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A study exploring a personalised digital prehabilitation programme, Fit 4 Surgery (F4S), for patients undergoing major surgery

Submission date
21/08/2023

Recruitment status
No longer recruiting

Registration date
30/08/2023

Overall study status
Ongoing

Last Edited
23/07/2024

Condition category
Surgery

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims:
Over 50,000 patients/year in the UK undergo major chest and abdominal surgery. Serious complications following major operations are common and are associated with an increased risk of death, intensive care unit admission, and a more extended stay in hospital. Avoidance of these complications would offer great benefits to patients and the NHS.
Face-to-face exercise training programmes before and after surgery may result in fewer complications and quicker recovery. Access to this type of support is severely restricted especially in the pre and post surgery self-isolation mandated by COVID. Hence, the use of an App could provide immediate access to such tailored-training and empower patients as they control when, where and how they undertake exercise.
Our team has developed and already pilot-tested F4S app on patients undergoing lung surgery within the NHS. It contains short descriptive videos of each suggested exercise as well as educational advice based on well-tested rehabilitation programmes. A participant's heart rate is actively recorded so they can track their progress on easy to read diagrams within F4S. This information advises them on the most appropriate intensity for each exercise. The information is also sent electronically to their clinician so that progress can be monitored.
The overarching aim of this research is to test whether using a bespoke and personalised exercise-based App, Fit for Surgery (F4S), used at home over the weeks before and after surgery is acceptable to patients and whether a larger trial to evaluate the performance of the App in improving individual outcomes would be feasible.

Who can participate?
Adult patients awaiting surgery.

What does the study involve?
If patients agree to take part in the study, we will be taking some assessments at 6 different points. These assessments include an exercise test and questionnaires within the app on symptoms, self-care, and well-being.

We will provide patients with access to 'Fit4Surgery' on your their own smart device (Tablet / Phone / Personal Computer) or on a device we provide to them with for the duration of the study which will need to be returned after the study finishes. The programme is personalised for patients based on their physical ability and preferences. They will be guided through a series of screens on the App/ smart device to build their own weekly programme, which includes a range of strengthening, mobility and cardiovascular exercises. They will be able to select the intensity and time they wish to work at for each exercise (e.g., easy, medium, hard).

They will be encouraged to use the programme every day for at least 30 minutes to achieve 150 minutes of exercise weekly as per rehabilitation guidelines. They will be provided with guidance to compete the exercises via videos and visual aids within the App. The programme also includes using a 'wearable wrist heart rate sensor', which provides personalised feedback on heart rate during the exercises, to enable them to gauge the intensity that they are working at. They will be given a heart rate sensor to use which will need to be returned after the study finishes. Once each exercise is completed, they will input their perceived intensity into the app using the exertion and breathlessness scales. This information is used to deliver personalised messages to them, encouraging them to increase or decrease the intensity and /or time of exercise to achieve their target. Within the programme they will be asked questions about their weight, diet and appetite. Based on these responses they may either be given some examples of protein rich snacks to consume after exercise or they will be asked to take nutritional drinks which will be provided and /or may be contacted by a dietitian who will provide them with additional support. The app has been designed to be used immediately after surgery and the exercises can be done in bed. These exercises have been structured by physiotherapists and it is customary for patients to do some exercises as per their routine clinical pathway. In addition, after they had their surgery, they will receive advice and information within the app on what to expect after surgery, how and when to restart exercising and what to do if they have any concerns.

There are questionnaires and assessments to be completed at 6 times in the study . It will take approximately 20 minutes to complete. The questionnaires will ask patients about their symptoms, self-care, and general well-being. We will ask patients to complete these;
1. When they agree to take part in the study.
2. Just before their operation.
3. During their hospital stay
4. On the day they are discharged from hospital after surgery, 1 month and 6 months after they have gone home after surgery.
The questionnaires will be completed within the App.

What are the possible benefits and risks pf participating?
Training/rehabilitation app programmes may reduce the risk of complications happening after surgery. The information gained from this study will help us to develop a larger study which will investigate the impact of this.
We do not envisage any problems occurring as a result of your participation in the study.

