iRehab
Remote rehabilitation after intensive care

# Tips and Guidance for iRehab Recruiters

Recruitment to RCTs can be challenging, and many trials fail to meet their recruitment target. These tips and guidance provide some suggestions on how to avoid (or overcome) any difficulties you might encounter when discussing the iRehab study with eligible patients. You may wish to consider integrating these points and approaches, whilst maintaining your own recruitment style.

The first page provides some tips about approaching patients and setting up an informed consent discussion. The remainder of the document provides advice regarding key content of informed consent discussions. We hope you find these tips useful and welcome your feedback and experiences. We will update the document over time based on your ongoing feedback and analysis of recruitment data. **Thank you for all your work to support iRehab.**

## Recruitment pathways and informed consent discussions

As a reminder, patients can consent to join iRehab within **12 weeks of discharge from hospital**, following an ICU admission, requiring mechanical ventilation ≥48 hours. Patients can be **screened/ approached** at different points in their recovery following ICU: in the ward/post ICU discharge; at hospital follow-up clinics; or they could also be telephoned/ invited by letter after being discharged home. It is important to **approach all eligible patients for the iRehab study**, so patients have an opportunity to decide whether or not they would like to participate in this research.

*Feedback from recruiting sites indicates the following points maybe helpful for recruitment:*

- Providing a short face-to-face introduction to the study while participants are in the hospital ward. If possible, the introduction should be from the PI or a member of the clinical team, so they can talk about recovery and the study.
- Including family or next of kin in informed consent discussions.
- Following potential participants up promptly following discharge from hospital (even if people then still want more time to make a decision about study participation).
- Gradually providing people with further information about the study.
- The importance of teamwork to support recruitment.

## Additional points to consider:

- Patients can decide to join the study within 3 months of discharge from hospital, so they have plenty of time to decide if the study is the right thing for them or not.
- It is important to encourage patients to **'keep an open mind'** and to re-assure patients when first approached, they don't have to make a decision now about study participation.
- People do not need to have a computer to join the iRehab study. They can also join by phone. If people are randomised to the intervention group, they will be provided with materials in the post and can also be provided with a telephone or other electronic device if requested.
- iRehab has co-enrolment agreements with many ICU studies, so it is important to offer the study to all eligible participants.

**Diversity and inclusion:**

The iRehab study aims to be inclusive and reach out to ethnic minority groups who are generally under-represented in ICU research. Including ethnic minorities in research is an important way to understand and address health inequalities. Please take additional time to reach out to potential participants from ethnic minority backgrounds and include family or next of kin in discussions about the iRehab study. You should spend additional time to elicit concerns about participation in the iRehab study and tailor information and support to address barriers to participation such as language, technology. Please get in touch with Warwick CTU if you require any additional support.

**Arranging an informed consent discussion:**

We envisage that most informed consent discussions with potential iRehab patients will take place by phone once the patient has returned home following hospital discharge. When calling back to discuss the study in more detail, it is important to make sure you are speaking to the person at a convenient time (check they have 10-15 minutes time to spare) and that the patient is able to sit down and is comfortable to take your call. The following key points should be included in discussions about **the study** *(preferred term, as some people don't like the idea of a trial as something that is difficult, or experimental or can lead to confusion).*

1. **Opening up the discussion about iRehab:**

- Patients and doctors in the UK agree there is a need to improve the long-term health of people after getting home following a stay in intensive care.
- Follow up services vary across the country. Many hospitals do not offer any support. There is no evidence about what works best to help patients recover after a stay in intensive care.
- You and the [hospital] team are part of a **research study called iRehab**
- The NHS and your local hospital recognise this is an important question, so they have decided to take part in the iRehab study.
- Hospitals **across the UK** are taking part in iRehab to improve the care they provide to patients in the future.
- The study will compare local standard NHS care with a new rehabilitation programme which you can follow from home. You may get either one of these treatments. If you were given the rehabilitation programme, this will include weekly contact with a healthcare professional via telephone or computer for six weeks.
- We don't know which, *if either*, is best to support people recovering after being in intensive care.

2. **Explaining the need for the study:**

- It takes time for people to recover following a stay in intensive care. 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 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** (that can be accessed from home using a telephone or computer) can help people recover more quickly **after they are home from hospital**.

- To find the answer to this question, we need intensive care patients to join the study – both **those who think they might benefit** from a support package and **those who feel they are progressing well** with their recovery.
- We know that most patients eventually **recover after intensive care**. We just don't know if patients will benefit more quickly from the support and exercise programme, compared to standard follow up care from your local hospital. Either option is suitable for your recovery.

