# PROTOCOL

## Full title of the study

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

## Short study title

Continuity therapy for couples living with brain injury

## Protocol version number and date

Version 6.0; 21.11.2023

## Research reference numbers

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| **IRAS Number** | 320276 |
| **Sponsor reference number** | RG_22-128 |
| **ISRCTN number** | 93611293 |
| **REC reference number** | 23/SS/0012 |

## Signature page

The undersigned confirm that the following protocol has been agreed and accepted and that the Chief Investigator agrees to adhere to the signed University of Birmingham's Sponsorship CI declaration.

I agree to ensure that the confidential information contained in this document will not be used for any other purpose other than the evaluation or conduct of the investigation without the prior written consent of the Sponsor

I also confirm that I will make the findings of the study publicly available through publication or other dissemination tools without any unnecessary delay and that an honest accurate and transparent account of the study will be given; and that any discrepancies from the study as planned in this protocol will be explained.

Chief Investigator:

Signature:  Date: 21.11.2023

Name: (please print): Gerard Riley

## Sponsor statement:

Where the University of Birmingham takes on the sponsor role for protocol development oversight, the signing of the IRAS form by the sponsor will serve as confirmation of approval of this protocol.

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## Key study contacts

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## Study summary

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

Study Design: Developmental

Study Participants: Couples living with acquired brain injury

Planned Size of recruitment target: 10 couples

Planned Study Period: April 2023 to March 2025

Research Aims: (1) To develop and refine an initial version of the therapy, producing detailed guidelines for its use (2) To give couples living with brain injury the opportunity to contribute to this development (3) To collect information about its potential effectiveness so that we can decide whether the therapy merits further research in the future

## Funding and support in kind

| **FUNDER(S)** | **FINANCIAL AND NON FINANCIALSUPPORT GIVEN** |
|---|---|
| National Institute for Health and Care Research<br>Scott Thomson, Programme Manager, Research for Patient Benefit<br>Email: scott.thomson@nihr.ac.uk Tel.: 0203 692 7971 | £129,707.00 |
| Birmingham Community Healthcare NHS Foundation Trust<br>Dr Christine Burt, Director of Research and Innovation<br>Email: christine.burt2@nhs.net Tel.: 0121 466 7537 | NHS host for the research |

## Role of study sponsor and funder

The University of Birmingham, as study sponsor, has overall responsibility, and controls the final decision, regarding study design, conduct, data analysis and interpretation, manuscript writing, and dissemination of results.

## Roles and responsibilities of study management committees/groups and individuals

A Project Advisory Group, consisting of the Chief Investigator (Dr G. Riley), two co-investigators (Dr N. Yasmin Felles and Dr G. Yeates) and two couples living with ABI, will be established. This group will meet on two occasions per year during the funded period. It will set research targets (relating to recruitment, therapy delivery etc.), monitor whether these targets are being met, and address any obstacles to the timely achievement of the targets. It will also consider the outcomes of the research and any adverse events or concerns that have been raised about its conduct, and agree on steps to be taken to address any issues that have arisen. The Research and Innovation service of the host Trust will also provide a governance framework to ensure that the project is delivered on schedule, and to ensure appropriate financial management of the funding.

## Protocol contributors

This protocol was drawn up by the Chief Investigator (G. Riley) and was based on input from:

- A review by the Research Design Service (West Midlands)
- Feedback from the grants committee of the Research for Patient Benefit scheme of the National Institute for Health and Care Research
- Two couples living with brain injury
- Two co-investigators (Dr N. Yasmin Felles and Dr G. Yeates)

## Study flow chart

# Study protocol

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

## 1. Background and rationale

**1. Background and Rationale**

Acquired brain injury (ABI) is a major health issue. In the UK, there are approximately 1 million people living with long-term disability after traumatic brain injury and approximately half a million after stroke[29]. The impact on quality of life and psychological wellbeing is high[14,27,36]. This project addresses two factors that contribute to this impact - the substantial negative effect that ABI has on the self-identity and self-esteem of the person with the injury [46] and the harm that it does to marriages/partnerships resulting in high rates of dissatisfaction and separation[7,24,48].

Previous research suggests that one important contributor to difficulties in self-identity and partnerships is a sense of discontinuity between life before and after the injury. Discontinuity in self-identity refers to the experience of the injured partner that they are no longer the same person as they were before the injury, and discontinuity in the relationship refers to the experience of the non-injured partner that their relationship is radically different. This project aims to develop an intervention that addresses this disconnect by enhancing the couple's sense of continuity with the past. In a previous case report[68] we described an initial version of this psychological therapy. The project aims to develop the therapy further, and to carry out some preliminary evaluation.

*1.1 Previous intervention research*

In its focus on enhancing continuity, the therapy represents a novel intervention for addressing problems in the relationship and self-identity. Previous intervention research addressing these two problems is, in any case, very limited[4,26,42,47]. This was confirmed by a systematic search of several bibliographic databases and trial registries that we conducted in May 2021.

In terms of interventions addressing relationship difficulties, the focus has been primarily on improving communication[6,70] and intimacy[4]. Much of the research describes the application of a generic intervention developed to address relationship difficulties in the general population[12,17] and rarely has the intervention been developed on the basis of an analysis of the specific difficulties known to be important contributors to relationship problems after ABI[4,42,70]. Most of the papers reported uncontrolled evaluations of effectiveness [12,60,70]. Only four papers reporting RCTs were found[4,26,35,50], and the interventions in these studies each addressed a range of issues, only some of which concerned the relationship.

