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Multicentre research programme to enhance return to work after trauma (ROWTATE) – feasibility study

Submission date
13/12/2019

Recruitment status
No longer recruiting

Registration date
23/01/2020

Overall study status
Completed

Last Edited
20/03/2024

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
Moderate or severe traumatic injuries can be life changing or life threatening; often caused by road accidents, falls, sporting injuries or assaults. Such injuries are common, but more patients now survive due to improved care and recently developed Major Trauma Centres. However, many suffer physical and psychological problems, reducing quality of life and the chance of returning to work. Recent estimates suggest one third of these patients have not returned to work after one year and many suffer physical, psychological and financial problems.

Despite Major Trauma Centres, rehabilitation and help for injured people to return to work is patchy and poorly developed. There is strong evidence that being in work is good for physical and psychological health. Individualised support (vocational rehabilitation) can help patients with some conditions (e.g. back pain, spinal cord or brain injuries, mental health problems) to stay in or return to work. The project team have already developed a vocational rehabilitation programme for people with brain injuries. As trauma includes many different types of injuries which result in different work-related problems, this programme needs to be adapted to cover these and test if it is feasible to deliver this programme.

The aim of this study is to assess the feasibility of providing a return-to-work programme to moderately and severely injured patients.

Who can participate?
Adults aged 16 – 69 years admitted to a participating major trauma centre with an Injury Severity Score > 8 on admission

What does the study involve?
The study involves training occupational therapists and psychologists to deliver the vocational rehabilitation programme (called ROWTATE) and assessing how well the training prepares them to deliver the programme. Forty patients with moderate or severe injuries will be recruited and have the ROWTATE programme provided to them. Patients will complete questionnaires measuring a range of impacts of injury including physical and psychological wellbeing, impact on

work and finances and health service use. The number of patients agreeing to take part in the study and the number completing the study will be measured. Patients, occupational therapists, psychologists, employers and commissioners of health services will be interviewed to find out their views about the ROWTATE programme. Contacts between occupational therapists or psychologists and patients will be observed to measure how well the programme is being delivered. Focus groups or interviews will be conducted with patients who did and did not take part in the study to find out about factors that might help or hinder patients to take part and to stay in the study.

Patient and public involvement
A group of trauma survivors will be involved throughout the study. They will provide advice, undertake some aspects of the research, as well as contributing to analysing data, interpreting findings, writing reports for publication and advising on communicating the study results to the public.

What are the possible benefits and risks of participating?
Participating patients will receive additional care from occupational therapists and psychological support as well if they would find this helpful. A similar programme of support has already been shown to help patients with other conditions make a successful return to work. It is anticipated that the programme will help patients with serious injury make a successful return to work, but it cannot be guaranteed. Involvement in the study may also help future patients with serious injury to make a successful return to work.

The ROWTATE programme does not involve any medication or invasive medical treatment and there are no anticipated risks to taking part. Participating in the programme will take time and the participant will need to be committed to physical and mental preparation for returning to work or study. Participants may find discussing their problems is distressing, but occupational therapists will be trained to discuss these issues in a sensitive way and psychological support will be provided as part of the programme if needed

Where is the study run from?
1. Nottingham University Hospitals NHS Trust (UK)
2. Barts Health NHS Trust (UK)

When is the study starting and how long is it expected to run for?
February 2020 to July 2022

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

Who is the main contact?
Prof. Denise Kendrick
denise.kendrick@nottingham.ac.uk
Dr Blerina Kellezi
blerina.kellezi@nottingham.ac.uk

Study website
http://www.ROWTATE.org.uk

Contact information

Type(s)
Scientific

Contact name
Prof Denise Kendrick

ORCID ID
http://orcid.org/0000-0003-3603-6542

Contact details
Division of Primary Care
Tower Building
University Park
Nottingham
United Kingdom
NG7 2RD
+44 (0)1158466914
denise.kendrick@nottingham.ac.uk

