

# Positive psychotherapy for people with a brain injury

<b>Submission date</b> 17/07/2020	<b>Recruitment status</b> No longer recruiting	<input checked="" type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
<b>Registration date</b> 11/11/2020	<b>Overall study status</b> Completed	<input type="checkbox"/> Statistical analysis plan <input checked="" type="checkbox"/> Results
<b>Last Edited</b> 08/11/2024	<b>Condition category</b> Injury, Occupational Diseases, Poisoning	<input type="checkbox"/> 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

**Contact name**  
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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**

**Morrison Hospital**

Traumatic Brain Injury Service

Morrison

Swansea  
United Kingdom  
SA6 6NL

**Study participating centre**

**Morrison Hospital**

Brain Injury and Complex Neurological Service  
Old Creche Building  
Morrison  
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

**Sponsor details**

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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?
<a href="#">Protocol file</a>	version v2	16/04/2020	11/11/2020	No	No
<a href="#">HRA research summary</a>			28/06/2023	No	No
<a href="#">Protocol article</a>		21/02/2024	22/02/2024	Yes	No
<a href="#">Funder report results</a>		28/03/2024	08/11/2024	No	No