In addressing self-identity difficulties, the general aims of intervention are to help the person understand what changes have occurred because of the injury; to help them come to terms emotionally with those changes; and to facilitate the development of a strong and positive self-identity that recognises and does not ignore the changes[37,46,47,71]. The great majority of the intervention in this area has focused on helping individuals to understand and come to terms with the changes[53], and few have addressed the development of a positive post-injury identity[47]. We found only two studies[19,63] only one of which reported an evaluation of effectiveness.

*1.2 Rationale for developing an intervention focused on promoting continuity in the relationship*

In previous research[8,64], we investigated how some non-injured partners experience their post-injury relationship as a continuation of the loving relationship they shared before the injury, but others experience the relationship as being very different from what went before. Perceptions of the identity of the person with the ABI are a major component of the experience of discontinuity in the relationship. A sense of continuity is difficult when the other person is experienced as radically changed (e.g. " He's not the man I

married.")[8,64]. Other components include changes in feeling towards the person with the injury ("The care's still there, but the love's took a real beating"), losing the sense of belonging to a couple, and a redefining of the relationship ("I feel more like a father than a husband")[8,64].

We found that experiences of discontinuity are associated with a range of adverse outcomes for the non-injured partner. Maintaining a loving pre-injury relationship acts as a buffer against the negative emotional impact of the challenges posed by the injury. When this buffer is removed, there is a greater sense of burden [8,51,64], more depression and anxiety[49], and more negative emotional reactions to challenging care needs such as aggression[8,52,64]. Discontinuity is also associated with doubts about remaining within the relationship[8,64], lower ratings of the general quality of the relationship[67], and a less person-centred approach to providing care and support [8,52,64].

These associations between discontinuity and adverse outcomes provide the rationale for our expectation that an intervention designed to enhance the sense of continuity in the relationship may have beneficial outcomes for the non-injured partner. The injured partner would also be expected to benefit from the subsequent improvements in the relationship.

*1.3 Rationale for developing an intervention focused on promoting continuity of self-identity*

Previous literature suggests that, once the person with ABI starts to appreciate the changes that the injury has brought about, they often get stuck at the stage of struggling to come to terms emotionally with these changes and they find it difficult to move on and establish a positive self-identity[16,18]. A contributory factor to the emotional struggle, and a barrier to a positive self-identity, is a sense of discontinuity between the pre-injury and current self. The 'old-self' is described as 'broken' or 'lost', and unfavourable comparisons are made between the new and old self[15,20,22,32,37,45]. In a review of studies investigating these comparisons, Beadle et al.[5] reported that larger discrepancies between the new and old self (i.e. a greater sense of discontinuity) were associated with greater anxiety and depression, and lower self-esteem.

The importance of maintaining continuity of self-identity in times of change and transition is highlighted by Continuity Theory[3,38]. The theory suggests that continuity will benefit psychological wellbeing by providing a greater sense of security and predictability during the transition, and a more effective way of making sense of change[10,39,54,65]. Furthermore, life goals are based on a sense of who we are[71]. By maintaining links with the pre-injury self, continuity can provide a greater sense of direction and purpose when faced with life choices. Continuity also supplies a firmer base for a strong and positive self-identity[3,38,54]. If the pre-injury identity is lost, there is a risk that the person comes to define themselves primarily in terms of brain injury and internalises the sense of inadequacy and stigma associated with having a brain injury. The theory predicts, then, that a sense of continuity of self-identity will lead to a stronger sense of self-identity, a stronger sense of purpose and direction in one's life, less anxiety and higher self-esteem.

*1.4 Case study*

Based on this evidence of the negative impact of discontinuity, we began to develop a psychological therapy to enhance the experience of continuity. This initial version of the therapy is described in a recently published case study[68]. The study involved a couple in which the husband had suffered a stroke. The therapy comprised several components:

- Ways in which the couple expressed love and caring to one another before the stroke were identified, and they were supported in re-establishing these exchanges.
- The couple were encouraged to restore valued pre-injury habits and activities that they used to do together but had been abandoned since the stroke.
- The therapy aimed to re-balance the relationship so that it was more like a husband-and-wife relationship, and less like a caregiver and care-receiver relationship. For example, the husband was encouraged to be less passive in self-care activities.

- The wife interpreted some of the changes in her husband's behaviour as evidence of changes in his feelings towards her. She was supported in reinterpreting these in a way that promoted a sense of continuity. For example, she took his lack of communication as evidence that he did not care for her anymore. Through the therapy, she came to appreciate that the lack of communication was due partly to his stroke and partly to his wish not to overburden his wife, which was consistent with his pre-stroke caring feelings towards her.

It should be emphasised that the therapy included discussion and reflection on what changes had occurred in the husband and in the relationship because of the stroke. The therapy is not about ignoring or denying change, which is unhelpful.

Pre- and post-intervention questionnaires were completed. The wife showed increases in her perception of continuity in the relationship, decreases in stress and burden, and increased satisfaction with the relationship. The husband (who only completed the wellbeing questionnaire) also reported a decrease in stress. The study thus provided preliminary evidence that it may be possible to increase the perception of continuity, and that this may lead to improvements in the relationship and wellbeing.

