The RecoverED Study

A rehabilitation programme to improve recovery after delirium

Welfare attorney, welfare guardian or nearest relative - Scotland

You are being invited to consider giving your permission for the person you represent to take part in the RecoverED research study. This is permissible under the Adults with Incapacity (Scotland) Act 2000.

We are inviting people to take part in a research study called the **RecoverED Study**. RecoverED is a study for people aged over 65 who have had an episode of delirium while admitted to hospital. The RecoverED Study involves a rehabilitation programme once back at home to help people recover from delirium.

We would like to invite the person you represent to take part in the RecoverED Study. Because of their memory problems (this is officially known as 'lacking mental capacity'), we feel they are unable to make an informed decision themselves about whether or not to take part.

We ask that you put your own views about the research aside to consider and take into account, the past and present wishes and feelings of the person you are being asked to consent for, had they been able to consent for themselves.

Please take time to read the following information carefully and discuss it with others if you wish.

We are asking you as you are someone who:

- Is a personal legal representative (welfare attorney, welfare guardian or nearest relative) of the person who lacks mental capacity
- Knows the person who lacks mental capacity well
- Is not employed to look after the person who lacks mental capacity

We are asking you to consider offering consent on their behalf **if you believe they would wish to take part in the study** if they were able to decide for themselves. You do not have to do this if you don't want to. You can say you don't want to decide and we will not ask anything more of you.

Do they have to take part?

No. It is up to you to decide whether they would wish to take part in the study or not. If you decide that they would wish to take part you are free to change your mind at any time and without giving a reason. This will not affect their care in any way, now or at any stage in the future.

What will I have to do?

Before you decide whether they would wish to take part, it is important for you to understand why we are doing the RecoverED Study and what taking part will involve for the person you are being asked to consent for.

Enclosed is a copy of the **Participant Information Sheet** which all people who are eligible to take part in the study receive. This is the same participant information sheet given to people who can make decisions for themselves so as you can read it exactly as they would. It gives details of what we would like the person you are being asked to consent for to do. Please **read this information carefully** and discuss it with others if you wish.

A member of the research team at the hospital will discuss the study with you in more detail. The person you are consenting for will also be involved in the discussion as much as possible depending on their mental capacity. The researcher will explain what participation would involve and answer any questions you might have. It would also be helpful if you let us know of any advance statements they have made about participating in research.

What happens if I do not think they would wish to take part?

If you do not think they would want to take part, please let us know. We will not ask you to do anything more and their care will not be affected.

What happens if I think they would wish to take part?

If you decide they would wish to take part, we will ask you to complete a consent form and give you a copy to keep. If the person you are being asked to consent for subsequently show any unwillingness to take part or seems to be uncomfortable or agitated by the presence of the researcher, then we will withdraw them from the study.

After joining the study, if the person you are consenting for regains their mental capacity and is able to make decisions for themselves, will we contact them and ask if they wish to continue in the study.

Thank you very much for reading this information.

Yours sincerely,
<PI Signature>
<Insert principal investigator name and job title>

The RecoverED Study
A rehabilitation programme to improve recovery after delirium

Participant Information Sheet

We would like to invite you to take part in a research study.

This information sheet explains why the research is being done and what taking part would involve. Please take time to read the following information carefully. Talk to family and friends about the study if you wish. You can also ask us if there is anything that is not clear or if you would like more information.

Thank you for reading this.

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 you with daily tasks, activities which help with thinking and momory and the opportunity to discuss your 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.

Why have I been invited to take part?

You have been given this leaflet because you have had an episode of delirium while in hospital.

Do I have to take part?

No. It is entirely up to you to decide whether or not to take part. Your 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 come to see you while you are in hospital to talk to you about the study and answer any questions you may have. Or, if you have already been sent home they will phone you to speak about the study.

If you are interested in taking part in the study, the research nurse or doctor will ask you for **contact details of a close family member or friend.** This is because everyone who takes part in the study needs to have someone taking part with them for help and support. Your family member or friend will also need to complete some questionnaires for the study. Some of the questionnaires they complete will be about you and some will about them.

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. You will either complete the consent form in hospital, or the research nurse or doctor will arrange to visit you at home at a time that suits you.

The **diagram on the next page** shows what taking part in the study will involve.

Study pathway

In hospital or at home

- Assessment of your delirium, memory and mobility.
- Complete a questionnaire about your wellbeing with help from the research nurse of doctor if needed.
- The research nurse or doctor will collect some information from your medical notes, but they will only look at information that is relevant to the study.

