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Development of an online, group-based, clinical neuropsychology rehabilitation programme

Submission date
30/08/2023

Recruitment status
No longer recruiting

Registration date
15/09/2023

Overall study status
Completed

Last Edited
02/04/2024

Condition category
Nervous System Diseases

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

Plain English summary of protocol
Background and study aims
Acquired brain injury (ABI) is caused by medical conditions (e.g., stroke) or injuries (e.g., traffic accidents). In the UK, 1.4 million people live with the consequences of ABI, which can be lifelong, costing the economy £15 billion annually (10% NHS annual budget). Approximately 20% of ABI survivors experience emotional and/or thinking skills problems. These can impact return to hobbies and work, increasing risk of isolation and resulting in distress and reduced quality of life. Neuropsychological rehabilitation is useful in treating such problems but is typically delivered face-to-face. However, due to the lack of NHS resources, not all ABI survivors get thee help they need. Furthermore, limited clinic space and other restrictions mean group sessions cannot always be provided safely, if at all.

The study aims to test whether people with ABI find a newly developed online, group-based neuropsychological rehabilitation programme useful and acceptable.

Who can participate?
Adults who have experienced an acquired brain injury and left hospital at least three months prior to the study commencing.

What does the study involve?
To test the intervention participants will:
1. Complete questionnaires at the start of the study
2. Take part in a session to find out more about their presenting strengths and challenges and adjustments that could be helpful with the Clinical Neuropsychologist
3. Take part in 8 weekly, online, group sessions
4. Complete questionnaires at the end of the study, and provide feedback in an interview with a researcher

What are the possible risks and benefits of participating?
The risk of serious harmful effect due to participating in the study is considered low. Participants will be completing questionnaires and talking about topics, and they may experience some

distress if they find they are not performing as well as they think and/or if sensitive topics are raised. To minimise risk all members of the research team will be trained to identify and respond to signs of distress in a sensitive manner, and a risk protocol will be in place.

Whilst there is no guarantee of benefit, the neuropsychological rehabilitation programme could potentially improve participants' emotional wellbeing, quality of life, and ability to 'live well' with ABI by offering education and strategies.

Where is the study run from?
The study is run from the University of Nottingham, in collaboration with Nottinghamshire Healthcare NHS Trust and Midlands Partnerships University NHS Foundation Trust (UK).

When is the study starting and how long is it expected to run for?
March 2022 to March 2024

Who is funding the study?
This project is funded by the National Institute for Health and Care Research (NIHR) under its Research for Patient Benefit (RfPB) Programme (Grant Reference Number NIHR202753).

Who is the main contact?
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Contact information

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Scientific

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Additional identifiers

EudraCT/CTIS number
Nil known

IRAS number
316145

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
CPMS 55258, NIHR202753, IRAS 316145

Study information

Scientific Title
Development and refinement of an online, group-based, clinical neuropsychology rehabilitation programme to improve psychological well-being and quality of life after acquired brain injury

Acronym
NeRO Work Package 3

Study objectives
To examine preliminary acceptability and fidelity of a new, online, group-based, clinical neuropsychology rehabilitation programme. To determine (preliminary) promise of the intervention.

Ethics approval required
Ethics approval required

Ethics approval(s)
Approved 23/03/2023, London Harrow (Level 3, Block B, Whitefriars, Bristol, BS1 2NT, United Kingdom; +44 207 104 8154; harrow.rec@hra.nhs.uk), ref: 23/LO/0149

Study design
Interventional non-randomized

Primary study design
Interventional

Secondary study design
Non randomised study

Study setting(s)
Internet/virtual, Other therapist office

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
Acquired brain injury

Interventions
Baseline assessment
All participants at the baseline stage will complete questionnaires online with the study Research Support Fellow. Questionnaires will assess well-being, mood, anxiety, suicide risk, acceptance, compassion, living towards values, self-perceived cognitive deficits and quality of life.
If thought to be eligible for the study, the research support fellow will also check availability to attend intervention sessions and schedule an initial individual session with the clinical neuropsychologist.

