[INSERT TRUST LOGO]
[SITE PI]

iRehab
Remote rehabilitation after intensive care

Participant Information Leaflet

Remote multicomponent rehabilitation in survivors of critical illness after hospital discharge – the iRehab Trial

We want to find out whether a support and exercise programme can help people recover after being in intensive care.

Introduction

You are invited to take part in the iRehab trial. This information sheet explains the iRehab trial and what taking part will involve. Before you decide if you want to take part, we would like to explain why the research is being done and what it would involve for you. Talk to others about the trial if you wish. A member of the hospital research team can talk to you to explain the trial and answer any questions that you have.

This leaflet is divided into two parts. **Part One** tells you about the trial and what will happen to you if you take part. **Part Two** gives more detailed information about how the trial will be carried out.

Part One

Why are we doing this trial?

People treated in intensive care need a great deal of special care and support. After discharge from hospital, some people find their muscles are still weak and their ability to exercise and to do everyday things may still be affected. They can also have confused memories of their time in the intensive care unit. For most people, these problems get better on their own, but for other people, they may continue for a long time after leaving hospital.

We want to find out if a rehabilitation programme can help people recover more quickly after they are home from hospital. This trial will test a programme of 'remote' support, where patients talk to healthcare staff over video or telephone. They will also have help to do some exercises to help their recovery. This

trial will be the first to test a remote approach to rehabilitation. We want to find out if remote support is better than standard NHS care for people recovering from a critical illness.

Why have I been asked to take part?

We are asking you to take part in this trial because you were treated in an intensive care unit and spent some time on a breathing machine (mechanical ventilation). We would like 428 people from across the UK to take part in the trial. People can only join the trial if they were discharged from hospital less than three months ago.

Do I have to take part?

It is up to you to decide if you want to take part. If you agree to take part, we will ask you to complete a consent form. Even after completing the consent form, you can withdraw at any time without giving a reason. If you decide not to take part, or you withdraw, the standard of care you receive will not be affected.

If you decide to withdraw, we will keep the information about you that we have already collected. If you do not want this to happen, please tell us.

What does taking part in this trial involve?

You will have received this information leaflet if you are going home from hospital soon or if you were discharged from hospital less than three months ago. The clinical team or a member of the iRehab team will speak to you about the trial either before you leave hospital or by telephone if you are at home. You will have a chance to ask any questions that you may have, and you can decide if you would like to take part.

Consent to taking part

If you agree to take part, you will be asked by the research team to complete a consent form. You can either sign a paper copy of this or give the researcher permission to confirm your consent to the trial over the telephone/via videocall. We will then post you a copy of the completed consent form to you to keep. After you have given your consent, we will contact you and ask you to complete the trial questionnaires.

Your hospital care

Once you have provided consent, the hospital where you were treated in intensive care will provide the trial team with your contact details and information about how long you were in hospital for and the type of care you received. This information will help us to contact you and to understand how your stay in hospital affects your ongoing recovery.

Trial questionnaires and measurements

You will be asked about how being in an intensive care unit has affected your physical and mental health, and your quality of life. This information will be collected either by using your computer or smart phone to

click on a link directly to the questionnaires. Or it can be collected by speaking to a member of the research team by telephone or email. This will take about 30 minutes to complete. You can take a break and return to the questionnaires at any time. You will also be asked to do a short physical test that involves standing up and sitting down from a chair. This is called a 'sit-to-stand' test and it tells us about your general fitness. You will be provided with a device to measure your blood oxygen levels that you may use during this. A member of the trial team will contact you about the sit-to-stand test via telephone (including WhatsApp if you have the internet and smart phone or text message) and/or email. You can contact us by phone Tel: 02476151367 or email (irehab@warwick.ac.uk) if you are having any problems with the questionnaire or the website.

You will be asked to complete study questionnaires before you come into the trial, and then again after two and six months. At two months you will also be asked to complete a questionnaire about your participation in the trial. This will take approximately 5 minutes. You will receive a link to enter data onto a third-party software/database to collect your answers. This is for the purpose of the study only. Your responses may also be collected by phone or via post.

If we have any questions for you during the trial, we will get in touch.

What equipment or devices do I need to take part?

You will need to use either a computer or a telephone for the trial.

If using a computer (tablet, laptop or smartphone), you will need internet access, and an email address so we can contact you. If your device has a camera, then we will arrange a video call. We will use email or text to send you a link to fill in the trial questionnaires. If you have a mobile phone, we may send you a reminder text message when your next questionnaire is due.