Where is the study run from?
University Hospitals Birmingham NHS Foundation Trust including mainly Queen Elizabeth Hospital (UK)

When is the study starting and how long is it expected to run for?
August 2022 to August 2026

Who is funding the study?
University Hospitals Birmingham Charity (UK)

Who is the main contact?
Prof. Babu Naidu, b.naidu@bham.ac.uk
Mr Matar Alzahrani, MSA033@student.bham.ac.uk

Contact information

Type(s)
Principal investigator

Contact name
Prof Babu Naidu

ORCID ID
https://orcid.org/0000-0002-8756-4049

Contact details
Institute of Inflammation and Ageing
University of Birmingham
Birmingham
United Kingdom
B15 2TT
+44 1213713228
b.naidu@bham.ac.uk

Type(s)
Public

Contact name
Mr Matar Alzahrani

Contact details
Institute of Inflammation and Ageing
University of Birmingham
Birmingham
United Kingdom
B15 2TT
+44 7426761268
MSA033@bham.ac.uk

Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
306274

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
RG_21-184, IRAS 306274

Study information

Scientific Title
A mixed-methods study exploring the efficacy of a personalised digital prehabilitation programme, Fit 4 Surgery (F4S), for patients undergoing major surgery: A feasibility study

Acronym
Fit 4 Surgery

Study objectives
Using a personalised digital prehabilitation programme, Fit 4 Surgery (F4S), before and after surgery enhances the recovery of physical function after major elective surgery

Ethics approval required
Ethics approval required

Ethics approval(s)
approved 17/08/2022, Black Country Research Ethics Committee (The Old Chapel, Royal Standard Place, Nottingham, NG1 6FS, United Kingdom; +44 20 7104 8049; blackcountry.rec@hra.nhs.uk), ref: 22/WM/0135

Study design
Multi-centre controlled mixed-methods design

Primary study design
Interventional

Study type(s)
Quality of life, Screening, Efficacy

Health condition(s) or problem(s) studied
Recovery of physical function after major elective surgery for patients undergoing lung cancer, lung transplants, LVRS, and UGI surgeries

Interventions
All eligible patients will be given the F4S app which is tailored for individual patient needs using baseline data collected within the app. Specifically, the app collects baseline demographic data, comorbidities, symptom burden using simple questions and Visual Analogue Scales, and the outcome measure of Quality of Life, health and wellbeing scores. This information is used to deliver personalised feedback, support, and guidance when using the App.

The digital programme or ‘App’ comprises three prehabilitation interventions:

1. STRUCTURED HOME EXERCISE PROGRAMME - Patients are guided through a series of screens to build their own programme, including a range of strengthening, mobility and cardiovascular exercises. Baseline suggestions on programme level/ intensity are made based on a ‘sit to stand test’ conducted within the App. Once the programme is built, patients are encouraged to

exercise daily to achieve at least 30 minutes of exercise/week as per pulmonary rehabilitation guidelines. Heart rate is recorded using a wearable sensor provided free of charge to the patient. Once each exercise is completed, the patient inputs their perceived intensity using the BORG perceived exertion scales to the App. This data is used to encourage the patient via personalised messages to increase or decrease intensity at the next session to achieve the target intensity of BORG perceived exertion as per rehabilitation guidelines [43]. Regular data uploads allow health care professionals (HCP) to view patients' progress, whilst the App allows the patient to request support from the HCP if required. Patients are also able to record any other exercise they undertake e.g. swimming, running etc. Whilst the programme is focussed on pre-surgery, exercise can also benefit recovery post-surgery, so the patient will be permitted to use the programme after surgery, but will be adapted/reset according to patients' post-surgery 'sit to stand test' performance (on postoperative day 1).

2. INDIVIDUALISED NUTRITIONAL CONDITIONING- At the time of enrolment, patients complete a nutritional screening questionnaire (Patient-Generated Subjective Global Assessment (PG-SGA score) within the App, which tailors nutritional advice and supplementation based on symptoms and nutritional risk. All patients will be encouraged with the aid of a "ready reckoner" to intake a high protein (20g) snack within 90 minutes of exercise to stimulate muscle protein synthesis and a positive protein balance. Patients will record in the App when they have taken a protein snack. Patients deemed 'Medium risk' (PG- SGA score 4-9) will be started on a low volume, high calorie, high protein oral nutritional supplement (ONS) containing 20g protein twice a day until surgery. High risk patients (Score ≥ 9) will be started on supplements as above and referred to a dietitian for optimisation of supplement prescription. We conducted a prospective audit at a high-volume thoracic surgery unit, finding 9% of patients fall in the high-risk group. Whilst the programme is focussed on pre-surgery, it is acknowledged that after surgery, calorie and protein requirements are high at a time when intake may be impaired by after effects of surgery. Therefore, nutritional intervention will continue for 2 weeks post-surgery. Patients will complete PG-SGA score using the App on postoperative day 1 and based on this therapy will be tailored as described above.

