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Critical Care, Anaesthesia & Peri-operative Medicine Dept,
Research office CE 93. MP 24,
University Hospital Southampton,
Tremona Road,
Southampton
SO16 6YD

Tel: 023 8120 5308
Fax: 023 8120 5378

Study Number:
Patient Information Number:

The Wessex Fit-4-Cancer Surgery Trial

The **WesFit** study: to assess the effect of a prehabilitation programme in cancer patients undergoing surgery

Patient Information Sheet

We would like to invite you to take part in our research study, but firstly we would like to explain why this research is important. This form should take about 20 minutes to read. Please contact us if there is anything that is unclear or if you have any questions.

Why we are doing the research:

We want to find out if a personalised intervention (i.e. exercise training and psychological support) before cancer surgery is feasible and tolerable and can improve physical fitness in patients prior to major surgery in an attempt to improve outcomes after surgery. We want to test if this exercise works best in the hospital, commercial gym or community centre. We also aim to find out if a psychological support programme can help prepare patients for their cancer treatment and surgery.

The aim of this exercise training will be to improve fitness. We believe that increases in physical fitness will improve recovery following surgery. The aim of the psychological support programme is to help patients prepare for the treatment ahead and manage the challenges of being diagnosed with cancer.

In this study you will be randomly selected to receive standard care, exercise training, psychological support, or exercise training and psychological support.

Who has reviewed the study?
National Health Service England, Cancer Transformation National Regional, National Teams and the NHS Research Ethics Committee (Insert IRAS number) have reviewed the study.

Why have you received this invitation?

Your doctor has told you that you have a form of cancer that may require surgery. This is routine care for this condition. In some circumstances you may undergo a course of cancer treatments (chemotherapy, radiotherapy or a combination of both treatments) to try to reduce the size of the cancer, followed by surgery to remove the cancer. This is also routine care for some types of cancer. We are inviting patients like you, who are waiting for an operation, to be in our study. We would like to improve your fitness and wellbeing before, during, and after surgery.

Will my treatment be any different if I take part?

If you agree to take part in this study, your cancer treatment will not be any different. You will be randomly assigned to one of four groups.

WesFit Pathway Cohort: (Surgery ± neoadjuvant cancer treatments pathways).

Group 1: Standard cancer treatment (surgery +/- neoadjuvant cancer treatments).

Group 2: An in-hospital SRETP, then rolled out into a community-based setting prior to surgery +/- during neoadjuvant cancer treatments at a community gym. Personal trainers delivering the SRETP will be trained in healthy conversation skills to support participants to exercise beyond the trial.

Group 3: Psychological support prior to surgery +/- during neoadjuvant cancer treatments at a cancer support centre in Wessex.

Group 4: An in-hospital SRETP, then rolled out into a community-based setting. Personal trainers delivering the SRETP will be trained in healthy conversation skills to support participants to exercise beyond the trial. Also provided with psychological support prior to surgery +/- during neoadjuvant cancer treatments at a cancer support centre in Wessex.

All patients will receive additional specialist monitoring before and after surgery. All aspects of the Recovery Package will be performed as standard care.

If you are assigned to an exercise group (Group 2 or 4), you will be asked to undergo a supervised exercise program before surgery. Our exercise program will run alongside your treatment. If you are assigned to psychological support (Group 3 or 4), you will be invited to attend weekly sessions with a support worker at a Cancer Support centre before surgery. This will run alongside your treatment. This study will not cause any delays to your treatment. If you are assigned to the standard group you will not be given any exercise training or additional support but you will have additional monitoring.

Whichever group you are randomly assigned to, you will be asked to undergo some additional exercise-based tests, activity monitoring, assessment of your nutritional wellbeing and complete some questionnaires.

The study will not cause any delays in your cancer treatment.

Do I have to take part?

No. It is up to you to decide whether or not you should take part. If you decide to give us permission, we will give you this information sheet to keep and ask you to sign our consent form. Anyone taking part can withdraw from the research project at any time and without giving any reason. If you decide to withdraw or not take part, this will not affect the quality of care you receive whilst in hospital.

If you choose not to take part we would be interested to discuss with you the reasons for this. This will help support future cancer services. As with the broader research study, you are under no obligation to do so and this will not affect the quality of care you receive.