If you do not have internet access or a computer, we will contact you by telephone to give you the trial information. If you do not have access to a telephone, please let the research team know using the contact details below and they will be able to advise on this.

What will we test in this trial?

We will test a support and exercise programme to find out if it can help people recover after being in intensive care. We want to find out if the new programme is better than standard NHS care.
After you have completed your first questionnaire and your sit-to-stand test, you will be put into one of two groups, and this is decided by chance. This means neither you nor the clinical team nor the research team can choose which group you will be put in, so the study treatments can be compared fairly. Patients have a chance of being in one of two groups:

Group 1: Standard care
OR
Group 2: A six-week support and exercise (rehabilitation) programme

What will I have to do next?

This will depend on which group you are assigned to:

Group 1: Standard care

People in this group will be provided with the usual care that is currently given to patients who have been in intensive care. In many cases rehabilitation is not provided as part of standard NHS care when people go home from hospital after an admission to intensive care. This is standard care in the NHS.

Group 2: iRehab Support and exercise (rehabilitation) programme

People in this group will be asked to take part in the new rehabilitation programme. This involves contact with one or more trained healthcare staff (iRehab specialists) every week for six weeks, using computers or by telephone. You do not need to leave your home to take part in the programme.

The programme has three parts:

1. ***Weekly appointments with iRehab team***

We will explain the support programme to you in the first appointment. This session will last up to one hour. The iRehab specialist will ask you about your symptoms and how you are coping, and then prescribe a plan that will include some easy exercises to do for the week ahead. They will give advice on how to cope with your symptoms (e.g. fatigue, problems eating, worries, low mood). We will send you the iRehab patient manual(s) with some easy exercises to do at home, and some advice about walking and managing common problems after being in intensive care. The exercises will have pictures and written instructions to guide how to do these. The manual will include tips that can help with recovery after being in intensive care. You may also be offered the use of a step counter to help you with this activity. The iRehab specialist will provide you with instructions on how to use this. You will have a video call or telephone call with your iRehab specialist every week for six weeks.

If our conversations with you highlight any health problems (physical or mental) that may require further treatment, we may inform your GP or other relevant healthcare staff.

2. ***Weekly exercise sessions***

As well as your weekly call with the iRehab specialist, you can do an additional exercise session every week. This will be either online using a computer, or, if you don't have access to a computer, you can follow your exercises or do some walking. We will help you plan which option suits your needs and include this in your plan for the week ahead. You will not need any special exercise equipment to take part.

If you do the additional exercise session online using a computer, the iRehab specialist will send you a link to special website called BEAM. In this case you will be asked to register with BEAM. The trial team will be available to help you with the use of computers, tablets, phones, and other devices for this. The website is referred to as a third party because we do not directly control it. The website will ask you to read and agree to the terms and conditions, then register an account using your name and email address.

During the online group sessions, you may be visible on screen to the iRehab specialist and the other people in the group. You can choose to remain anonymous by creating a nickname instead of your own name. You will be asked to complete some brief questions before and after each group exercise session. This is to check you are feeling well enough before and after exercising and to see how the session went.

Any data collected in this way will be coded (encrypted) and stored safely according to NHS and UK Government standards.

3. ***Weekly iRehab Café***

You will be invited to join a weekly online support group, called the iRehab café. This will be either online using a computer and the special website BEAM (as above), or, if you don't have access to a computer you can join by telephone. Here, you can meet with other people who have been in intensive care, to share and discuss your experiences of recovery. Someone from the iRehab team will be at the group.

Your iRehab patient manual(s) will have information about the support sessions, and space to record the dates and times of your appointments.

We will record some or all of your online or telephone appointments to check the quality of our research team's delivery. This is for quality control purposes and to provide the iRehab team with an understanding of the problems that are bothering patients.

Interview: After two months, we may invite you to take part in an interview to explore your experience of being in the iRehab trial and how it made you feel. If you consent to being contacted for an interview, we may be in touch to provide further information about the interviews and ask you to provide separate consent. You can still take part in iRehab, even if you do not want to be interviewed.

How long will the trial last?

The iRehab trial will run across the UK. It will take three years to complete the whole study from start to finish, including writing and publishing reports about all the results. We will recruit people over a period of 18 months. Each person will only be involved in the study for six months.

What are the benefits of taking part?