3. PERSONALISED HEALTH INFORMATION is displayed within the App as short informational videos with subtitles. Information is responsive, and guided by symptom data and whether the patient is pre- vs. post-surgery, as recorded in the App. For example if the patient reports feeling breathless, information on how best to manage it is displayed. Information on surgery is prominent to the patient before surgery whilst recovery and symptom management e.g. pain control are prominent after. Further details of the programme can be found on www.Fit4surgery.uk.

The study aims for a recruitment period of 24 months with an additional 6-month follow up.

Intervention Type
Behavioural

Primary outcome(s)
Qualitative interviews and technology acceptance questionnaires with patients and staff will be undertaken to provide an in-depth understanding of how F4S has been used, including compliance in practice and the barriers and facilitators to its optimal use.

Key secondary outcome(s))
1. Patient recovery, assessed by questionnaires, 1 month post-surgery. The feasibility study will measure the following at baseline, on the day of surgery, during hospital stay, on day of hospital

discharge, 1 month after surgery, and 6 months after surgery:
1.1. Patient-reported outcomes: generic health (EQ-5D-5L), and disease specific (e.g., EORTC-QLQ-C30)-related quality of life.
1.2. Exercise capacity assessed by incremental shuttle walk test (ISWT) is an important secondary outcome measure following rehabilitation studies.
1.3. Mental health/well-being will be calculated using the Hospital Anxiety and Depression Scale; and using the Subjective Vitality Scale.
2. Clinical Outcomes - Complication rates using a modified Clavien-Dindo classification system and its derivative comprehensive complication index, length of stay in hospital/high dependency /intensive care, 30-day mortality, and readmission.
3. Process Measures - Being a complex intervention, a process evaluation based on the MRC guidance framework (2008) will be conducted building on three themes: implementation, mechanisms, and context. We will capture ‘fidelity’; ‘dose’, how it was delivered, ‘reach’ etc. via a modified TIDieR template.

Completion date
17/08/2026

Eligibility

Key inclusion criteria
1. Major elective surgery for benign or malignant diseases
2. Able to provide written informed consent
3. Before surgery at time of consent
4. Age >18 years

Participant type(s)
Patient, Health professional

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Emergency surgery required
2. Inability to perform project outcome measures

Date of first enrolment
01/01/2023

Date of final enrolment
01/07/2025

Locations

Countries of recruitment
United Kingdom

England

Study participating centre
University Hospitals Birmingham NHS Foundation Trust
Queen Elizabeth Hospital
Mindelsohn Way
Edgbaston
Birmingham
United Kingdom
B15 2GW

Sponsor information

Organisation
University of Birmingham

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Charity

Funder Name
Queen Elizabeth Hospital Birmingham Charity

Alternative Name(s)
QEHB Charity, Queen Elizabeth Hospital Charity, University Hospitals Birmingham Charity, Queen Elizabeth Hospital Birmingham, QEHB

Funding Body Type
Private sector organisation

Funding Body Subtype
Trusts, charities, foundations (both public and private)

Location
United Kingdom

Results and Publications

Individual participant data (IPD) sharing plan
Upon completion and publication of the study, individual participant data will be shared that support the results reported in study after de-identification. Additional related documents will be available including the study protocol, statistical analysis plan an analytical code. This data will be available in the beginning 3 months and the 5 years following article publication to those who provide a methodologically sound proposal for analysis to achieve the aims in the approved proposal. All proposals should be directed to b.naidu@bham.ac.uk. To gain access, requestors will need to sign a data access agreement. Data will be available for 10 years at a public facing database.

IPD sharing plan summary
Stored in non-publicly available repository, Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Study website	Study website	11/11/2025	11/11/2025	No	Yes