

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

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| Submission date 25/04/2023 | Recruitment status Recruiting | <input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol |
| Registration date 04/05/2023 | Overall study status Ongoing | <input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results |
| Last Edited 01/04/2025 | Condition category Cancer | <input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year |

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>

Study website

<https://www.birmingham.ac.uk/fit4surger2>

Contact information

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Additional identifiers**EudraCT/CTIS number**

Nil known

IRAS number

317416

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

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

Secondary study design

Randomised controlled trial

Study setting(s)

Hospital

Study type(s)

Other

Participant information sheet

See study outputs table

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 measure

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

Secondary outcome measures

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 (BPNSSES), 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

Overall study start date

01/05/2022

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

Age group

Adult

Lower age limit

18 Years

Sex

Both

Target number of participants

Planned Sample Size: 902; UK Sample Size: 902

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**

England

Scotland

United Kingdom

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
Bristol
United Kingdom
BS2 8HW

Study participating centre

Imperial College Healthcare NHS Trust

Hammersmith Hospital
Du Cane Road
London
United Kingdom
W12 0HS

Study participating centre

Oxford University Hospitals NHS Foundation Trust

John Radcliffe Hospital
Headley Way
Headington
Oxford
United Kingdom
OX3 9DU

Study participating centre

South Tees Hospitals NHS Foundation Trust

James Cook University Hospital
Marton Road
Middlesbrough
United Kingdom
TS4 3BW

Study participating centre

The Royal Wolverhampton NHS Trust

New Cross Hospital
Wolverhampton Road
Heath Town

Wolverhampton
United Kingdom
WV10 0QP

Study participating centre

Leeds Teaching Hospitals NHS Trust

St. James's University Hospital
Beckett Street
Leeds
United Kingdom
LS9 7TF

Study participating centre

Golden Jubilee National Hospital

Agamemnon Street
Clydebank
United Kingdom
G81 4DY

Study participating centre

Royal Infirmary of Edinburgh at Little France

51 Little France Crescent
Old Dalkeith Road
Edinburgh
Lothian
United Kingdom
EH16 4SA

Study participating centre

University Hospitals of Leicester NHS Trust

Leicester Royal Infirmary
Infirmary Square
Leicester
United Kingdom
LE1 5WW

Study participating centre

University Hospitals Plymouth NHS Trust

Derriford Hospital
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PL6 8DH

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Blackpool Teaching Hospitals NHS Foundation Trust
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Study participating centre
Sheffield Teaching Hospitals NHS Foundation Trust
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Study participating centre
Royal Brompton & Harefield NHS Foundation Trust
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Sydney Street
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Study participating centre

University Hospitals Coventry and Warwickshire NHS Trust

Walsgrave General Hospital

Clifford Bridge Road

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Study participating centre

Mid and South Essex NHS Foundation Trust

Prittlewell Chase

Westcliff-on-sea

United Kingdom

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Study participating centre

Hull University Teaching Hospitals NHS Trust

Hull Royal Infirmary

Anlaby Road

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Study participating centre

Guy's and St Thomas NHS Foundation Trust

Guy's Hospital

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Sponsor information

Organisation

University of Birmingham

Sponsor details

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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**

Government

Funder Name

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

Results and Publications**Publication and dissemination plan**

Planned publication in a high-impact peer-reviewed journal

Intention to publish date

01/12/2028

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? |
|---|-------------|--------------|------------|----------------|-----------------|
| Participant information sheet | version 3.0 | 18/04/2023 | 03/05/2023 | No | Yes |
| Protocol file | version 3.0 | 18/04/2023 | 03/05/2023 | No | No |
| HRA research summary | | | 20/09/2023 | No | No |
| 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 |
| Protocol file | version 4.0 | 05/09/2024 | 24/10/2024 | No | No |