[Participating site logo to be added here]

Participant Information Sheet (Trauma Patients)

ROWTATE: : Multicentre Research Programme to Enhance Return To Work After Trauma – Implementation study (Observations)

Chief Investigators: Dr Kate Radford & Professor Denise Kendrick

Invitation

You are being invited to take part in a research study. Before you decide whether or not to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully, and discuss it with others if you wish.

Ask us if there is anything that is not clear, or if you would like more information. Take time to decide whether or not you wish to take part.

Contact details

Principal Investigator
[To be added/deleted as appropriate for each participating site]

Name:

Name:

Research/Specialist Nurse

Name <<add Name>>
Tel. Number: <<add Tel. number>>

Researcher

Name <<add Name>>
Tel. Number: <<add Tel. number>>

Contents

1. What is the purpose of the study?

This study (implementation) is additional to the main study of the ROWTATE programme that you are receiving. The aim of this study is to find out how well the ROWTATE programme is working and its impact on helping patients return to work or study. We would like to observe one of your meetings with the staff providing the ROWTATE programme and look at the records they have made about the care you have received over the first 12 months of the programme.

The observation will take place during the time you are taking part in the ROWTATE programme. We are inviting patients from major trauma centres in England to take part.

2. Why have I been asked to take part?

You have been invited to take part because you are receiving the ROWTATE programme.

A number of occupational therapists and clinical psychologists are providing the ROWTATE programme to patients like yourself. We are inviting one patient who is receiving the ROWTATE programme from each occupational therapist and clinical psychologist to take part in the study. Only patients whose occupational therapist or clinical psychologist has also agreed to be observed will be invited.

3. Do I have to take part in this study?

No. It is up to you to decide whether or not to take part. If you decide to take part you will be given this information sheet to keep and be asked to sign a consent form to confirm that you understand what is involved when taking part in this study. If you decide to take part you are free to leave the study at any time and without giving a reason.

If you withdraw from the study, we will keep the information about you that we have already obtained. 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. A decision to withdraw at any time, or a decision not to take part, will not affect your legal rights nor the quality of care you receive. You will continue to receive the ROWTATE programme.

4. What will happen to me if I take part in the study?

After reading this information sheet, the researchers will discuss the study with you, what it involves and answer any questions you have. There are two aspects to this study: observing and/or recording one of your meetings with staff providing the ROWTATE programme and looking at records of the care you have received.

The researcher will ask your permission to observe and/or record one of your meetings with staff providing the ROWTATE programme. If your meeting takes place face to face with staff we will observe it and/or audio-record it. If your meeting takes place via video-call we would like to record this. The researcher will not take part in the meetings in any way; they will simply observe the meeting and make notes about what is discussed. The researcher will also look at the records completed by staff providing the ROWTATE programme to see what care was provided.

To thank you for allowing us to observe and/or record one of your meetings we will give you a £20 gift voucher.

5. What do I have to do?

If you agree to take part in this additional study, a researcher will telephone you to discuss the study further and check some details with you. If you proceed with the study, you will be asked to sign a new consent form for this aspect of the study.

The researcher will also ask for your permission to observe and/or record one of your meetings with staff providing the ROWTATE programme. The researcher will also ask your permission to look at the records completed by staff providing the ROWTATE programme to you.

- If you are unable to sign the consent form due to your injury, you will be asked to make a mark on the consent form to indicate your consent. Then, one of your representatives (family or friend) will be asked to sign the consent form as a witness to your verbal consent to participate.

6. What are the possible disadvantages of taking part?

We do not anticipate any risks associated with taking part in the study. We do not anticipate any disadvantages to having one of your meetings with staff providing the ROWTATE study being observed and/or recorded or to having your records about the ROWTATE programme looked at.

7. What are the possible benefits of taking part?

The study may not be of direct benefit to you, but the information we get from this study will help us develop the return to work programme (ROWTATE), which may help injured patients in the future.

8. What happens when the research study stops?

This information we gather from you will help us to develop the ROWTATE programme to help injured people return to work or study. The findings from this study may be published as an article in a research journal and presented to local patient or service provider groups, at academic conferences and to relevant charities. You will not be identifiable in any publications or presentations.

9. What if there is a problem?

If you have a concern about any aspect of this study, you should ask to speak with the researchers who will do their best to answer your questions. If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure. Details can be obtained from the hospital or you can contact the Patient Advice and Liaison Service (PALS) telephone 0800 183 0204.

In the event that something does go wrong and you are harmed during the research study there are no special compensation arrangements. If you are harmed and this is due to someone's negligence then you may have grounds for a legal action for compensation but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you.

10. Will my taking part in the study be kept confidential?

Yes. All the information about your participation in this study will be kept confidential. The University of Leeds and Nottingham University Hospitals NHS Trust will act as joint Data Controllers for this study under the General Data Protection Regulations (GDPR). This means that we are responsible for looking after your information and using it properly. The Chief Investigators of this study (Dr Kate Radford & Professor Denise Kendrick) are the Data Custodians (manage access to the data).

