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Fit 4 Surgery 2: Using an app to get fit for lung cancer surgery

Submission date 25/04/2023	**Recruitment status** Recruiting	[X] Prospectively registered [X] Protocol [_] Statistical analysis plan [_] Results [_] Individual participant data [X] Record updated in last year
Registration date 04/05/2023	**Overall study status** Ongoing	
Last Edited 01/04/2025	**Condition category** Cancer	

Plain English summary of protocol

Background and study aims
Surgery remains the best option for the cure of patients with lung cancer. Around 7000 people in the UK undergo lung surgery each year, but up to 45% of patients developed post-operative complications leading to readmission to hospital and potentially poorer quality of life. National and international cancer, surgery and nutrition guidelines recommend a combination of exercise and nutritional support before and after surgery to help reduce post-operative complications. However it is not clear what is the best way to deliver this. Personalised exercise, nutrition and health information programmes delivered via an App may be a way to provide the right advice and support at the right time for each individual patient.

The F4S-2 trial aims to find out if providing an App that delivers personalised exercise, nutrition and health information, in addition to any support that lung surgery patients would normally receive, improves physical recovery, reduce the chances of developing complications or the impact of them on quality of life, and save cost in the NHS.

Who can participate?
To be eligible for the trial, patients must be: aged 18 or over; with a suspected clinical or pathological diagnosis of primary lung cancer; undergoing elective curative lung resection; able to undergo F4S-2 intervention for minimum 2 weeks prior to surgery; able to complete F4S-2 questionnaires and provide informed consent.

What does the study involve?
We will invite 902 patients from 20 NHS Trusts into the trial. All participants will receive usual care, but half of the group (allocated randomly) will also use the App. We will follow the progress of all participants for 6 months.

The trial has an embedded ‘Study Within A Trial’ that aims to find out reasons behind patients declining to join the trial and provide valuable information for the design of future exercise and nutrition clinical trials.

What are the possible benefits and risks of participating?
Training/rehabilitation programmes delivered via the App may reduce the risk of complications

occurring after surgery. Whilst there is no direct benefit to participants in the usual care group, the information gained from this study will help us determine whether the App is any better than what we already provide i.e. usual care.

Where is the study run from?
University of Birmingham (UK)

When is the study starting and how long is it expected to run for?
May 2022 to December 2027

Who is funding the study?
The National Institute for Health and Care Research (NIHR) (UK).

Who is the main contact?
Laura Ocansey, l.ocansey@bham.ac.uk

https://www.cancerresearchuk.org/about-cancer/find-a-clinical-trial/a-study-using-app-help-with-exercise-diet-programme-before-lung-cancer-surgery-fit-4-surgery-2

Contact information

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
317416

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number
CPMS 55877, NIHR134214, IRAS 317416

Study information

Scientific Title
Fit 4 Surgery 2: A randomised controlled trial to investigate an App-based, motivation-theory grounded, personalised, comprehensive, prehabilitation programme in addition to usual care versus usual care alone to enhance recovery of physical function and reduce complications after lung cancer surgery

Acronym
F4S-2

Study objectives
The F4S-2 trial aims to find out if providing an App that delivers personalised exercise, nutrition and health information, in addition to any support that lung surgery patients would normally receive, improves physical recovery, reduce the chances of developing complications or the impact of them on quality of life, and save cost in the NHS.

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 27/04/2023, East of England – Essex Research Ethics Committee (Equinox House, City Link, Nottingham, NG2 4LA, UK; +44 2071048227; Essex.REC@hra.nhs.uk), ref: 23/EE/0079

Study design
Interventional randomized controlled trial

Primary study design
Interventional

Study type(s)
Other

Health condition(s) or problem(s) studied
Recovery from lung cancer surgery

Interventions
TRIAL INTERVENTION
Usual Care vs F4S-2 digital platform (App) and Usual care

Usual Care: This may be a range of healthcare services that provide all or one of the following: information for the participant (with or without links to further information), formal rehabilitation via physiotherapy, nutritional support via dietitian, and/or routine follow up as per standard of care.

THE F4S-2 APP
The advice given to the participant is determined by their unique, dynamic, personal health status. That is, as a patient engages with the App, the advice regarding exercise and nutrition adapts. Specifically, the App collects baseline demographic data, comorbidities, symptom burden using simple questions and Visual Analogue Scales, and the outcome measures of Quality of Life, Health and wellbeing scores. This information is used to deliver personalised feedback, support and guidance when using the App. e.g. if diabetic, guidance on avoiding a hypoglycaemic event. This will not constitute trial data, and is part of the data to inform the intervention itself. The digital programme or 'App' comprises three prehabilitation interventions.

