<Insert local Trust logo>

The RecoverED Study

A rehabilitation programme to improve recovery after delirium

Summary information sheet

Why is the research being done

Delirium is when a person becomes suddenly confused or more confused than they normally are. The symptoms of delirium usually improve within a few days to weeks but it can sometimes take several months for people to recover fully.

We would like to find ways to help people recover from delirium at home after they have left hospital.

Why have I been invited to take part?

You have been given this leaflet because your family member or friend has had an episode of delirium while in hospital. They have been invited to take part in the RecoverED study and need a family member or friend to take part with them.
We would like to invite you both to take part in the RecoverED study.

What would taking part in the RecoverED study involve?

- Supporting your family member who has had delirium with a home-based rehabilitation programme.
- The rehabilitation programme will led by a professional NHS rehabilitation support worker.
- Complete some questionnaires on health and wellbeing at the beginning, middle and end of the study. Some of the questionnaires will be on behalf of your family member or friend and some will be about you.

If you are happy to take part in the study you will be asked **to sign a consent form**, of which you will receive a copy.

Where to find more information

If you are interested in learning more about the RecoverED study, please continue to read the participant information leaflet below. A member of healthcare staff from the study team at this hospital will also speak with you about it.
At this hospital the **main contact** for this study is <insert name and email/phone no.>

The RecoverED Study

A rehabilitation programme to improve recovery after delirium

Family and Friend Information Sheet

Why have I been given this information sheet?

You have been given this leaflet because your family member or friend has had an episode of delirium while in hospital. They have been invited to take part in the RecoverED study and need a family member or friend to take part with them. Your family member or friend, or someone close to them, has suggested you might be suitable to take part with them as you normally provide care for them. **We would like to invite you both to take part in the RecoverED study.**

What is the study about?

Delirium is a medical word used to describe when a person becomes suddenly confused or more confused than they normally are. Their behaviour and concentration may also be affected. **Delirium is usually caused by an illness such as an infection**. The symptoms of delirium usually improve within a few days to weeks but it can sometimes take several months for people to recover fully.

Previous research has looked at how to treat delirium while people are in hospital but there has been no research into how to help people recover from delirium after they have been discharged home. **We would like to find ways to help people recover at home.**

We have designed a rehabilitation programme aimed at helping people recover from delirium at home. This has been designed by a group of experts with help from people who have experienced delirium.

- It involves gentle physical activities to help with daily tasks, activities which help with thinking and memory and the opportunity to discuss worries and feelings, over several weeks.
- It is carried out at home with the **help of a family member or friend** and a rehabilitation support worker.

Do I have to take part?

No. It is entirely up to you to decide whether or not to take part. Your family member or friend's care will not be affected, in any way, should you choose not to take part. You do not have to give a reason if you do not want to be involved.

If you decide to take part, and then change your mind later that is fine too. There is more information about that later on in this leaflet.

What will I have to do?

A research nurse or a doctor will contact you to talk to you about the study and answer any questions you may have**.** They have received your contact information from your friend or family member in hospital or from their immediate care team at the hospital.

Everyone who takes part in the study needs to have a family member or friend taking part with them for help and support. Your main role will be **supporting your family member who has had delirium with the rehabilitation programme**.

We will also ask you to complete some questionnaires on health and wellbeing at the beginning, middle and end of the study. Some of the questionnaires will be on behalf of your family member or friend and some will be about you.

If you are happy to take part in the study you will be asked **to sign a consent form**, of which you will receive a copy.

The **diagram on the next page** describes what taking part in the study will involve for you.

Your study pathway

<u>In hospital, at home or over the phone</u>

- You will complete a questionnaire about yours and your family member/friends wellbeing.

<u>At home after your family member or friend leaves hospital*</u>

- Visit by an occupational and/or physiotherapist to arrange for you and your family member/friend to start the rehabilitation programme.
- **You will support your family member or friend with the rehabilitation programme: 10 sessions for up to 12 weeks.**

  Each session will take up to one hour. It will help if you are present but you do not have to be there.
- A rehabilitation support worker will be present to lead the rehabilitation programme.

<u>At home or by visiting the hospital*</u>

- A research nurse or doctor will arrange to see you **3 months** and **6 months** after your family member or friend gets home from hospital.
- You will complete a questionnaire about yours and your family member/friends wellbeing.
- Each visit will take approximately **1 hour 40 minutes.**

<u>Optional interview (after finishing the programme)</u>

- A researcher will contact you by phone or video call.
- They will ask about your experience of participating in the programme
- This will take no more than **1 hour.**

<u>At the end of the study</u>

- The study ends when the questionnaires are complete after 6 months.
- **Your family member or friends care will continue as normal and your involvement in the study will be complete.**

*A different NHS service provider may deliver this part of the study

Optional parts of the study

Interviews

We are inviting people to be interviewed as part of this study to get feedback on the rehabilitation programme from the people who take part. The interview is an **optional** part of the study. **All interviews will be audio-recorded**. You and your family member or friend can still take part in the rehabilitation programme without taking part in an interview if you wish. Interviews will be carried out by telephone or video call (depending on your preference) by a trained member of the study team (a 'Researcher') based at the University of Exeter.

