REVERE Breathe

Information for Participants

Study title

Feasibility of the use of Interactive Technology-enhanced Incentive Spirometry (InspireVR) to reduce post-operative pulmonary complications following elective oesophagectomy and total gastrectomy

Invitation to take part

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. One of our team will go through this information sheet with you and answer any questions you have. This should take approximately 30 minutes.

What is the purpose of the research?

We are looking for new ways to help patients carry out breathing exercises for following elective oesophagectomy (removal of oesophagus) or gastrectomy (removal of stomach).

We advise patients who have undergone one of these operations to practice regular breathing exercises (incentive spirometry) during their early recovery to reduce the risk of postoperative complications, such as pneumonia and chest infections. We recommended that patients complete 10 deep breaths every hour during the day for the first few days after their operation. Currently, we give patients a device called a Spiroball to help them to complete the exercises. This research will evaluate whether a new device, InspireVR, can also be used by patients to help them complete these exercises with a better outcome.

Who is doing this research?

The research team (hereby referred to as “we”) is a group of doctors, nurses and specialists in interactive technologies from the University of Birmingham. Some members of the research team are using this study to contribute towards higher research degrees, e.g. PhD.

Why have I been invited to take part?

We will carry out this study in all consenting patients who are undergoing an elective oesophagectomy or gastrectomy and will be admitted to the intensive care (critical care) unit at the Queen Elizabeth Hospital, Birmingham (QEHB) or Birmingham Heartlands Hospital between the dates 1st November 2016 to 30th April 2017.

Do I have to take part?

No. It is entirely your choice and there are no negative consequences for not choosing to take part. If you choose to participate in the study, you will be asked to sign a form giving your consent. This will be INFORMED consent, which means that the person inviting you to participate in the study will go through the written information with you in order to make sure that you fully understand what you are signing. You will also be given time to think about your decision and ask any questions.

What will I be asked to do?

There will be a screening process to decide if you are suitable to be selected as a participant. We will review your medical notes and discuss your planned care with your doctors and nurses before your admission for the operation. A member of the research team will see you during your visit to the preoperative assessment clinic. They will ask if you would like to participate in this study and answer any questions you have. If you would like to talk part, written consent will be taken at this point. During the preoperative assessment clinic visit the physiotherapist will demonstrate the current device (Spiroball) and new device (InspireVR) used for breathing exercises after the operation. We will ask you to participate in the study for three days after your operation. You will be advised to carry out the breathing exercises every hour during the daytime, up to 10 times a day. We will ask you to alternate the device you use, Spiroball then Inspire VR, each hour. If you are unable to use the InspireVR, you may just use the Spiroball for each set of breathing exercises. The InspireVR will not be available to use after the trial has ended, you will be offered the Spiroball instead.

Each day, we will ask you a few questions about your experience using each device. At the end of the study, we will invite you to take part in a short interview with one of the research team to discuss your experience.

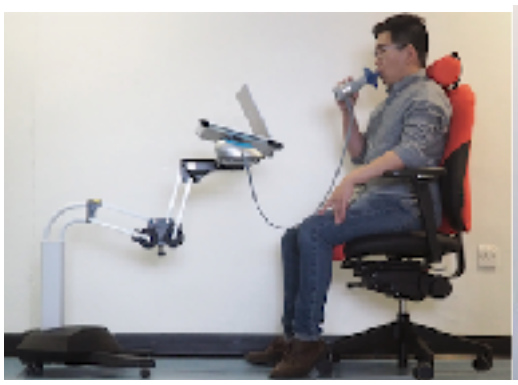
We are asking some patients if they would agree to a video recording of their bedspace, for one day of the study. When we introduce new equipment into a hospital setting, it is important for us to see whether it interferes with your care, for example, whether it gets in the way of the nurses as they look after you. To assess this, we would like to video record the activity within your bedspace for 10 hours. Your privacy will be respected at all times during the video recording, it will be covered during undressing, bathing, using the commode and at any other time you request. This recording will be analysed by the research team to assess the impact of the new device on its surroundings. This analysis will happen immediately after it has been collected. The video recording will not be shared with, or accessed by, anyone apart from the research team. The video recordings will be destroyed as soon as they've been analysed by the research team. **This part of the study is not mandatory - if you would prefer not to participate in video recordings you may still participate in the rest of the study.**

We would like to review your patient records 30 days after you have completed the trial to look for any post operative complications. This information is routinely collected by your clinical team so will not involve any extra time or hospital visits.

What is the device or procedure that is being tested?

