-risk patients will be produced. During the consultation, your doctor will review and discuss the information from the decision aid with you using pictures, graphs and simple texts.

Some intervention group hospitals are also collecting some more detailed data about how decision-making occurs. If applicable, one of the researchers will ask if you are also willing to have us record your consultation with the surgeon. The recordings will be anonymised before anyone else hears it. Your name will be "bleeped" and other identifying features will be anonymised. At the end of the consultation the researcher will check that you are still willing for the recording to be used in the research. The researcher will also conduct a brief (no more than 20 minutes) interview and questionnaire with you following the consultation to explore any decisions you made regarding your treatment. This can either take place immediately after the consultation or via a phone call later on. Only with your permission and after written

consent, would the researcher audio record the interviews. Please note this is optional and you can take part in the main study and say no to this part if you wish. This will be documented in the informed consent form.

On the day of your surgery and the period shortly after, we will be reviewing your medical records and may talk to your doctors to collect information about you and your recovery. We will also contact you by telephone in one month and again in six months time to ask you some simple questions about your wellbeing. The phone call will last around 10 minutes.

What should I consider?

The main things to consider are whether you are comfortable with providing your views and expectations on long-term surgical outcomes in the decision support aid and having the researchers observe or record a consultation between you and the surgeon with the provision you have consented for the recording.

Are there any possible disadvantages or risks from taking part?

The main disadvantage of taking part is we are asking you to commit some time to answer questions on your experience in the consultation. For the recording component of the study, the researchers will be able to hear you having a consultation, which you might prefer should be kept private to you and the surgeon.

What are the possible benefits of taking part?

The main benefit of taking part in the research is an opportunity for you to contribute to a programme of research that focuses on improving shared decision-making processes during surgery for other people like yourself.

What if I am not happy about the study?

Taking part in the study does not affect the way you are cared for in hospital. However, if you have a concern about any aspect of this study, you should ask to speak with someone from the research team, who will do their best to answer your questions. You may also contact the doctors and nurses who lead the study at this hospital on the telephone number at the bottom of this information sheet. You can also contact your Patient Advisory Liaison Service (PALS) [change according to site-specific department name] if you have any concerns regarding the care you have received, or as an initial point of contact if you have a complaint. Please telephone [insert local equivalent] or email [insert local equivalent]. You can also visit PALS [change according to site-specific department name] by asking at hospital reception. QMUL has agreed that if in the unlikely event you experience harm as a direct result of the procedures

you received during the study, you will be compensated. These special compensation arrangements apply where an injury is caused to you that would not have occurred if you were not in the study. These arrangements do not affect your right to pursue a claim through legal action.

How will we use information about you?

Our procedures for handling, processing, storage and destruction of data are compliant with the Data Protection Regulations. We will need to use information from you and from your medical records for this research project. This information will include your:

- Initials
- NHS number*
- Name*
- Date of birth and age*
- Gender
- Ethnicity
- Postcode*
- Contact details*

The information will be used to:

- do the research or to check your records to make sure that the research is being done properly by researchers, the Sponsor (and its representatives), regulatory authorities, and the NHS Trust/ Health Board, where it is relevant to this research.
- send your identifying information (marked with *) from Queen Mary University of London to NHS Digital which is a government organisation that holds information on hospital admissions (Hospital Episode Statistics) and mortality data sourced from Civil Registration Data and supplied by NHS Digital on behalf of the Office for National Statistics (ONS). The identifying information we send is the minimum amount we can use to make sure we get information about the right person. It is transferred securely to maintain confidentiality, and the information NHS Digital sends back uses your unique study ID number but not your identifying information.

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 unique study ID instead. We will keep all information about you safe and secure. Once we have finished the study, we will keep some of the data including the consultation recordings for 25 years by Queen Mary University of London so we can check

the results. All documents including the recordings will be destroyed following archiving. We will write our 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 we will keep information about you that we already have.
- If you choose to stop taking part in the study, we would like to continue collecting information about your health from central NHS records and your hospital. If you do not want this to happen, tell us and we will stop.

We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

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/
- by asking one of the research team
- by sending an email to admin@osiris-programme.org
- by ringing us on 020 3594 0352
- by emailing the QMUL data protection officer at: data-protection@qmul.ac.uk

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

If you decide not to take part, or later withdraw, this will not affect the standard of care you receive. You are free to stop taking part at any time without giving a reason, but the research team will keep your research data. You can find out what would happen with your data before you agree to take part in the study.

Who is organising and funding the research?

The study is funded by the National Institute for Health Research and coordinated by the Critical Care and Perioperative Medicine Research Group at QMUL. QMUL will also act as the Sponsor and the data controller for this study. Your doctor will not receive any payment for including you in the study.

Who has reviewed the study?

All research in the NHS is reviewed by an independent Research Ethics Committee, to protect the interests of the patients who take part. This study has also been reviewed and granted a favourable opinion by the Health Research Authority (HRA), Medicines and Healthcare products Regulatory Agency (MHRA).

What will happen to the results of this study?

Once we have finished the study, we will keep some of the data including any so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study. QMUL is required by research regulations to keep the study data for a minimum of 25 years after the study has been completed. The data will be kept in a secure facility only accessible to authorised personnel.

Thank You!

Thank you for considering taking part in this study and for reading this information sheet, which is yours to keep. If you decide to take part in the study, you will also be given a copy of your signed consent form.

Your study doctor is:	
Name:	Contact phone number:
Your research/specialist nurse is:	
Name:	Contact phone number: