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Preparing individuals with severe head injury for a brief compassionate imagery exercise

& Clinical Research Portfolio

Volume I (Volume II bound separately)

> Melanie Gallagher August 2014

Submitted in partial fulfilment of the requirements for the degree of Doctorate in Clinical Psychology (DClinPsy)

University of Glasgow Mental Health and Wellbeing August 2014

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Chapter One: Systematic Review

Adapting CBT for anxiety and depression following brain injury: A systematic review and narrative synthesis

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ABSTRACT

Background Due to diverse cognitive, emotional and interpersonal changes following brain injury, existing psychological therapies may need to be adapted to suit the needs of this complex population. These issues have not yet been subjected to systematic review and narrative synthesis.

Aims To synthesise recommendations of modifications to therapy following brain injury, and to determine how often such modifications have been utilised within cognitive behavioural therapy (CBT) for the commonly reported problems of anxiety and depression following brain injury.

Method Systematic review and narrative synthesis of *recommended* modifications to therapy from review articles, and *recorded* modifications from intervention studies.

Results A total of 688 papers were identified from a systematic search, from which eight review articles and 12 intervention studies were included for review. A further four intervention studies were included from searching articles which cited and were cited by the included articles. From the review articles, a list of commonly recommended modifications to therapy were organised into a checklist under the headings of: therapeutic education and formulation; attention; communication; memory; and executive functioning. When marked against this checklist, intervention studies reported such modifications, and other themes in modifications were found, involving additions to CBT (motivational interviewing and cognitive remediation), and further amendments to the common components of CBT.

Conclusions Adequate reporting of adaptations will allow researchers and clinicians to more easily replicate therapies. The present list of modifications to therapy provides an empirical basis for future adaptation-oriented research and practice.

INTRODUCTION

Brain injury can have profound negative consequences on an individual's functioning, via effects in cognitive, emotional, sensory, motor and psychosocial domains (Arlinghaus, Shoaib & Price, 2005). Judd and Wilson (2005) have argued that organic brain damage should be conceptualised and treated in a way that recognises the connected effects of both organic *and* psychological consequences of brain injury. When considering treatment of the common psychological consequences of *anxiety* and *depression* following brain injury (e.g. Gould, Ponsford, Johnston & Schönberger, 2011), it might be expected that existing psychological therapies would require adaptation, in order to sensitively react to organic changes, and create the best chance of success. The present review aims to examine current recommendations on adaptations made to cognitive behavioural therapy (CBT) within this context.

The terms 'acquired brain injury' (ABI) and 'brain injury' are often used interchangeably to describe damage to the brain from diverse causes (SIGN, 2013; Turner-Stokes, Nair, Sedki, Disler & Wade, 2011). 'Brain injury' will be adopted in the present article to cover both terms. Such damage can be focal or diffuse and can vary in severity and location within the brain, leading to a multitude of possible changes in functioning. The World Health Organisation's International Classification of Functioning (WHO ICF) has highlighted this heterogeneity, indicating that every individual affected by brain injury will have a unique set of needs (Wade & Halligan, 2003). People will therefore require psychological therapies that are suitably adapted to meet these diverse needs.

Current guidelines recommend that rehabilitation after brain injury takes place within a holistic neuropsychological rehabilitation programme, using a multidisciplinary team which can address cognitive, emotional and behavioural difficulties with the aim of improving functioning in meaningful everyday activities (SIGN, 2013). When considering emotional difficulties, CBT has been recognised as being theoretically suitable for treating depression and anxiety following brain injury, as it can offer a structured approach which focuses on concrete thoughts and behaviours (Hodgson, McDonald, Tate and Gertler, 2005). In practice, CBT has been recommended for the treatment of anxiety symptoms following mild-to-moderate traumatic brain injury, as part of a broader neurorehabilitation programme (SIGN, 2013).

A greater understanding of how best to treat the diverse cognitive, emotional and interpersonal problems following brain injury is required. There is currently no systematic review evidence on which to base adaptations to psychological therapies for people affected by brain injury. Insight into the techniques used to *adapt* CBT at the level of individual therapy could improve therapy within the holistic, multidisciplinary approach recommended for brain-injury

treatment. The present review will focus on the common psychological difficulties of *anxiety* and *depression* following brain injury (Broomfield et al., 2011; Gould et al., 2011); the most frequently recommended form of individual therapy, namely CBT; and on adaptations made in order to account for cognitive changes following brain injury. The first aim of the present review is to use existing review articles to identify the currently recommended modifications to therapy. This information will then be used to systematically analyse current intervention-study evidence (from randomised controlled trials and case studies) to determine how many of these modifications are reported in intervention studies, and to identify any further modifications made within intervention studies. Finally, the quality of the *reporting* of treatment within intervention studies will be analysed, using an adapted version of the CONSORT checklist as the standard of comparison (Boutron, Moher, Altman, Schulz, & Ravaud, 2008).

METHODS

The search strategy was conducted in accordance with the PRISMA statement (Moher, Liberatti, Tetzlaff & Altman, 2009). The initial search produced a pool of papers from which review articles and intervention studies were then extracted.

Search Strategy

Relevant studies were identified by searching the following electronic databases:

- •Embase (1980 to 2014 Week 23)
- •Embase Classic (1947-73)
- Ovid Medline(R) In-Process & Non-Indexed Citations and Ovid Medline(R) (1946- June, 2014)
- •CINAHL (1981-June, 2014)
- •PsycARTICLES (up to June, 2014)
- Psychology and Behavioural Sciences Collection (up to June, 2014)
- •PsychInfo (up to June, 2014)

The following terms were entered as text word searches into the above databases:

•(((Acquired brain injur*) OR ABI or (traumatic brain injur*) OR TBI OR (brain injur*) OR (head injur*) OR stroke OR CVA))

•((CBT OR (behavio*r* therap*) OR (cognitive therap*) OR (cognitive behavio*r* therap*) OR (psycho* therap*) OR psychotherapy*))

•((depress* OR (low mood) OR (mood disorder*) OR (affective disorder) OR anx* OR OCD OR PTSD OR trauma OR panic OR phobia))The three searches were combined using the Boolean operator AND.

Extraction of review articles

Articles were included if they:

- •Were review articles (narrative review, systematic review, or other reviews)
- Provided recommendations on alterations to cognitive behavioural therapy provided within a brain-injury population.
- •Contained recommendations which are specific to CBT or which do not conflict with the CBT model

Articles were excluded if they:

•Reviewed any area of brain-injury research but did not provide recommendations for adapting therapy to this population

Extraction of intervention studies

Studies were eligible for inclusion if they met the following criteria:

•Participants were aged 16 years and older and had a diagnosis of brain injury, either traumatic or non-traumatic, including stroke, hypoxia, ruptured aneurysm or metabolic encephalopathy

- Written in English
- •The psychological treatment used was CBT, provided in an individual format

• The primary outcome was measurement of depression, 'low mood', or anxiety (described as: 'anxiety,' OCD, PTSD, panic disorder, GAD, social anxiety)

•Contained a description of the psychological intervention used, including the length of intervention

Studies were excluded if:

•CBT was provided in a format other than one-to-one with a clinician (e.g. group or internetbased delivery) •Treatment was targeted at challenging behaviour or post-concussion syndrome for interventions

•Only an army-veteran population was studied

•Third-wave versions of CBT (CFT, ACT, mindfulness) were utilised

•Mixed-group and individual CBT was provided within a larger cognitive-rehabilitation or neuropsychological-rehabilitation setting which targeted numerous outcomes.

•The work was an unpublished dissertation or conference abstracts

Once eligible studies were identified, the reference lists were manually searched for additional articles that met the review criteria. Articles which cited the selected studies were checked using the electronic database Web of Science (June, 2014); any hits were then evaluated according to the inclusion/exclusion criteria.

Finally, where the use of a treatment manual or protocol which could be made available to readers was mentioned in an intervention study, the authors were contacted and a copy of the treatment manual requested.

Data extraction and synthesis

A narrative-synthesis approach to a systematic review is recommended where there is considerable heterogeneity in the included studies in terms of methods, participants and interventions (Popay et al., 2006). This approach was therefore adopted in the present review, where heterogeneity existed in type and cause of brain injury, types of adaptation, and study design (RCT or single case).

One rater (M.G.) extracted data on recommendations for modifications to therapy from the review articles and intervention studies. The stages of the narrative-synthesis approach consisted of: 1) developing a preliminary synthesis 2) exploring relationships between articles, and 3) assessing the robustness of the synthesis. This approach followed guidelines for each stage outlined by Mays, Pope and Popay (2005) and Popay et al. (2006), and consulted the study structure used within a high-quality narrative synthesis (Leamy, Bird, Le Boutillier, Williams & Slade, 2011). This process was modified in order to fit the two-element data collection (*recommended modifications* from review articles and *reported modifications* from intervention studies) within the present study.

Stage 1: Developing a preliminary synthesis

a) Creation of a data-extraction framework (from review articles)

Recommended therapy modifications were extracted from each review article. Themes in recommendations were searched for and defined using step-by-step guidance on thematic analysis (Braun &Clarke, 2006). Steps included 'familiarising self with data,' 'generating initial codes,' 'searching for themes' and 'refining themes'; these steps were fitted to the present study focus of extracting recommended therapy modifications. Following the familiarisation stage, each recommendation from each article was coded. For example, one recommended modification was to provide 'psychoeducation to raise patient (and family) awareness of stroke-related cognitive damage' (Broomfield et al., 2011, p. 211). Another indicated that 'clear information about the physical, emotional, and behavioural consequences of the individual's brain injury and mood disturbances is a vital component of therapy and should be provided for both the patient and carers' (Khan-Bourne & Brown, 2003, p.103). These both produced similar codes of 'stroke-related psychoeducation,' 'involvement of family in psychoeducation' and 'provision of brain-injury related education.' Alongside other recommendations from other articles, the collation of codes led to the overall recommendation 'theme' to 'provide clear information/education on effects of brain injury in order to raise awareness and normalise common reactions.'

Once themes within adaptations had been identified, vote counting was used to identify the frequency with which recommended modification themes appeared across all articles. If one recommendation-related theme was present in at least *two* articles, it was added to a data-extraction framework (the Modification-Extraction List). All adaptations within this framework were then grouped by the researcher, using categories informed by 'domains' of cognitive functioning as a preliminary guideline (Lezak, Howieson, Bigler & Tranel, 2012). This framework therefore provided an overview of recommended adaptations to therapy found in review articles.

b) Preliminary synthesis of intervention studies

A preliminary synthesis of the intervention studies (RCTs and single-case studies) was conducted through tabulation of data, including: study design, sample characteristics, number and duration of treatment sessions, treatment description, and main outcomes.

Stage 2. Exploring relationships between recommended adaptations and reported adaptations

The relationship between those recommended modifications (within the Modification-Extraction List) and reported modifications within intervention studies were explored in a three-step process.

Firstly, the treatment-description within each intervention study was examined, and adaptations were extracted. Secondly, these adaptations were matched to the Modification-Extraction List; those adaptations which matched were summed *within* intervention articles to provide the total number of adaptations per article, and summed *across* articles to show which adaptations were most frequently reported in intervention studies. Finally, the remaining modifications which were reported within intervention studies but not within the Modification-Extraction List were collated. Then, thematic analysis of the type described above was utilised to synthesise final modification-related themes.

The overall quality of the *reporting of therapeutic interventions* was then assessed, and a subgroup comparison made between the two study designs: single-case studies or series and RCTs. This quality assessment was made using an adapted version of the 'treatment' section of the CONSORT checklist extension for non-pharmacologic treatments (Boutron et al., 2008). The adapted scoring scale was as follows:

- Precise details of the experimental treatment were offered (score of 0, 1, or 2)
- •Description of the different components of the intervention was included (0 or 1)
- •Description of the procedure for tailoring the intervention to individual participants was present (0 or 1)
- Details of how the intervention was, or could be standardised were specified (0 or 1)
 Details of how adherence to the protocol was assessed or enhanced were included
 (0 or 1)

To assess the reliability of the quality rating and use of the Modification-Extraction List, a second reviewer rated a subset of the treatment-trial articles (n=4). Initial overall agreement was 85% for quality rating and 86.8% for the Modification-Extraction List. Disagreements were resolved by discussion.

Stage 3. Assessing the robustness of the synthesis

The robustness of the synthesis was judged through reflecting critically on the synthesis process (as recommended by Popay et al., 2006) and through using the reliability ratings described above.

RESULTS

The flow diagram for the included research and review articles is shown in Figure 1. The search retrieved 755 records, 67 of which were duplicates. The titles and/or abstracts of all remaining 688 studies were reviewed against inclusion/exclusion criteria, and 639 were deemed unsuitable. A total of 23 potentially eligible review articles and 26 intervention studies were identified, of which eight review articles and 12 intervention studies met all inclusion criteria. Following this, four further intervention studies were identified through checking the reference sections of identified articles and through checking studies which had cited the identified articles, providing a total of eight review articles and 16 intervention study articles for review.

Stage 1a) Creation of a data-extraction framework (from review articles)

A summary of the included review articles can be found in Table 1. The Modification-Extraction List created from analysis of these articles is displayed in Table 2. This included 18 items, with most adaptations being recommended by two articles (seven adaptations) or three articles (six adaptations). The adaptation recommended by the highest number of articles was that therapists should provide clear information on the effects of brain injury in order to raise awareness and normalise common reactions (recommended by six articles). Further details on which specific articles recommended each adaptation are displayed in Appendix 1.3.

Stage 1b) Preliminary synthesis of intervention studies

The tabular synthesis of intervention studies can be found in Table 3.

Study	Reason for therapeutic modification	Psychological disorder	Main type of therapy
Block & West (2013)	Traumatic brain injury	-	'psychotherapeutic treatment' including CBT, behaviour therapy, CRATER therapy (a milieu/holistic-based treatment which combines cognitive retraining with psychotherapy), narrative therapy
Rossiter & Holmes (2013)	'Cognitive impairment' (including brain injury as a cause), learning disabilities and/or neurodevelopmental disorders	-	СВТ
Tsaousides et al. (2013)	Traumatic brain injury	Depression	CBT, behavioural interventions, mindfulness training, group coping skills, physical activity
Soo, Tate & Lane-Brown (2011)	Brain injury	Anxiety	АСТ
Broomfield et al. (2011)	Stroke	Depression	CBT
Kangas & McDonald (2011)	Brain injury	'Psychological problems'	ACT, CBT
Khan-Bourne & Brown (2003)	Brain injury	Depression	СВТ
Kinney (2001)	Brain injury	-	Cognitive therapy, rational emotive behaviour therapy

Table 1. Review articles used to develop the Modification-Extraction List

Stage 2. Exploring relationships between recommended adaptations and reported adaptations

Studies noted a variety of adaptations; these were initially mapped onto the Modification-Extraction List to determine which *recommended* adaptations were most commonly reported by intervention studies. The number of intervention studies which reported each adaptation within the Modification-Extraction List is shown in Table 2; these adaptations are also explored further in the section below.



Figure 1. Flowchart of study selection

Table 2. Modification-Extraction List, with number of intervention studies which recorded each modification to therapy

	Recommended Modification	Included in N of intervention studies (/16)
Therapeutic education and formulation	Include strengths and weaknesses, based on cognitive assessment, within formulation	3
specific to brain injury	Educate client on CBT model and treatment, ensuring that links between cognitions and affect are understood	8
	Provide clear information/education on effects of brain injury in order to raise awareness and normalise common reactions	3
Attention,	Provide breaks for rest during therapy sessions	2
concentration and alertness	Shorten length of sessions (Time not specified, but assume <50 minutes)	1
	Increase frequency of sessions (More than once per week)	2
Communication	Use clear, structured questioning, and limit the use of lengthy, open- ended, or multiple questions	0
	Incorporate visual resources into the session to enhance comprehension and draw attention to important points	4
	Place emphasis on behavioural techniques (such as behavioural activation)	2
Memory	The client should have a therapy notebook or folder, review this during the session, and place important points from sessions and homework in this	6
	Use memory aids such as written notes or audiotapes during the session – these can be reviewed between sessions	8
	Summarise and repeat salient points at frequent intervals during the session (to refocus and help memory and learning)	7
	Involve a family member/close friend/carer in formulation, therapy and homework tasks to enhance generalisation	2
Executive functioning	Present information more slowly during session and allow extra time for response (due to slowed processing speed)	4
	Use summarising or an agreed-upon signal to alert the client if/when they have become tangential	1
	Focus on concrete examples and aid clients to generate alternative solutions (due to difficulty in flexible thinking)	5
	Therapist to take a directive and structured approach if necessary due to executive functioning/attentional deficits	2
	Model homework completion- 'say it, show it, do it' - and encourage completion of homework across a variety of situations to enhance generalisation	7

Recorded adaptations within intervention studies (from most to least frequently reported)

One of the most frequently recorded adaptations (eight out of 16 studies) was that the client was *educated on the CBT model*. This is a normal component of CBT training, and is perhaps why it was so frequently reported. Yet this adaptation specifically relates to ensuring an

understanding of the links between cognition and affect, as this understanding may be disrupted following brain injury. The use of *memory aids* such as written notes or audiotapes during the session was also recorded by eight studies. This typically took the form of writing down formulations and homework tasks (Gracey, Oldham & Kritzinger, 2007; Kneebone & Hull, 2009, Tiersky et al., 2005), writing down coping thoughts on cue cards (Hsieh et al., 2012a, 2012b), and tape-recording of sessions and relaxation exercises (D'Antonio, Tsaousides, Spielman & Gordon, 2013; Hodgson et al., 2005; Kneebone & Jeffries, 2013).

Following this, in seven studies, *summarising and repeating* information and *modelling homework completion and generalising homework* were noted as adaptations. This included practising homework in sessions, such as beginning exposure work in session (Hodgson et al., 2005; Hsieh at al., 2012a; Kneebone & Jeffries, 2013), monitoring success of homework activities during the week through recording effect of daily relaxation (Hsieh et al., 2012a, 2012b), providing written instructions to enhance homework compliance (Kneebone & Hull, 2009), and applying newly learned techniques to daily activities in the home (Tiersky et al., 2005).

After this, six studies recommended that clients should have a *therapy notebook or folder*, which can be reviewed in session. Five articles indicated that therapists utilised *concrete examples and helped clients to generate alternative solutions*, sometimes through providing alternative thoughts during cognitive restructuring (e.g. Hsieh et al., 2012a, 2012b, 2012c), and incorporating role play (Hsieh et al., 2012a, 2012b, 2012c; Hodgson et al., 2005).

Within four studies, the *slower presentation* of materials to accommodate slowed informationprocessing was noted as a useful adaptation; incorporation of *visual resources* was also reported within four studies with the purpose of using these resources in order to enhance comprehension. These included the use of diagrams and cartoons to describe the development and maintenance of anxiety (e.g. Hsieh et al., 2012c).

Within three articles, it was highlighted that the formulation of participants' strengths and weaknesses were *based on cognitive assessment* through, for example, noting weaknesses in working memory following cognitive assessment, and adapting the formulation and treatment plan accordingly. Furthermore, clear information on the *effects* of brain injury were reported to have been provided in three studies.

Two articles reported the adaptation to provide *breaks for rest* during sessions. Furthermore, two studies explicitly indicated that the therapist was to take a *directive and structured approach*, and also that sessions were provided in *increased frequency* of more than one per week. It may be worth noting that seven articles reported weekly sessions. The *involvement of*

a family member or friend was reported in two studies, to aid with exposure work (McMillan, 1991) and to facilitate learning (Hsieh et al., 2012c). Two studies also placed emphasis on *behavioural techniques*. This 'emphasis' was difficult to judge clearly; all studies included some behavioural techniques, but only two specifically reported that behavioural techniques were most prominent.

Only one study described *shortened length* of sessions, and use of a *hand signal* to alert a client when they had become tangential. It is worth noting that one study also utilised lengthened, rather than shortened, sessions (90 minutes), within the initial stage of treatment (Hofer et al., 2013). No studies specifically noted that the therapist used *clear, structured questioning*, and that the use of lengthy, multiple, or open-ended questions was limited. A copy of the adaptation checklist with specific intervention studies which recorded each adaptation can also be found in Appendix 1.4.

'Extra' additions to CBT

Reviewing the intervention studies identified some modifications not mentioned in the existing reviews and therefore not included on the Modification-Extraction List. The following were noted in intervention studies as additions to CBT.

Hsieh et al. (2012b, 2012c) added three sessions of *motivational interviewing* (MI) to CBT for anxiety in a sample of individuals affected by TBI, finding that CBT was superior to treatment as usual, and that CBT plus MI was more effective still for reducing anxiety. Motivational interviewing was also suggested as a possible intervention within one of the review articles (Broomfield et al., 2011), but was the only review article to note this, therefore this addition was not included in the Modification-Extraction List.

Tiersky et al. (2005) completed an equal number of CBT and *cognitive remediation sessions* (focused on attention, information-processing and memory), and Hofer et al. (2013) also described a short period of *executive skills training*, which aimed to address deficits in cognitive functioning in order to enhance engagement within CBT.

Further themes in adaptations across studies reported in intervention studies

Several studies noted the use of *adapted diary forms*, for example, diary forms which provided examples of common physical sensations associated with anxiety in order to reduce reliance on free recall (Hodgson et al., 2005; Hsieh et al., 2012a, 2012c; Kneebone & Hull; Lincoln, Flannaghan, Sutcliffe & Rother, 1997). Adaptations to change the emphasis of common components of CBT were also made. For example, some studies highlighted the importance of using *personalised metaphors* and discussed clients' personal role models, indicating that this

may help to reduce load on memory, particularly if someone has difficulty learning new verbal information (Hsieh et al., 2012a, 2012c). Frequent, mid-week *prompting to complete homework* through telephone calls was also noted as a modification (Hodgson et al., 2005; Rasquin, Van De Sande, Praamstra & Van Heugten, 2009; Tiersky et al., 2005). Clients were often *guided* to choose specific, measurable and realistic goals, in order to accommodate executive dysfunction, which may affect planning, abstract thinking and idea-generation (Hsieh et al., 2012a, 2012c). Finally, several studies noted the nature of *complex formulations* within this population, suggesting that a biopsychosocial model would be appropriate, due to the reported overlap between psychological symptoms and brain-injury symptoms in OCD (Hofer et al., 2013), PTSD (King, 2002; Kneebone & Hull, 2009; McMillan, 1991; McNeill & Greenwood, 1996) and seizure-related panic after stroke (Gracey et al., 2007).

Quality of treatment reporting

An analysis of the quality of the *reporting* of treatment showed that all articles provided a description of the general components of CBT covered in their interventions. Yet considerable variability was found between studies on all other levels of the quality-measurement scale (n=16 studies, median quality rating=4, range=1-5, maximum score of 6 on quality-rating scale). Single-case studies showed a higher median quality rating (rating=4; n=11 studies) than RCTS (rating=3; n=5 studies). A closer examination of the results showed that single-case studies provided a more precise description of treatment and more fully described the tailoring of interventions to each individual, although RCTs more commonly reported how interventions were standardised. Therefore, although RCTs are considered to provide a higher level of evidence when judging research outcomes (e.g. levels of evidence within SIGN guidelines, 2013), single-case studies have been able to provide a greater overall quality of treatment description within the present area. Only two out of the 16 studies measured adherence to treatment. Overall quality of treatment-reporting ratings for each study can be found in Table 3, and further details are available in Appendix 1.2.

Stage 3: Assessing the robustness of the synthesis

An attempt was made to contact authors who indicated that a treatment manual was available, in order to determine whether adaptations collected from studies reflected the true state of adaptations within intervention studies. Five authors were contacted and none provided the manual (two authors did not reply, one manual was not available in English, one manual was currently being used in another research trial, and one author was unable to locate the manual). This process might have helped to determine whether all modification-related themes had emerged, and thus reached saturation, or whether further adaptations might have been present within manuals. Reaching saturation is recommended within narrative synthesis guidance (Mays et al., 2005). Other points regarding the strengths and limitations of the Modification-Extraction List and overall synthesis are addressed in the discussion section.

Reference Diagnosis Type of brain injury	Design	Sample	Length of therapy	Treatment description	Main outcomes	No. of Adapt- ations from marking tool	Adapt- ed CONS- ORT quality rating
D'Antonio et al. (2013) Depression TBI	RCT	CBT group (N=22), supportive psychotherapy group (SPT) (N=22). Average age: 48.8 years, 26 female, all participants were at least 12 months post- TBI.	16 sessions over 3 months (initial session 90 minutes, all other sessions 50 minutes), twice-weekly sessions for first month, weekly sessions for second and third months; follow-up at 6 months post- treatment.	Manualised treatment protocol for SPT or CBT. CBT: cognitive restructuring, increasing social outreach and relaxation. SPT: provided empathetic environment to discuss issues related to depression, education about depressive symptoms, and promoting the individual's ability to talk about their experience, without introducing specific elements of CBT.	Participants in both groups were significantly less depressed at the end of treatment. No significant differences between groups at baseline or at the end of treatment.	3	3

	1		1				
Hofer et al. (2013) OCD TBI	Single case	27 year old male, severe TBI, 3 years post-injury.	Diagnostic phase: approximately nine sessions over 2 months. Preparation phase: time not specified. Intervention phase: approximately 13 sessions over 4 months.	Pharmacological treatment (paroxetine). Prolonged exposure to distressing situations, objects or thoughts, with simultaneous prevention of compulsive acts; cognitive restructuring; relapse prevention.	Y-BOCS from 'extreme' to 'moderate' clinical level. Diagnosis of OCD remained on SCID. Positive changes in social life noted.	3	4
Kneebone & Jeffries (2013) <i>Anxiety</i> <i>Stroke</i>	Single case (2)	<i>Client 1:</i> 62 year old male, seven months after stroke. <i>Client 2:</i> 80 year old female, one year after stroke.	<i>Client 1:</i> Seven sessions of 45 to 60-minute duration over 3-4 months. <i>Client 2:</i> Nine sessions 50-60 minutes in duration over 5-6 months	<i>Client 1:</i> Psychoeducation, relaxation training, cognitive disputation and cognitive rehabilitation. <i>Client 2:</i> Psychoeducation, relaxation training, hierarchy work, cognitive disputation.	<i>Client 1</i> : HADS-A from 'moderate' pre-treatment to 'normal' at end of treatment and follow-up. Time at work and use of telephone had increased. <i>Client 2:</i> GAI from 'clinical' level pre-treatment to subclinical at end of intervention follow-up (3 months). Engagement with previously enjoyed activities and solo travel were noted.	9	4

