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Multicentre research programme to enhance return to work after trauma

Submission date
22/01/2021

Recruitment status
No longer recruiting

Registration date
27/07/2021

Overall study status
Ongoing

Last Edited
03/07/2024

Condition category
Injury, Occupational Diseases, Poisoning

[X] Prospectively registered
[X] Protocol
[ ] Statistical analysis plan
[ ] Results
[ ] Individual participant data
[ ] Record updated in last year

Plain English summary of protocol

Background and study aims
Injuries are a global public health problem, resulting in more than 5 million deaths each year or 9% of the total number of deaths worldwide. Injuries are a particular problem in working-age adults. This study focusses on trauma of at least moderate severity (Injury Severity Score (ISS) >8), which is a major cause of death, disability and NHS resource use in the UK. Despite improved survival rates, many survivors experience physical and psychological problems, reduced quality of life and difficulty returning to work - We recently found that one third of trauma patients with ISS>8 had not returned to work one year post-injury.

Trauma of at least moderate severity often involves multiple physical injuries, affecting several body regions, frequently with psychological and/or cognitive problems impacting on work ability. Systematic reviews demonstrate vocational rehabilitation (VR) improves employment outcomes across a range of conditions (brain/spinal cord injury, back pain, mental health problems). VR involves helping people find work, prevent job loss and support career progression, despite disability. Current VR evidence addresses single conditions, conditions affecting single body regions, or psychological or physical problems, not both.

The ROWTATE intervention is an individually tailored VR that seeks to lessen the impact of injury by assessing the participant's role as a worker / student and finding acceptable strategies to overcome problems. This study aims to determine whether the ROWTATE intervention plus usual care is more effective than usual care alone at improving participants self-reported work /education outcomes 12 months after randomisation.

Who can participate?
injury survivors aged 16 - 69 years, who are employed at the time of injury.

What does the study involve?
Participants are randomly allocated to receive the ROWTATE intervention plus usual care or usual care alone. The ROWTATE intervention is delivered by Occupational Therapists and Clinical Psychologists (if required) who are trained to assess the impact of injury on the participant and their job; coordinate appropriate support from NHS, employers and other stakeholders; negotiate workplace adjustments, monitor return to work and explore alternatives where

current work is not feasible or cannot be sustained. It is tailored to individual needs. Usual care is the usual NHS rehabilitation provided by the usual care team, which may involve outpatient /community physio, speech or occupational therapy, psychology, and medical follow-up. The intervention lasts for as long as is needed up to 12 months. Participants are followed up by postal/online questionnaire at 3, 6 and 12 months. The success of the ROWTATE intervention is measured by the number of participants who are in employment (paid or unpaid) or education for ≥80% of pre-injury hours at 12 months post randomisation. Changes in psychological wellbeing, disability, quality of life, work self-efficacy, financial impact of injury, purpose in life and the number of NHS services needed for participants are also being measured.

What are the possible benefits and risks of participating?
This study aims to improve rehabilitation services for people in employment who have suffered a traumatic injury. It is hoped that this study will help to support trauma survivors in returning to work. No disadvantages or risks are expected. Any appointments are arranged at times to suit the participants.

Where is the study run from?
This study is organised and run by Nottingham University Hospitals NHS Trust and the Clinical Trials Research Unit (CTRU) at the University of Leeds. (UK)

When is the study starting and how long is it expected to run for?
November 2020 to December 2025

Who is funding the study?
National Institute for Health Research (NIHR) (UK)

Who is the main contact?
Catherine Fernandez, rowtate@leeds.ac.uk

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

Contact information

Type(s)
Scientific

Contact name
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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
290159

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 47711, IRAS 290159

Study information

Scientific Title
ROWTATE: Multicentre research programme to enhance return to work after trauma - work packages 3 and 4

Acronym
ROWTATE - Work Packages 3 & 4

Study objectives
Is the ROWTATE intervention plus usual care a clinically and cost-effective therapy to help people return to work after trauma, when compared with usual care alone.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 22/12/2020, North of Scotland Research Ethics Committee (Summerfield House, 2 Eday Road, Aberdeen, AB15 6RE, United Kingdom; +44 (0)1224558458; nosres@nhs.net), ref: 20/NS/0140