STRUCTURED HOME EXERCISE PROGRAMME:
Participants 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, participants are encouraged to exercise daily to achieve 150 minutes of exercise/week as per pulmonary rehabilitation guidelines. Heart rate is recorded using a wearable sensor provided free of charge to the participants. Once each exercise is completed, the participant inputs their perceived intensity using the BORG perceived exertion scales to the App. This data is used to encourage the participant 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. Regular data uploads allow health care professionals (HCP) to view participants' progress, whilst the App allows the participant to request support from the health care professional HCP if required. Only these health care professionals are able to view the information within the App. They will be able to see alerts from the participant through the admin page. The App app has safety messages to advise participants to seek medical advice when required (in the same way that usual care patients are directed to contact depending on the situation). Participants are also able to record any other exercise they undertake e.g. swimming, running etc. Whilst the programme is focused on pre-surgery, exercise can also benefit recovery post-surgery, so the participant will be permitted to use the programme after surgery for a period of 6 weeks, but it will be adapted/reset according to participants' post-surgery 'sit to stand test' performance (on postoperative day 1).

INDIVIDUALISED NUTRITIONAL CONDITIONING:
At the time of enrolment, participants complete a nutritional screening questionnaire (Participant-Generated Subjective Global Assessment (PG-SGA score)) within the App, which tailors nutritional advice and supplementation based on symptoms and nutritional risk. All

participants 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. Participants will record in the App when they have taken a protein snack. Participants deemed ‘Medium risk’ (PG-SGA score 4-9) will be started on a low volume, high calorie, high protein oral nutritional supplement (ONS) containing at least 18g of protein twice a day until surgery. High risk participants (score ≥ 9) will be started on supplements as above and referred to a dietitian for optimisation of supplement prescription. While the recommendations above are aligned with national guidance, sites can adhere to local policies. Whilst the programme is focused on pre-surgery, it is acknowledged that after surgery, calorie and protein requirements are high at a time when intake may be impaired by the after effects of surgery. Therefore, nutritional intervention will continue for 4 weeks post-surgery. Participants will complete the PG-SGA using the App on postoperative day 1, and based on this nutritional advice and supplementation will be tailored as described above. Standard care will be followed regarding the supplementation and monitoring

PERSONALISED HEALTH INFORMATION:
Displayed within the App as short informational videos with subtitles. Information is responsive, and guided by symptom data and whether the participant is pre- vs. post-surgery, as recorded in the App. For example, if the participant reports feeling breathless, information on how best to manage this is displayed. Information on surgery is prominent to the participant before surgery, whilst recovery and symptom management e.g. pain control are prominent after. Further details of the programme can be found on https://www.Fit4surgery.uk. Motivational processes – In app data collection will include Motivational processes underpinning engagement with the App /behaviour change, autonomous and controlled motivation for engagement in exercise and physical activity and an assessment of autonomy, competence, and connection

Intervention Type
Behavioural

Primary outcome(s)
1. Patient-reported quality of physical function scale recovery (using the EORTC-QLQ-C30) at 30 days after surgery
2. Surgical complications (using the Comprehensive Complication Index (CCI)) at 30 days after surgery

Key secondary outcome(s))
Current secondary outcome measures as of 24/10/2024:
1. Days Alive and at Home Within 30 days (DAH30)
2. Patient-reported quality of life (using the EORTC-QLQ-C30 & LC 29) at Baseline, Day of Surgery, 30 days, 3 and 6 months after surgery
2.1. EORTC-QLQ-C30 Domains: Global Health Status, Physical Functioning, Role Functioning, Emotional Functioning, Cognitive Functioning, Social Functioning
2.2. EORTC-QLQ-LC29 Domains: Coughing, Shortness of Breath, Side Effects of Treatment, Fear of Progression, Surgery related problems
3. Mental health/well-being (using the Hospital Anxiety and Depression at Scale (HADS)) at Baseline, Day of Surgery, 30 days, 3 and 6 months after surgery
3.1. Domains: Anxiety, Depression
4. Motivational processes at Day of Surgery, 30 days and 3 months after surgery (Intervention only):
4.1. Questionnaires: Behavioural Regulation in Exercise Questionnaire (BREQ), Basic Psychological Need Satisfaction in Exercise Scale (BPNSES), Health Care Climate Questionnaire

(HCCQ)
5. Physical status assessed by the incremental shuttle walk test (ISWT) at Baseline and 30 days after surgery; sit-to-stand test and hand grip test at Baseline, Day of Surgery, Day of Discharge and 30 days after surgery.
6. Nutritional assessment including weight (PG-SGA (SF)) at Baseline, Day of Surgery and 30 days after surgery.