## 2. Research question/aims

1. *To refine and expand the therapy, incorporating new components*: The literature review described earlier suggested some additional components that will be used to expand the therapy. Feedback from participants and therapists will be used to refine and expand the therapy.
2. *To give couples living with ABI the opportunity to contribute to the development of the therapy*: It is important that a psychological therapy is perceived by the recipients to address their needs in a credible way, and that it does not place unreasonable demands on them - otherwise compliance and benefit are likely to be poor. People living with ABI should therefore be involved in the development of the therapy to evaluate whether it meets these criteria. They are also uniquely placed to suggest how the therapy can be improved and to provide information about what factors might impact on its effectiveness.
3. *To collect information on contextual factors that might impact on the effectiveness of the therapy:* Psychological therapies are complex interventions. Contextual factors impact on effectiveness, and the exact form the therapy takes therefore needs to be tailored to meet the needs and circumstances of the individuals involved. It is important when developing complex therapies to gather information about these contextual factors[40].
4. *To collect information to enable a decision about whether a subsequent controlled evaluation of the therapy is merited*: The project will not provide evidence of the therapy's effectiveness, but data will be gathered to enable a judgment about its potential effectiveness.
5. *To develop detailed guidelines for delivering the therapy that can be used in a subsequent controlled evaluation*: Detailed guidelines will be needed to deliver the therapy in this study, but also for any subsequent evaluation.

## 3. Study design and methods of data collection and data analysis

### *3.1 Overview*

The aims will be achieved in the context of delivering the therapy to 10 couples. An initial version of the guidelines for delivering the therapy will be produced that incorporate the new elements identified in the literature review (Aim 1). This version will be used to deliver the therapy to the first three couples that take part in the study. Therapists and participants will be interviewed about their experience of the therapy (Aims 1, 2 and 3). Based on this feedback and data from a Report Form, further changes and refinements will be made to the guidelines. The revised guidelines will be used for the next three couples. Further revision will be considered after six couples have completed. Dependent on whether the therapy will be taken forward for formal evaluation, the guidelines will be revised and finalised at the end of the study (Aim 5). Before and after

the therapy, participants will complete questionnaires evaluating their perceptions of continuity, their psychological wellbeing and the quality of their relationship. Although this will not provide evidence of the therapy's effectiveness, a lack of improvement would suggest that there is no merit in pursuing its controlled evaluation (Aim 4).

*3.2 Production of the written guidelines*

There are several published sets of guidelines for the delivery of psychological therapies, many of which have been used to direct therapy delivery in randomised controlled trials. We will use these as templates to guide the development of the written guidelines. The Society of Clinical Psychology provides an extensive list of such manuals: https://div12.org/psychological-treatments/ Many of the manuals provide detailed session-by-session instructions; worksheets and other resources used in delivery of the therapy; and guidance about dealing with potential challenges and barriers to effective delivery. In producing the written guidelines, we will similarly provide guidelines with these characteristics.

*3.3 Expansion of the therapy*

Expansion will be informed by research identified in the literature review described earlier. For example, methods associated with narrative therapy could be adapted and used to foster continuity[12,19]. Taking a broader life-review perspective on the injury provides an opportunity for the couple to see how their response to the injury is shaped by their pre-injury identity as individuals and as a couple. Participants and therapists will also be asked to suggest ways of expanding the therapy.

*3.4 Participants and recruitment*

A convenience sample of participants will be recruited through the ABI rehabilitation service and community outreach programmes of the host and other NHS Trusts, through branches of Headway, and through other charitable organizations providing support for people living with brain injury. Headway is a national charity providing support services to those living with the long-term effects of brain injury. The study will be advertised using flyers, posters and on-line notifications. The posters and on-line notifications will contain the same information as the flyer. Flyers will be provided on the premises of participating organisations for people to take as they wish. Participating charities will be asked to publicise the study on their websites. The flyer will be sent to those on the mailing lists of the community outreach programmes and charities.

The flyer will invite interested people to contact the researchers directly or to ask a staff member to contact the researchers on their behalf. If they chose to do the latter, they will be asked to sign a 'consent to contact' form that provides their preferred contact details, and to give this to a staff member who will forward it to the research team.

All recruitment and research procedures (including providing explanations of the research and taking informed consent) will be conducted by members of the research team. Staff at the sites will not be actively involved other than to make the flyers available. They will be notified of who has expressed an interest in taking part and asked whether they have any serious concerns about the psychological wellbeing of one or both members of the couple, or about the fragility of their relationship (see exclusion criteria below).

The aim will be to ensure that 10 couples receive the full course of therapy (10 sessions). This number is based on an assessment of how many therapy sessions can be delivered within the budget limitations of a Tier 3 study. Also, after a certain point in data collection, the involvement of more participants adds progressively less new information, meaning that the costs of the research are rising but returns are diminishing.

The West Midlands is an area of significant socioeconomic and cultural diversity, and every effort will be made to recruit a diverse sample. The NHS Trust hosting the research has a *Community Connexions Programme* and a *BAME network* that can be used as routes for reaching diverse communities. No protected characteristic will disadvantage potential participants in terms of recruitment except in the circumstance that a person's disability is so severe that they are unable to give informed consent or take a meaningful part in verbal therapy. It is acknowledged, however, that the small sample size precludes recruitment of a sample that is properly representative of the West Midlands area.

**Inclusion criteria**

- Couples must be living together at the time of participation.
- Couples must have lived together for at least 2 years before the injury. The concept of continuity/ discontinuity in the relationship has less application if the pre-injury relationship was brief.
- The injury must have occurred at least 1 year previously. The therapy is focused on what happens after the person with the injury develops an awareness of the effects of the injury and this may take some time to develop. Relationship difficulties also typically take some time to emerge.
- The injury must have occurred no more than 10 years previously. Continuity would be difficult to establish if the pre-injury identity and relationship are too far in the past.
- One or both partners must report some dissatisfaction with their current relationship.
- Both participants are over the age of 21. There is no upper age limit.