Hsieh et al. (2012a) Anxiety TBI	Single case (2)	<i>Client 1</i> : male, late 40s, severe TBI, cause of injury was a fall, 14 months post-TBI. <i>Client 2</i> : female, early 30s, severe TBI caused by motor accident, 3 years 5 months post-TBI.	Nine sessions of CBT (60 minutes each) which 'generally took place weekly.'	Treatment based on a CBT manual developed for the study including: two sessions psychoeducation regarding anxiety, relaxation and slow breathing; six sessions on cognitive therapy (identifying, labelling, modifying unhelpful thoughts) and exposure exercises; one session of relapse prevention and ways of getting support from others.	<i>Client 1</i> : HADS-A reduced by five points and moved from clinical to normal range by end of CBT. <i>Client 2:</i> HADS-A reduced from severe to moderate, this was maintained at follow-up.	9	5
Hsieh et al. (2012b) Anxiety TBI	Pilot RCT	Moderate or severe TBI, diagnosed with at least one anxiety disorder (DSM-IV-TR). CBT+MI group N=9 CBT+NDC group N=10 TAU group N=8	Three motivational interviewing (MI) or non-directive counselling (NDC) sessions, nine CBT sessions. Weekly for approx. 50 minutes.	Both interventions were manualised. <i>Treatment included:</i> assessment/feedback; anxiety management; cognitive therapy/thinking strategies; graded exposure; relapse prevention. <i>Optional</i> <i>elements:</i> lifestyle	CBT+NDC and CBT+MI group showed significant reduction on HADS-A as compared to TAU, MI+CBT group showed greater reduction on HADS-A than NDC+CBT. Attrition: Completion rate of 96.3% on primary outcome measured.	7	5

						1	
		Mean age=38, mean time since HI=37.9 months, mean PTA=23.1.		balance/behavioural activation; structured problem -solving, self- soothing strategies.			
Hsieh et al. (2012c) Anxiety TBI	Single case	Male, early 40s, severe TBI resulting from RTA, 4 months post TBI.	Three-weekly MI sessions of 50-60 minutes. Nine weekly sessions CBT, lasting 50-60 minutes.	<i>MI:</i> discussing and setting realistic goals. <i>CBT:</i> psychoeducation, anxiety management, cognitive therapy, graded exposure and relapse prevention.	HADS-A reduced from moderate to mild by the end of MI sessions, and further reduced to normal by end of CBT.	5	5
Kneebone & Hull (2009) PTSD Hydrocephalus	Single case	Male, 23 years old, 5 months post-surgery. Cognitive assessment indicated changes in judgment, abstract reasoning, and ability to problem-solve; did not meet full criteria for PSTD according to DSM- IV.	20 sessions, from 45 minutes to 75 minutes in length, duration unknown.	Trauma-focused CBT including exposure, cognitive disputation and relaxation training.	Decrease in anxiety on HADS-A and IES from clinical to subclinical levels; maintained at follow-up at 1, 3 and 6 months.	3	4
Rasquin et al. (2009) Depression Stroke	Single case (5)	Four female, one male, mean age=46.2 years (range 39-54)	Eight weekly sessions of 60 minutes. Client contacted twice- weekly by an assistant psychologist to offer	Mood recording introduced and practised (1-3 sessions), relaxation exercises (3 sessions), cognitive restructuring (3 sessions), planning	Three clients showed clinically significant improvement on BDI (to below clinical cut-off). Attrition: Seven participants began the study, two dropped out	4	4

			help performing homework.	of useful and enjoyable activities (1 session), evaluating treatment (1 session).	(one during baseline for cardiac surgery, one due to psychologist's opinion that lack of insight would mean therapy would not be beneficial).		
Gracey, Oldham and Kritzinger (2007) Anxiety (seizure related panic) Stroke	Single case	Male, 43 years old, 20 months after haemorrhage.	10 weekly sessions and two follow-up sessions (at 3 and 6 months).	Collaborative formulation, cognitive restructuring, behavioural experiments, relapse prevention.	Increased engagement with social activities (other than when affected by fatigue), reduction in HADS-A from mild range to non-clinical range.	6	4
Hodgson et al. (2005) Social anxiety Brain Injury	RCT	12 participants in total, split into matched pairs, seven males, five females. CBT group N=6, mean age=44.2 years, mean time since injury=96.7 months. Waitlist control group N=6, mean age=33.8	Weekly individual CBT sessions for 9-14 weeks, lasting 60 minutes.	Relaxation, cognitive strategies, graded exposure and assertiveness-skills training.	General improvement in social anxiety across the groups at follow-up compared to post- treatment. Trend of reduction in social anxiety in treatment group, as compared with waitlist, but this was not significant. General anxiety and depression reduced significantly in	9	2

		years, mean time since injury=150.5 months. Cause of brain injury: nine closed-head injury, one stroke, one hypoxic brain injury, one cerebral oedema.			treatment group but not in waiting list group. Attrition: Two participants from an original 16 dropped out, and the data from their matched pairs was also excluded.		
Tiersky et al. (2005) Depression and anxiety TBI	RCT	Treatment group N=11, waitlist control group N=9, mild and moderate TBI. Mean age= 46.48 years; 11 females, 18 mild TBI, 2 moderate TBI. Cause: RTA (N=14), falling object (N=3), fall (N=2), sports related (N=1). Mean time since injury=6.25 years.	50 minutes of CBT and 50 minutes cognitive remediation (individual) three times per week for 11 weeks <i>Control group</i> : Met 2-3 times over 11 weeks for 45 minutes to discuss nonspecific topics. Follow-up at 1 and 3 months.	Treatment: CBT and cognitive remediation using a clearly defined protocol from a structured manual. CBT contained: <i>Phase 1</i> : engagement. <i>Phase 2</i> : active treatment (thought- record work, behavioural experiments, cognitive rehearsal). <i>Phase 3</i> : prevention of relapse, planning for discharge.	Lower depression and anxiety noted on the SCL- 90R, which was a significant difference in treatment group, although mean score still met 'caseness' for depression after intervention, mean anxiety score reduced to within normal range; no change in waitlist control. Attrition: From original 21 participants, one in treatment group dropped out due to a medical emergency.	5	5

Lincoln & Flannaghan (2003) Depression Stroke	RCT	CBT group (N=39), mean age= 67.1. Attention placebo (N=43), mean age= 66.1 years. Standard care (N=41), mean age= 65.0 60 female, 63 male. Some participants recruited 1-3 months after stroke, some more than 3 months after stroke, although these numbers are not specified.	Attention placebo and CBT groups: 10 visits of 60-minute duration for 3 months.	Attention placebo: conversation focusing on day-to-day occurrences and life changes. <i>CBT:</i> manualised from Lincoln (1997) pilot study, included: education, graded task assignment, activity scheduling and identification, and modification of unhelpful thoughts and beliefs.	No significant differences between the groups in patients' mood, independence in activities of daily living, handicap, or satisfaction with care. There was a significant improvement in mood over time but this was independent of group. Attrition: Before assessment at 3 months: two died, three refused. Before assessment at 6 months: three died and four refused.	0	2
King (2002) PTSD Severe TBI with dysexecutive impairment	Single case	Male, 47 years old, TBI as a result of fall and being hit by a boat propeller, PTA suggestive of moderate TBI, 24 months post TBI.	 Phase 1: Seven sessions over 11 months. Period of acute distress: three more sessions, then 10-day admission to hospital. Phase 2: eight sessions over 16 months. 	Information about PTSD and head injury, anxiety-management training, systematic desensitisation, and exposure to talking about the accident.	 Phase 1: improvements in social functioning. After hospital admission: acute and prolonged reexperiencing of event, suicidal ideation. Phase 2: less socially anxious, habituated to 	1	4

					trauma, small but not clinically significant reduction on the IES.		
Lincoln et al. (1997) Depression Stroke	Single case series (19)	19 participants, mean age 67.1 years. Experienced stroke mean of 43 weeks prior to the study (range=8- 109 weeks).	Maximum of 10 sessions in 3 months (mean= 8.4 sessions).	"Variety of cognitive and behavioural techniques", including distraction activities, behavioural tests, graded task assignments, activity scheduling, and identifying/challengin g negative thought patterns.	Four patients consistently showed beneficial treatment effects on BDI, six showed some benefit and nine showed no benefit. For the group as a whole there was a significant decrease in depression on BDI, but no significant change in functional abilities. Attrition: three participants discontinued after three sessions, stating therapy was not helpful.	0	1
McNeill & Greenwood (1996) <i>PTSD</i> <i>TBI</i>	Single case	Male, 28 years old, severe TBI as result of RTA 6 months post- injury.	Seven weeks of treatment, number and length of sessions uncertain.	Phase 1: Traditional anxiety management and graded exposure to avoided stimuli.Phase 2: Devise an accurate account of what had happened.Phase 3: Education about the nature of	Score on IES-R reduced and nightmares stopped completely.		3

				TBI, specifically retrograde amnesia and post-traumatic amnesia.			
McMillan (1991) PTSD TBI	Single case	Female, 19 years old, severe head injury as a result of RTA, 14 months post injury.	4 months of treatment, number or length of sessions uncertain.	Cognitive-behavioural exposure techniques, use of social support.	Score on BDI fell to below clinical level, able to engage in social activities which were previously avoided, maintained at 4 month follow-up.	1	3

Key to abbreviations in Table 3.

Treatment/Diagnosis related abbreviations: MI=motivational interviewing; TAU=treatment as usual; TBI= traumatic brain injury; PTA=post traumatic amnesia; RTA=road traffic accident. **Abbreviations of outcome measures**: BDI=Beck Depression Inventory; DSM-IV-TR: Diagnostic and Statistical Manual of Mental Disorders-Fourth Edition (Text Revision);GAI=Geriatric Anxiety Index; HADS-A= Hospital Anxiety and Depression Scale- Anxiety subscale; IES=Impact of Events Scale; IES-R=Impact of Events Scale-Revised; SCLR-90= Symptoms Checklist 90-Revised; Y-BOCS: Yale-Brown Obsessive Compulsive Scale SCID: Structured Clinical Interview for DSM-IV.

DISCUSSION

Findings

This is the first systematic review and narrative synthesis of adaptations made to CBT for postbrain-injury depression and anxiety. An adaptation checklist (Modification-Extraction List) was developed from recommendations within review articles using thematic analysis and votecounting; this identified 18 recommended modifications to therapy. These were organised into five categories: therapeutic education and formulation specific to brain injury; attention, concentration and alertness; communication; memory; and executive functioning. Existing intervention studies examining CBT for depression and anxiety were analysed according to this checklist, and further adaptations were documented. This review highlights overlaps between adaptations to psychological treatments recommended in brain-injury review studies and those reported within intervention studies. Yet, it is also apparent that some modifications reported in intervention studies are not clearly identified in existing review articles.

Analysis of the *quality* of treatment description within intervention studies showed that the level of detail varied widely between studies, and that the description of treatment was of a higher quality within single-case trials when compared to RCTs. This highlights the potential of single-case experimental designs (SCEDs) to provide useful information on the development of complex interventions which are adapted to suit this population, fitting in with recent guidance on the use of SCEDs within this population (e.g. Evans, Gast, Perdices & Manolov, 2014).

Many of the recommended modifications collated from review articles relate to providing support for the specific changes in functioning after brain injury (e.g. following memory deficits), and many of the *additional* adaptations noted in intervention studies appear to relate to shifts in the intention or emphasis placed on components of routine CBT. For example, goal-focused work is a typical component of CBT, but within brain-injury intervention studies, therapists were encouraged to provide more guidance on realistic goals, due to clients' lack of insight into problems and difficulties with idea generation.

The *emphasis* placed on adapting therapy within intervention studies may explain the differences in frequency of reported adaptations. Specifically, some studies reported adapting therapy as a primary aim, whereas others had a different aim, for example, to determine whether PTSD can occur with amnesia for the traumatic event. Furthermore, due to the mixed quality of reporting of treatment protocols, it is possible that all adaptations have not been reported. If this is the case, subsequent researchers and clinicians will find it difficult to arrive at a reasonably similar therapeutic outcome when they apply the same techniques with their

patients. Although no data is available on the effect of specific adaptations, it is important to note that it seems that the suitability of adaptations for each individual client, rather than the *number* of adaptations, would be more likely to be effective. Finally, some adaptations may also appear to be competing, such as shortening session length to account for changes in attention, and lengthening interaction to provide support for slowed processing speed.

Implications for research and practice

The present review presents an initial framework with which to understand modifications made to CBT following brain injury, in order to support cognitive deficits. The results of this systematic approach could provide a useful tool for clinicians in the field and may allow adaptations to be more easily identified and reported in future intervention studies, providing a structured approach around which future brain-injury research could be oriented. Furthermore, there is a recognition that adapting CBT is a core skill necessary for working with individuals affected by the cognitive impairments that are associated with a wide range of presentations (such as learning disabilities, pervasive developmental disorders, severe trauma, depression and psychosis)(Rossiter & Holmes, 2013). Thus, the present article may also provide a basis for clinicians working in a wide variety of fields, in order to address health inequalities by improving the accessibility of CBT (Rossiter & Holmes, 2013).

It is important to note that the present synthesis does not provide a definitive 'checklist' of items which *should* be applied, but rather outlines modifications which *can* be applied, in order to suit the specific needs of each individual client; it is not yet possible to know what the 'key' adaptations are.

Limitations

Although the Modification-Extraction List was created from a systematic examination of literature, it is recognised that this is not an exhaustive list of all adaptations to account for cognitive changes following brain injury. Furthermore, the method of collating all themes for modification, although conducted in as transparent and systematic a way as possible, was based on the work of one individual and could therefore have resulted in a different format if more researchers were to have created the tool. Structure was brought by grouping the adaptations into categories, but a replication study may not provide the same themes. Finally, the recommended adaptations were based on review articles alone; other sources of information such as books and book chapters may have suggested further therapy adaptations.

Popay et al. (2006) have recommended methods to assess the robustness of a narrative synthesis, which includes completing only a 'best-evidence synthesis' from those studies with

the highest methodological quality. This advice was not followed because the aim of the present review was to gain a view of the 'overall' state of research in this relatively small area. Popay et al. (2006) also recommend checking the synthesis with authors of primary studies, yet this recommendation was not conducted due to time restrictions. A critical analysis of the methodology of intervention studies was therefore not an aim of the present review, and other review articles have offered insight into the strengths and limitations of the research in this field (e.g. see Cattelani, Zettin & Zoccolotti, 2010; McMillan, 2013; Waldron, Casserly & O'Sullivan, 2012).

Recommendations for future research

The present review highlights that there are variations in the use and reporting of adaptations between studies. In order to determine whether 'modified' vs 'unmodified' CBT is more effective within the present population, a trial could be conducted which compares the two forms of treatment. Researchers could use and refine the current Modification-Extraction List in order to describe adaptations made to therapy, with the aim of accurately reporting existing and new modifications.

It is also recognised that the present review mainly focused on adaptations to support cognitive changes following brain injury. Future research could examine the effects of *content*-based adaptations, such as the addition of grief work, in order to determine whether this provides enhanced outcomes. Future research on third-wave therapies, such as Acceptance and Commitment Therapy following traumatic brain injury (Whiting, Simpson, McLeod, Deane & Ciarrochi, 2012), will also provide further information on content adaptations as opposed to 'pure' CBT, and should therefore be examined for modifications.

The present review also discussed individual CBT treatment, and was therefore unable to evaluate other adaptations which could be brought into therapeutic work, such as the use of technology within therapy (e.g. the use of the Sensecam; Brindley, Bateman & Gracey, 2011), neurobehavioural approaches (e.g. Arco, 2008) or therapy within a large neurorehabilitation programme (Williams, Evans & Fleminger, 2003; Williams, Evans & Wilson, 2003). As holistic programmes for treatment have been recommended (McMillan, 2013; SIGN guidelines, 2013), such studies are likely to provide insight into further adaptations which could fit within a wider model than individual therapy.

Conclusions

In relation to therapy following brain injury, the adaptations that were *recommended* in review articles were also *reported* in intervention studies focusing on anxiety and depression. Yet, intervention studies also provide additional information on adaptations to the emphasis placed

on routine CBT components. The adaptation checklist developed within the present review could be used to guide future research in this area, as it will be necessary for future studies to report therapeutic adaptations within their protocols, in order for the most useful adaptations for subgroups of clients to be identified.

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Preparing individuals with severe head injury for a brief compassionate imagery exercise

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Prepared in accordance with submission requirements for Neuropsychological Rehabilitation (*See Appendix 1.1*)

PLAIN ENGLISH SUMMARY

Aims of study Initial research with people who have experienced a severe head injury suggests that an 'imagery exercise' (i.e. visualising images in the mind's eye) which focuses on imagining compassionate or relaxing feelings can produce some positive effects, such as feeling more compassionate towards oneself (O'Neill & McMillan, 2012). As the effects of head injury can make people feel more 'cut-off' from others – but compassion is thought to help people to connect with those around them – it is important to determine whether imagery exercises can be improved. O'Neill & McMillan (2012) suggested that low motivation for therapy and high fears of feeling compassion might have interfered with participants' ability to take part in the imagery exercise. The present study therefore aimed to determine whether preparing people for an imagery exercise could enhance the effect of the exercise.

Procedure Twenty-four participants who had experienced a head injury watched a brief 20minute 'preparatory video' and took part in a short discussion about imagery tasks. The video explained reasons for taking part in an imagery task, highlighted common difficulties when practising imagery (e.g. having a 'wandering mind'), and provided tips on how to overcome these challenges. Participants completed questionnaires relating to their mood, motivation for taking part in an imagery task, and fears of feeling compassion before and after viewing the video. All participants then entered a follow-on treatment study where they took part in an imagery intervention which was either focused on feeling compassion or relaxation.

Results After viewing the video, participants reported being more motivated to take part in an imagery task, but did not experience any change in anxiety, negative feelings or fears of feeling compassion. The group as a whole reported high fears of feeling compassion. When participants then took part in an imagery task, they reported feeling more relaxed after this, but did not report changes in empathy or their feelings of compassion towards themselves.

Conclusions These findings suggest that preparing people who have experienced a head injury for therapy using a short video can be beneficial for increasing motivation and helping people engage in therapy. It seems that high fears of feeling compassion may interfere with a compassion-focused imagery task, therefore future work should determine how to reduce fears of feeling compassion.

ABSTRACT

Objective Head injury can result in problems with the ability to empathise and connect with others emotionally. Compassion-focused techniques have been used within a general adult population to develop soothing and affiliative emotions. A recent trial found a trend for increased self-compassion following a compassion-focused and relaxation-based imagery intervention within a severe head injury (SHI) sample (O'Neill & McMillan, 2012). The present pilot study aimed to determine whether providing a short preparatory task could enhance effectiveness of a compassion-focused imagery intervention within a SHI sample.

Methods The study employed a repeated measures design. All participants (n=24) completed a preparatory task, which involved viewing a 20-minute preparatory video and a short discussion of examples of imagery. Fears of compassion, motivation for an imagery intervention, state anxiety and negative affect were measured pre- and post- preparatory tasks. All participants then entered a follow-on treatment study, where they were randomised to a compassionate-imagery intervention or a relaxation-imagery intervention.

Results There was a significant increase in motivation for an imagery task following preparatory information, but no significant change on other outcome measures. Fears of compassion were high within the present sample, when compared to norms. Self-compassion and empathy scores following a compassionate-imagery task were not significantly different from those following a relaxation-imagery task.

Conclusions Preparatory tasks can enhance motivation to engage participants in therapy. Thereafter, it is likely that more work on fears of compassion or more prolonged exposure to imagery exercises may be required in order for a similar sample of individuals to benefit from compassion-focused imagery.

INTRODUCTION

Severe head injury (SHI) often has a significant impact on personality, resulting in disinhibition, heightened irritability, and impairments in executive functioning (Howitt, 2002). Metacognitive problems after head injury may affect the capacity for self-reflection, and the ability to conceptualise relationships between self and others. As a result, individuals affected by head injury might appear distant and unempathic to others (McMillan, 2013; O'Neill & McMillan, 2012; Wood & Williams, 2008). Such changes in *emotional processing* and *personality* can have a profound impact on an individual's life, and have been described by family members of those affected by SHI to be the most stressful effect of the injury (Brooks & McKinlay, 1983). Although research has commonly examined the effect of therapies such as cognitive behavioural therapy on 'challenging' behaviour, aggression, anxiety and depression (e.g. Cattelani, Zettin & Zoccolotti, 2010; McMillan, 2013), relatively little research has commented on the ability of therapy and rehabilitation to alter empathy, self-reflection and the conceptualisation of relationships between self and others. Gaining a greater understanding of effective therapy which might alter experiences of empathy and emotional connection is therefore a key target for research, and could have a beneficial impact on life after head injury for an individual and their family.

Transdiagnostic approach for improving emotional functioning

Compassion-focused therapy (CFT) was originally developed to target transdiagnostic concepts of shame and self-criticism, and places particular emphasis on altering *emotional experiences* (Gilbert & Procter, 2006). Gilbert's (2000, 2005, 2009) model of CFT is based on social, evolutionary and neurophysiological models of affect regulation. This model predicts that 'threat-focused' emotions (such as anxiety, anger and disgust) can be regulated through the development and expression of 'affiliative' soothing emotions (through kindness, caring, support, encouragement and validation). Over activation of the 'threat system' outlined in CFT may be relevant when considering common changes in emotion after head injury, such as heightened aggression and irritability (Ashworth, Gracey & Gilbert, 2011). Compassionfocused *imagery* (CFI) is a central practice in CFT, and is based upon research indicating that internal stimuli (for example, *imagining* ones favourite meal) can affect brain regions in a similar way to external stimuli (physically seeing and smelling this meal) (Gilbert, 2010). Crucially, there is accumulating evidence that compassion can be *trained* and, that through developing skills in CFI, problematic emotions and behavioural patterns can be altered.

O'Neill and McMillan (2012) recently compared the effectiveness of a short 30-minute compassionate-imagery exercise versus a 30-minute relaxation-imagery exercise in individuals

with SHI. This preliminary study showed that although there was no effect of the intervention on relaxation or empathy measures, an increase in self–compassion was found when the compassionate-imagery and relaxation-imagery groups were analysed together as a 'non-specific imagery' group. This result approached significance (T=8.00, p =.07, r = -.26), leading to the suggestion that improvements in the provision of the intervention and study design might produce significant effects of a short imagery intervention on self-compassion.

Possible barriers to using compassion-focused imagery (CFI) within a head injury population

The data provided by O'Neill and McMillan (2012) suggested that certain key areas could be targeted in order to make compassionate-imagery procedures more effective for a severe head injury population.

Firstly, they hypothesised that high *fears of compassion* may have disrupted engagement with compassionate-imagery. Gilbert (2009) suggests that asking participants to feel kindness and compassion for themselves or others can activate a threat response, particularly if thoughts of compassion trigger personal memories of feeling alone, abused, shamed or vulnerable within past relationships. This would then lead to 'protection' or disengagement with the compassion-focused task. Secondly, O'Neill and McMillan (2012) also recognised that *low motivation* for treatment may have been a barrier to treatment. Apathy, a disorder of diminished motivation, has been reported in 71% of individuals after head injury (Kant, Duffy & Pivovarnik, 1998), and involves a deficiency in behavioural, emotional and cognitive components of goal-directed behaviour (Lane-Brown & Tate, 2009). Such difficulties would therefore be likely to impact on beginning and maintaining engagement in therapy.

O'Neill and McMillan (2012) also remarked that the *language* used in their compassion-focused imagery intervention (for example, 'warmth,' 'acceptance, 'gentleness,' and 'soothing,') may have been unacceptable within the demographic group most commonly affected by severe head injury, namely, younger men from lower socio-economic backgrounds. Finally, they reported that adapting the therapeutic protocol in order to support *cognitive deficits* following brain injury, may improve engagement in an imagery exercise.

The role of preparation for therapy

Several studies have highlighted that providing psychoeducation prior to therapy is particularly necessary for those affected by head injury. One purpose of this would be to ensure understanding of links between cognition and affect prior to CBT (e.g. Broomfield et al., 2011; Kangas & McDonald, 2011). Many of the concepts of compassion-focused therapy and/or

imagery interventions are likely to be unfamiliar to clients, therefore psychoeducation could be a particularly necessary component which could also help to address some of the potential barriers to therapy outlined in the section above. Providing video-based information on psychological therapy within an adult-mental-health setting can reduce pre-therapy state anxiety, and provide patients with more accurate therapy expectations (e.g. Deane, Spicer & Leathem, 1992). Furthermore, Hsieh, Wong, Schönberger, McKay, and Haines (2012) reported utilising video-based information to prepare individuals affected by head injury for CBT targeted at anxiety. Although no information was available on the outcome of this preparation, the authors did indicate that the video format was designed to help participants overcome difficulties with idea generation, through providing information about the possibility and methods of overcoming anxiety (Hsieh et al., 2012). A video-based format would allow psychoeducational issues to be addressed in a way which is theoretically driven and uniform across participants within a piece of research. This could be used to provide education about CFI and could incorporate elements to support cognitive deficits after head injury, such as enhancing idea generation.

The present study

The present study is part of larger piece of research which aimed to replicate and extend O'Neill and McMillan's (2012) trial by determining whether treatment effects on self-compassion, empathy and relaxation could be enhanced by adding preparatory information modified for a head injury population and lengthening an imagery intervention from 30 minutes to 50 minutes. The main focus of the present research was to determine, in the form of a pilot study, whether short preparatory video-based information reduces potential barriers to engagement in compassion- focused imagery (fears of compassion, state anxiety and negative affect relating to therapy, and low motivation for therapy), and thereby augments the effects of a compassion-focused imagery exercise used in the larger study.

It was recognised that a short preparatory intervention would be unlikely to eliminate fears of compassion, due to the often gradual, sensitive nature of the work required to do this (Gilbert et al., 2011). The current study aimed to examine rates of fears of compassion noted within a SHI sample, and to determine whether a reduction in fear could be achieved after viewing short video-based preparatory information.

HYPOTHESES

• Exposure to preparatory information will be associated with pre-post reductions in fears of compassion (primary outcome measure), negative affect, anxiety and information–processing bias towards threat/compassion (secondary measures).

• Preparatory information will produce an increase in reported motivation to engage in the imagery interventions (primary outcome measure).

• The follow-on treatment study will find a greater effect of compassion-focused imagery on key outcome measures (self-compassion, empathy and relaxation) than those effects found by O'Neill and McMillan (2012).