We cannot promise that the trial will help you. However, the information we get from the trial will be useful in deciding whether or not this rehabilitation programme could help patients discharged home after intensive care admission in the future.

What are the risks of taking part?

We do not anticipate any serious risk to you. One possible disadvantage of taking part is the inconvenience it may cause you to complete the questionnaires. If you are in the rehabilitation group there is a very small chance that exercise can make you feel unwell. Exercise may cause tiredness, breathlessness and sore muscles, but this should get a bit easier each time you exercise. You will be advised and monitored by specialist staff. Although unlikely, if you feel unwell during any exercise sessions, an iRehab specialist will contact you online or by telephone to see if further emergency medical help is needed. Although there is only a very small risk of becoming unwell during exercise, we recommend that you have another person nearby at home when you are doing your first few exercise sessions. We ask for your consent to hold next of kin contact details for the duration of the trial. These details are only used in the event of an emergency e.g. during the sit to stand test or iRehab Support and exercise (rehabilitation) programme [group 2]. Or alternatively, if you would prefer us to contact your next of kin in relation to your participation in the trial.

Sometimes, people can find the questionnaires or support sessions upsetting. Our specialist staff are fully trained and will provide appropriate support and assistance if needed. There may be times when the trial team need to act upon confidential information for safeguarding reasons e.g. if our questionnaires or conversations with you highlight specific health problems (physical or mental). If so, we may refer you to your GP or other healthcare staff.

Expenses and payments

There are no payments for taking part in this research trial.

What are the alternatives to the iRehab programme?

Only a small number of NHS centres offer a structured rehabilitation programme for people after discharge home from hospital. These programmes have not yet been tested. We ask that you do not take part in these other rehabilitation programmes over the six months you are taking part in iRehab if they are similar to the one the trial is offering. You may of course receive other treatments during the six months you are taking part in iRehab and we will ask you to keep a note and tell us about these.

What if new information becomes available?

Sometimes during a research trial, new information becomes available about the treatment we are investigating. If so, someone from the iRehab team will contact you to discuss your involvement in the trial. If you decide to withdraw from the trial, you should discuss your care with your doctor. If you continue in the trial, you may be asked to complete an updated consent form. In addition, we will contact you directly by letter and/or email to keep you updated. New information will also be available here: www.warwick.ac.uk/iRehab.

Part Two

How will we use information about you?

Ulster University is the sponsor for the trial. The trial will be managed by Warwick Clinical Trials Unit at the University of Warwick. Ulster University and the University of Warwick will use information you provide and information from your hospital records to carry out this trial and will act as joint data controllers for the trial. This means that, together, they are responsible for looking after your information and using it properly. The team of rehabilitation specialists who will talk to you by telephone or via video call will be based at Ulster University and Belfast Health and Social Care Trust.

We will need information from you and from your medical records for this research project. This information will include your name, date of birth and contact details. NHS sites will pass these details to Ulster University and the University of Warwick, along with the information collected from you and your medical records. NHS sites, Ulster University, the University of Warwick, Queen's University Belfast and Belfast Health and Social Care Trust will use this information, as needed, to contact you about the research

trial. This could be to make sure that relevant information about the trial is recorded for your care, and to oversee the quality of the trial. Individuals from Ulster University, the University of Warwick and regulatory organisations may look at your medical and research records, including information that identifies you, to check the accuracy of the data collected during the research trial.
The only other people at Ulster University, Belfast Health and Social Care Trust, Queen's University Belfast and the University of Warwick who will have access to information that identifies you, will be people who need to contact you about the trial to follow up on your progress or check questionnaires are completed, the researcher doing the sit-to-stand test, the iRehab specialists delivering the programme and people who host the database where your information will be stored. The people who analyse trial information will not be able to identify you and will not have access to your name or contact details.

Ulster University, the University of Warwick, Queen's University Belfast, and NHS sites will keep identifiable information about you for 12 months after the trial has finished. Following this your name and contact details will be deleted but we will keep all other information about you from this trial for 10 years after the trial has finished.

With your consent, some of your contact information will be shared with third parties only for the purpose of the study. If you agree to take part your name and telephone number will be shared with a third-party text and email messaging service so that we can contact you about the trial. If you are allocated to the six-week rehabilitation programme you will also be asked to register on the website for the online exercises and iRehab café (BEAM). If you have a smart phone and access to the internet, we may also message you using WhatsApp.

