

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	<input type="checkbox"/> Prospectively registered <input type="checkbox"/> Protocol
Registration date 30/08/2023	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 23/07/2024	Condition category Surgery	<input type="checkbox"/> Individual participant data <input type="checkbox"/> 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 complete 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

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Study website

<https://www.fit4surgery.uk>

Contact information

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Principal Investigator

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

306274

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

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

Secondary study design

Non randomised study

Study setting(s)

Home, Hospital

Study type(s)

Quality of life, Screening, Efficacy

Participant information sheet

Not available in web format, please use contact details to request a participants information sheet

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 measure

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.

Secondary outcome measures

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.

Overall study start date

17/08/2022

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

120

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**

England

United Kingdom

Study participating centre

University Hospitals Birmingham NHS Foundation Trust

Queen Elizabeth Hospital

Mindelsohn Way

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Sponsor information**Organisation**

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Sponsor type

University/education

Website

<http://www.birmingham.ac.uk/index.aspx>

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

Publication and dissemination plan

The aim of this feasibility study is to identify if a larger trial is possible. Although a definitive answer on the effectiveness of the Fit 4 Surgery app in major surgery cannot be provided, the outcome of this study will be in the scientific interest of others in their own right. The feasibility study will be registered on <https://www.isrctn.com/> (ISRCTN). The dissemination strategy will consist of four strands:

1. The first will ensure that patients and the public are informed of the trial results.
2. The second will engage practitioners and health care planners locally to implement the findings.
3. The third will involve consulting with policy makers for maximum impact.
4. Finally, the plan to increase the impact of the of this research is publish its findings in related journals, present the findings in pertinent local and international conferences, and if proven efficacy, conduct the research internationally outside the scope of the UK.

Intention to publish date

01/05/2026

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 and 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