

## Participant Information Sheet (Trauma Patients)

### **ROWTATE: Multicentre Research Programme to Enhance Return To Work After Trauma – Interviews (acceptability and implementation)**

**Chief Investigators: Dr Kate Radford & Professor Denise Kendrick**

## Invitation

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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

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**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

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1. What is the purpose of the study?
2. Why have I been asked to take part?
3. Do I have to take part in this study?
4. What will happen to me if I take part in the study?
5. What do I have to do?
6. What are the possible disadvantages of taking part?
7. What are possible benefits of taking part?
8. What happens when the research study stops?
9. What if there is a problem?
10. Will my taking part in the study be kept confidential?
11. What will happen if I don't want to carry on with the study?
12. Use of your personal data in research
13. What will happen to the results of this study?
14. Who is organising and funding this study?
15. Who has reviewed this study?
16. Contact for further information

## **1. What is the purpose of the study?**

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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 invite you to two interviews to find out your views and experiences of receiving the ROWTATE programme. One interview will focus on the acceptability of the intervention, the other interview will be about the wider context for the programme.

The interviews will take place during or after you have completed the ROWTATE programme. We intend to interview patients from major trauma centres in England.

## **2. Why have I been asked to take part?**

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

We are inviting up to 15 participants like you to take part in the study.

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

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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?

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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 interviews in this study. One interview will focus on the acceptability of the intervention, the other interview will be about the wider context for the programme.

If you agree to take part, the researcher will agree interview dates and times with you and whether you prefer to be interviewed face-to-face, over the telephone or remotely, for example via video call (using a NHS Trust approved platform). The researcher will also ask you if you prefer to be interviewed by one researcher alone, or if you are happy to be interviewed by the researcher together with a member of the public. This member of the public is acting as a patient and public representative in the study, they are not part of your usual care team or sponsor team, and they have lived experience of injury. If you are doing interviews face-to-face, the researcher will ask you to complete a consent form before the interviews start. If you are doing the interviews over the phone or via video-call, the consent form will be completed verbally with you over the phone or video-call. If required, an interpreter from an approved interpreting service can be provided to help you understand the study information, complete the consent form and take part in the interviews.

The interviews will last up to 60 minutes and for each interview we will give you a £20 gift voucher to thank you for your time.

During the interviews, we will discuss:

- Your experiences (both positive and negative) of the ROWTATE programme
- Your experiences of making decisions about returning to work or study, and what affected these decisions
- What helped or hindered your taking part in the ROWTATE programme
- What was most important in helping you get ready to return to work or study and why
- Whether you have returned to work/study or not and your views about the timing of this return

With your permission, we will be audio recording the interviews so that we do not miss any important points. The audiotapes will be typed up by a trusted transcription service known to the university who will sign a confidentiality agreement before receiving any recordings. Direct quotes may be used, but we will remove any names of people (including your own name) or services when we do this so that you remain anonymous. The audio recordings will be deleted from transportable

## 5. What do I have to do?

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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.

A researcher will then arrange a convenient time to visit you to conduct the interviews or a convenient time for phone or video-call interviews. If the interviews are done face-to-face you will be asked to sign a consent form before the interviews start. 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.

If the interviews are done by phone or video-call the consent form will be completed with you verbally immediately before the interviews start.

## **6. What are the possible disadvantages of taking part?**

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We do not anticipate any risks associated with taking part in the study. A possible disadvantage is that it may inconvenience you to attend interviews in person or be available at a specific time during the day. We will arrange the interviews at a time and date that is suitable for you and if you prefer, they can be conducted over the phone or by video-call. Patients may find discussing their problems is distressing, but researchers will be trained to discuss these issues in a sensitive way. You can also consult your GP if you need additional support.

## **7. What are the possible benefits of taking part?**

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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?**

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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?**

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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?**

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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 transcripts 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.

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

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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

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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 s at the above mentioned institutions 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](http://www.hra.nhs.uk/information-about-patients)
- by visiting [www.nuh.nhs.uk/gdpr](http://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](mailto: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](http://www.nuh.nhs.uk/patients-and-public-ri)

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

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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?**

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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?**

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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

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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.