

# REVERE Breathe

<b>Submission date</b> 10/04/2017	<b>Recruitment status</b> No longer recruiting	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
<b>Registration date</b> 24/04/2017	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
<b>Last Edited</b> 08/11/2017	<b>Condition category</b> Respiratory	<input type="checkbox"/> Individual participant data <input type="checkbox"/> Record updated in last year

## Plain English summary of protocol

### Background and study aims

Patients who are undergoing major surgery to remove part of the oesophagus (gullet) or stomach are advised to complete deep breathing exercises during their early recovery to reduce the risk of post-operative complications, such as lung infections. These exercises may include the use of a device called an incentive spirometer (a medical device used to help patients improve the functioning of their lungs). The patient breathes in through the device as slowly and as deeply as possible, and then holds their breath for three seconds. At present, these are non-electronic devices that do not record how well or how often the patient uses them, nor gives feedback as to how their lungs are performing. This study is looking at a new device called InspireVR, which has been developed to help patients undertake incentive spirometry. Commercial-off-the-shelf products have been combined with purpose-built software to produce an incentive spirometry-based “game”. InspireVR has been designed to remind patients to complete incentive spirometry, encourage them to perform the exercises correctly and record activity for their clinician to review. The aim of this study is to evaluate the usability of this device.

### Who can participate?

Adults who are undergoing major surgery to remove part of the oesophagus (gullet) or stomach.

### What does the study involve?

At the start of the study, participants are screened to find out if they are suitable to take part. This involves the research team reviewing medical notes and discussing planned care with doctors and nurses before admission for the operation. Patients are seen by a member of the research team during their visit to the preoperative assessment clinic, who ask if they would like to participate in the study and answer any questions. If the patient would like to talk part, written consent is taken at this point. During the preoperative assessment clinic visit the physiotherapist demonstrates the current device (Spiroball) and new device (InspireVR) used for breathing exercises after the operation. Patients participate in the study for three days after their operation. They are advised to carry out the breathing exercises every hour during the daytime, up to 10 times a day, alternating the device used, Spiroball then Inspire VR, each hour. Each day, a member of the research team interviews the participant about their experience using each device. Some patients are also asked if they would agree to a video recording of their bedspace, for one day of the study. This recording is analysed by the research team to assess the impact of the new device on its surroundings.

What are the possible benefits and risks of participating?

The study may not benefit participants, but the information gained will help the treatment of future patients who undergo this type of surgery. 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. Symptoms usually subside a few minutes after turning the device off.

Where is the study run from?

1. Queen Elizabeth Hospital (UK)
2. Birmingham Heartlands Hospital (UK)

When is the study starting and how long is it expected to run for?

August 2016 to January 2018

Who is funding the study?

Ministry of Defence - Defence Medical Services (UK)

Who is the main contact?

Dr Charlotte Small

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## Contact information

**Type(s)**

Public

**Contact name**

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## Additional identifiers

**Protocol serial number**

32850

## Study information

**Scientific Title**

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

### **Study objectives**

The aim of this study is to evaluate the usability of a novel device called InspireVR. InspireVR has been developed using a human-centred design process to help patients undertake incentive spirometry.

### **Ethics approval required**

Old ethics approval format

### **Ethics approval(s)**

West Midlands - Edgbaston Research Ethics Committee, 22/02/2017, ref: 16/WM/0458

### **Study design**

Non-randomised; Interventional; Design type: Treatment, Prevention, Education or Self-Management, Device, Psychological & Behavioural, Complex Intervention

### **Primary study design**

Interventional

### **Study type(s)**

Treatment

### **Health condition(s) or problem(s) studied**

Specialty: Critical care, Primary sub-specialty: Critical Care; UKCRC code/ Disease: Cancer/ Malignant neoplasms of digestive organs

### **Interventions**

The intervention under investigation is an interactive technology-enhanced incentive spirometry, via a device named InspireVR. This novel device will consist of a mouthpiece, through which the patient inhales (Vitalograph Pneumotrac). This mouthpiece contains a pneumotachograph measuring maximum inspiratory capacity (MIC); the signal from which will be converted a novel, bespoke game via purpose built "middleware". The game will be presented on a touch-screen display device (Windows Notebook), which will be incorporated into a stand to allow comfortable interaction. Those recruited into the study will be advised to attempt incentive spirometry sessions hourly from the morning after their operation (day 1), aiming for 10 sessions per day. Each incentive spirometry session will consist of 10 MIC breaths, with short intervals between to allow recovery if required. The patients will be offered the Spiroball and InspireVR device on an alternating basis for each session of incentive spirometry. If the patient is unable to use the InspireVR device, they will be advised to use the alternative Spiroball device instead. The order of which device is offered first each day will be randomised between patients, and alternate each day. The participants will take part in the trial for their first three post-operative days following elective oesophagectomy or total gastrectomy.