We will need to use information from you and your medical records for this study. If you consent to take part in this study, the records obtained while you are in this study will remain strictly confidential at all times. The personal information will be held securely on paper and electronically on University of Nottingham and [NHS site] computers under the provisions of the Data Protection Act 2018 and the General Data Protection Regulation (and any future data protection laws). Your name will not be passed to anyone else outside the research team or the sponsor, who is not involved in the study. You will be allocated a study number, which will be used as a code to identify you on all study forms. All identifiable information will be kept under locked cupboard in a locked office, and password protected file in a password protected PC and separate from study data. All recordings will be anonymized and be kept separate from information about the identity of the participants and documents with patient identifiable data (consent forms, recruitment logs).

Although what you say to the researchers is confidential, should you disclose anything to us which we feel puts you or anyone else at any risk, we may feel it necessary to report this to the appropriate persons. We will also contact your GP if you disclose anything to us which we feels puts you at any risk of self-harm.

The information collected about you may also be shown to authorised people from the UK Regulatory Authority and Independent Ethics Committee; this is to ensure that the study is carried out to the highest possible scientific standards. All will have a duty of confidentiality to you as a research participant.

11. What will happen if I do not want to carry on with the study?

Your participation is voluntary, and you are free to withdraw at any time, without giving a reason, and without your legal rights or medical care being affected. You will continue to receive the ROWTATE programme.

If you withdraw then the information collected so far may not be possible to erase and may still be used in the study analysis.

12. Use of your personal data in research

Nottingham University Hospitals NHS Trust is the sponsor for this study. Data will be stored and analysed by the University of Nottingham and [NHS site] on secure university and NHS networks. At the end of the study your personal data and research data will be securely transferred to the Nottingham University Hospitals NHS Trust (sponsor) and a copy stored securely at the University of Nottingham. In line with Good Clinical Practice guidelines, your personal data (address, telephone number) will be kept for 12 months after the end of the study. All research data will be kept securely for at least 7 years following the end of the study and may be used in possible future research during that time if you have provided consent for this. Such usage in future research would have to be approved by investigators at the University of Nottingham, Nottingham University Hospitals NHS Trust and the National Institute for Health Research before anonymised data is released. During the time your data is being stored all precautions will be taken by all those involved to maintain your confidentiality and only members of the research team will have access to your personal data. After this time your data will be disposed of securely.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. If there is any loss of capacity (the ability to make your own decisions) during the study, your identifiable data would be retained for the purposes of the study. To safeguard your rights, we will use the minimum personally-identifiable information possible, this information will include your name, date of birth, NHS number, address, telephone number(s), email address (if you have one). People will use this information to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your name or contact details.

[NHS site] will collect information from you for this research study in accordance with our instructions.

[NHS site] will use your name and contact details to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Individuals from Nottingham University Hospitals NHS Trust and regulatory organisations may look at your research records to check the accuracy of the research study.

[NHS site] will pass these details to Nottingham University Hospitals NHS Trust along with the information collected from you. The only people in University of Nottingham, Nottingham University Hospitals NHS Trust and [NHS site] who will have access to information that identifies you will be people who need to contact you to discuss your participation in the study or audit the data collection process. The people who analyse the information will not be able to identify you and will not be able to find out your name, or contact details.

You can find out more about how we use your information:

- at www.hra.nhs.uk/information-about-patients
- by visiting www.nuh.nhs.uk/gdpr
- by asking one of the research team
- by emailing the Data Protection officer for NUH at DPO@nuh.nhs.uk
- by ringing the Data Protection Officer for NUH on 0115 924 9924 (extension 63975)
- the Nottingham University Hospitals NHS Trust Privacy Notice is available to read at www.nuh.nhs.uk/patients-and-public-ri

13. What will happen to the results of this study?

When the study is complete the results will be published in a medical journal and presented at academic conferences, but no individual participants will be identified. The results will also be made available to all participants via the ROWTATE website:

https://www.rowtate.org.uk/the-rowtate-project

14. Who is organising and funding this study?

The Nottingham University Hospitals NHS Trust will act as sponsor for the research. The National Institute for Health Research (NIHR) will fund the research.

15. Who has reviewed the study?

All research in the NHS is looked at by an independent group of people called a Research Ethics Committee, to protect your safety, rights, well-being and dignity. This study has been reviewed and given a favourable opinion by the NHS by the North of Scotland Research Ethics Committee. The study has also been reviewed and approved by the Research & Innovation department of Nottingham University Hospitals NHS Trust.

16. Contact for further information

If you have any questions about the study, please speak to the principal investigator or study researcher, who will be able to provide you with information about the tasks involved. If you wish to read the research on which this study is based, please ask the chief investigator. If you require any further information or have any concerns while taking part in the study please contact one of the following people:

Chief Investigators:

Professor Denise Kendrick
Email: Denise.kendrick@nottingham.ac.uk
Tel: 0115 8466914

Dr Kate Radford
Email: Kate.radford@nottingham.ac.uk
Tel: 0115 823 0226

Principal Investigator [delete as appropriate depending on site]:

Researcher: TBC
Email:
Phone:

Independent Contact:

You can have more time to think this over if you are at all unsure.

Thank you for taking the time to read this information sheet and to consider this study.