Type(s)
Scientific

Contact name
Dr Blerina Kellezi

Contact details
Division of Primary Care
Tower Building
University Park
Nottingham
United Kingdom
NG7 2RD
+44 (0)115 7487440
blerina.kellezi@nottingham.ac.uk

Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
19OT006

Study information

Scientific Title
Multicentre Research Programme to Enhance Return to Work after Trauma (ROWTATE) – Feasibility of providing a vocational rehabilitation and psychological intervention to adults with moderate to severe traumatic injury

Acronym
ROWTATE

Study objectives
Current study hypothesis as of 02/12/2020:
The specific objectives of the feasibility study are to:
1. Adapt the ROWTATE intervention to make it suitable for remote delivery, as much as possible, via tele-rehabilitation and tele-psychology
2. Adapt the ROWTATE occupational therapist and clinical psychologist training to make it suitable for remote delivery
3. Deliver the adapted ROWTATE intervention and assess feasibility and fidelity of remote delivery via tele-rehabilitation and tele-psychology
4. Assess acceptability, barriers and facilitators to remote delivery of the ROWTATE intervention via tele-rehabilitation and tele-psychology

Previous study hypothesis:
Objectives of the feasibility study are:
1. To assess recruitment and follow-up rates, data collection tools, processes and data completeness
2. To deliver the ROWTATE intervention, evaluate and optimize intervention usage and acceptability; ways to assess and minimise contamination and evaluate importance and acceptability of outcome measures
3. Evaluate occupational therapist and clinical psychologist training to deliver the intervention
4. Assess intervention fidelity
5. Identify factors that may affect the running of the definitive trial, including barriers and facilitators to recruitment and retention

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 20/08/2019, North of Scotland Research Ethics Service (NHS Grampian, Marquis Rd, Aberdeen, AB24 2QU, UK; +44 (0)1224 558474; nosres@nhs.net), ref: 19/NS/0130

Study design
Non-randomized feasibility study

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Other

Study type(s)
Treatment

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

Health condition(s) or problem(s) studied
Moderate to severe traumatic injury (injury severity score >8)

Interventions
Current interventions as of 02/12/2020:
The ROWTATE intervention will commence within 12 weeks of injury and be tailored in duration and frequency according to individual need over a 12-month period.
An occupational therapist will work in a case coordinator role with a wider team of healthcare professionals, employers, family members and other agencies (e.g. solicitors, insurance agencies) to:
- Assess the impact of the injury on the patient, family and the patient's role as a worker
- Educate patients, employers and families about the effects of the injury and its impact on work and find acceptable strategies to lessen the impact
- Continually monitor and assess the patient's post-injury life and work goals
- Prepare patients for work by establishing structured routines with gradually increased activity levels and opportunity to practice work skills
- Liaise with employers, employment advisers, solicitors and the healthcare team to advise about the effects of the injury and to plan and monitor a phased return to work
- Screen for mental health problems and refer to a clinical psychologist for assessment and provision of evidence-based approaches for managing trauma-related mental health issues as needed. Occupational therapists and clinical psychologists will deliver the programme via tele-rehabilitation and tele-psychology where possible.
Occupational therapists and clinical psychologists will be supported by an appointed mentor (an experienced occupational therapist or clinical psychologist) providing monthly telephone mentoring.

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Occupational therapists and clinical psychologists will be supported by an appointed mentor (an experienced occupational therapist or clinical psychologist) providing monthly telephone mentoring.

Intervention Type
Behavioural

Primary outcome measure
Current primary outcome measures as of 02/12/2020:
1. Occupational therapist and clinical psychologist knowledge, skills, professional role, social influences and environmental context in relation to tele-rehabilitation and tele-psychology plus current practice, barriers and facilitators and options in terms of delivering the adapted intervention; measured using interview pre and post training
2. Occupational therapist and clinical psychologist views on training to use the adapted intervention, measured using interview post training
3. The number, content and mode of delivery of occupational therapist and clinical psychologist contacts with patients and employers, fidelity of the intervention and problems and potential solutions in relation to the delivery of the intervention, measured 0-12 months post patient recruitment
4. Occupational therapist, clinical psychologist, patient and employer views of the acceptability of and barriers and facilitators to delivery of the adapted ROWTATE intervention, measured using interview 1-3 months post patient recruitment

