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Positive psychotherapy for people with a brain injury

Submission date
17/07/2020

Recruitment status
No longer recruiting

Registration date
11/11/2020

Overall study status
Completed

Last Edited
08/11/2024

Condition category
Injury, Occupational Diseases, Poisoning

[X] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aims
Acquired brain injury – injury caused to the brain by an event like an accident or infection – can have profound and life-changing consequences. Treatment typically focuses on rehabilitation – trying to recover as much function as possible in commonly-affected areas like mobility and thinking skills, and helping people compensate for long-term problems.
We have worked with patients to develop a new treatment that focuses on wellbeing by building opportunities for positive psychological experiences, positive health behaviours and social connectivity.

This project will test the feasibility of running a full-scale trial of our treatment and answer important questions about how best to run such a trial.

Who can participate?
Adults over 18 years, with acquired brain injury and psychological distress, living in the community.

What does the study involve?
Participants will be randomly assigned to either 'treatment as usual' or 'group-based positive psychotherapy.' The intervention consists of an eight-week group-based positive psychotherapy that has been developed by the researchers. The intervention will be delivered by clinical psychologists working in NHS brain injury services. Each session lasts 2.5 hours with activities to try at home between sessions. Several measures will be recorded at baseline, after the eight-week intervention and at 3 months follow-up.

What are the possible benefits and risks of participating?
The study will provide important information that is needed to establish if a full-scale study could take place. The intended benefits of this will be to increase wellbeing and decreasing psychological distress for people with an acquired brain injury, as well as giving a meaningful role to survivors of brain injuries.

A level of 'psychological distress' is an eligibility criteria for participation in the intervention, therefore some psychological distress may be experienced during the intervention, we have

safety procedures in place to manage this. Acquired brain injuries can cause different types of cognitive problems, we have set out eligibility criteria relating to cognition so we can be reasonably sure the participants will be able to engage in the intervention. This also means we can avoid including participants that may be unable to engage in the intervention, which could potentially cause them psychological distress. Like in all studies, there is a risk of data breaches that could expose confidential information. We have managed this by not including personally identifiable participant information on our database, including data procedures for all staff to follow, and by setting a training standard for all staff involved in the study.

Public involvement
Our research is shaped by the feedback that we have received from brain-injury survivors. They have told us clearly what they want from healthcare providers. Our patients have been involved in developing the new treatment and planning this proposal. A key aspect of our treatment is the use of patient-mentors. Importantly, three service users are co-applicants on our application and all have experienced the intervention as participants and mentors. These individuals have individual skills that add considerable value to the intervention as well as the research team.

Where is the study run from?
Swansea University (UK)

When is the study starting and how long is it expected to run for?
October 2019 to March 2024

Who is funding the study?
Health and Care Research Wales (UK)

Who is the main contact?
Dr Andrew Kemp, a.h.kemp@swansea.ac.uk

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number
271251

ClinicalTrials.gov number
Nil known

Secondary identifying numbers
IRAS 271251

Study information

Scientific Title
Group-based positive psychotherapy for people living with Acquired Brain Injury: A feasibility study

Acronym
PP4ABI

Study objectives
The methodological approach will be feasible to determine the clinical and cost-effectiveness of a novel positive psychology intervention in a future trial for people living with ABI compared to a 'treatment as usual' control group (TAU)

Ethics approval required
Old ethics approval format

Ethics approval(s)
Approved 06/01/2020, Health Research Authority and Health Care Research Wales (Health Care Research Wales, Castle Bridge 4, 15-19 Cowbridge road East, Cardiff, CF11 9AB, UK; +44 (0)7973 687815; Wales.REC1@wales.nhs.uk), ref: 19/WA/0336
Amendments relating to COVID-related delays approved 12/08/2022

Study design
Feasibility multi-centre randomized controlled trial

Primary study design
Interventional

Secondary study design
Randomised controlled trial

Study setting(s)
Community

Study type(s)
Quality of life, Treatment

Participant information sheet

Not available in web format, please use contact details to request a participant information sheet

Health condition(s) or problem(s) studied
Acquired brain injury

Interventions
Participants will be randomly assigned using an electronic database system, to either 'treatment as usual' or 'group-based positive psychotherapy.' The novel intervention consists of an eight week group-based positive psychotherapy that has been developed by the researchers. The intervention has been developed using the 'GENIAL' model of well-being. The intervention will be delivered by clinical psychologists working in NHS brain injury services. Each session last 2.5 hours with activities to try at home between sessions. Several measures will be recorded at baseline, after the eight week intervention and at 3 months follow-up.