Study design
Interventional randomized controlled trial with embedded qualitative study

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Hospital

Study type(s)
Treatment

Participant information sheet
Not available in web format, please use the contact details to request a patient information sheet

Health condition(s) or problem(s) studied
Specialty: Trauma and Emergency Care, Primary sub-specialty: Emergency Medicine; Health Category: Generic health relevance

Interventions
The ROWTATE intervention is a specialist vocational rehabilitation intervention plus usual care.

The ROWTATE intervention will be compared to a usual care (control) group.

Intervention group: The ROWTATE intervention will be delivered by Occupational Therapists and Clinical Psychologists (if required) who are trained to assess the impact of injury on the participant and their job; coordinate appropriate support from NHS, employer and other stakeholders; negotiate workplace adjustments, monitor return to work and explore alternatives where current work is not feasible or cannot be sustained. It will be tailored to individual needs.

Usual care (UC) group: Usual NHS rehabilitation provided by usual care team and may involve primary care, secondary care, community and social services.

The intervention will commence within 2 weeks of randomisation and last for as long as is needed up to 12 months post-randomisation. Participants will be followed up by postal/online questionnaire at 3, 6 and 12 months post-randomisation.

Intervention Type
Behavioural

Primary outcome measure
Current primary outcome measure as of 19/06/2023:

To determine whether the ROWTATE intervention plus usual care is more effective than usual care alone at improving participants self-reported work/education outcomes 12 months after randomisation. Self-reported return to work/education of ≥80% of pre-injury hours at 12 months post randomisation.

Previous primary outcome measure:

The number of participants who have returned to employment/full-time education at >=80% of pre-injury working hours, 12 months post randomisation self-reported by the participants via completion of study questionnaires

Secondary outcome measures
Current secondary outcome measures as of 19/06/2023:

1. To determine whether the intervention improves other employment/education outcomes: Number of hours returned to work/education, percentage of pre-injury hours returned to work

/education, work/education intentions, job/education retention, job/education changes (role /course, hours), time to return to work/education, retirement, sickness absence, (bespoke questions).
2. To determine whether the intervention improves psychological wellbeing: The Patient Health Questionnaire (PHQ-9), The Generalised Anxiety Disorder Assessment (GAD-7), Impact of Event Scale-6 (IES (6 item scale))
3. To determine if the intervention improves work self-efficacy: Work Ability Index (items 1 and 2)
4. To determine if the intervention reduces the financial impact of injury: Financial chronic stress scale (3 item scale)
5. To determine whether the intervention improves purpose in life: Purpose in Life Test -Short Form scale (4 item scale)
Health Economics
6. To determine the resource implication of the intervention compared to usual care from a health and societal perspective: Purposely designed Health Economic Resource Proforma
7. To determine if intervention is cost effective compared to usual care: Cost-effectiveness analysis, Cost-utility analysis
8. To determine if the intervention improves health related quality of life: EuroQoL 5-dimension health questionnaire, 5 level (EQ-5D-5L)
9. Embedded process evaluation and implementation study
Acceptability of the intervention, content of usual care and the intervention, intervention fidelity, competency to deliver the intervention, and facilitators and barriers to the delivery of the intervention will be measured using an embedded mixed-methods process evaluation and implementation study. This will include using a range of methods including observations, qualitative interviews with participants, service providers, employers, carers, GPs and commissioners, study mentors and study therapists. pre and post training questionnaires and document analysis (case records and intervention proformas) in a sample of study participants (who consent to take part).