METHODS

Design

The study used a repeated-measures design. All participants watched a preparatory video and completed pre- and post- video measures. The main dependent variables were measures of state anxiety, motivation for the therapeutic intervention, fears of compassion and negative affect. As all participants received the same preparatory information, only within-subjects differences were considered.

Sample Size Estimation

O'Neill and McMillan (2012) perceived a trend-level increase in self-compassion following an imagery intervention studied within a severe head injury sample (n=24). Adding preparation may decrease barriers to the treatment and enhance treatment effect, and the present pilot study aimed to test this. All participants within the present 'preparatory' study would be required to then take part in an imagery task (CFI or relaxation-imagery), within a linked study, for which the power calculation indicated a sample size of 24 (see Appendix 2.9 for study abstract). As this was a pilot study and no previous studies have examined preparation for therapy within this population, a decision was made to aim for a sample size of 24, as this would fit with previous research in this field (O'Neill & McMillan, 2012), and with the overall aim of the research, namely to study effects of a brief CFI exercise. It was recognised the collected data could be used in sample size estimates for future studies, a commonly recognised purpose of pilot studies (Lancaster, Dodd & Williamson, 2004). With this sample size, an 80% power to detect an effect, and an alpha set at .05, the effect size which could be detected with these

numbers was calculated to be 0.54, a medium effect size as defined by Cohen (1992). This was calculated using G*Power3 (Faul, Erdfelder, Lang & Buchner, 2007).

Participants

Participants were recruited from a Glasgow community brain injury service and inpatient rehabilitation units in Glasgow and Lanarkshire.

Inclusion criteria: Participants aged 18 to 65 years old, with a history of serious head injury (defined as post traumatic amnesia > 1 day; Russell, 1935) that occurred at least three months prior to testing. All participants were considered to have capacity to consent by professionals responsible for their care.

Exclusion criteria: Individuals with a learning disability; diagnosis of a degenerative neurological condition; ongoing alcohol- and/or drug-abuse disorder; visual, hearing or communication difficulties that might affect ability to consent to or understand/comply with test procedures; or severe mental illness which, in the judgement of the clinical team or experimenter, would prevent meaningful participation in the study.

Ethics

Ethical approval was obtained from the East of Scotland Research Ethics Committee (reference number 13/ES/0139). Management approval was granted by NHS Greater Glasgow and Clyde Research and Development (see Appendix 2.1 for approval documents). Written consent was obtained from all participants before testing (see Appendix 2.2 for information sheet and consent form).

Procedures

Construction of Preparatory Information

information An online version of the preparatory can be found at https://vimeo.com/82151402, and the preparatory video script can be found in Appendix 2.6. The construction of preparatory information was based upon the results from a small focus group (n=8; 6 individuals affected by brain injury, 2 professionals working within a brain injury rehabilitation setting), discussion with an expert in the field of brain injury and CFT (Dr Fiona Ashworth), and consultation of relevant literature on adapting therapy for individuals affected by head injury (e.g. Block and West, 2013; Broomfield et al., 2011; Khan-Bourne & Brown, 2003). 'Preparing for compassionate exercises' and 'introducing imagery' information from a published compassion-focused therapy manual (Gilbert 2010; p.32-47) were utilised as a framework. It was determined that the primary aim of the video was to introduce concepts

which individuals were likely to find difficult during imagery, for example, experiencing a 'wandering mind,' or not forming 'clear images,' as discussed by a small focus group (Appendix 2.7) and Gilbert (2010), and to offer information on how to overcome such difficulties. Further details of the construction of this video can be found in Appendix 2.7. Because all participants would view the same preparatory video, but would then go on to receive either a compassion-focused imagery intervention *or* relaxation-imagery intervention, it was important that the video could prepare participants for both types of imagery intervention. Within the video, information was presented from the perspectives of a professional psychologist and an individual affected by head injury who had previously taken part in an imagery task. The main issues addressed were:

- 1. What is 'mental imagery' and who does it work for?
- 2. What does the therapy involve and what will happen during the therapy?
- 3. Tips to help when practising mental imagery (examining difficulties such as 'wandering mind' or experiencing 'no clear pictures')
- 4. Definition of compassion and developing compassion
- 5. Definition of relaxation and developing capacity for relaxation
- 6. A summary of key points covered (to aid retention by supporting memory rehearsal)

The video was paused twice for two minutes (following points four and five outlined above), and the researcher and participant discussed examples of compassion-focused imagery and relaxation-imagery which the participant might use within the imagery intervention. Adaptations were made to this information to tailor it to a population affected by severe head injury; a summary of such adaptations can be found in Table 1.

Possible consequences of severe head injury	Adaptation made to preparatory information			
Poor memory and attention	•Summaries given after each section and at the end of video			
	•Information provided verbally and in			
	 Participants redirected to video by experimenter if required 			
	 Visual 'timetable' of study provided Short 'quiz' at the end of video; main points 			
	consolidated following this			
Executive function, specifically difficulties with cognitive flexibility/concreteness	•Concrete examples of imagery provided by 'patient' in video to link this with imagery task linked to common interests within this			
	sample (such as football)			
	 Two short breaks provided during video to 			
	decide on own situations to use in imagery task			
Slow processing speed	Time for reflection during two short breaksContent of video minimised and repeated			
	through summaries			

Table 1. Adaptations to preparatory information for a severe head injury sample

Study Procedure

Potential participants were approached by a professional involved in their care and provided with an information sheet relating to the present study. If they indicated they were interested in taking part, they were then telephoned by the researchers and a time for completing the study was arranged. Participants attended a 3.5 hour session, which included the present study (relating to preparatory information for an imagery task) and the follow-on treatment study (relating to the imagery task itself). Following written consent, participants then completed the measures outlined in Figure 1. All questions were read aloud and answers written down by the researcher, except the Symbol Digit Modalities Test and Imbedded Word Task, which were completed by participants writing their response. A heart-rate monitor was then attached and the participant watched the 20-minute preparatory video; within the last 5 minutes this video was paused twice to discuss a compassionate-imagery and relaxation-imagery scenario which participants might use in the next phase of the study. Participants then completed post-video measures as outlined in Figure 1 and were then given a 15-minute break. Following this, participants entered the follow-on treatment study. They were randomised to a relaxationimagery intervention or a compassionate-imagery intervention using an online randomisation code generator (Haar, 2010), and then completed further measures; the assessor was blinded to the form of imagery intervention which participants received.

Measures

Assessments conducted prior to exposure to preparatory information

•**Measure of Social Deprivation**. This was calculated using a participant's postcode and the Scottish Index of Multiple Deprivation (Scottish Government, 2009), which categorises postcodes into deciles, from 1 (most deprived) to 10 (least deprived).

•Test of Premorbid Functioning (ToPF) (Wechsler, 2011). A measure to estimate preinjury IQ and memory abilities. The TOPF is based on a reading paradigm, requiring the reading and pronunciation of words that have irregular grapheme-to-phoneme translation. Cronbach's alpha was found to be 0.95, indicating excellent reliability (Wechsler, 2011).

•The Symbol-Digit Modalities Test (Smith, 2010). This provides a measure of executive function by requiring attention, visual scanning, and motor and psychomotor speed. The test allows for written or verbal response. It involves the conversion of meaningless geometric designs into written and/or oral number responses and can be used for screening for cerebral dysfunction (Smith, 2010). Test-retest reliability was tested within a sample of adults without brain injury for the written and oral form. The test-retest correlation was found to be .80 for the written SDMT and .76 for the oral SDMT. The SDMT has been shown to be effective as a test of "general" brain impairment (Smith, 2010).

•Extended Glasgow Outcome Scale (Wilson, Pettigrew & Teasdale, 1998). This measure categorize disability outcome of patients in the community with traumatic brain injury. The GOS-E has 8 categories: Dead, Vegetative State, Lower Severe Disability, Upper Severe Disability, Lower Moderate Disability, Upper Moderate Disability, Lower Good Recovery, and Upper Good Recovery. Very good inter-rater reliability has been demonstrated (kappa values of 0.85) (Wilson et al., 1998). This measure was used to describe disability outcome in the TBI group.

Pre- and post-preparatory information assessments

• **Positive and negative affect schedule (PANAS)** (Watson, Clark, & Tellegen, 1988). This 20item schedule assesses positive affect (PA), such as feeling enthusiastic, active, and alert; and negative affect (NA), such as feeling anger, contempt, disgust, fear, and nervousness. Items are rated from 1 to 5 and totalled, yielding a positive affect summary score and a negative affect summary score. Cronbach's alpha is .89 (95% CI = .88–.90) for the PA scale, and .85 (95% CI= .84-.87) for the NA scale, showing good reliability within a general adult sample (n=1003) (Crawford & Henry, 2004).

• **Fears of Compassion Scales** (Gilbert, McEwan, Matos & Rivis, 2011). These three scales measure fears of: compassion for others (10 items), compassion from others (13 items), and

compassion from self (15 items). The items are rated on a 5-point Likert scale (0 = Don't agree at all, 4 = Completely agree). A fear of compassion may inhibit the capacity of compassionate-imagery to increase self-compassion and empathy. This measure has been shown to have good reliability (Cronbach's alphas ranging from .76 to .92; Gilbert et al. 2011).

•Motivation for intervention scale. This was adapted from the Intrinsic Motivation Inventory (IMI) (Ryan, 1982), a 45-item measure of participants' interest/enjoyment, perceived competence, effort, value/usefulness, felt pressure and tension, and perceived choice while performing a given activity, which was designed to be adapted by researchers to answer their specific question. Intrinsic motivation has been described as a measure of 'state' motivation, and should therefore be appropriate for the present study (Choi et al., 2012). The version created for the present study aimed to examine motivation for an imagery intervention. Appendix 2.3 shows the adapted version for the present study.

• **State-Trait Anxiety Inventory, Short form** (STAI, six item version). (Marteau & Bekker, 1992) This six-item version can be used to measure state anxiety. It shows a Cronbach's alpha of .82, indicating good reliability. Tests of validity also showed similar concurrent validity for the 20-item and 6-item version of STAI (Marteau & Bekker, 1992).

• Imbedded Word Task measure of information-processing bias to compassion/threat words. This is an adaptation of the Imbedded Work Task (Wenzlaff, Rude, Taylor, Stultz & Sweatt, 2001), which requires identification of words embedded in a letter grid or 'word search' to measure information-processing bias (in its original version to measure bias of depression-prone individuals to positively/negatively valenced words). This was altered for the present study to measure change in information-processing bias towards threat or compassionate words before and after preparatory information, and was included to support the aim of the present pilot work – to use a range of measures which would be sensitive to change across many dimensions (in the present case, towards attentional processes). An example of this letter grid can be found in Appendix 2.4.

Post- preparatory information assessment:

•Measure of knowledge of imagery intervention. This consisted of four short multiplechoice questions to determine whether participants had retained information outlined in the preparatory video. The questions were: •What can imagining pictures in your mind achieve? •If your mind wanders during the exercise, what should you do? •What does compassion involve? •What does relaxation involve? A full copy of this measure can be found in Appendix 2.5.

Measures Completed as Part of Linked Study (see Appendix 2.9 for abstract)

• **The Self-Compassion Scale** (Neff, 2003). This scale measures the degree to which individuals display self-kindness against self-judgement, common humanity versus isolation, and mindfulness versus over-identification.

•**The Empathy Quotient** (Baron-Cohen & Wheelwright, 2004). This measures cognitive and affective components of empathy.

•**Relaxation measure** (O'Neill & McMillan, 2012). This is a self-report measure of relaxation taken on a Likert scale which measures change in feelings of relaxation pre and post intervention.

Participant given outline of study and written informed consent sought. Demographic information collected: Age, postcode, date of head injury, type of head injury

Participant completed pre-intervention only measures:

Test of Premorbid Functioning

•The Symbol Digit Modalities Test

Participant completed further measures:

PANAS
 Intrinsic Motivation Inventory
 Fears of Compassion Scale
 STAI-short form

•Imbedded Word Task

(Three measures relating to a linked study were also collected at this point)



- •Video (20 mins)
- •Discussion of compassionate-imagery and relaxationimagery (4 mins)

Participant completed:

• PANAS •Intrinsic Motivation Inventory •Fears of Compassion Scale •STAI-short form •Imbedded Word Task • Knowledge of imagery intervention questionnaire

Participants progressed to linked study, which included receiving a 50-minute imagery intervention (compassionate-imagery or relaxation-imagery)

Figure 1. Schematic Summary of Procedure

Data Analysis

All analyses were completed using SPSS Version 21. Continuous data were tested for normality by visually inspected histograms and the Shapiro-Wilk test of normality. Boxplots revealed outliers on the negative affect, motivation, self-compassion and STAI scales. These were further examined using z-scores, none of which exceeded 3.29, which is deemed acceptable for a normal distribution (Field, 2009). For data which was not normally distributed, analyses were conducted using non-parametric tests (motivation for intervention, state anxiety, attentional bias and relaxation scale score when CFI group and RI group were combined in follow-on treatment study).

ANCOVAs were utilised to determine differences between the compassion-focused imagery (CFI, treatment) group and relaxation-imagery (RI, control) group within the follow-on treatment study. Independence of covariates and treatment effects, and the assumption of homogeneity of regression slopes, were met for these analyses.

RESULTS

Demographic variables

Characteristics of the sample on age, gender, education, cause of and time since head injury, and key baseline measures, can be viewed in Table 2.