**Exclusion criteria**

- Participants must report that the pre-injury relationship was at least satisfactory. It makes little sense to try to reconnect with an unsatisfactory pre-injury relationship.
- Both participants must be capable of giving informed consent and taking part in verbal therapy.
- One or both members of the couple find it difficult to participate in verbal therapy conducted in English.
- There are co-morbid serious mental or physical health conditions for either partner that may impact on their meaningful participation.
- Staff in the service from which participants are recruited have serious concerns about the psychological wellbeing of one or both members of the couple, or about the fragility of their relationship.

Couples interested in participation will meet with the researcher who will carry out the therapy on one occasion prior to commencing therapy. The meetings will take place at the University of Birmingham, Moseley Hall Hospital (where the brain injury service of Birmingham Community NHS Trust is based), on the premises of a Participating Identification Centre, a Headway centre (recruitment will be through several Headway centres), or some other venue agreed by all parties. The session will provide full details about the study, using the participant information sheet as a guide to what needs to be discussed. The couple will be given an opportunity to ask questions about what participation involves and raise any concerns. The inclusion/exclusion criteria will be explained in detail, and potential participants asked to indicate if they fail to meet the criteria. Because they have not yet consented to take part, potential participants will not be required to provide detailed information about which criteria they meet but only to say whether, overall, they do or do not meet the criteria. To minimise participant withdrawal, there will be an emphasis on the challenges of taking part. They will be given the participant information sheet to keep.

If the couple remain interested, a second meeting will be arranged for the following week with an interval of at least 4 days. Twenty-four hours before the second meeting, the member of the research team responsible for evaluation will contact the couple, using their preferred method of contact, to ask whether they want to go ahead with a second meeting. Thus, couples will have at least 3 days to make their decision. The second session will involve answering any further questions the couple may have, receiving informed consent and completing the pre-intervention questionnaires.

**Informed consent**

Informed consent will be given through signing the consent form. It will be requested only after the research has been fully explained in the first meeting; the participants have had an opportunity in the first meeting to ask questions about the research and a further opportunity to do so in the second meeting; each participant has been asked separately if they have any concerns about taking part; and the researcher is satisfied that both individuals have the capacity to consent. During the second meeting, the researcher will see each member of the couple separately for part of the meeting. This individual time will provide the opportunity for the potential participant to raise any concerns they might have. If the researcher has any concerns about the capacity of the person to give informed consent, this will be assessed during this individual time.

Capacity to give informed consent will be assessed in accordance with the requirements of the Mental Capacity Act. Specifically, they will be judged to have capacity if they can:

- understand information about the decision to be made
- retain that information in their mind
- use or weigh that information as part of the decision-making process
- communicate their decision

In practice, having received information about the study, the potential participant will be asked to describe in broad terms what participation will involve, and what the advantages and disadvantages of taking part might be. Satisfactory answers to these questions will be taken as evidence that the person has capacity to give consent.

*3.5 Delivery of the therapy*

The therapy sessions will be conducted by the lead applicant (G. Riley), one of the co-investigators (N. Yasmin), and other clinical psychologists involved in the project. Diversity in who delivers the therapy is expected to lead to more productive discussions about improvements.

The planned number of sessions for each couple is 10. This figure is based on the number of sessions required in the case study described earlier[68]. Depending on individual need and preference, earlier sessions will be weekly but later sessions will be spaced out to allow participants time to work on goals set during the therapy. Sessions are likely to last approximately 60 minutes. Sessions will take place at the University of Birmingham, Moseley Hall Hospital (where the brain injury service of Birmingham Community NHS Trust is based), the premises of a Participant Identification Centre, a Headway centre (recruitment will be through several Headway centres) or a venue agreed by both parties.

Session notes will be kept by the therapist delivering the therapy. Section 5.6 gives details about the recording and storage of these notes. They will serve as aids for delivering the therapy (e.g. a reminder of what has been covered in previous sessions). They will be identified through a unique code given to the couple and will not contain specific identifying details such as names.

3.6 *Data collection*

*3.6.1 Sample description measures*

Data will be gathered about the demographic characteristics of both members of the couple, including protected characteristics. Information about the injury, specifically the type of injury and the date of its occurrence, will also be collected. To obtain a measure of the level of disability caused by the injury, the non-injured partner will be asked to complete the *European Brain Injury Questi*onnaire[59]. These data will be

obtained during the second recruitment interview once informed consent has been given. Documents will be identified using a unique code for each participant, and will not contain their names.

*3.6.2 Interviews with the therapists and the participants*

Each couple will be interviewed once their course of 10 sessions is complete. Each therapist will also be interviewed twice during the period of the project. Interviews will be conducted by a psychologist employed for the purposes of the project and tasked with the evaluation of the therapy.