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Previous secondary outcome measures:

Measured at 3, 6 and 12 months:
1. Employment/education outcomes: Work/education intentions, job/education retention, job /education changes (role/course, hours), time to return to work/education, retirement, sickness absence, assessed via bespoke questions
2. Work limitations (including productivity loss), assessed via the Work Limitation Questionnaire (only for participants who have returned to work)
3. Psychological wellbeing, assessed using the Patient Health Questionnaire (PHQ-9), the Generalised Anxiety Disorder Assessment (GAD-7) and the Impact of Events Scale (IES)
4. Health related quality of life, measured using the EuroQol 5 dimension health questionnaire, 5 level (EQ-5D-5L)
5. Disability, assessed using the WHODAS 2.0 (at 12 months only)
6. Recovery expectations, assessed using questions developed by Cole and colleagues (3 and 6 months only)
7. Work ability, measured using items from the Work Ability Index (12 months only)
8. Financial impact of injury, measured using the Financial Chronic Stress Scale
9. Purpose in life, assessed using the Purpose in Life Scale (12 months only)
10. Health and social care resource use and cost effectiveness, measured using a bespoke patient completed resource use questionnaire.
11. Embedded process evaluation and implementation study

Acceptability of the intervention, content of usual care and the intervention, intervention fidelity, competency to deliver the intervention, and facilitators and barriers to the delivery of the intervention will be measured using an embedded mixed-methods process evaluation and implementation study. This will include using a range of methods including observations, qualitative interviews with participants, service providers, employers, carers, GPs and commissioners, pre and post training questionnaires and document analysis (case records and intervention proformas) in a sample of study participants (who consent to take part).

Overall study start date
12/11/2020

Completion date
31/12/2025

Eligibility

Key inclusion criteria
Current inclusion criteria as of 19/06/2023:

1. Aged 16 – 69 years
2. In work (paid or unpaid) or full time education at the time of injury
3. Admitted to MTC within the last 12 weeks
4. Injury Severity Score (ISS) >8 at admission
5. Have capacity to provide informed consent to participate in the study.
6. Have a fixed address
7. Have sufficient proficiency in English to contribute to the data collection or be willing to use an approved interpreting service for data collection.
8. Resides in MTC catchment area
9. Not returned to work/voluntary work/education for ≥80% of pre injury hours)
10. No plans to retire within the next 12 months

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Previous inclusion criteria:

1. Aged 16 – 69 years
2. Admitted to a participating MTC within the last 12 weeks with an ISS > 8 at admission
3. In work at time of injury (including self-employed, full-time education and voluntary work)
4. Has not returned to work/voluntary work/education
5. No plans to retire within the next year
6. Not participating in other vocational rehabilitation trials
7. Have sufficient proficiency in English to contribute to the data collection required for research or be willing to use an approved interpreting service for data collection
8. Have capacity to provide informed consent to participate in the study
9. Resides in MTC catchment area

Participant type(s)
Patient

Age group
Adult

Lower age limit
16 Years

Upper age limit
69 Years

Sex
Both

Target number of participants
Planned Sample Size: 722; UK Sample Size: 722

Total final enrolment
710

Key exclusion criteria
1. No fixed address at the time of screening
2. Returned to work/voluntary work/education for ≥80% of pre-injury hours

Date of first enrolment
12/11/2021

Date of final enrolment
31/03/2024

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
St James's University Hospital
Leeds Teaching Hospitals NHS Trust
Beckett Street
Leeds
United Kingdom
LS9 7TF

Study participating centre
Addenbrooke's Hospital
Cambridge University Hospitals NHS Foundation Trust
Hills Road

Cambridge
United Kingdom
CB2 0QQ

Study participating centre
Southmead Hospital
North Bristol NHS Trust
Southmead Road
Westbury-On-Trym
Bristol
United Kingdom
BS10 5NB

Study participating centre
The Royal London Hospital
80 Newark Street
London
United Kingdom
E1 2ES

Study participating centre
Queen's Medical Centre
Nottingham University Hospitals NHS Trust
Derby Road
Nottingham
United Kingdom
NG7 2UH

Study participating centre
Southampton
Southampton General Hospital
Tremona Road
Southampton
United Kingdom
SO16 6YD

Study participating centre
The Newcastle upon Tyne Hospitals NHS Foundation Trust
Freeman Hospital
Freeman Road
High Heaton