Clinical Neuropsychology session
Once baseline measures have been completed, and the participant is determined as eligible to take part, the participant will meet with the clinical neuropsychologist to complete an initial formulation session. This will develop an understanding of the participants presenting challenges and strengths, and consider helpful adaptations. Eligibility criteria will also be reconsidered at this stage.

Neuropsychological rehabilitation
The intervention group will involve weekly online group-based neuropsychological rehabilitation (NPR) sessions for 8 consecutive weeks. The sessions will last approximately 1 hour each and will involve two groups with 4-6 participants each.

All intervention sessions, screening assessments and outcome assessments will be conducted online via MS Teams video conferencing or alternative HS Compliant platform. All participants will be given instructions on how to use MS Teams (or alternative) if needed.

Outcome assessment
The outcome assessment will take place 2- weeks after intervention completion. This will be completed online directly with the participants. The participant will complete a change and feedback interview, and complete outcome measures.
Assessments will be completed by the research support fellow who will not be involved in delivering the intervention.

Intervention Type
Behavioural

Primary outcome measure
1. Mood/Depression measured using Patient Health Questionnaire 9 at baseline, and 2-weeks post intervention completion.
2. Risk of suicide using the Columbia Suicide Severity Rating Scale at baseline, and 2-weeks post intervention completion.
3. Anxiety using the Generalised Anxiety Scale-7 at baseline, and 2-weeks post intervention completion.

4. Acceptance using the Acceptance and Action Questionnaire at baseline, and 2-weeks post intervention completion.
5. Living towards values using the Valued Living Questionnaire at baseline, and 2-weeks post intervention completion.
6. Self-compassion using the Self-Compassion questionnaire at baseline, and 2-weeks post intervention completion.
7. Cognition using the ACE-III (mini) at baseline, and 2-weeks post intervention completion.
8. Goal attainment using the GAS-Lite at baseline, and 2-weeks post intervention completion.
9. Quality of life measured using the QOLIBRI at baseline, and 2-weeks post intervention completion (awaiting confirmation from ethics as submitted as an amendment)

Secondary outcome measures
There are no secondary outcome measures

Overall study start date
01/03/2022

Completion date
31/03/2024

Eligibility

Key inclusion criteria
1. Acquired brain injury experienced as an adult (>18 years), at least three-months prior to joining the study
2. Age >18 years
3. Self-reported sense of being ‘stuck’ and/or emotional difficulties related to ABI rehabilitation (screened during initial interview)
4. English-speaking
5. Able to access the online platform
6. Ability to give informed consent and complete outcome measures

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
Planned Sample Size: 12; UK Sample Size: 12

Total final enrolment
11

Key exclusion criteria
1. Pre-existing intellectual disability
2. Severe psychiatric disorder (at time of screening or in previous year), and/or factors (e.g., suicidal intent or ideation) indicating alternative treatment may take priority
3. Comorbid neurodegenerative condition
4. Indication that group intervention may not be appropriate (screened during baseline and initial interview)

Date of first enrolment
30/05/2023

Date of final enrolment
31/08/2023

Locations

Countries of recruitment
England

United Kingdom

Study participating centre
Midlands Partnership NHS Foundation Trust
Trust Headquarters
St Georges Hospital
Corporation Street
Stafford
United Kingdom
ST16 3SR

Study participating centre
Leicestershire Partnership NHS Trust
Riverside House
Bridge Park Plaza
Bridge Park Road
Leicester
United Kingdom
LE4 8PQ

Study participating centre
University Hospitals of Derby and Burton NHS Foundation Trust
Royal Derby Hospital
Uttoxeter Road

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DE22 3NE

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Sponsor type
University/education

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ROR
https://ror.org/01ee9ar58

Funder(s)

Funder type
Government

Funder Name
NIHR Central Commissioning Facility (CCF)

Results and Publications

Publication and dissemination plan
Planned publication in peer-reviewed journals.

Intention to publish date
01/03/2025

Individual participant data (IPD) sharing plan

The datasets generated during and/or analysed during the current study will be stored in a non-publicly available repository.
The datasets generated and/or analysed during the current study will be available upon request from Kim Fletcher (kimberley.fletcher@nottingham.ac.uk)

IPD sharing plan summary

Stored in non-publicly available repository, Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
HRA research summary			20/09/2023	No	No