F4S-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

Fit 4 Surgery 2 (F4S-2)
Participant Information Sheet

Summary of the F4S-2 trial

- Surgery remains the best option for curative intent of patients with lung cancer but post-operative complications can occur in patients leading to readmission to hospital and potentially poorer quality of life after surgery.
- National and international cancer, surgery and nutrition guidelines recommend a combination of exercise and nutritional support before and after surgery. This helps reduce complications. However, it is not clear what is the best way to deliver this for an individual patient
- Personalised exercise, nutrition and health information programmes using a smartphone, tablet or computer may be a way to address this problem. Using a digital solution would provide the right advice and support at the right time for each individual patient.

This Information Sheet

We would like to invite you to take part in our research study. Joining the F4S-2 study is voluntary. This Participant Information Sheet (PIS) explains the purpose of the study, what will happen to you if you take part, and detailed information about the how the study will be carried out. A member of our research team will go through this information sheet with you, to help you decide whether or not you would like to take part and to answer any questions you may have. Please feel free to talk to others about the study if you wish. If you wish to contact the researchers, details can be found on the final page of this information sheet.

If you would like to take part we will give you information about why the research is being done and what this would involve for you. This is described in **Section 1**.

If you are interested in taking part after reading Section 1, please continue to **Section 2** which describes who is organising this study and how we will use your information collected during the study.

Section 1

Purpose and background to the research

About 7000 people in the UK have lung surgery every year. In the period just before and just after surgery, patients can benefit from some form of physical exercise and help with their nutrition to aid their recovery after surgery.

How much support people receive with setting exercise goals and healthy eating can vary from one area of the country to another. This can often depend on whether there are services available for people to join exercise sessions or if the hospital has dieticians available. Often the support may only be a printed leaflet about any local services available.

Many people already have smart phones or devices. A group of lung cancer health care professionals and patients have developed a digital programme or App (F4S-2) for patients like you, to help you exercise at home and choose the best foods for you to eat and drink before and after surgery. Using a smart phone or device, you will be asked information about yourself, using this information, the advice you receive will be tailored to your lifestyle and preferences.

This programme does not replace any services that your clinical team would offer you as part of routine care. We want to find out if adding this digital programme to any support you would normally receive improves physical recovery and reduces the chances of developing and the impact of complications after surgery.

This trial is taking place all across the UK and over several years. It will eventually involve approximately 900 patients like you.

Why have I been chosen?

We are inviting you to take part in this study because you are due to have lung surgery. Before you decide whether or not you wish to take part, you should read the information given below carefully and discuss it with your family, friends, GP or surgical or nursing team should you wish. Please take time to ask questions about the study, do not feel rushed or under any obligation to make a snap decision. You should clearly understand the risks and benefits of participating in this study so that you decide what is right for you. If you decide not to take part your medical care will not be affected.

What would taking part involve?

When designing this study, we have worked with a group of lung surgery patients and members of the public to make sure that taking part will not take up too much of your time.

When you have read this information sheet and decide to take part in the study, we will ask you to sign a consent form and give you a copy of the signed consent form to keep. In some instances we may take verbal consent via videocall or over the phone. A member of the research team will then ask some questions about your general health and ask you to complete a set of questionnaires and some physical tests (a hand grip test, one-minute 'sit to stand' fitness test and walk test). These may take around 1 hour 30 minutes to complete. Section 2 of this information sheet describes what data we will be collecting.

The researcher will enter your information into a secure online database, and a computer will then pick one of the two groups for you at random:

- Usual care

OR

- Usual care and use of the F4S-2 App which will collect brief information about you and also tailors a programme of structured exercise, nutrition and useful health information based on your needs and preferences

The researcher will let you know which group you have been put into. Neither you, the researcher nor the clinical team can choose which group you will be in. This process ensures there is an equal chance of being placed in each of the groups and is the best way to make sure that there is a fair comparison between the different groups.

Whether in the usual care or F4S-2 App group you will access the healthcare services available to patients at your hospital before and after your surgery. We will also ask you to complete some questionnaires and physical tests outlined in the section below.

If you are in the App group, the research team will either lend you a tablet computer with the App on it or download the App onto your own personal smart phone or device. They will show you how to use the App. Additionally, there are short videos and a pictorial paper guide to help you. This should take no longer than 30 minutes. The research team will provide a smart watch that will monitor your heart rate.

Once you have answered the initial questions within the App it will create your own personal exercise programme, including some strengthening, mobility and cardiovascular exercises. It will also tailor some nutritional advice and supplementation based on your symptoms.