Analyses

1. Did participants retain information from the preparatory video?

Data on the number of questions answered correctly within a short quiz after the video showed that five participants (20.83%) answered three out of four questions correctly, and 19 (79.17%) participants answered all four questions correctly.

2. How do fears of compassion within a Severe Head Injury (HI) sample compare with other reported samples?

For ease of comparison, fears of compassion found within the present sample have been displayed alongside results from Gilbert et al. (2011) in Table 3. Descriptively, all dimensions

Table 2. Participant Characteristics

Characteristic	Prevalence	
Gender (N)		
Male	20(83.3%)	
Female	4 (16.7%)	
Age (years)	Mean = 46.96, SD= 8.89	
	(range = 30 – 59)	
Age when left education (years)	Mean= 16.75, SD= 1.85	
	(range = 15 – 22)	
stimate of premorbid Full Scale IQ (FSIQ) Mean= 91.92, SD = 9.83		
(Test of Premorbid Functioning)	(range = 75 –113)	
Cause of Head Injury (N):		
Road traffic accident	9 (37.5%)	
Fall	11 (45.83%)	
Assault	4 (16.67%)	
Time since head injury (months)	Mean = 140.63, SD=131.21	
	(range = 5 – 481)	
Glasgow Outcome Scale-Extended		
Score (N):		
Lower severe disability	4 (16.7%)	
Upper severe disability	3 (12.5%)	
Lower moderate disability	e disability 10(41.7%)	
Upper moderate disability	5 (20.8%)	
Lower good recovery	2 (8.3%)	
Upper good recovery	0 (0%)	
Symbol Digit Modalities Score	Mean = 28.33, SD = 11.05	
	(range = 5 - 56)	
Measure of social deprivation (N):		
Highest deprivation (Deciles 1-3)	17 (70.83%)	
Medium deprivation (Deciles 4-7)	3 (12.50%)	
Lowest deprivation (Deciles 8-10)	4 (16.67%)	

Table 3. Fears of compassion for self, for others and from others found within a severe HI sample, student sample and therapist sample

	Present Sample	Student sample	Therapist Sample	
	Severe HI	from Gilbert et al.	from Gilbert et al.	
	(n=24)	(2011) (n=222)	(2011) (n=53)	
	Mean (SD)	Mean (SD)	Mean (SD)	
Fear of compassion	20.13 (13.00)	16.12 (10.38)	8.15 (6.51)	
for self				
Fear of compassion	20.58 (8.17)	15.78 (7.81)	8.81 (7.41)	
from others				
Fear of compassion	24.00 (7.08)	21.18 (6.71)	10.51 (5.36)	
for others				

of fear of compassion (for self, for others and from others) were higher within the present severe HI sample compared to a university student and therapist sample within Gilbert et al. (2011).

3. Does a change in fears of compassion, motivation for intervention, state anxiety, negative affect and information-processing bias to threat/compassion words occur following preparatory information?

Descriptive statistics for pre-post preparatory information for the primary outcome measures of fears of compassion and motivation for intervention and the secondary outcome measures of negative affect and state anxiety can be found in Table 4. Paired-samples-t-tests and Wilcoxon signed-rank tests were used to examine the effect of the preparatory information on these measures.

	Before Preparatory Information		After Preparatory Information	
	Mean (SD)	Median (IQR)	Mean (SD)	Median (IQR)
Fears of	64.71	64.50	60.54	59.5
compassion	(23.44)	(45.50 – 83.00)	(29.37)	(42.00 – 78.75)
Motivation for	27.46	27.50	30.13	32.00
intervention*	(4.05)	(25.00 – 29.75)	(3.86)	(26.25 – 32.75)
State anxiety	9.96	10.00	9.42	9.00
	(3.18)	(7.00 – 12.75)	(3.28)	(6.00 – 12.75)
Negative affect	14.63	13.00	14.83	13.00
	(5.00)	(10.25 – 17.75)	(5.81)	(10.00 – 16.00)

Table 4. Main outcome measures before and after preparatory information

*Significant difference pre-post on non-parametric test

a) Fears of Compassion

The overall reduction in fear of compassion scores from pre (M=64.71, SE= 4.78) to post preparatory video (M=60.54, SE=6.01) was not statistically significant (t(23)=1.34, p=.19, r=.27).

b) Motivation for Intervention

A Wilcoxon signed-rank test indicated that there was a statistically significant increase in motivation from pre- video (Mdn=27.50) to post- video (Mdn=32.00), (T=149.0, z=3.44, p=0.001, r=.50).

c) State anxiety

For the group as a whole, there was no statistically significant change in state anxiety from prevideo (Mdn=10.00) to post video (Mdn=9.00) (T=81.0, z=.93 p=.35, r= .13).

d) Negative affect

On average, participants did not experience a significant change in negative affect from pre-(M=14.63, SE=1.10) to post- preparatory video (M=14.83, SE=1.19) (t(23)=-.33, p=.742, r=.12).

e) Information-processing bias to threat and compassion

When information-processing bias was measured, there was no statistically significant change in 'threat' word detection found from pre- (Mdn=0.38, range=0-1) to post- video (Mdn=0.38, range=0-2) (T=18, z=.00, p= 1.0, r= .00). There was a statistically significant increase in 'compassion' word detection from pre- (Mdn=0.21, range=0-2) to post- video (Mdn=1.04, range=0-3) (T=120, z=3.57, p <.001, r= .52).

4. Did the inclusion of preparatory information amplify the imagery treatment effect?

Results from the imagery intervention (compassion-focused imagery or relaxation-imagery) which participants received in the follow-on study are presented below (abstract for this study available in Appendix 2.9). These will be compared to results from O'Neill and McMillan (2012), a similar study which did not include preparatory information, within the discussion section.

a) Was there a difference on key outcome measures between compassion-focused imagery (CFI) and relaxation-imagery (RI) groups?

To examine whether there were differences between the CFI group and RI group on key outcome measures, ANCOVAs were used, with the pre-intervention score as a covariate. No significant differences were found between the CFI group and RI group in change on the empathy quotient (F(1,21)=0.577, p=0.456), self-compassion scale (F(1,21)=0.131, p=0.721) or relaxation scale (F(1,21)=0.426, p=0.521).

b) Was there a significant effect on key outcome measures after a non-specific imagery intervention?

When both the CFI and RI group results were analysed together as a 'non-specific imagery group,' paired samples t-tests showed that there was no significant difference between pre- and post- imagery intervention on self-compassion (t(23)=-0.189, p=0.852, r=0.04), although there was a non-significant trend towards increased empathy post intervention (t(23)=-1.945,

p=0.064, r=0.38). A Wilcoxon signed-rank test showed a significant increase on a measure of relaxation from pre- (*Mdn*=15.00) to post- (*Mdn*=19.00) intervention (T=118.5, z=2.87, p<0.01, r=0.41).

DISCUSSION

This is the first study to investigate whether providing brief video-based preparatory information to people affected by severe head injury (SHI) could reduce potential barriers to treatment for a compassion-focused imagery task. Participants with a SHI were recruited; all viewed a preparatory video and took part in a short discussion relating to imagery interventions. Measures for potential barriers to treatment were taken before and after the preparatory tasks. These measures included: motivation for therapy, state anxiety, negative affect, fears of compassion, and sensitivity towards 'compassion' or 'threat' words.

Motivation for an imagery intervention significantly increased following preparatory tasks. However, these tasks had no significant effects on fears of compassion, anxiety or negative affect. Fears of compassion were higher than reported norms (Gilbert et al., 2011), and compassionate word detection significantly increased following the preparatory tasks.

The main aim of the present study was to determine whether the addition of preparatory information enhanced the effect of compassionate-imagery on empathy and self-compassion. Results were therefore compared with a study which provided no preparatory information (O'Neill & McMillan, 2012), and this shall be discussed below. The main results will then be discussed in relation to the following: motivation; fears of compassion; alterations for cognitive deficits after head injury; anxiety and, negative affect.

Comparison to O'Neill and McMillan (2012)

O'Neill and McMillan (2012) found no effect of compassionate-imagery on measures of selfcompassion or empathy, which mirrored the effects found in the present study.

When O'Neill and McMillan (2012) combined both the compassion-focused imagery (CFI) group results (n=12) together with the control group results (relaxation-imagery, RI, n=12), to make a 'non-specific imagery intervention' group (n=24), they found a near-significant increase in self-compassion, but no effect on empathy or relaxation. This near-significant increase in self- compassion was replaced in the present study by a near-significant increase in empathy, and a significant increase in relaxation, when both the relaxation- and compassionate-imagery results were analysed together (n=24).

Therefore, following the addition of preparatory information, adapting the imagery intervention to support cognitive deficits and increasing the length of imagery intervention, the main difference in effect was a significant increase in relaxation following an 'imagery intervention' (which included both the CFI and RI groups).

Main Findings

As the present study aimed to remove potential barriers to engaging in an imagery intervention, the statistically significant increase in motivation following simple preparatory information is promising. Although this did not link to an increased effect of compassionate-imagery, it is possible that this increase in motivation suggests a *shift* in motivation which could encourage further participation in treatment. This could perhaps be conceptualised within Prochaska and DiClemente's (1984) transtheoretical model of change, where small, cumulative effects via multiple pathways would enhance engagement in psychological treatment along a pathway of precontemplation, contemplation, preparation, action and maintenance. Within a population where apathy is noted to be high (Kant et al., 1998), and therefore goal-directed behaviour is a difficulty, an increase in motivation towards compassion-focused therapy could be a significant change, which is one step towards participants engaging in more empathic, less self-attacking behaviours which enhance relationships. The measure of motivation used within the present study was developed from the Intrinsic Motivation Inventory specifically for this study, therefore replication of such findings or validation of this scale within a SHI population would add to the reliability of this result.

Fears of compassion within the present sample were high, when compared to a non-head injured adult sample (Gilbert, 2011), and they did not decrease following preparatory information. Rockliff, Gilbert, McEwan, Lightman and Glover (2008) reported that fears of compassion interfered with participants' ability to engage in a compassionate-imagery task in a student sample. Furthermore, Gilbert (2009) indicated that a crucial part of therapeutic work within compassion-focused interventions is to address fears and resistances to becoming self-compassionate, and to becoming compassionate to others, through normalising, validating, containing and working with such feelings during therapy. Preparatory information may help to support this work but it seems unlikely that it would be able to replace it. Considering high fears of compassion within this sample, the purpose of brief preparatory information may be to enhance motivation enough for individuals to enter individual therapy or more prolonged therapy, and to begin the process of defusing fears of compassion.

The present study also made adjustment to procedures to reduce the impact of cognitive deficits, for example, through repetition of information in order to support memory deficits. It

is possible that that participants may require further adaptations, such as repetition over time rather than repetition within one session, in order to engage more fully with a new imagery exercise. Within a trial for brief mindfulness training for attentional problems after head injury, McMillan, Robertson, Brock and Chorlton (2002) asked participants to complete five 45-minute sessions of supervised mindfulness exercises over a four-week period, using an audio-tape. Participants were also asked to listen to this tape daily. No significant effect of this training was found on attentional problems, in comparison with a physical exercise control group. Yet this study provides an insight into a design which may help to determine whether more prolonged use of *compassionate-imagery* techniques would enable clients to build a familiarity with compassionate-imagery and feeling. It is possible that a series of short imagery exercises repeated over the course of several days may be more beneficial than the *brief* preparatory and imagery exercises completed in the follow-on study.

No effect of preparatory information was found on anxiety and negative affect within the present study. Mean scores on both constructs were relatively low at the beginning of the study (mean anxiety score=9.96, from a maximum score of 24 and a minimum of 4; mean negative affect score=14.63, from a maximum of 50 and minimum score of 10), suggesting that perhaps negative affect and anxiety were not barriers to engaging in an imagery task. Alternatively, low anxiety may also have been due to apathy often noted within a head injury sample (Kant et al., 1998), meaning that the 'uncertainties' of therapy were not considered and therefore did not cause distress.

Strengths and limitations

The present study used a standardised format to provide preparatory information, which included recommended adaptations for a SHI population (e.g. Block & West, 2013). The sample included within the present study was comparable to other studies with a focus on severe head injury, in terms of cause of head injury and proportion of male and female participants (Majdan, et al., 2011; O'Neill & McMillan, 2012; Sumpter & McMillan, 2006; Thornhill, et al., 2000), suggesting that the sample was representative. All participants who were recruited were also able to complete the study protocol.

The sample size within the present study was comparable to or larger than other therapeutic studies within a brain injury population (e.g. Hodgson et al., 2005, RCT, n=12; Hsieh et al., 2012, RCT, n=27; Tiersky et al., 2005, RCT, n=20), although is significantly smaller than studies examining the effect of preparatory information within a non-head injury adult mental health setting (Deane et al., 1992 n=138; Johansen, Lumley & Cano, 2011, n=105). This, in comparison

with the small effect sizes found within the present study, might suggest that significantly larger sample sizes would be required to accurately test the effects of preparatory information.

One limitation of the present research was that it did not include a control group, as all participants within the follow-on treatment study were required to receive identical preparatory information. Although O'Neill & McMillan's (2012) study did allow for comparison between a treatment trial with and without preparation, there are limitations of this comparison as further alterations were made to the imagery treatment procedures within the present follow-on treatment trial. It would have been preferable if outcome measures had been administered by an independent researcher in order to ensure blinding of outcome assessment, although this is not required within a pilot study, and the small effects suggests little or no bias from assessors being unblinded. Furthermore, no qualitative information was collected in order to gauge individual reactions to compassionate-imagery and preparatory information; this would have allowed the measurement of treatment acceptability. Finally, three of the measures used were developed for the purposes of the present study, and will therefore require standardisation.