Audio-recording rehabilitation sessions

We need to look at the way the rehabilitation support worker delivers the rehabilitation programme. To do this, we wish to **audio-record** a small number of the **rehabilitation sessions**. This is **optional** and you can chose not to do it. If you do agree to it, the rehabilitation support worker will bring a secure recording device with them to record sound during one of the sessions. If you and your family member or friend agree to this, either of you can opt out at any time before the session is recorded.

Are there any possible disadvantages to taking part?

The risk of you coming to any harm while taking part in this study is low. The supportive listening sessions or interview could make you feel emotional but the rehabilitation support worker or a member of the study team will be there to help you if necessary. Some people find it a beneficial experience to talk about what they have been through.

What type of study is RecoverED?

You are being invited to take part in a **'feasibility study'**. This means it is a study with a small number of people to help us find out if it the rehabilitation programme is acceptable for people recovering from delirium. We also want to see if it is possible to carry out a much larger study in the future.

Will I receive any payment?

- You will not be paid for taking part in the study.
- If you go to the hospital to do the questionnaires 3 months and 6 months after you leave hospital, we will reimburse you for your travel and parking costs.

What difference will the study make?

This study will help us decide:

- If it is **possible to carry out a much larger study** in the future called a 'clinical trial' to find out if the rehabilitation programme is better at helping people recover from delirium than the current standard care
- If it is possible to provide the rehabilitation programme to **patients within the NHS**
- If any parts of the rehabilitation programme should be **changed or improved**

Stopping taking part in the study

What if I change my mind about taking part?

Your participation in the study is **voluntary**. You can leave the study at any time without giving a reason. However, if you are willing to share your reason it could help us make improvements in the future. If you decide to stop taking part, we will ask your family member or friend if there is another person who could be invited to take part in your place.

If you decide to continue taking part in the study but your family member or friend decides to stop/withdraw, we will ask them if it is ok for you to continue completing the questionnaires about them. They can say no to this.

We may withdraw you from this study

We need to start the rehabilitation programme as soon as possible after their hospital admission with delirium. This means, if you and your family member/friend agree to take part in the study but they are discharged from the hospital to another hospital or care home for more than 4 weeks before returning home, we will need to withdraw you both from the study.

We may withdraw you from this study, continued

If you lose the ability to make decisions for yourself during the study (this is officially known as 'lacking mental capacity') we will need to withdraw you.

Will my taking part in the study be kept confidential?

Yes. All information collected in this study will be kept **safe and secure.** We will store information either on an encrypted password protected computer, on secure servers in the EEA or in locked cabinets at the hospital, other NHS premises and at Exeter University, which can only be **accessed by authorised members of the study team.**

You will be allocated a unique participant number, which will ensure the information we collect about you is protected and cannot be identified by anyone else. Any personally identifiable information will be stored separately and securely from information obtained from the study and will be securely destroyed at the end of the study. Your personal details will only be used for the purposes of conducting the study.

This hospital may need to refer to a different NHS service provider for some parts of the study. If this is the case, your information will be securely referred so they are able to contact you and deliver the service.

When you complete questionnaires for the study we ask that you don't share your answers with your family member/friend who is taking part with you and that they don't share their answers with you. This is so the answers you give aren't influenced by the other person.

If you agree to take part in an **interview**, we will **audio-record it**. We may also ask you if we can **audio-record** one of your **rehabilitation programme sessions**. We will store the audio-recordings securely. The recordings may be typed up by a researcher from Exeter University or may be sent to a company called *Victoria Pink* (based within the UK) to be typed up. The company have strict confidentiality policies and are registered with the information commissioner's office (ICO). Once *Victoria Pink* have typed up the recording, they will securely delete their copies of the files. If we use any extracts from the interviews when we are writing up the project, we will make sure they are **anonymous** so that your identity is protected.

Will my taking part in the study be kept confidential, continued

The Royal Devon University Healthcare NHS Foundation Trust (Royal Devon) is responsible for making sure that the study is conducted properly. Data collected during the study may be looked at by responsible individuals from the Royal Devon, or from regulatory authorities to make sure that procedures are being followed correctly.

How will we use information about you?

We will need to use information from you for this study. This information will include personal identifiable data:

- Name
- Home address
- Email address

We will only collect this information if you consent to join the study. We will use this information to:

- Do the study and make sure that the study is being done properly
- To send you occasional newsletters about the study (***optional***)
- To send you a summary of the study results at the end (***optional***)
- To refer you to other NHS service providers if needed

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 unique participant number instead. We will never pass your contact details on to anyone outside the study team.