BEAM will collect and store information on your attendance at classes and any answers to online questions completed before and after the exercise sessions. This information will be stored alongside your name and email address. Ulster University, Queen's University Belfast, Belfast Health and Social Care (HSC) Trust and the University of Warwick will be given access to this data to review your attendance and activity at sessions, use of online videos, answers to any questions and your safety. The data collected will be encrypted and stored safely to NHS and UK GDPR standards until 12 months after the trial has finished; after this time period it is destroyed. Personal identifiable data shared with or stored by third parties will be securely deleted when it is no longer needed and the trial has ended.

With your consent, Ulster University, Belfast HSC Trust, Queen's University Belfast and the University of Warwick will collect information about you for this research trial from you and your medical records. This information will include ethnicity, and health information, which is regarded as a special category of information. If you agree to take part, we may use the information collected for future research. Any future research will only proceed if approved by a Research Ethics Committee where necessary. This information will not identify you and will not be combined with other information in a way that could identify you.

How will we keep your data safe?

All information we collect about you during the trial will be kept strictly confidential and will only be accessible to authorised people. The only reason we would break confidentiality would be in an

emergency. If you are assigned to the six-week rehabilitation programme, the iRehab team will keep paper records of your contact details and medical health information as per their safety protocol. These records will be stored securely and are only accessible to some trial staff. These records will not be passed onto the University of Warwick. If your own health, or somebody else's health, was in danger, we may contact you, the emergency services or other healthcare staff.

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. To safeguard your rights, we will use the minimum personally identifiable information possible. You can read the privacy statements on the Ulster University and University of Warwick websites:

https://www.ulster.ac.uk/about/governance/compliance/gdpr/privacy

https://warwick.ac.uk/services/sim/privacynotices/research

You can also find out more about how we use your information here:
http://www.hra.nhs.uk/patientdataandresearch

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. We will write our reports in a way that no-one can work out that you took part in the trial.

Involvement of the General Practitioner

Your GP who provides care to you, and the hospital consultant who looked after you in hospital will be notified that you are participating in this trial. We will let your GP know some of your questionnaire results, if you have feelings of worry or low mood. This information may help your GP look after your health.

What will happen to the results of the trial?

At the end of the trial, we will publish the findings in medical journals and at medical conferences. You will not be identified in any reports or publications. Once all patients have been followed up and the results have been analysed, we will make a copy of the trial results available on the trial website: www.warwick.ac.uk/iRehab.

Who is organising and paying for the trial?

This trial is sponsored by Ulster University and is being coordinated by the University of Warwick. The trial is funded by the National Institute for Health and Care Research, Health Technology Assessment programme (NIHR 132871).

Who has reviewed the trial?

Any research that involves the NHS and patients is reviewed by an independent group of people called a Research Ethics Committee. This committee is there to protect your interests. This trial has been reviewed and been approved by London – Central REC. People who have been in intensive care have also been involved in designing and setting-up this trial.

What if something goes wrong?

If you have any concerns about any aspect of this trial, you should ask to speak to the research team who will do their best to answer your questions.

If you are still concerned and wish to discuss your concerns with someone else or make a complaint, you can do this through the Ulster University Complaints Procedure. Details can be obtained from the web at https:// www.ulster.ac.uk/research/our-research/research-integrity (or Tel +44 28 9536 5123).

Alternatively, to voice and register your complaints or for independent advice, you should go through the hospitals local complaints procedure (eg. NHS Patient Advice and Liaison Service-PALS) using the details below or phone NHS 111:

[INSERT LOCAL PALS/COMPLAINTS MANAGER CONTACT DETAILS]

In the unlikely event that you are harmed by taking part in this trial, compensation may be available. If you suspect that the harm is the result of someone's negligence, you may be able to take legal action, but you may have to pay any costs involved and you should get legal advice about this. The normal NHS complaints mechanism will still be available to you.

Contact for further information:

If you have any questions about the trial, either now or in the future, please contact your local research team/ or the iRehab Trial Management using the details below:

[Insert Local Contact Details]

iRehab Trial Manager
Warwick Clinical Trials Unit
Email: iRehab@warwick.ac.uk
Tel: 02476151367

Thank you for taking the time to read this information and for considering taking part in this trial.

FUNDED BY NIHR | National Institute for Health and Care Research

WARWICK CLINICAL TRIALS UNIT

Ulster University

This trial is funded by the National Institute for Health and Care Research (NIHR) Health Technology Assessment programme (project number 132871). The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.