What will happen to me if I take part?

We would like to start by assessing your fitness objectively using a test called a 'cardiopulmonary exercise test' or CPET (see below for more information). This is part of routine care in certain hospitals e.g. University Hospitals Southampton. This appointment will take approximately an hour. We will ask you to answer questions about your health and wellbeing. Then all patients will be divided randomly into one of the four groups. You will be randomised using a computer programme removed from the study group.

If you are in one of the exercise group, we will ask you to attend a number of exercise training sessions. If you are undergoing cancer treatments prior to surgery, then this will take place twice per week during your cancer treatments, and thereafter 3 times per week up to the time of surgery. If you are not undergoing cancer treatments prior to surgery then this will take place 3 times per week. If you feel particularly unwell on a training day, then sessions can be cancelled or rescheduled. The first 2 exercise training sessions will take place in a supervised, safe hospital environment, in our exercise laboratory. Thereafter, the exercise training sessions will take place in a supervised, safe community environment by our highly trained personal trainers who you will meet at one of your in-hospital exercise-training sessions.

We advise you to wear suitable clothes for exercising at all exercise training appointments. The level of exercise will be individually tailored to your current fitness levels, using the results from the CPET tests. Exercise training sessions will last 30-40 minutes. During exercise sessions you will be monitored with heart rate and oxygen saturation monitors, to ensure you are exercising at a safe level.

There are changing facilities available at the study sites and a shower can be made available to patients, upon request. Both groups will be asked to perform the fitness tests during their treatment before their surgery, and 2 times after surgery.

If you are in the psychological support group, you will be asked to attend weekly appointments at a Cancer Support centre in Wessex. You will meet with a support worker to discuss any concerns you might have and be supported to manage the effect of your diagnosis on day to day life.

If you are randomised to the standard care group with additional monitoring, you will receive no formal exercise training. However, you will receive exercise and lifestyle advice and additional monitoring throughout the study.

All groups will be asked to perform the fitness tests during their treatment before their operation. We will also give all groups a wristwatch to wear (to monitor your daily activity levels) for the duration of the study, and for up to one-year thereafter to monitor your recovery from surgery.
We will also ask you to complete a few short questionnaires and undergo assessment of your nutritional wellbeing.

The following assessments will be included but not restrictive to depending on availability at each sites:

- An online questionnaire about your diet and food habits
- A questionnaire asking about symptoms and appetite
- Your height and weight (part of standard care)
- A malnutrition screening tool (part of standard care)

Cardiopulmonary Exercise Testing
All participants recruited to all 4 groups will complete CPET's at your hospital. These tests will be repeated a number of times (depending on whether you are having additional chemotherapy and/or radiotherapy) prior to surgery, and 2 times after your surgery. This involves cycling on an exercise bike for 8-12 minutes, therefore we advise you to wear suitable clothes for exercising at all CPET appointments. The test will start with a very low resistance on the pedals. After 3 minutes of cycling with no resistance, the resistance will gradually increase at a constant rate until you can no longer turn the pedals at the required speed. Your heart will be monitored using an electrocardiogram machine (ECG). You will be required to wear a soft rubber mask over your mouth and nose in order to continuously sample expired air with an online breath by breath gas analyser.

This test is common practice prior to operations and provides an accurate measure of physical capacity. Each CPET appointment will last approximately one hour. In most hospitals in Wessex this is part of routine care.

Blood samples and Tumour Samples
As part of this research project, all patients recruited will have a blood test as part of your standard care. Some patients will be asked to consent to take tumour samples prior to and during surgery for other research studies. If this is the case, they will be asked to consent for this separately.

Activity Monitoring
We are also interested in how active you are on a daily basis, and whether this changes with your treatment. Therefore we will ask you to wear an "accelerometer", which is a small watch-like

device worn on your wrist. This will be worn for the duration of the study and thereafter up until one-year following your surgery.

Computer Tomographic Scans (CT scans)
As part of your normal cancer treatment pathway you will have a series of scans that will be used by the clinical team to evaluate your tumour. Special assessments of these scans will be undertaken using specialist medical software in order to define changes in fat and muscle bulk.