Implications for future research

Fears of compassion were high within the present sample. Given that this is thought to be a barrier to engaging fully in exercises which enhance compassion and soothing emotions (Gilbert, 2009), this could be a useful target for future intervention. Preparatory information may help to build motivation for, and engagement in, treatments. A higher 'dose' of intervention addressing fears of compassion could also be trialled before beginning compassionate-imagery and other aspects of compassion-focused therapy. Alternatively, a study which provides more sessions of supervised practice and perhaps the repeated use of audio recordings, following preparatory information, could be trialled. Furthermore, a qualitative study may offer further insights into possible barriers to engagement in compassionate-imagery for those affected by head injury.

Finally, a fears of compassion scale was used as a primary outcome measure within the present sample. There may be more salient outcome measures which could be utilised within a head injury sample, perhaps involving significant others in measures, or use of biological measures such as heart-rate variability or cortisol (Rockliff et al., 2008) in order to reduce reliance on self-report. Related to this point, an Imbedded Word Task was trialled within the present sample, as a secondary outcome measure to examine information-processing bias towards threat or compassion. Results from this offered very preliminary findings that, even within a sample with high fears of compassion, learning more about a compassionate-imagery task did

not increase detection of threat words, and did increase detection of compassionate words. Measures which focus on the attentional system could therefore be examined in more depth than was possible within the present study.

Conclusions

The present research suggests that brief preparatory information is able to increase motivation for an imagery intervention. This did not translate into a greater effect within the imagery intervention itself, perhaps due to high fears of compassion within the present sample. Future studies could therefore build upon increased motivation from preparatory tasks, and also examine whether prolonged work on fears of compassion and more frequent use of imagery would allow individuals affected by severe head injury to develop greater self-compassion and empathy through the use of compassionate-imagery.

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Chapter Three: Advanced Clinical Practice I

Reflective Account

Are you asking me? A reflective, developmental account of becoming confident when providing 'expert' psychological knowledge, principles and methods through group work and training

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ABSTRACT

Introduction: The main focus of this reflective account is my personal experience of beginning to feel comfortable with providing group work and training as part of my role as a Trainee Clinical Psychologist. The importance of such competencies of training, consultation and supervision have been outlined within governmental policy, as a progressively more relevant role of the Clinical Psychologist in increasing access to psychological therapies (The Scottish Government, 2011). The present reflective account utilises Kolb's Experiential Learning Model (1984), Gibbs' Model of Reflection (1988) and the Integrated Developmental Model (Stoltenberg, 1981) to structure reflection and learning from each year of training in Doctoral training in Clinical Psychology.

Reflection: I feel that my development over the three years of clinical training has been gradual and well supported, although I have struggled at times, particularly with the feeling that I was not qualified enough to provide my professional opinion. One main reflection from each year of training has therefore been provided to chart my developmental progress in moving towards feeling more confident about communicating psychological knowledge and principles through group work and training.

Reflective Review: My main reflections and learning points are outlined under the headings of 'personal experience of learning', 'theoretical basis for learning and training' and finally, 'service development.' Overall, these points relate to the effect of reflection on increased openness, creativity and my search for a personal style of training, alongside a greater awareness of and enthusiasm for the purpose and evaluation of training, consultation and supervision within psychological services.

Chapter Four: Advanced Clinical Practice II

Reflective Account

Seeing what has not been seen: A reflective account of a first experience of supervising others

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ABSTRACT

Introduction: The main focus of this reflective account is my experience of supervising an assistant psychologist and support worker, and the ways in which I found this to be a process that was satisfying and rewarding, but also frustrating and anxiety-provoking. The importance of such competencies of training, consultation and supervision have been outlined within governmental policy, as a progressively more relevant role of the Clinical Psychologist in increasing access to psychological therapies (The Scottish Government, 2011). The present reflective account utilises Vygotsky's 'Zone of Proximal Development' theory (1978), the four stages of learning model and the Seven-Eyed Process Model of Supervision (Hawkins & Shohet, 1989) to structure reflection and learning from the experience of supervising others.

Reflection: I feel that I initially 'jumped in' to provide supervision, without a consideration of the skills which would be necessary. In some ways I was too confident, not recognising my limitations, but in other ways I was not confident enough, as I did not consciously recognise my own skills in CBT and other therapeutic skills which could be applied to this situation. My reflections are analysed according the models outlined in the introduction.

Reflective Review: The experience of supervising others has been utilised to reflect on my past experience of being supervised, and to consider how I would like to both supervise *others* and engage in *my own supervision* in the future. These points relate to an overall desire to grow in my own reflective capacity as a psychologist, but also to encourage others to learn through the process of supervision, which has the unique ability to be adapted to each individual supervisee and each of their individual clients.

Appendix 1.1 Guidelines for submission to Neuropsychological Rehabilitation

Instructions for authors

Submission of Manuscripts

All submissions should be made online at the *Neuropsychological Rehabilitation* <u>Scholar One</u> <u>Manuscripts</u> website. New users should first create an account. Once logged on to the site, submissions should be made via the Author Centre. Online user guides and access to a helpdesk are available on this website.

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Two authors: Smith and Jones (2012) or (Smith & Jones, 2012)

Three to five authors: At first mention: Smith, Jones, Khan, Patel, and Chen (2012) or (Smith, Jones, Khan, Patel, & Chen, 2012). At subsequent mentions: Smith et al. (2012) or (Smith et al., 2012). In cases where two or more references would shorten to the same form, retain all three names.

Six or more authors: Smith et al. (2012) or (Smith et al., 2012)

Author with two works in the same year: Put a, b, c after the year (Chen, 2011a, 2011b, in press-a)

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More authors: Include all names up to seven. If there are more than seven authors, list the first six with an ellipsis before the last. Author, M., Author, B., Author, E., Author, G., Author, D., Author, R., ... Author, P. (2001).

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Journals

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Two authors: Author, A. A., & Author, B. B. (2004). Title of article. *Title of Journal, 22,* 123–231.

Three authors: Author, A. A., Author, B. B., & Author, C. C. (1987). Title of article. *Title of Journal, 22*, 123–231.

More authors: Include all names up to seven. If there are more than seven authors, list the first six with an ellipsis before the last. Author, M., Author, B., Author, E., Author, G., Author, D., Author, R., ... Author, P. (2001).

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Appendix 1.2 Quality rating scores

Study	Precise details of the	Description of the	Description of the	Details of how the	Details of how	Total
	experimental	different	procedure for	intervention was or	adherence to the	
	treatment (0,1 or 2)	components of the	tailoring the	could be	protocol was	
		intervention (0 or1)	intervention to	standardised (0 or 1)	assessed or	
			individual		enhanced (0 or 1)	
			participants (0 or 1)			
D'Antonio (2013)	0	1	0	1	1	3
Gracey et al. (2007)	2	1	1	0	0	4
Hodgson (2005)	1	1	0	0	0	2
Hofer (2013)	2	1	1	0	0	4
Hsieh et al. (2012a)	2	1	1	1	0	5
2 case studies CBT						
Hsieh et al. (2012b-	2	1	0	1	1	5
pilot RCT)						
Hsieh et al. (2012c –	2	1	1	1	0	5
MI case studies)						
King (2002)	2	1	1	0	0	4
Kneebone & Hull	2	1	1	0	0	4
(2009)						
Kneebone & Jeffries	2	1	1	0	0	4
(2013)						
Lincoln &	0	1	0	1	0	2
Flannaghan (2003)						
Lincoln et al. (1997)	0	1	0	0	0	1
McMillan (1991)	1	1	1	0	0	3
McNeill &	1	1	1	0	0	3
Greenwood (1996)						
Rasquin et al.	2	1	0	1	0	4
(2009)						
Tiersky et al. (2005)	2	1	1	1	0	5

item)		
Therapeutic education and formulation specific to ABI	Include strengths and weaknesses based on cognitive assessment within formulation Educate client on CBT model and treatment, ensuring that links between cognitions and affect are understood	Broomfield et al. (2011); Kinney (2001) Broomfield et al. (2011); Khan Bourne & Brown (2003)
	Provide clear information/education on effects of ABI in order to raise awareness and normalise common reactions	Broomfield et al. (2011); Kangas & McDonald (2011); Khan-Bourne & Brown (2003); Kinney (2001); Soo, Tate & Lane-Brown. (2011); Tsaousides et al. (2013)
Attention, concentration	Provide breaks for rest during therapy sessions	Block & West (2013); Broomfield et al. (2011)
and alertness	Shorten length of sessions	Khan-Bourne & Brown (2003); Broomfield et al. (2011); Rossiter &
	(Time not specified, but assume <50 mins)	Holmes (2013)
	(At least once per week in initial stages)	Kangas & McDonald (2011); Khan Bourne & Brown (2003); Rossiter & Holmes (2013)
Communication	Use clear, structured questioning, and limit the use of lengthy, open-ended or multiple questions	Block & West (2013); Kinney (2001)
	Incorporate visual resources into the session to enhance comprehension and draw attention to important points	Block & West (2013); Kinney (2001); Rossiter & Holmes (2013)
	Place emphasis on behavioural techniques (such as behavioural activation)	Broomfield et al. (2011); Kinney et al. (2011); Khan Bourne &Brown (2003); Soo et al.(2011)
Memory	The client should have a therapy notebook or folder; review this during the session and place important points from sessions and homework in this	Block & West (2013); Broomfield et al. (2011); Kangas & McDonald (2011)
	Use memory aids such as written notes or audiotapes during the session – these can be reviewed between sessions	Broomfield et al. (2011); Kangas & McDonald (2011); Khan Bourne & Brown (2003); Kinney (2001); Soo et al. (2011)
	Summarize and repeat salient points at frequent intervals during the session (to refocus and help memory and learning)	Block & West (2013); Broomfield et al. (2011); Khan Bourne and Brown (2003); Soo, Tate & Lane-Brown (2011)
	Involve a family member/close friend/carer in formulation, therapy and homework tasks to enhance generalisation	Khan Bourne & Brown (2003); Kinney (2001); Rossiter and Holmes (2013)
Executive functioning	Present information more slowly during session and allow extra time for response (due to slowed processing speed)	Block & West (2013); Kinney (2001); Soo, Tate & Lane-Brown (2011)
	Use summarising or an agreed-upon signal to alert the client if/when they have become tangential	Block & West (2013); Khan Bourne & Brown (2003)
	Focus on concrete examples and aid clients to generate alternative solutions (due to difficulty in flexible thinking)	Block & West (2013); Soo, Tate & Lane-Brown (2011)
	Therapist to take a directive and structured approach if necessary due to executive functioning/attentional deficits	Khan Bourne & Brown (2003); Kinney (2001)
	Model homework completion- say it, show it, do it (Zeiss and Steffen, 1996) and encourage completion of homework across a variety of situations to enhance generalisation	Broomfield et al (2011); Kinney (2001); Block &West (2013)

Appendix 1.3 Modification-Extraction List (review articles which identified each item)

nemj		
Therapeutic education and formulation specific to ABI	Include strengths and weaknesses based on cognitive assessment within formulation	Gracey, Oldham & Kritizinger (2007), Hsieh et al. (2012c), Kneebone & Jeffries (2013)
	Educate client on CBT model and treatment, ensuring that links between cognitions and affect are understood	Gracey, Oldham & Kritizinger (2007), Hsieh et al. (2012b), Hsieh et al.(2012a), King (2002), Kneebone & Hull (2009), Kneebone & Jeffries (2013), McNeill & Greenwood (1996),Tiersky et al. (2005)
	Provide clear information/education on effects of ABI in order to raise awareness and normalise common reactions	Gracey, Oldham & Kritizinger (2007), Hofer et al. (2013), Kneebone & Jeffries (2013)
Attention, concentration	Provide breaks for rest during therapy sessions	Hodgson (2005), Hofer et al. (2013)
and alertness	Shorten length of sessions (Time not specified, but assume <50 mins)	Hodgson (2005)
	Increase frequency of sessions (At least once per week in initial stages)	Tiersky et al. (2005), D'Antonio et al (2013)
Communication	Use clear, structured questioning, and limit the use of lengthy, open-ended or multiple questions	
	Incorporate visual resources into the session to enhance comprehension and draw attention to important points	Gracey, Oldham & Kritizinger (2007), Hsieh et al.(2012a), Hsieh et al.(2012b), Hsieh et al. (2012c)
	Place emphasis on behavioural techniques (such as behavioural activation)	Kneebone & Jeffries (2013), McMillan (1991)
Memory	The client should have a therapy notebook or folder; review this during the session and place important points from sessions and homework in this	D'Antonio (2013), Hodgson (2005), Hsieh et al.(2012a), Hsieh et al. (2012b), Rasquin et al. (2012), Tiersky et al. (2005)
	Use memory aids such as written notes or audiotapes during the session – these can be reviewed between sessions	D'Antonio (2013), Gracey, Oldham & Krtizinger (2007), Hodgson (2005), Hsieh et al. (2012a), Hsieh et al.(2012b), Kneebone & Hull (2009); Kneebone & Jeffries (2013), Tiersky et al. (2005)
	Summarize and repeat salient points at frequent intervals during the session (to refocus and help memory and learning)	Gracey, Oldham & Krtizinger (2007), Hodgson (2005), Hofer