The research team will answer any immediate questions that you have about using the App. You will also be provided with access to a telephone helpline and a picture guide. If we have provided you with a tablet computer, it will come with a SIM card which allows it to connect to the internet.

When and how will I complete the questionnaires and physical tests?

The researchers will ask you to repeat the set of questionnaires (with additional questions) and the physical tests that you have completed when you agree to take part in the study and several times during the study as described in the following table:

Timepoint	Where?	Questionnaires	Physical tests	Time to complete
1. Baseline (prior to surgery)	At Hospital	✓	✓	Up to 2 hours
2. On the day of surgery	At hospital	✓	✓	30 minutes
3. Day of discharge	At hospital		✓	15 minutes
4. Thirty days after surgery	At hospital visit	✓	✓	1 hour
5. Three months after surgery	At home via post	✓		10 minutes
6. Six months after surgery	At home via post	✓		10 minutes

Please contact a member of the research team if you need assistance with the postal questionnaires. We will post you a set of questionnaires before each timepoint stated in the table above. The questionnaires will take around 10-15 minutes to complete. It would be a great help if you can return your completed questionnaires as promptly as possible (we will provide a freepost return envelope). In situations where we have not received your postal questionnaires after a reminder, a research team member may contact you

in case you have not received them through the post. In addition, you may also be contacted if we have a query on your returned questionnaires (e.g. omitted answer) that require your clarifications.

What are the possible benefits of taking part?

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.

What are the possible disadvantages and risks of taking part?

All participants in this study will receive information and exercise provided by their surgical team as part of usual care. Participants randomised to the App group will also be using the App which will provide exercise and nutritional advice through a digital format tailored to individual needs, your care team will have access to view your progress within the App. There are no additional side effects of the study because the recommendations used to create the App are based on current guidelines on health information, exercise and diet used in routine clinical practice.

If you are entered into the F4S-2 App group, you will be provided with a smartwatch. The watch strap contains nickel so please make the research team aware of any allergies. This will not prevent you from taking part in the trial.

Involvement of General Practitioner / other healthcare practitioner

With your permission, your GP will be informed you are taking part in the study.

What if I do not want to take part?

Taking part in this study is entirely voluntary and the standard of care you receive will not be affected if you decide not to take part or would like to withdraw at any stage of the study.

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.

If you decide to stop taking part in the study, we would like to continue collecting information about your health from your hospital. If you do not want this to happen, tell us and we will stop. Data collected up to the time of your withdrawal (or if you lose capacity to consent during the study) will be kept and used anonymously as part of the study outcome.

If you choose to withdraw from any aspect of participation, please speak to a research team member. Their contact details can be found at the end of this information sheet.

Section 2

How have patients and the public been involved in this study?

Both patients with lung cancer and members of the public helped to develop this study. Patient representatives are included in the study team and a patient advisory group is regularly consulted. This information sheet has been produced by researchers and patients working in partnership, and a further information booklet and video will be produced with patients to explain the results.

Please note that only healthcare staff and researchers, and no patients or members of the public, will have access to your personal records.

What if something goes wrong?

We do not envisage any problems as a result of your participation in the study. If you have a concern about any aspect of this study, you should ask to speak to a member of the research team who will do their best to answer your questions. Their contact details can be found at the end of this information sheet.

If you remain unhappy and wish to complain formally, the National Health Service complaints mechanisms will be available to you. Copies of these guidelines are available on request. If you wish to complain about how you have been treated during this study, please contact Patient Advice and Liaison Service (PALS) at your local hospital (in England and Wales) or Patient Advice and Support Service (in Scotland). Contact details can be found at the end of this PIS or via these websites:

https://www.nhs.uk/common-health-questions/nhs-services-and-treatments/what-is-pals-patient-advice-and-liaison-service/

PASS | Patient Advice and Support Service Scotland (pass-scotland.org.uk)

You can also contact the University of Birmingham Research Governance team: researchgovernance@contacts.bham.ac.uk

Will my expenses be reimbursed?

The follow up visits in this study are routine clinic visits during standard care. Therefore, there is no travel or parking reimbursement available for our participants beyond that normally offered by the hospital.

What happens if new information becomes available?

Sometimes we get new information about the treatment being studied. If this happens, a research team member will tell you and discuss whether you should continue in the study.

If your research doctor is happy for you to continue in the study, you will have the option to decide whether you wish to continue. You may be asked to re-sign a consent form if you decide to continue taking part in the study. If you decide not to carry on, a member of the research team will arrange for your standard clinical care to continue.