Intervention Type
Behavioural

Primary outcome measure
The primary outcome regarding feasibility will be assessed against the ACCEPT criteria for the trial. This includes recruitment across sites, recruitment rate, intervention compliance clinicians, interventions compliance participants, randomisation process, data collection from participants, attrition rates and differences between groups in serious adverse events (SAEs) measured using case report forms and patient records.

Secondary outcome measures
1. Psychological distress measured using the DASS-21 at time 1 (before the intervention), 2 (after the intervention), and 3 (follow-up at 3 months)
2. Well-being measured using the PERMA profiler at time 1, 2 and 3
3. General health and well-being using heart rate variability at time 1, 2 and 3
4. General capability measured using the ICECAP-A at time 1, 2 and 3
5. General health state and quality of life using the EQ-5D-5L at time 1, 2 and 3
6. Health care costs using the client service receipt inventory (CSRI) at time 1 and 3
7. Participant experience of recruitment, eligibility, consent and their experience of several aspects of the intervention (session context, length, homework, their experience of using the materials) will be explored using qualitative methods and analysis. This only applies to the participants who attended the positive psychotherapy group at time 2

Overall study start date
01/10/2019

Completion date
18/03/2024

Eligibility

Key inclusion criteria
1. Confirmed diagnosis of ABI
2. Ability to actively engage in the intervention as determined by their neuropsychological assessment scores and their clinician

3. Living in the community
4. Psychological distress (evidenced by their scores on the Depression, Anxiety and Stress Scales)
5. Age 18 y or older
6. Living within the catchment area of one of the participating health boards
7. At least three-month post injury at the point of recruitment allowing time for spontaneous recovery and for the person to become aware of their difficulties and the implications of this on their lives

Participant type(s)
Patient

Age group
Adult

Lower age limit
18 Years

Sex
Both

Target number of participants
60

Key exclusion criteria
1. Receptive or expressive language difficulties, or extremely low memory function that may preclude people from engaging meaningfully
2. Medical or psycho-social reasons (based on risk assessment by the referring clinician)
3. Potentially disruptive to other group members as determined by their clinician
4. Not able to provide informed consent

Date of first enrolment
01/09/2022

Date of final enrolment
31/10/2023

Locations

Countries of recruitment
United Kingdom

Wales

Study participating centre
Morriston Hospital
Traumatic Brain Injury Service
Morriston

Swansea
United Kingdom
SA6 6NL

Study participating centre
Morriston Hospital
Brain Injury and Complex Neurological Service
Old Creche Building
Morriston
Swansea
United Kingdom
SA6 6NL

Study participating centre
Rookwood Hospital
Cardiff Brain Injury Team
18-20 Fairwater Road
Llandaff
Cardiff
Cardiff
United Kingdom
CF5 2YN

Sponsor information

Organisation
Research & Development, Swansea Bay University Local Health Board

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Sponsor type
Hospital/treatment centre

Funder(s)

Funder type
Government

Funder Name
Health and Care Research Wales

Alternative Name(s)
Health & Care Research Wales, Ymchwil Iechyd a Gofal Cymru, Health Care Research Wales, HCRW

Funding Body Type
Government organisation

Funding Body Subtype
Local government

Location
United Kingdom

Results and Publications

Publication and dissemination plan
We plan to publish our findings in a high-impact peer-reviewed journal.

Intention to publish date
18/03/2025

Individual participant data (IPD) sharing plan
The datasets generated and/or analysed during the current study during this study will be included in the subsequent results publication

IPD sharing plan summary
Other

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version v2	16/04/2020	11/11/2020	No	No
HRA research summary			28/06/2023	No	No
Protocol article		21/02/2024	22/02/2024	Yes	No
Funder report results		28/03/2024	08/11/2024	No	No