Five years after the end of the study we will destroy all study information that identifies you. We will keep the anonymised data indefinitely on secure servers at the Exeter University for future ethically approved research in this area.

Due to regulatory changes in the way that data is processed (UK General Data Protection Regulation 2018 and the Data Protection Act 2018) the Royal Devon's lawful basis to process personal data for the purposes of carrying out research is termed as a 'task in the public interest'. The Royal Devon will endeavour to be transparent about its processing of your personal data and this information sheet should provide a clear explanation of this. If you have any queries about the Royal Devon's processing of your personal data that cannot be resolved by the research team, further information may be obtained from the Data Protection Officer by emailing rde-tr.dataprotectionofficer@nhs.net or phoning **01392 403055**.

If you have any concerns about how the data is controlled and managed for this study then you can also contact the Royal Devon Sponsor Representative, Alison Kerridge, Assistant R&D Manager using the **contact details on page 12**.

What are your choices about how your information is used?

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.** To safeguard your rights, we will use the minimum personally-identifiable information possible.

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.

Where can you find out more about how your information is used?

You can find out more about how we use your information in the following ways:

- at www.hra.nhs.uk/information-about-patients/
- by asking one of the research team (see **page 12 for contact details**)
- by sending an email to **rde-tr.dataprotectionofficer@nhs.net** or
- by phoning the Royal Devon on **01392 403055**

What will happen to the results of this study?

- We will send you a newsletter with the results if you choose to receive them.
- The results will be presented at medical conferences and in scientific journals.
- We will also put the results on our website (see page 12 for details).
- This could be around 2 years after you join the study.

You will not be identified in any report or publication. We may use your words in reports and publications. However, we will not use your name or other identifying details so that you cannot be recognised.

Who is organising and funding this study?

This study is sponsored by the Royal Devon University Healthcare NHS Foundation Trust (Royal Devon) and funded by the National Institute for Health and Care Research (NIHR) project number 202338.

Who has reviewed this study?

The study has been reviewed by London South East Research Ethics Committee and has received a favourable opinion. The ethics committee who reviewed the study are independent from the research team.

What if there is a problem?

If you have a concern about any aspect of this study, you should speak to the research nurse or doctor at the hospital first who will do their best to answer your questions (their contact details are at the end of this leaflet).

Or you can contact the local Patient Advice and Liaison Service (PALS) <insert local PALS details>.

If you are still concerned and wish to complain formally, you can contact the Sponsor representative, Alison Kerridge, Assistant R&D Manager (see page 12 for contact details).

What will happen next?

The research nurse or doctor will discuss this study with you and see if you have any questions. You will then be asked whether you would like to take part.

Contact Information

Principal Investigator:
<Insert PI Name>,
<Insert PI email>,
<insert PI phone number>

Research Nurse:
<Insert research nurse name>,
<Insert research nurse email>,
<Insert research nurse phone number>

Trial Manager:
Abby O'Connell,
Exeter Clinical Trials Unit,
University of Exeter.
Email: RecoverED-Study@exeter.ac.uk

Sponsor Representative:
Alison Kerridge,
Royal Devon University Hospitals NHS foundation Trust.
Email: rduh.research-eastern@nhs.net

Visit our **website** for more information: https://blogs.exeter.ac.uk/recovered

Thank-you for reading this leaflet.

Additional information

Different team members involved in this study:

Research studies can involves lots of different people and organisations working together. Here are some of the types of people involved:

Principal investigator – a medical doctor who is responsible for the study at your hospital and is employed by the NHS Trust. In this study, the principal investigator is an expert in older people's health care.

Research nurse – a nurse who specialises in research. Research nurses are employed by the NHS Trust where your hospital is based and are subject to the same strict confidentiality laws as all other NHS employees. In this study, research nurses will visit your family member/friend in hospital, and later at home to complete the questionnaires.

Occupational and physiotherapists – experts in helping people to be able to do everyday tasks. They are NHS employees who will visit you at home to prepare for the intervention sessions.

Rehabilitation support worker – an NHS healthcare worker who visits people's homes to help them with rehabilitation. They will do the rehabilitation programme with you and your family member or friend at home. The rehabilitation support worker may be employed by a different NHS Trust to your hospital.

Trial manager – a trial manager looks after all aspects of a research study to make sure everything runs well and answers questions about the study. In this study, the trial manager works at the University of Exeter.

Researcher – a person who interviews people for research studies to find out what they think about the study or their health condition. In this study, the qualitative researcher works at the University of Exeter. You will meet them if you consent to an interview.

Funder notice:
This study is funded by the National Institute of Health and Care Research Programme Grants for Applied Research Programme (NIHR202338). The views expressed are those of the author(s) and not necessarily those of the NIHR or the Department of Health and Social Care.

FUNDED BY
NIHR | National Institute for Health and Care Research