Health Economic Outcomes
7. Health-related quality of life (EORTC-QLQ-C30, LC-29 and EQ-5D-5L) at Baseline, Day of Surgery, 30 days, 3 and 6 months after surgery
8. Health resource usage at 30 days and 6 months after surgery

Previous secondary outcome measures:
1. Days Alive and at Home Within 30 days (DAH30)
2. Patient-reported quality of life (using the EORTC-QLQ-C30 & LC 29) at 14 days, 30 days, 3 and 6 months after surgery
3. Mental health/well-being (using the Hospital Anxiety and Depression Scale (HADS)) at 14 days, 30 days, 3 and 6 months after surgery
4. Symptom score (using a 0-10 point VAS) (intervention only) at baseline.
5. Motivational processes measured using a motivational processes and shortened scale of behavioural change questionnaires at the day of surgery, 30 days and 3 months
6. Physical status assessed by the incremental shuttle walk test (ISWT) at baseline and 30 days, sit-to-stand test and hand grip test at baseline, day of surgery, day of discharge and 30 days.
7. Patient-generated subjective global assessment short form (PG-SGA SF) at baseline, day of surgery and 30 days.

Health Economic Outcomes
8. Health-related quality of life (EORTC-QLQ-C30, LC-29 and EQ-5D-5L) at 14 days, 30 days, 3 and 6 months after surgery
9. Health resource usage measured using a Health Resource Usage questionnaire at 30 days and 6 months

Completion date
31/12/2027

Eligibility

Key inclusion criteria
1. Adults aged 18 years or over
2. With a suspected clinical or pathological diagnosis of primary lung cancer
3. Selected for elective curative lung resection
4. Able to undergo F4S.2 intervention for minimum 2 weeks prior to surgery
5. Willing and able to provide informed consent
6. Willing to use F4S app
7. Willing to complete study questionnaires

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
18 years

Sex
All

Key exclusion criteria
1. Emergency surgery
2. Patients requiring parenteral nutrition

Date of first enrolment
12/10/2023

Date of final enrolment
31/12/2026

Locations

Countries of recruitment
United Kingdom

England

Scotland

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

Study participating centre
University Hospitals Bristol and Weston NHS Foundation Trust
Bristol Royal Infirmary
Marlborough Street
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Study participating centre
Imperial College Healthcare NHS Trust
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W12 0HS

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Study participating centre
The Royal Wolverhampton NHS Trust
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WV10 0QP

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Study participating centre
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Study participating centre
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Study participating centre
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Study participating centre
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Sponsor information

Organisation
University of Birmingham

ROR
https://ror.org/03angcq70

Funder(s)

Funder type
Government

Funder Name
NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC)

Results and Publications

Individual participant data (IPD) sharing plan

Requests for data generated during the F4S-2 study will be considered by the University of Birmingham Clinical Trials Unit (BCTU). Data will typically be available 6 months after the primary publication. Only scientifically sound proposals from appropriately qualified Research Groups will be considered for data sharing. The request will be reviewed by the BCTU Data Sharing Committee in discussion with the CI and, where appropriate (or in absence of the CI) any of the following: the Trial Sponsor, the relevant Trial Management Group (TMG), and independent TSC. Requests can be made to BCTU-Info@adf.bham.ac.uk

A formal Data Sharing Agreement (DSA) may be required between respective organisations once the release of the data is approved and before data can be released. Data will be fully de-identified (anonymised) unless the DSA covers the transfer of participant-identifiable information. Any data transfer will use a secure and encrypted method.

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			20/09/2023	No	No
Participant information sheet	version 3.0	18/04/2023	03/05/2023	No	Yes
Participant information sheet	version 5.0	26/09/2023	16/10/2023	No	Yes
Participant information sheet	version 6.0	18/07/2024	24/10/2024	No	Yes
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Protocol file	version 3.0	18/04/2023	03/05/2023	No	No
Protocol file	version 4.0	05/09/2024	24/10/2024	No	No
Study website	Study website	11/11/2025	11/11/2025	No	Yes