The interviews will be semi-structured. Questions for the couple will address:

- their general experience of the therapy
- what they found helpful
- whether there was anything that was less helpful
- whether there was anything upsetting, distressing or demanding about the therapy
- suggestions for improvements
- their understanding of what the therapy's aims were and whether those aims were meaningful to them as a couple (i.e. credibility)
- circumstances that might have impacted on therapy effectiveness
- whether, overall, they felt they benefited from the therapy

Similarly, questions for the therapists will address:

- their general experience of the therapy
- what aspects of the therapy they thought were beneficial, and why
- what aspects were less helpful
- whether any aspect of the therapy was upsetting, distressing or too demanding for one or more couples
- any suggestions for improvements
- whether the rationale for the therapy was convincing, given their experience of applying it
- what factors may have had an impact on the effectiveness or ineffectiveness of the therapy

Interviews will typically be face-to-face and conducted at the venue where the couple received the therapy sessions. There will also be the option of interviews by telephone or on-line, using a secure service such as Zoom or Microsoft Teams and an NHS-authorised account. Interviews will be semi-structured, using a set list of questions, and will be audio-recorded using an encrypted device. The recording will be transcribed by the person who conducted the interview. No specific identifying details (such as names and places) will be included in the transcription. A unique code for each participant will be used to identify transcripts.

*3.6.3 Measures of mechanism and outcome*

Participants will complete a set of questionnaires before and after they have received the therapy. The questionnaires will be administered by the psychologist recruited for the purpose of evaluating the therapy (see Section 3.9 below). Questionnaires will be completed on paper. Names will not appear on the questionnaires which will be identified with a unique code for the participant. Participants will be required to complete the questionnaires separately and not to discuss the content or show the completed questionnaires to one another.

In accordance with MRC recommendations about evaluating complex interventions[44], the mechanisms whereby the intervention is expected to have its effect will be assessed as well as the outcomes themselves. In the present case, the therapy is expected to enhance continuity in self-identity and the relationship, and increased continuity is expected to lead to a range of beneficial outcomes.

Based on research described in Section 1.2 and Section 1.3, several benefits are expected. The questionnaires will not address all of these potential benefits because validated questionnaires are not available. Questionnaires marked with an asterisk* will only be administered before the therapy; questionnaires marked with a caret^ will only be administered after the therapy.

The injured partner will complete:

- Background:
  - Demographic information and questions relating to the brain injury*
- Mechanisms:
  - *Continuity of Self-Identity Questionnaire*[74] – measure of continuity in self-identity
- Outcomes:
  - *Rosenberg Self-Esteem Scale* [16,66] - self-esteem
  - *Warwick-Edinburgh Mental Wellbeing Scale* [58] and *Depression, Anxiety and Stress Scale*[2] - general psychological wellbeing
  - *Index of Marital Satisfaction*[72] - relationship quality and satisfaction with the relationship
- Therapy:
  - Two questions relating to their experience of the therapy itself^

The non-injured partner will complete:

- Background:
  - Demographic information and questions relating to the brain injury*
  - *European Brain Injury Questionnaire, informant version*[59] *– questions about the impact of the injury on the person with the brain injury
- Mechanisms
  - *Birmingham Relationship Continuity Measure for Acquired Brain injury*[67] - experience of continuity in the relationship.
- Outcomes:
  - The *Head Injury Behaviour Rating Scale*[55] - extent to which changes in the person with the brain injury are perceived as distressing and burdensome.
  - *Warwick-Edinburgh Mental Wellbeing Scale* [58] and *Depression, Anxiety and Stress Scale*[2] - general psychological wellbeing and anxiety
  - *Index of Marital Satisfaction*[72] - relationship quality and satisfaction with the relationship.
- Therapy:
  - Two questions relating to their experience of the therapy itself^

### *3.6.4 Report Form*

A report form will be developed with sections for recording:

- comments about what they found helpful / unhelpful
- suggestions about improvements
- whether the demands of the therapy are unreasonable
- whether anything was upsetting or distressing
- ideas about contextual factors that might impact on effectiveness

Participants will be given a copy of this form and asked to add comments as appropriate. At an appropriate point near the end of the therapy, the therapist will set aside some time to discuss with the participants any comments entered onto this form and whether they have any other thoughts about these issues.

The therapists will also have a copy of the same form with additional sections addressing:

- any adverse events experienced by the couple during the time of their participation, whether these are related to the therapy or not
- issues about the clarity of the guidelines (for the therapist only)

*3.7 Participant withdrawal*

If, at any point during their participation, one or both members of the couple express a wish to withdraw, their wish will be respected. They will be given the opportunity to discuss the reasons for withdrawal, but it will be made clear to them that they are under no obligation to explain themselves if they do not wish to do so. The researcher will not make any attempt to change their decision. If only one member of a couple wishes to withdraw, the couple will be withdrawn from the research. The therapist will not provide any further intervention for the person who does not wish to withdraw.

The aim is to recruit and deliver the full course of therapy to 10 couples. Consequently, if a person or couple drop out, another couple will be recruited, and this will continue until at least 10 couples have completed the full course.

Participants who withdraw prematurely will not be asked to complete any questionnaires or provide any further information following their decision to withdraw. However, any relevant information previously obtained from the report form and the pre-therapy questionnaires provided by these participants will be retained and included in the evaluation of the therapy.

*3.8 Data analysis*

For the mechanism and outcome questionnaires, the Reliable Change Index[41] will be used to compare pre- and post-therapy scores for each participant to determine whether there is any statistically reliable improvement on each questionnaire. The criterion of $\pm$1.645 will be used as recommended for use when comparing scores in individual cases[73].

