

Continuity therapy for couples living with brain injury

Submission date 02/06/2023	Recruitment status No longer recruiting	<input type="checkbox"/> Prospectively registered <input checked="" type="checkbox"/> Protocol
Registration date 06/06/2023	Overall study status Completed	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 06/03/2025	Condition category Nervous System Diseases	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Brain injuries such as stroke and head injuries can put a severe strain on marriages/partnerships. Our previous research suggests that one contributing factor is a sense of 'discontinuity'. This refers to the non-injured partner that the person with the injury is now very different compared to who s/he was before the injury ("He's not the person I married") and that their relationship is also radically changed ("I feel like her carer, not her husband"). The injured partner can also feel very different and evidence suggests that this can undermine the person's self-esteem and psychological wellbeing. To address these issues, we have been developing a psychological therapy for couples focused on increasing their sense of continuity between past and present. In a published report, we described using this therapy with a couple. Following therapy, the couple showed promising improvements in their relationship and wellbeing.

The study aims:

- To expand and develop this initial version of the therapy, producing detailed guidelines for its use
- To give couples living with brain injury the opportunity to contribute to this development
- To collect information about its potential effectiveness so that we can decide whether the therapy merits being properly evaluated in a future controlled trial.

Who can participate?

Any couples in which one partner has experienced a brain injury within the last 5 years (but not within the last 12 months); and who feel that the brain injury has had a bad effect on their relationship.

What does the study involve?

Participants will take part in approximately 10 therapy sessions with a clinical psychologist. They will also complete questionnaires before the therapy starts and after it has finished. The questionnaires are about psychological wellbeing and the quality of the relationship. Participants will also take part in an interview after the end of the therapy about their experience of the therapy.

What are the possible benefits and risks of participating?

Participants may experience an improvement in their relationship and psychological wellbeing.

In terms of risk, it may be upsetting at times to talk about what has happened in your life and about your relationship and there is a risk that this will make things worse for participants' wellbeing and relationship.

Where is the study run from?

The study is a collaboration between the University of Birmingham and Birmingham Community Healthcare NHS Foundation Trust (UK)

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

February 2023 to March 2025

Who is funding the study?

National Institute for Health and Care Research (UK)

Who is the main contact?

Dr Gerard Riley, g.a.riley@bham.ac.uk

Study website

<https://continuity-therapy.squarespace.com/>

Contact information

Type(s)

Principal Investigator

Contact name

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

320276

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

IRAS 320276, CPMS 55029

Study information

Scientific Title

Continuity Therapy for couples living with brain injury: A tier 3 study focused on development of an intervention

Study objectives

The study aims to develop an complete some initial uncontrolled evaluation of a psychological therapy to improve the relationship of couples living with brain injury

Ethics approval required

Old ethics approval format

Ethics approval(s)

Approved 22/02/2023, South East Scotland Research Ethics Committee 02 (2nd Floor, Waverley Gate, 2-4 Waterloo Place, Edinburgh. EH1 3EG, UK; +44 131 536 9000, ruth.fraser4@nhslothian.scot.nhs.uk) ref: 23/SS/0012

Study design

Single-centre focused on the initial development and uncontrolled evaluation of a psychological therapy

Primary study design

Interventional

Secondary study design

Non randomised study

Study setting(s)

Charity/Voluntary sector, Hospital

Study type(s)

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 injuries such as stroke and traumatic brain injury

Interventions

Once enrolled onto the study, participants will complete the baseline questionnaires. They will then receive 10 sessions of psychological therapy. Each session will last about 1 hour. The first 5 sessions will take place weekly, but will be fortnightly thereafter. Once the therapy is

completed, participants will complete the post-intervention questionnaires and take part in an interview about their experience of the therapy. This post-intervention meeting will last about 1.5 hours.

Intervention Type

Behavioural

Primary outcome measure

For the partner with a brain injury:

1. Psychological wellbeing will be assessed using the Head Injury Semantic Differential Scale, the Rosenberg Self-Esteem Scale and the Warwick-Edinburgh Wellbeing Scale at baseline and 18 weeks
2. Relationship satisfaction with the Index of Relationship Satisfaction at baseline and 18 weeks
3. Changes in perceptions of continuity of self-identity with the Continuity of Self-Identity Scale at baseline and 18 weeks

For the partner who does not have a brain injury:

1. Psychological wellbeing will be assessed using the Brain Injury Behaviour Rating Scale and the Warwick-Edinburgh Wellbeing Scale at baseline and 18 weeks
2. Relationship satisfaction with the Index of Relationship Satisfaction at baseline and 18 weeks
3. Changes in perceptions of continuity with the relationship with the Birmingham Relationship Continuity Measure at baseline and 18 weeks:

Secondary outcome measures

There are no secondary outcome measures

Overall study start date

22/02/2023

Completion date

31/03/2025

Eligibility

Key inclusion criteria

1. One member of the couple must have experienced an acquired brain injury
2. One or both partners report some dissatisfaction with their current relationship.
3. Couples must be living together at the time of participation.
4. Couples must have lived together for at least 5 years before the injury.
5. The injury must have occurred at least 1 year previously.
6. The injury must have occurred no more than 5 years previously.
7. Both participants are over the age of 21. There is no upper age limit.

Participant type(s)

Patient, Carer

Age group

Adult

Lower age limit

21 Years

Sex

Both

Target number of participants

10 couples (=20 individuals)

Total final enrolment

32

Key exclusion criteria

1. People cannot take part if they are not capable of giving informed consent or taking a meaningful part in verbal therapy conducted in English.
2. People who have serious additional mental or physical health conditions that may have a serious impact on their participation.
3. There are significant concerns about the psychological wellbeing of one or both members of the couple.
4. There are significant concerns that the couple are about to split up.

Date of first enrolment

01/04/2023

Date of final enrolment

30/11/2024

Locations

Countries of recruitment

England

United Kingdom

Study participating centre

Moor Green Outpatient Brain Injury Service

Moseley Hall Hospital

Alcester Road

Moseley

Birmingham

United Kingdom

B13 8JL

Sponsor information

Organisation

University of Birmingham

Sponsor details

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United Kingdom
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+44 (0)121 414 3344
researchgovernance@contacts.bham.ac.uk

Sponsor type

University/education

Website

<https://www.birmingham.ac.uk/index.aspx>

Funder(s)

Funder type

Government

Funder Name

National Institute for Health and Care 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

We will share the findings with researchers and clinicians working in brain injury, brain injury charities, and couples living with brain injury. Dissemination will be through a local West Midlands event, online platforms, and an academic conference and journal.

Intention to publish date

01/02/2026

Individual participant data (IPD) sharing plan

Anonymised pre and post-therapy questionnaires will be stored in a publicly available repository at the Mendeley data store <https://data.mendeley.com/>
Material containing potentially identifying information will be stored in a non-publicly available Research Data Store at the University of Birmingham.

IPD sharing plan summary

Stored in publicly available repository, Stored in non-publicly available repository

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Protocol file	version 6	21/11/2023	12/02/2024	No	No