We are testing the feasibility of using a new device, InspireVR. InspireVR has been designed to help patients to complete breathing exercises (incentive spirometry) following oesophagectomy ot gastrectomy. The aim of incentive spirometry is to increase the maximum volume that patients can breathe in. This encourages the lungs to open up fully and reduces the risk of developing postoperative pulmonary complications, such as pneumonia and chest infections.The device consists of a breathing tube (spirometer) which measures the volume of the inhaled, and sends the information to a computer program. This program converts the patient's breath into the movement of a trebuchet (catapault) on a computer screen. The trebuchet fires rocks into the sea. The greater the volume of the breath (the deeper the patient breathes in) the further the rock will be thrown. Patients will be able to move up levels in the game as their breath volume increases.

InspireVR has been designed to be used by patients independently, without the help of the nurses or therapists.




Images of InspireVR

Image of Spiroball

What are the benefits of taking part?

We cannot promise the study will help you but the information we get from this study will help the treatment of patients who have undergone an oesophagectomy or gastrectomy.

What are the possible disadvantages and risks of taking part?

Previous studies using computer games have reported occasional nausea, a bit like travel sickness. This is called cybersickness. Approximately 3-5% of participants will experience this, usually within 5-10 minutes after viewing starts. If you feel this, we can turn off the InspireVR system and the symptoms will subside quickly. A very small number of sufferers of cybersickness will experience flashbacks of the nausea at a later date.

Can I withdraw from the research and what will happen if I don't want to carry on?

Yes. Once you give your consent to us, you are able to withdraw this consent at any time with no adverse consequences to your medical care. Once data is collected from you, you are entitled to ask us to remove this data from our records within the first 14 days after its collection. This is because once the data is put onto a database, it becomes anonymous so it will not be possible to identify which data belongs to you.

Are there any expenses and payments which I will get?

No. The study will not involve any extra time or visits to the hospital and will form part of your treatment whilst you stay in hospital. Therefore there are no expenses to claim for.

Will my taking part or not taking part affect my medical care?

No, absolutely not. Taking part in the study is voluntary and will not impact on other parts of your medical care. The Hospital Consultant(s) responsible for your care will be informed of your participation in this study.

Whom do I contact if I have any questions or a complaint?

If you have a concern about any aspect of this study, you should ask to speak to any member of the research group who will do their best to answer your questions. 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 remain unhappy and wish to complain formally, you can do this via the patient services team. They can be contacted via: Patient Services Manager,
4th Floor, Nuffield House,
Queen Elizabeth Hospital,
Birmingham, B15 2TH
Telephone: 0121 627 2950

What happens if I suffer any harm?

If for any reason you come to any harm, the study will be stopped and you will receive any necessary treatment for this. We must emphasise that the nature of this study means that the risk of any potential harm is very minimal. In the event that something does go wrong and you are harmed during the research and this is due to someone‘s negligence then you may have grounds for a legal action for compensation against University Hospitals Birmingham NHS Trust. but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you

Will my records be kept confidential?

Yes. All information which is collected about you during the course of the research will be kept strictly confidential. All participants will be allocated a unique reference number to maintain confidentiality. The data will be used to report findings of the study but it will remain anonymous. Direct quotes obtained from the research may be used in the publication of this trial but participants will not be identified in any way. Data will be stored securely and will be encrypted.

Who is organising and funding the research?

The chief investigator is Dr Charlotte Small, an Anaesthetic Registrar. The Principal Investigator for this unit is Dr Catherine Snelson. The Ministry of Defence has approved and will fund the research. This research is being carried out not for profit.

Who has reviewed the study?

All research in the NHS and MoD is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given favourable opinion by the local NHS Research Ethics Committee and Medicines and Healthcare products Regulatory Agency (MHRA).

Further information and contact details.

Dr Charlotte Small. Dept of Anaesthesia Queen Elizabeth Hospital Birmingham, Mindelsohn Way, Edgbaston, Birmingham, B15 2WB. Tel: 0121 371 2777 Should you have any questions about taking part in research you can contact Dr Tom Clutton- Brock, Consultant Intensive Care Medicine, at the above address. Should you have any questions about taking part in this project you can contact Dr Tony Whitehouse, Consultant Intensive Care Medicine and Anaesthesia, at the above address. If you, or your family or friends, wish to talk to someone independently about the study and whether you wish to take part you might want to contact the Patient Advisory Liaison Service on 0121 371 3280

Compliance with the Declaration of Helsinki.

This study complies with the Declaration of Helsinki, which is a statement of ethical principles for medical research including human subjects.