For analysing the data from the interviews and the report forms, framework analysis will be used[21]. This technique is suitable for the proposed study because it allows one to structure the analysis according to pre-set categories of interest (e.g. what participants found helpful or unhelpful) but also provides an opportunity to develop more specific novel themes within these broader pre-set categories (e.g. participants might find the intervention too directive). The analysis provides a systematic way of grouping and summarising the data. A key feature is a matrix composed of participants (rows) and categories/themes (columns) into which specific excerpts from the data are inserted. In accordance with framework analysis[21], an initial list of categories will be used to code the data from the first three participants. The categories/themes will then be modified as necessary and used to code data from subsequent interviews and report forms, but will be continually updated to accommodate any new themes.

*3.9 Separation of therapy delivery and data collection/analysis*

A psychologist will be employed specifically to conduct the interviews and to administer the pre- and post-intervention questionnaires, and will take no part in administering the therapy. Participants are likely to feel more comfortable about criticising the therapy if the interviews and questionnaires are administered by a different person. To further promote separation of the delivery and evaluation of the therapy, the conduct

and analysis of the interviews and questionnaire data will be supervised by a co-investigator who will not be involved in delivering therapy (G. Yeates).

*3.10 Decision about progression*

One aim of the project is to collect information to enable a decision about whether a subsequent controlled evaluation of the therapy is merited. Several sources of information will be used in making this decision:

- Participants will complete questionnaires before and after the therapy (Section 3.6.3). Although this will not provide evidence of the therapy's effectiveness, a failure to observe any statistically reliable improvement in these outcomes would suggest that there is no merit in pursuing its controlled evaluation.
- At the end of therapy, participants will complete a brief questionnaire containing two items about their experience of the therapy (Section 3.6.3). Information about this will also be gathered from the interviews and report form (Sections 3.6.2 and 3.6.4). The number of couples who prematurely withdraw from the study is also relevant. If the therapy is assessed poorly in these terms, this would raise questions about the value of further evaluation.
- Information about contextual factors impacting on effectiveness will also be gathered from the interviews and report forms. This information is relevant to the decision because it may help explain a poor response.

In making the decision about progress, there are several issues that need to be considered. First, it is important that the therapy impacts on both the hypothesised mechanism (an increase in the sense of continuity) and the outcomes[44]. An improvement in outcome without any change in the mechanism would suggest that the benefits occurred for some other reason; and an improvement in the mechanism without change in outcome would suggest that the theory underlying the therapy is incorrect. Second, if the majority of the sample of 10 couples were, by chance, influenced by contextual factors that adversely impacted on effectiveness, then a decision not to progress on the basis of a relatively poor average response might be premature. Third, there is a possibility that the therapy might be beneficial for the non-injured partner but less so for the injured partner (or vice versa). In this case, it might be worth progressing to a controlled evaluation of a version of the therapy that focused more on one partner.

Taking these issues into consideration, progression will occur if all three of the following conditions are met:

- More than half of the 20 participants who complete the therapy (= 10 couples) show statistically reliable improvement on both a hypothesised mechanism of effect and an outcome measure.
- More than half of these 20 participants give positive ratings to the therapy on the brief questionnaire about their experience of the therapy.
- Fewer than half of the couples who start the therapy decide to withdraw before the end.

An exception to this decision process will be considered if the information collected about contextual factors provides a plausible explanation of why all three conditions were not met, and thereby provides a plausible basis for expecting that, with better-informed selection criteria or methods of implementation, the therapy could prove effective.

## 4. Safety reporting

At the start of each therapy session, the therapist will ask the couple about any adverse events that have occurred since the previous meeting. The therapist will immediately notify the Chief Investigator of any serious adverse events (i.e. any event requiring intervention from NHS or Social Care services or third-sector equivalent, or any serious fracture in the relationship such as one person moving out of the shared home). The Chief Investigator will make a decision about whether this may be causally connected to the intervention (i.e. a serious adverse reaction). Notifications and decisions will be recorded and, in the event of a serious adverse reaction, a meeting of the Project Advisory Group will be convened and will make a decision about how to proceed (i.e. whether to stop further delivery of any therapy or to make amendments to the protocol and/or the guidance for its delivery).

Delivery of the therapy to 10 couples will be spread over an 18-month period. The outcomes for each couple will be reviewed at the end of their therapy. The trial will be prematurely terminated if the first 5 couples show little benefit from the therapy, there have been one or more serious adverse reactions, and there is no plausible explanation for these findings and therefore no realistic prospect of making changes to the delivery of the therapy in order to improve outcome.

## 5. Ethical and regulatory considerations

### 5.1. Assessment and management of risk

There is a moderate risk of distress for participants during sessions, and a slight risk that the therapy may have a more general negative impact on the psychological well-being of the participants and their relationship. To assess these risks, the therapist will ask at the start of each therapy session whether there have been any adverse events since the last session and the wellbeing of participants will be monitored during sessions.

To manage these risks:

- People will not be recruited if staff have serious concerns about their current psychological wellbeing or the fragility of their relationship.
- The risks will be explained to potential participants in the participation information leaflet and in the initial recruitment meeting with the couple.
- The therapy will be delivered by qualified clinical psychologists or clinical psychologist in training who have experience working in the field of brain injury and working with psychological distress. They will have skills in identifying and managing any distress or conflict that arises during sessions. Regular clinical supervision will also take place and risk issues will be a standing item on the agenda.
- During the therapy itself, each component will be explained to the couple before it is implemented, and they will be asked whether they are happy to proceed. The component will not be implemented without the explicit agreement of the couple.
- The participant information leaflet will contain information about services available to support psychological wellbeing or relationship crises. If the therapist has any concerns about these issues, the participants will be directed to this information. The therapist will also offer to assist the participants in making contact with these services.
- Participation in the research will require a considerable commitment of time from the participants. Apart from the two initial meetings focused on recruitment and the collection of pre-intervention data, there will be 10 therapy sessions (approximately 60 minutes at weekly intervals), two interviews about their experience of the therapy (60 minutes) and one meeting to collect post-intervention outcome data. This heavy time commitment will be stressed in the participant information leaflet and in the initial recruitment meeting with potential participants. They will be advised to take part only if they feel able to

make this commitment. There will also be some flexibility about the timing of meetings to allow for holidays, unforeseen life events etc.