Previous primary outcome measures:
1. Recruitment rate and and follow-up rate at 3 months
2. Patient preferences for paper/online/telephone versions of the outcome data collection tools, number and type of reminders required and data completeness. Measured using self-completion questionnaires at recruitment and 3 months follow-up
3. Patient, occupational therapist, clinical psychologist, employer and commissioner experiences of the ROWTATE intervention and of returning to work (or not); factors facilitating or hindering engagement with the intervention or return to work; perceived appropriateness of timing of return to work; mechanisms considered important in determining key outcomes; importance and acceptability of outcome measures; acceptability of trial procedures; policy drivers for commissioning vocational rehabilitation, and service quality factors and contracting issues of importance. Measured using semi-structured interviews 1-3 months post patient recruitment
4. Occupational therapist, and clinical psychologist readiness to deliver the ROWTATE intervention following training and potential improvements to training. Measured using self-completion questionnaires (Evidence-Based Practice Confidence Scale, Evidence-Based Practice Attitude Scale and bespoke questions on confidence to deliver intervention components) and by observing management of a fictional case, with responses measured against expert-agreed model answers immediately post-training
5. Identification of potential contamination issues. Measured by completion of mentoring and contamination records throughout study period
6. Fidelity of, and contextual and process issues related to intervention delivery. Measured by completion of intervention content proformas, observations of therapist/patient contacts and review of clinical records 0-6 months post patient recruitment and by completion of mentoring records 0-12 months post patient recruitment
8. Patient views on trial recruitment and retention strategies, preferences, and barriers and facilitators to trial recruitment and retention. Measured by focus groups and/or interviews 1-6 months post patient recruitment

Secondary outcome measures
All feasibility study outcomes are listed as primary outcomes

Overall study start date
23/04/2018

Completion date
31/07/2022

Eligibility

Key inclusion criteria
1. Aged 16-69 years
2. Admitted to a participating major trauma centre with an Injury Severity Score >8 on admission
3. Employed, self-employed, in full-time education or voluntary work at the time of injury
4. No plans to retire within the next year
5. Not participating in other vocational rehabilitation trials
6. 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
7. Not returned to work/voluntary work/education for ≥80% of pre-injury hours
8. Able to give informed consent

Added 02/12/2020:
9. Resident in the MTC catchment area

Participant type(s)
Patient

Age group
Adult

Sex
Both

Target number of participants
10

Total final enrolment
10

Key exclusion criteria
No fixed address

Date of first enrolment
01/10/2020

Date of final enrolment
26/01/2021

Locations

Countries of recruitment
England

United Kingdom

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

Study participating centre
Barts Health NHS Trust
The Royal London Hospital
Whitechapel Road
London
United Kingdom
E1 1FR

Sponsor information

Organisation
Nottingham University Hospitals NHS Trust

Sponsor details
Research & Innovation
Nottingham University Hospitals NHS Trust
Nottingham Integrated Clinical Research Centre
C Floor, South Block
Queen’s Medical Centre Campus
Derby Road
Nottingham
England
United Kingdom
NG7 2UH
+44 (0)115 970 9049
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
National Institute for Health Research

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
30/03/2025

Individual participant data (IPD) sharing plan
Current IPD sharing statement and summary:
The datasets generated during and/or analysed during the current study are/will be available upon request from ROWTATE@nottingham.ac.uk. The data that participants have consented to share will become available to potential researchers at the end of this study. Requests detailing the research aims and use of the data should be sent to the research team.

Previous IPD sharing statement and summary:
The current data sharing plans for this study are unknown and will be available at a later date

IPD sharing plan summary

Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol article	protocol	20/01/2021	22/01/2021	Yes	No
HRA research summary			26/07/2023	No	No