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Continuity therapy for couples living with brain injury

Submission date
02/06/2023

Recruitment status
No longer recruiting

Registration date
06/06/2023

Overall study status
Completed

Last Edited
06/03/2025

Condition category
Nervous System Diseases

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

Contact information

Type(s)
Principal investigator

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Additional identifiers

Clinical Trials Information System (CTIS)
Nil known

Integrated Research Application System (IRAS)
320276

ClinicalTrials.gov (NCT)
Nil known

Protocol serial number

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

Study type(s)
Treatment

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(s)
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:

Key secondary outcome(s))
There are no secondary outcome measures

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

Healthy volunteers allowed
No

Age group
Adult

Lower age limit
21 years

Sex
All

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
United Kingdom

England

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

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

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
Study website	Study website	11/11/2025	11/11/2025	No	Yes