Data will be collected daily during the patients' ICU stay, and will consist of:

1. Demographic and Patient technology acceptance at pre-admission clinic
2. Daily record of InspireVR and Spirometry use, reasons for refusal of device usage, significant events, pain during incentive spirometry, evidence of PPC. Usage is recorded automatically by the InspireVR system and manually for the Spiroball by the patient and nursing staff.

3. Modified System Usability Scale (Patients and Staff Users)
4. Video capture and link analysis of activity during one daytime shift
5. Performance during InspireVR game. MIC achieved, levels achieved. Recorded automatically by the InspireVR system
6. Qualitative feedback of patient experience of InspireVR using a semi-structured interview on discharge from critical care. Data will be collected on written proformas and entered into NVivo for thematic analysis
7. Focus group to include all staff user groups – Physiotherapists, nurses, doctors. All those who have cared for patients in the study will be invited. Two from each role will be included in each focus group (six persons in total). This will be undertaken three times at eight week intervals during the trial to maximise recall. Focus groups will be recorded and transcribed for thematic analysis using NVivo.
8. Follow up data – PPCs, and other post operative morbidity (Clavien-Dindo classification), length of critical care unit and hospital stay, survival status on hospital discharge and at 30 days post operatively

## **Intervention Type**

Device

## **Primary outcome(s)**

Successful patient usage of the InspireVR. Usage will be defined as the total number of successful attempts (patient able to record a MIC breath) using InspireVR compared with number of successful attempts when using Spiroball (as reported by the patient). Feasibility of the device will be established if the number of successful attempts at incentive spirometry during InspireVR use is equal to or higher than the number of patient-reported successful uses of the Spiroball device. InspireVR usage will be collected via the device software. Use of Spiroball will be reported by the patient and bedside staff using a paper log.

## **Key secondary outcome(s)**

1. User (patients) acceptance and experience of the InspireVR device is assessed using a 10 item likert scale, based on the validated System Usability Scale on day 3-4 of trial, following completion of intervention
2. User (physiotherapists and nurses) acceptance and experience of the InspireVR device is assessed using a 10 item likert scale, based on the validated System Usability Scale (Focus group during trial period)
3. Compliance with incentive spirometry. Each session will be recorded by embedded software within the InspireVR device. Use of the Spiroball will recorded by the patient and on the patient nursing records (current standard practice) daily during intervention.
4. Patient achievement of prespecified targets for MIC on the InspireVR is assessed via InspireVR software daily during intervention
5. Side effects and adverse events whilst using the InspireVR device are collected daily during intervention
6. Pain and discomfort experience during use of InspireVR and Spiroball is assessed using a 0-3 Verbal rating scale at each IS session
7. Therapist/clinical staff (doctor/nurse/physiotherapist) user acceptance and experience is assessed through semi structured interviews and free text comments during the trial period
8. Post-operative pulmonary complications (PPCs) as defined by the PROVE network investigators is collected routinely
9. All cause 30 day morbidity (Clavien-Dindo classification)
10. Critical Care Unit length of stay
11. Hospital length of stay

- 12. In hospital mortality
- 13. All cause 30 day mortality

**Completion date**

01/01/2018

## Eligibility

**Key inclusion criteria**

Patient Inclusion criteria:

1. All consecutive patients undergoing elective oesophagectomy and total gastrectomy for cancer treatment on their first post-operative admission to the critical care units (intensive care or high dependency units) at QEHB or BHH
2. Age 18 years and over
3. All genders

**Staff Inclusion criteria**

All clinical, nursing and physiotherapy staff who have had direct care responsibilities for patients participating in the trial will be invited to participate in the focus groups during the study. Physiotherapists, nursing staff and doctors allocated to care for participants will be identified during the intervention days of the study and approached by the research team.

**Participant type(s)**

Mixed

**Healthy volunteers allowed**

No

**Age group**

Adult

**Lower age limit**

18 years

**Sex**

All

**Key exclusion criteria**

1. Patient refusal
2. Cognitive impairment preventing patient cooperation with breathing exercises
3. Severe visual impairment, such that the patient is unable to visualise the computer display
4. Post-operative complications necessitating placement of tracheostomy

**Date of first enrolment**

03/04/2017

**Date of final enrolment**

03/10/2017

## Locations

## **Countries of recruitment**

United Kingdom

England

## **Study participating centre**

**Queen Elizabeth Hospital**

Mindelsohn Way

Birmingham

United Kingdom

B15 2TH

## **Study participating centre**

**Birmingham Heartlands Hospital**

Bordesley Green E

Birmingham

United Kingdom

B9 5SS

## **Sponsor information**

### **Organisation**

University of Birmingham

### **ROR**

<https://ror.org/03angcq70>

## **Funder(s)**

### **Funder type**

Government

### **Funder Name**

Ministry of Defence - Defence Medical Services

## **Results and Publications**

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study are/will be available upon request from [drcharlottesmall@gmail.com](mailto:drcharlottesmall@gmail.com)

## IPD sharing plan summary

Available on request

## Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Participant information sheet</a>	version V3.2	01/01/2017	24/04/2017	No	Yes