### 3. Explaining the treatments in a balanced way:

Try not to spend too much time describing the iRehab intervention arm compared to standard care. We know from other rehabilitation studies that if we place too much emphasis on the rehabilitation programme, patients can be disappointed if they are randomised to usual care. At the same time, it is important to inform people that by joining the study they should be prepared to commit to attend an appointment from home for one hour per week for six weeks. We will only know if they have to attend the appointments, after they joined the study if they are selected for the iRehab programme (see also randomisation).

In addition, we suggest you explain:

- If you are allocated to standard local NHS care:
    - People in this group will be provided with the usual care that is currently given to patients who have been in intensive care at your local hospital.
    - In many hospitals, rehabilitation is not routinely provided as part of standard NHS care when people go home from hospital after discharge from intensive care. (**INSERT FURTHER DETAILS ABOUT YOUR LOCAL CARE, IF APPLICABLE).**
    - This is a suitable option for people who are discharged from intensive care.
- If you are allocated to the iRehab Programme:
    - People in this group will be provided with access to a weekly support and exercise session with a health care provider (by telephone or computer), over a period of six weeks. Weekly sessions last for approximately one hour per week. People in this group will be given some information materials about recovery.
    - People will also have access to an online exercise class and peer support session, to talk with other patients who have been in ICU.
- This is also a suitable option for people who have been discharged from intensive care. Explain that **the patient will be monitored** by the study team **irrespective of which treatment they are allocated**. As part of that monitoring process, you will be asked to:
    - Fill out questionnaires about your health and your quality of life. This will take 30 minutes in total (you can take breaks and come back to it if you can't complete it all in one go). You can fill this out using a computer, smart phone, or with the help of a health care professional or a researcher who can help you over the phone.
    - Complete a measurement to assess your general fitness which will require you to move from sitting down in a chair to a standing position.
    - Use a small device on your finger to measure your blood oxygen level, before you do the standing test.
    - You will be asked to do these research procedures 3 times in total (when you join the study, then again after 2 months and after 6 months).
    - If you agree, we may invite you to take part in an interview so we can learn from patients about their recovery and experiences taking part in the study.

## 4. Addressing patient preferences (i.e. concerns about either treatment arm)

By exploring patient preferences, you can support patients to make an informed decision about study participation and **tailor additional information** to address any concerns or **misconceptions**. If you get a sense that the patient has a preference for the local standard care or the rehabilitation programme, gently explore the reasons underlying this. For example:

*"Is there anything about [non-preferred treatment] that concerns you?"*

Here are a few examples of concerns that some potential participants have expressed about joining the iRehab programme and thus joining the iRehab study and how you might address them:

1. Time commitment – you can re-assure patients they are only asked to take part in at least one activity each week. Group sessions are available, and they can take part in these if they would like to.
2. The need for a computer – people can access the intervention by telephone only and fill out questionnaires by post. They do not need an email address to take part. If randomised to the intervention, they will receive study materials (manuals etc.) in the post.
3. Concern about the ease or difficulty of the exercise programme – you can re-assure patients the sessions that the sessions will be delivered by experienced staff who will tailor and personalise the programme to cater to their individual needs and abilities.
4. If a person reports they are recovering well, you could suggest they can take their time to decide about taking part in the study or not once they see how they are progressing from home. You can also suggest they may learn things from the programme they hadn't thought of. They may also like to monitor their progress by taking part in the questionnaires and sit to stand test (available to both arms).

Whilst addressing particular concerns, it is also important to emphasise that the participant has a **50/50 chance of being randomised to the intervention arm**.

These are just some examples. You will come across many more in your discussions with patients.

Remember **to tailor additional information to address people's individual concerns**. Patients often become open to both study treatment options, once any misconceptions have been addressed, or they are equipped with new information that had not previously been aware of.

If people **are recently discharged from hospital and don't want to think about joining the study at that time,** you may also want to give people the **option to be called back in a few weeks** to see how they are getting along.

## 5. Explaining randomisation

Randomisation can be tricky to explain and for people to understand. The following wording may help to convey the need for randomisation:

- Treatment will be **determined by chance**, through a process of randomisation. This is a method of creating two groups of patients that are as similar as possible. Neither patients nor doctors/nurses can choose their group, because this could result in the groups being unequal.
- Each group receives one of the iRehab study treatments. This enables the treatments to be **compared fairly**. The only difference between the groups will be the treatments they receive. This means that at the end of the study, any difference between the two groups can be down to the treatment they received.