If any participant discloses information that suggests that they or someone else is at significant risk of harm, this will be communicated directly to the safeguarding service within the Trust hosting the research and their advice taken about how to address the issue. Participants will be informed in the participant information leaflet that their confidentiality will be protected but that the safeguarding service will be informed if any information is disclosed suggesting a risk of harm.

### 5.2. Research Ethics Committee and other regulatory review & reports

Before the start of the study, a favourable opinion will be sought from an NHS Research Ethics Committee for the study protocol, informed consent form and other relevant documents. Substantial amendments that require review by NHS REC will not be implemented until that review is in place and other mechanisms are in place to implement at site. An annual progress report will be submitted to the REC within 30 days of the anniversary date on which the favourable opinion was given, and annually until the study is declared ended. The Chief Investigator will notify the REC of the end of the study. If the study is ended prematurely, the Chief Investigator will notify the REC, providing the reasons for the premature termination. Within one year after the end of the study, the Chief Investigator will submit a final report with the results, including any publications/abstracts, to the REC.

Before any participants are recruited through an organization, the Chief Investigator will ensure that appropriate approvals from participating organisations are in place. For any substantial amendment to the study, the Chief Investigator will submit information to the organization in order gain their approval for the amendment.

Substantial amendments to the protocol will be decided by the Project Advisory Group. Submission of these amendments to the NHS REC for approval will be the responsibility of the Chief Investigator.

### 5.3. Peer review

This protocol has been reviewed by the grants committee of the Research for Patient Benefit scheme of the National Institute for Health and Care Research. This process involves review by five independent experts, including one expert-by-experience, and consideration of their feedback by the grants committee. The protocol was amended in response to their feedback, and the amended version accepted.

### 5.4. Patient & Public Involvement

Two couples living with ABI were involved in the development of this application. Initially, they were consulted about the importance and relevance of the project. Discussion addressed the personal importance to them of relationship and self-identity issues; their experience of how services dealt with these issues; whether they perceived a gap in services in terms of addressing the issues; and the credibility and acceptability of the proposed therapy. The two couples also provided feedback on the readability of the plain English summary.

It is important that a psychological therapy is perceived by the recipients to address their needs and concerns, has a credible rationale, and does not make unrealistic demands. Without these features, compliance and benefit are likely to be poor. People living with ABI should therefore be involved in the development of the therapy to evaluate whether it meets these criteria and to help develop it in a way that better meets the

criteria. The experience of living with ABI also gives people a better understanding of what might help foster a sense of continuity with the past, and so they may have ideas about how the therapy could be developed. The participants themselves will, therefore, be given the opportunity to provide feedback about the therapy and to contribute their own ideas about improvement through the interviews and report forms (Sections 3.5.2, 3.5.4). Two couples with experience of living with ABI (or at least one if recruitment proves difficult) will also be part of the Project Advisory Group. In this role, they will evaluate the feedback from participants and therapists, and contribute to the development and refinement of the therapy (Section 3.9). The couples will also be involved in producing written materials for couples taking part in the study (e.g. participant information sheet) and the lay summary (Section 4.1). Participants and the two couples will also be invited to contribute to the local dissemination event (Section 4.2). The Chief Investigator will act as PPI lead with support from a specialist PPI advisor at the West Midlands Research Design Service. Training workshops to facilitate PPI involvement are provided by this service, and the two couples will attend along with the Lead Applicant. NIHR INVOLVE guidelines will be followed to ensure that their participation in the study is meaningful, valued and appropriately recompensed. In consultation with the two couples, the Chief Investigator will also take responsibility for documenting their involvement and the contribution of the participants themselves, and what impact it had on the study outcomes.

### 5.5. Protocol compliance

A Protocol Adherence Form will be completed by those delivering the therapy, with one form covering all contact with one couple. The therapist will be instructed on the form to notify the Chief Investigator of any breaches of the protocol.

### 5.6. Data protection and patient confidentiality

All researchers will comply with the requirements of the General Data Protection Regulation and Data Protection Act 2018 with regards to the collection, storage, processing and disclosure of personal information and will uphold the Act's core principles. The NHS Code of Confidentiality will also be followed.

Personal data generated by the research include the consent-to-contact form, the consent-to-participate form, completed questionnaires, session notes kept by the therapist, audio recordings and transcripts of two interviews, and the potential publication of direct quotations from these interviews.

The consent-to-contact and the consent-to-participate forms will contain personal data such as names and contact details in a direct form, and will be completed on paper. Once completed, these forms will be scanned as soon as is practically possible and the electronic copy uploaded to the University of Birmingham's secure Research Data Store, with access restricted to Chief Investigator. The paper copy will then be securely shredded. If the forms cannot be scanned immediately, they will be stored in a locked drawer in a locked office on the premises of the NHS Trust hosting the research or the premises of the University of Birmingham or the University of Derby.