At home after you leave hospital

- Visit by an occupational and/or physiotherapist to arrange for you to start the rehabilitation programme.
- **Rehabilitation programme: 10 sessions for up to 12 weeks. Each session will take up to one hour.**
- A rehabilitation support worker and your family member or friend will be doing the rehabilitation programme with you.

At home or by visiting the hospital

- A research nurse or doctor will arrange to see you **3 months** and **6 months** after you leave hospital.
- Assessment of your delirium, memory and mobility.
- Complete a questionnaire about your wellbeing with help from the research nurse or doctor if needed.
- Each visit will take approximately **1 hour 40 minutes.**

Optional interview

- A researcher will contact you by phone or video call.
- They will ask you how you found the rehabilitation programme.
- This will take no more than **1 hour.**

At the end of the study

- The study ends when the questionnaires are complete after 6 months.
- **Your care will continue as normal.**

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 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 healthcare 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.

Are there any possible disadvantages to taking part?

The risk of you coming to any harm while taking part in this study is low. However, you may be asked to do more than if you weren't taking part in the study.

A family member or friend will be taking part in the study with you. They will be there to help and support you.

The things you should consider are:

- The activities might be tiring, but should help you in the long run.
- Physical activities can cause injury if not done correctly, but we will show you the correct way to do them.
- The supportive listening sessions or interview could be emotional, but your family member or friend will be there to help if necessary.

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 assessments and questionnaires 3 months and 6 months after you leave hospital, we will **reimburse you for your travel and parking costs**.

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.

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. You can also chose to stop some parts of the study and continue with others. For example, you may wish to stop the rehabilitation programme but continue with the questionnaires.

If you choose to stop taking part in the study, **we would like to continue collecting information** about your health from central NHS records, your hospital and your GP. If you do not want this to happen, tell us and we will stop. **Your care will not be affected, in any way, should you choose to stop taking part in the study at any time.**

A family member or friend will be taking part in the study with you. If they decide to stop taking part, we will ask you if there is another person who could be invited to take part in their place.

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

We may withdraw you from this study

We need to start the rehabilitation programme as soon as possible after your hospital admission with delirium. This means, if you agree to take part in the study but are discharged from this hospital to another hospital or care home for more than 4 weeks before returning home, we will need to withdraw you from the study. This means that you will not start the rehabilitation programme.

Your medical care team or your family member/friend may decide it is not safe for you to continue in the study. If this happens the research nurse or doctor will discuss with you and your family member/friend whether it would be in your best interest to withdraw you from the study.

During the study, **if you lose your ability to make decisions for yourself** (this is officially known as lacking mental capacity) you will **remain in the study**. This is because you will not be at any extra risk of harm compared to when you decided you wanted to join the study. But if a family member/friend or your medical care team object we will discuss whether 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 to make sure the information we collect about you is protected and you 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 after the end of the study. Your personal details will only be used for the purposes of conducting the study.

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.

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.

If you tell us anything during the course of the study that could put yourself or other people at risk, we would have to act on this information by telling your GP or appropriate authorities.

How will we use information about you?

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

- Name
- NHS number
- 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***)

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.

To make sure we are giving everyone a fair chance of joining the study we will collect a small amount of **anonymous information (age, sex and ethnicity) on everyone** who is invited to join the study. This will also help us see if there is a difference between people who do take part and people who don't.

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 13**.

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/
- Asking one of the research team (see **page 13 for contact details**)
- Sending an email to **rde-tr.dataprotectionofficer@nhs.net** or
- Phoning the Royal Devon on **01392 403055**

Will my GP be involved?

If you agree to take part, **we will inform your GP**, so that he/she will be aware that you are involved in this study and can contact us for further information or advice if needed.

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 13 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 both the London South East and the Scotland A Research Ethics Committees and has received a favourable opinion. The ethics committees 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 13 for contact details).

What will happen next?

The research nurse or doctor will visit you to discuss this study 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

Useful resources

You may find useful information about delirium and also dementia at the following websites. If you prefer, you can ask for any of these resources to be printed out for you. Just ask any of the people listed above.

https://www.alzheimers.org.uk/get-support/daily-living/delirium

https://www.rcpsych.ac.uk/mental-health/problems-disorders/delirium

https://livingwithdementiatoolkit.org.uk/

https://www.nhs.uk/conditions/confusion/

Thank-you for reading this leaflet.

Additional information

Who is 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 doctor or clinical specialist who is responsible for the study at your hospital and is employed by the NHS Trust.

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 you 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 be doing the rehabilitation programme with you and your family member or friend in your home.

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 researcher works at the University of Exeter. You will meet them if you consent to an interview.

Funder notice:
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