Newcastle upon Tyne
United Kingdom
NE7 7DN

Study participating centre
Imperial College Healthcare NHS Trust
The Bays
St Marys Hospital
South Wharf Road
London
United Kingdom
W2 1BL

Sponsor information

Organisation
Nottingham University Hospitals NHS Trust

Sponsor details
Trust Headquarters
Queens Medical Centre
Derby Road
Nottingham
England
United Kingdom
NG7 2UH
-
researchsponsor@nuh.nhs.uk

Sponsor type
Hospital/treatment centre

Website
http://www.nuh.nhs.uk/

ROR
https://ror.org/05y3qh794

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF); Grant Codes: RP-PG-0617-20001

Funder Name
National Institute for Health Research (NIHR) (UK)

Alternative Name(s)
National Institute for Health Research, NIHR Research, NIHRresearch, NIHR - National Institute for Health Research, NIHR (The National Institute for Health and Care Research), NIHR

Funding Body Type
Government organisation

Funding Body Subtype
National government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
Planned publication in a high-impact peer-reviewed journal

Intention to publish date
01/07/2026

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are available from the corresponding author on reasonable request.
CTRU-DataAccess@leeds.ac.uk. Data will be shared according to a controlled access approach. Data will only be shared for participants who have given consent to use of their data for secondary research. Requests will be reviewed by relevant stakeholders. No data will be released before an appropriate agreement is in place setting out the conditions of release

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Participant information sheet	WP3 Patient info sheet version v2.0	15/06/2021	21/07/2021	No	Yes
Participant information sheet	WP4 Carer interviews info sheet version v1.0	11/12/2020	21/07/2021	No	Yes

Participant information sheet	WP4 Commissioners interviews info sheet version v1.0	11/12/2020	21/07/2021	No	Yes
Participant information sheet	WP4 Employer interviews info sheet version v1.0	11/12/2020	21/07/2021	No	Yes
Participant information sheet	WP4 GP interviews info sheet version v1.0	11/12/2020	21/07/2021	No	Yes
Participant information sheet	WP4 Patient interviews info sheet version v1.0	11/12/2020	21/07/2021	No	Yes
Participant information sheet	WP4 Patient observations info sheet version v1.0	11/12/2020	21/07/2021	No	Yes
Participant information sheet	WP4 Therapist interviews info sheet version v1.0	11/12/2020	21/07/2021	No	Yes
Participant information sheet	WP4 Therapist observations info sheet version v1.0	11/12/2020	21/07/2021	No	Yes
Participant information sheet	WP4 Mentor participant interview information sheet version 1.0	21/12/2022	19/06/2023	No	Yes
Participant information sheet	WP4 Patient_Participant_Interviews_Info Sheet version 4.0	09/05/2023	19/06/2023	No	Yes
Participant information sheet	WP4 Therapist_Participant_Interviews_Info Sheet version 5.0	09/05/2023	19/06/2023	No	Yes
Participant information sheet	WP4 shortened employer information sheet version 2.0	09/05/2023	19/06/2023	No	Yes
Participant information sheet	WP4 shortened engagement event Employer Infomation sheet version 1.0	16/12/2022	19/06/2023	No	Yes
Participant information sheet	WP4_Carer_Participant_Interviews_Info Sheet version 3.0	04/01/2022	19/06/2023	No	Yes
Participant information sheet	WP4_Commissioners_Participant_Interviews_Info Sheet version 3.0	04/01/2022	19/06/2023	No	Yes
Participant information sheet	WP4_Employer_Participant_Interviews_Info Sheet version 3.0	04/01/2022	19/06/2023	No	Yes
Participant information sheet	WP4_GP_Participant_Interviews_Info Sheet version 3.0	04/01/2022	19/06/2023	No	Yes
Participant information sheet	WP4_OT_Observations_PIS version 2.0	09/02/2023	19/06/2023	No	Yes
Participant information sheet	WP4_Patient_Observations_PIS version 2.0	09/05/2023	19/06/2023	No	Yes
HRA research summary			28/06/2023	No	No

Protocol article	02/07/2024	03/07/2024	Yes	No