Wellbeing Measurement
We will ask you to fill in questionnaires to measure your health and wellbeing at your first visit and prior to your surgery. We will then ask you to complete these questionnaires 30 days after your surgery and at 3, 6 and 12 months post surgery to help us monitor your recovery.

Follow Up

After your surgery we will monitor your recovery by using two scoring systems: the Post Operative Morbidity Survey (POMs) and Clavien-Dindo Score. A member of the research team will record these during your hospital stay and on your day of discharge. This is part of routine clinical care.

In addition, we would like to assess your fitness after your surgery, by asking you to complete two further CPETs. These would be performed 6 and 12 weeks after your surgery, and only performed if you are deemed fit enough to do so by your clinical team.

What are the risks or side effects of taking part?
After exercising some people may feel achy or sore, but this should subside within a day or two. There is also a very small risk (1 in 10,000) associated with CPET of heart attacks or irregular heartbeat, but this is very rare and all CPET tests are performed in a safe hospital environment or safe community environment and your heart and lungs and all other vital signs will be continuously monitored during the CPET. The test will be stopped if there are any concerns for your wellbeing.

After support sessions at the Cancer Centre, you may feel different emotions, but your support worker will prepare you for this.

What if something goes wrong?
We have no reason to believe that anyone will come to any harm as a result of this research. If taking part in this research project harms you, there are no special compensation arrangements. However, if you are harmed due to someone's negligence then you may have grounds for a legal action in the usual way. If you wish to complain about any aspect of the way you have been approached or treated during the course of this study, the normal National Health Service complaints mechanisms are available. Any complaint about the way you have been dealt with during the study or possible harm you might have suffered will be addressed. Please raise your concerns in the first instance with the Chief Investigator (that is the lead researcher) via Lesley Hawkins (Assistant Operations Manager) on 02381205308. If you wish to make a more formal complaint, please contact the hospital's Patient Support Service (available 9 am to 4.30 pm Monday to Friday, out of hours there is an answer phone).

Patient Support Services
C Level Centre Block
Mailpoint 81
University Hospital Southampton NHS Foundation Trust
Southampton SO16 6YD

Email:
patientsupportservices@uhs.nhs.uk
Tel: 02381206325

What will happen if I don't want to carry on with the study?
All patients in the study can withdraw from the research project at any time and without having to give any reason, with no impact on their future clinical care. If you do withdraw we will ask for your permission to remotely document and collect routine clinical data including survival.

What will we do with the information we collect?

Your personal information (name, address, diagnosis, date of birth etc.) associated with your test results will not be available to anyone outside your medical team.

Information relating to the final study results will be available at the end of the study when all data is complete.

We expect that the data will be published in a medical journal to help doctors make decisions about patients in the future. All information will be anonymised; that is, all figures and numbers will not be traceable to individual patients and personal details (name etc.) will be removed. Your medical records may be accessed for research purposes by members of research staff not directly part of the clinical care team. The information collected will be held by the research team in an anonymous format. Hospital computers including laptops will be used by the clinical research team. These computers will be password protected and have the same security features as hospital computers. All manual files will be kept in a locked filing cabinet in a locked office.

What will happen to any samples I give?
All samples will be encoded in order to ensure your identity is kept confidential. Only the investigator will hold the information to link the coding to the person. Any samples will be kept frozen until analysis.

We are seeking permission to securely store your samples in an anonymised and unidentifiable form. These samples will be used in conjunction with other ethically approved research studies and may include genetic studies, however you will be consented for this separately.

Involvement of the General Practitioner/Family doctor (GP)
With your permission we will inform your GP if you decide to take part in this trial.

Contact Information
Lead Researcher – Dr Sandy Jack – Consultant Clinician Scientist (Sandy.Jack@uhs.nhs.uk)
Study Coordinator – Samantha Leggett – Exercise Physiologist (Samantha.Leggett@uhs.nhs.uk)
Consultant Surgeon – Professor Tim Underwood – Consultant Surgeon (Tim.Underwood@uhs.nhs.uk).

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Consultant Oncologist– Dr Judith Cave – Consultant Medical Oncologist (judith.cave@uhs.nhs.uk)
Telephone: 02381205308