The two interviews about participants' experience of the therapy will be audio-recorded on an encrypted recording device. The recording will be transcribed by the interviewer. Names and other potentially identifying information will not be included in the transcription, which will be identified by a unique code. Once the interview has been transcribed, the recording will be deleted from the device and the transcription will be stored on the University of Birmingham's Research Data Store, with access restricted to the Chief Investigator. An encrypted copy of the transcript will kept on a password-protected NHS account by the psychologist employed to evaluate the research and on a password-protected computer by Dr G. Yeates who will be supervising the analysis of the interview data. In dissemination of the research findings, direct quotations from participants may be included but these will not include any names or other identifying information. Pseudonyms will be used in the transcripts and when attributing direct quotations.

Questionnaires will be completed on paper. These will be identified by a unique code and not by the participants' names. Once completed, they will be scanned as soon as is practically possible and the electronic copy uploaded to University of Birmingham's Research Data Store, with access restricted to the Chief Investigator. The paper copy will then be securely shredded.

Session notes will also be handwritten on paper. These will be identified by a unique code and not by the participants' names. These will be kept in a locked drawer in a locked office on the premises of the NHS Trust hosting the research, of one of the Universities participating in the research, or another secure location. They will be securely shredded once the therapy for that couple is concluded. They will only function to assist in the delivery of the therapy and will not contain any research data.

Each participant will be allocated a unique code by the Chief Investigator for the purposes of identifying data they have provided. A list matching the code to the name of the participant will be created by the Chief Investigator as an electronic file. This will be stored on the University of Birmingham's secure Research Data Store, with access restricted to the Chief Investigator.

Medical records will not be accessed for this project. Personal data in the form of consent-to-contact and consent-to-participate will only be accessed by those members of the research team involved in recruitment, provision of the therapy, and interviewing participants about their experience of the therapy.

The Chief Investigator will act as custodian of the data on behalf of the sponsor and will be responsible for ensuring the protocol is followed in relation to data protection. Consent-to-contact and consent-to-participate forms will be securely destroyed once the project is finished. The questionnaires and transcripts will be kept for 10 years after the end of the project on University of Birmingham's Research Data Store in accordance with the Code of Practice for Research. They will then be securely destroyed.

### Indemnity

Indemnity is provided through existing arrangements at the University of Birmingham. The University has in force a Public Liability Policy and/or Clinical Trials policy which provides cover for claims for "negligent harm" and the research activities described in this document are included within that coverage.

### 5.7. End of study and archiving

The study will terminate either when the criteria for premature termination of the study have been met, or 10 couples have completed a full course of therapy and findings arising from their involvement have been analysed.

Research data will be kept, in electronic form, for 10 years on the University of Birmingham's Research Data Store. Access will be restricted to the Chief Investigator and anyone authorised to audit research materials as part of research governance.

## 6. Dissemination policy

A write-up of the study will be submitted for publication in an academic journal and for presentation at an academic conference, and two written summaries will be produced, one for a professional and one for a lay audience. Participants who request the summary will receive it at the end of the study. The lay summary of the study will be offered to Headway and the Stroke Association for posting on their national websites and social media platforms. The NHS Trust hosting the research belongs to the Community Healthcare Alliance of Research Trusts. This organization exists to generate and disseminate research of relevance to Community

NHS Trusts, to disseminate best practice, and to lobby national bodies about research issues of relevance to community settings. The organization communicates through conferences and an on-line forum, and these media will be used to disseminate the professional summary to CHART members.

A local West Midlands dissemination event will be advertised to local NHS clinicians, third sector workers, participants in the study and people living with brain injury. Prior to the dissemination event, a specialist in public and patient involvement from the West Midlands Research Design Service will be consulted about the best way to involve the study participants and the two couples from the Project Advisory Group at the event. This is likely to be in a panel format. Targeted invitations will be sent to the ABI rehabilitation service hosting the project, the local branches of Headway that assisted with recruitment, and the participants.

The University of Birmingham will own the data arising from the study. The funding body (NIHR) and the host NHS Trust (Birmingham Community Healthcare) will be acknowledged within all publications.

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## 8. Appendices.

### 8.1. Appendix – Amendment History

| Amendment No. | Protocol version no. | Date issued | Author(s) of changes | Details of changes made |
|---|---|---|---|---|
| 1 | 6 | 21.11.2023 | G. Riley | See below |
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List details of all protocol amendments here whenever a new version of the protocol is produced.
Protocol amendments must be submitted to the Sponsor for approval prior to submission to the REC.

**Summary of amendments made for Version 6, 21.11.2023**

1. Because of delays to starting the project, the planned study period (p.3) and GANTT chart (p.5) have been altered.
2. Because of difficulties with recruitment, the sources of recruitment have been widened (Section 3.4, p.9 and p.10) and the inclusion criteria made more liberal (Section 3.4, p.10).
3. Based on feedback from participants and therapists taking part in pilot work, later therapy sessions will be less frequent than weekly to allow participants more time to work on goals (Section 3.5, p.11); the number of questionnaires completed by participants has been reduced and two questions about how the participants would rate the therapy have been added (Section 3.6.3, p.13); and participants will only be interviewed about their experience of the therapy once the therapy is finished (rather than being interviewed halfway through and at the end) (Section 3.6.2, p.12).
4. Reflecting the addition of these two rating questions and changes to the inclusion criteria, the criteria for making the decision about whether to try to progress to a controlled trial have been changed (Section 3.10, p.15).