If, however, your research doctor considers that you should withdraw from the study, he/she will explain the reasons and arrange for your standard clinical care to continue.

What happens when the research study stops?

The final follow-up questionnaire will be sent to you 6 months after the date of your surgery. This will be the end of the study. Following this, your standard clinical care will continue.

Those in the intervention group will use the App up to 6 weeks following your surgery. If you borrowed a tablet device from the research team they will discuss with you the best way to return it. Participants are able to keep the smart watch.

The App will remain available for you to use if you downloaded it to your own device. However, no further benefit is expected after the 6 week trial period and use of the app will not be monitored by the clinical team.

What will happen to the results of the research study?

The findings of this study will be made public. We would like to publish our results in medical journals and present the findings at conferences, to help other doctors and medical staff learn from the findings and for patients to benefit. If we are successful with this, it will be in an anonymous manner so you cannot be identified.

We also plan to inform all participants of the findings, highlighting where the results are expected to make a clinical difference. This process will include both written material and a video.

Results will also be disseminated to study participants through our patient and public involvement group called RESOLVE based at University Hospitals Birmingham NHS Trust.

Will my taking part in this study be kept confidential?

We will need to use information from you and from your medical records for this research project. We need to process your information to conduct this research, which is a task performed in the public interest and for scientific or historical research purposes, statistical purposes or archiving purposes in the public interest. This information will include: name, date of birth, NHS number, email or postal address, health information, medical history and information from the questionnaires. If you have been randomised to the intervention group, we will also collect information from the app.

People will use this information to do the research or to check your records to make sure that the research is being done properly.

All information about you and your health will be kept private. The only people allowed to look at the information will be the researchers who are running the study, authorised staff at University of Birmingham and your hospital, and the regulatory authorities who check that the study is being carried out correctly. Further, there will not be any identifiable data collected through the app or the questionnaire. Certain individuals from the University of Birmingham and regulatory organisations may look at your medical and research records to check the accuracy of the research study. We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead.

We will keep all information about you safe and secure. Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

You can find out more about how we use your information

- at www.hra.nhs.uk/information-about-patients/
- our leaflet available from www.hra.nhs.uk/patientdataandresearch
- by asking one of the research team
- by sending an email to dataprotection@contacts.bham.ac.uk

If you agree to take part in this study, you will have the option to take part in future research using your data saved from this study

How will my personal data be kept secure?

The University of Birmingham takes great care to ensure that personal data is handled, stored and disposed of confidentially and securely. Our staff receive regular data protection training, and the University has organisational and technical measures in place so that personal data is processed in accordance with the data protection principles set out in data protection law.

We will keep all information about you safe and secure. In relation to this project, any paperwork containing identifiable data will be kept in an access-controlled and secured room inside a locked filing cabinet. Electronic data will be kept on secure, encrypted IT servers within the University of Birmingham.

How long will my personal data be kept?

Your data will be kept for 10 years after the trial finishes. If you withdraw from the study, we will keep the information we have already obtained but, to safeguard your rights, we will use the minimum personally identifiable information possible.

Who is organising and funding the research?

This study is funded by the government through the National Institute for Health Research (NIHR) Health Technology Assessment (HTA) programme (ref: NIHR134214).

The study is sponsored and insured by the University of Birmingham (UoB), which has certain legal and ethical responsibilities for the study (ref: RG_21-046) UoB is the data controller for the personal data that we process in relation to you. This study is being coordinated by Birmingham Clinical Trials Unit (BCTU), which is part of UoB.

All research in the NHS is reviewed by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed positively by East of England - Essex Research Ethics Committee.

The medical team at your hospital is not being paid for its role in this study.

Do you have any further questions?

Thank you for taking the time to read this information sheet and for considering taking part in this study. Should you require further information, would like to speak to someone about the study, or proceed to join the study, please contact:

< Contact Name > <Job Title> <Telephone and/or E-mail>

< PI Name > <Job Title> <Telephone and/or E-mail>

For independent advice or support, you can contact the NHS PALS (Patient Advisory and Liaison Service) in England and Wales or PASS (Patient Advice & Support Service) in Scotland.

Tel.: *< PALS/ PASS Telephone >* Email: *< PALS/PASS E-mail Adress >*

Contact details of F4S-2 Trial Office at the Birmingham Clinical Trials Unit:

Email: F4S-2@trials.bham.ac.uk Study website: www.birmingham.ac.uk/F4S-2

F4S-2 digital programme website: www.fit4surgery.uk

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