Appendix 1.4 Modification-Extraction List (intervention studies which identified each item)

		et al. (2013), Hsieh et al.(2012a), Hsieh et al. studies (2012b), Hsieh et al. (2012c), Kneebone & Jeffries (2013)
	Involve a family member/close friend/carer in formulation, therapy and homework tasks to enhance generalisation	Hsieh et al. (2012a), McMillan (1991)
Executive functioning	Present information more slowly during session and allow extra time for response (due to slowed processing speed)	Hsieh et al. (2012a), Hsieh et al. (2012c) Kneebone & Jeffries (2013), Rasquin et al. (2012)
	Use summarising or an agreed upon signal to alert the client if/when they have become tangential	Hodgson (2005)
	Focus on concrete examples and aid clients to generate alternative solutions (due to difficulty in flexible thinking)	Hodgson (2005), Hsieh et al. (2012a), Hsieh et al. (2012b), Hsieh et al. (2012c) Kneebone & Jeffries (2013)
	Therapist to take a directive and structured approach if necessary due to executive functioning/attentional deficits	Hodgson (2005), Rasquin et al. (2012)
	Model homework completion- 'say it, show it, do it,' and encourage completion of homework across a variety of situations to enhance generalisation	Hodgson (2005), Hsieh et al. (2012a), Hsieh et al.(2012b), Kneebone & Hull (2009), Kneebone & Jeffries (2013), Tiersky et al. (2005), Rasquin et al. (2012)

Appendix 2.1 Letters of ethical approval



R&D Management Office

1st Floor 38 Church Street Glasgow, G11 6NT,

Western Infirmary

Tennent Institute

Coordinator/Administrator: Dr Erica Packard/Mrs Elaine O'Neill Telephone Number: 0141 232 9448 E-Mail: erica.packard@ggc.scot.nhs.uk Website: www.nhsggc.org.uk/r&d

13 December 2013

Ms Melanie Gallagher Trainee Clinical Psychologist Gartnavel Royal Hospital 1055 Great Western Road Glasgow G12 0XH

NHS GG&C Board Approval

Dear Ms Gallagher,

Study Title:	Pilot study of the effects of a brief, structured, psychological intervention using compassion-focused imagery with patients who have suffered a traumatic brain injury (TBI).
Principal Investigator:	Ms Melanie Gallagher
GG&C HB site	Acquired Brain Injury Service, Dumbarton
Sponsor	NHS Greater Glasgow & Clyde
R&D reference:	GN13CP472
REC reference:	13/ES/0139
Protocol no:	V10; 25 Oct 2013

I am pleased to confirm that Greater Glasgow & Clyde Health Board is now able to grant **Approval** for the above study.

Conditions of Approval

- 1. For Clinical Trials as defined by the Medicines for Human Use Clinical Trial Regulations, 2004
 - a. During the life span of the study GGHB requires the following information relating to this site
 - i. Notification of any potential serious breaches.
 - ii. Notification of any regulatory inspections.

It is your responsibility to ensure that all staff involved in the study at this site have the appropriate GCP training according to the GGHB GCP policy (<u>www.nhsggc.org.uk/content/default.asp?page=s1411</u>), evidence of such training to be filed in the site file.

- 2. For all studies the following information is required during their lifespan.
 - a. Recruitment Numbers on a monthly basis
 - b. Any change of staff named on the original SSI form
 - c. Any amendments Substantial or Non Substantial
 - d. Notification of Trial/study end including final recruitment figures
 - e. Final Report & Copies of Publications/Abstracts

Please add this approval to your study file as this letter may be subject to audit and monitoring. Your personal information will be held on a secure national web-based NHS database.

I wish you every success with this research study

Yours sincerely,

Epackard

Dr Erica Packard Research Co-ordinator

Cc: Mr Iain Campbell Prof Tom McMillan

Board Approval Letter GN13CP472





East of Scotland Research Ethics Service (EoSRES) REC 1 Tayside Medical Sciences Centre (TASC) Residency Block C, Level 3 Ninewells Hospital & Medical School George Pirie Way Dundee DD1 9SY

Professor Thomas M McMillan Professor of Clinical Neuropsychology University of Glasgow Mental Health and Wellbeing, MVLS, Gartnavel Royal Hospital, 1055 Great Western Road, Glasgow G12 0XH Date: Your Ref: Our Ref: Enquiries to: Direct Line: Email: 26 November 2013

LR/13/ES/0139 Mrs Lorraine Reilly 01382 383878 eosres.tayside@nhs.net

Dear Professor McMillan

Study Title:

REC reference: IRAS project ID: A pilot study of the effects of a brief, structured, psychological intervention using compassion-focused imagery with patients who have suffered a traumatic brain injury (TBI). 13/ES/0139 137377

Thank you for your letter of 22 November 2013, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair and Alternate Vice-chair.

We plan to publish your research summary wording for the above study on the NRES website, together with your contact details, unless you expressly withhold permission to do so. Publication will be no earlier than three months from the date of this favourable opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to withhold permission to publish, please contact the Co-ordinator Mrs Lorraine Reilly, lorraine.reilly@nhs.net.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Ethical review of research sites

NHS sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).



Non-NHS sites

The Committee has not yet been notified of the outcome of any site-specific assessment (SSA) for the non-NHS research site(s) taking part in this study. The favourable opinion does not therefore apply to any non-NHS site at present. We will write to you again as soon as one Research Ethics Committee has notified the outcome of a SSA. In the meantime no study procedures should be initiated at non-NHS sites.

Conditions of the favourable opinion

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.

Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at <u>http://www.rdforum.nhs.uk</u>.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of approvals from host organisations

Registration of Clinical Trials

All clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database within 6 weeks of recruitment of the first participant (for medical device studies, within the timeline determined by the current registration and publication trees).

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non clinical trials this is not currently mandatory.

If a sponsor wishes to contest the need for registration they should contact Catherine Blewett (<u>catherineblewett@nhs.net</u>), the HRA does not, however, expect exceptions to be made. Guidance on where to register is provided within IRAS.

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:



Document	Version	Date
Evidence of insurance or indemnity		30 July 2013
Interview Schedules/Topic Guides	3	25 October 2013
Interview Schedules/Topic Guides	3	25 October 2013
Investigator CV: Mr Campbell		
Investigator CV: Dr McMillan		
Investigator CV: Ms Gallagher		26 July 2013
Investigator CV: Dr McLeod		12 August 2013
Other: correspondence re sponsorship		30 October 2013
Other: correspondence with questionnaires		30 October 2013
Participant Consent Form: Tracked changes	2	22 November 2013
Participant Information Sheet: Tracked changes	4	22 November 2013
Protocol	10	25 October 2013
Protocol	10	25 October 2013
Protocol	4	25 October 2013
Questionnaire: List of Measures	1	25 October 2013
Questionnaire: Fear of Compassion.		
Questionnaire: Glasgow Outcome Scale		
Questionnaire: PANAS		
Questionnaire: Self Compassion Scale		
Questionnaire: Stat-trait anxiety inventory short form		
Questionnaire: The Empathy Quotient		
Questionnaire: TOPF		
Questionnaire: Symbol Coding		
REC application		29 October 2013
Response to Request for Further Information		22 November 2013

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

After ethical review

Reporting requirements

The attached document *"After ethical review – guidance for researchers"* gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.



Feedback

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

Further information is available at National Research Ethics Service website > After Review

13/ES/0139: Please quote this number on all correspondence

We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at http://www.hra.nhs.uk/hra-training/

Yours sincerely

1. Reilly

pp Dr Lynda Cochrane Alternate Vice-chair

eosres.tayside@nhs.net

Enclosures:

Copy to:

"After ethical review – guidance for researchers" Erica Packard, NHS Greater Glasgow and Clyde

Erica Packard, NHS Greater Glasgow and Clyde Ms Gallagher Mr Campbell





East of Scotland Research Ethics Service (EoSRES) REC 1 Tayside Medical Sciences Centre (TASC) Residency Block C, Level 3 Ninewells Hospital & Medical School George Pirie Way Dundee DD1 9SY

Professor Thomas M McMillan Professor of Clinical Neuropsychology University of Glasgow Mental Health and Wellbeing, MVLS, Gartnavel Roval Hospital. 1055 Great Western Road, Glasgow G12 0XH

Date: Your Ref: Our Ref: Enquiries to: Direct Line: Email:

16 January 2014

LR/13/ES/0139 (SSA 14/ES/0009) Mrs Lorraine Reilly 01382 383878 eosres.tayside@nhs.net

Dear Professor McMillan

Cfunder 4141

Study title:	A pilot study of the effects of a brief, structured, psychological intervention using compassion-focused imagery with patients who have suffered a traumatic brain injuny (TPI)
REC reference:	13/ES/0139
SSA reference:	14/ES/0009
IRAS project ID:	137377

The REC gave a favourable ethical opinion to this study on 26 November 2013.

Following site-specific assessment by Committee, I am pleased to confirm the extension of the favourable opinion to the new site(s) and investigator(s) listed below:

Research Site	Principal Investigator / Local Collaborator
Headway Glasgow	Ms Melanie A Gallagher

The favourable opinion is subject to management permission or approval being obtained from the host organisation prior to the start of the study at the site concerned.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.



14/ES/0009:

Please quote this number on all correspondence

Yours sincerely

Reilly Z 0

Mrs Lorraine Reilly Senior REC Co-ordinator

eosres.tayside@nhs.net

Copy to:

Erica Packard, NHS Greater Glasgow and Clyde Ms Gallagher Mr Campbell







East of Scotland Research Ethics Service (EoSRES) REC 1 Tayside Medical Sciences Centre (TASC)

Residency Block C, Level 3 Ninewells Hospital & Medical School George Pirie Way Dundee DD1 9SY

Professor Thomas M McMillan Professor of Clinical Neuropsychology University of Glasgow Mental Health and Wellbeing, MVLS, Gartnavel Royal Hospital, 1055 Great Western Road, Glasgow G12 0XH Date: Your Ref: Our Ref: Enquiries to: Direct Line: Email: 16 January 2014

LR/13/ES/0139 (SSA 14/ES/0010) Mrs Lorraine Reilly 01382 383878 eosres.tayside@nhs.net

Dear Professor McMillan

Study title:	A pilot study of the effects of a brief, structured, psychological intervention using compassion-focused imagery with patients who have suffered a traumatic brain injury (TBI).
REC reference:	13/ES/0139
SSA reference:	14/ES/0010
IRAS project ID:	137377

The REC gave a favourable ethical opinion to this study on 26 November 2013.

Following site-specific assessment by Committee, I am pleased to confirm the extension of the favourable opinion to the new site(s) and investigator(s) listed below:

Research Site	Principal Investigator / Local Collaborator
Murdostoun Brain Injury Rehabilitation Centre	Ms Melanie A Gallagher

The favourable opinion is subject to management permission or approval being obtained from the host organisation prior to the start of the study at the site concerned.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.



14/ES/0010:

Yours sincerely

L. Reilly

Mrs Lorraine Reilly Senior REC Co-ordinator

eosres.tayside@nhs.net

Copy to:

Erica Packard, NHS Greater Glasgow and Clyde Ms Gallagher Mr Camobell





East of Scotland Research Ethics Service (EoSRES) REC 1 Tayside Medical Sciences Centre (TASC) Residency Block C, Level 3 Ninewells Hospital & Medical School George Pirie Way Dundee DD1 9SY

Professor Thomas M McMillan Professor of Clinical Neuropsychology University of Glasgow Mental Health and Wellbeing, MVLS, Gartnavel Royal Hospital, 1055 Great Western Road, Glasgow G12 0XH Date: Your Ref: Our Ref: Enquiries to: Direct Line: Email: 16 January 2014

LR/13/ES/0139 (SSA 14/ES/0014) Mrs Lorraine Reilly 01382 383878 eosres.tayside@nhs.net

Dear Professor McMillan

Study title:

REC reference: SSA reference: IRAS project ID: A pilot study of the effects of a brief, structured, psychological intervention using compassion-focused imagery with patients who have suffered a traumatic brain injury (TBI). 13/ES/0139 14/ES/0014 137377

The REC gave a favourable ethical opinion to this study on 26 November 2013.

Following site-specific assessment by Committee, I am pleased to confirm the extension of the favourable opinion to the new site(s) and investigator(s) listed below:

Research Site	Principal Investigator / Local Collaborator
Graham Anderson House	Ms Melanie A Gallagher

The favourable opinion is subject to management permission or approval being obtained from the host organisation prior to the start of the study at the site concerned.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.



14/ES/0014:

Please quote this number on all correspondence

Yours sincerely

Reilly 2 0

Mrs Lorraine Reilly Senior REC Co-ordinator

eosres.tayside@nhs.net

Copy to:

Erica Packard, NHS Greater Glasgow and Clyde Ms Gallagher Mr Campbell



Appendix 2.2 Participant consent form and information sheet





Study title: A pilot study of the effects of a brief, structured, psychological intervention using imagery with patients who have suffered a traumatic brain injury (TBI).

Information Sheet

Our names are Melanie Gallagher and Iain Campbell and we are required to undertake a project as part of our course. We invite you to take part in this study. However, before you decide to do so, we need to be sure you understand firstly why we are doing it, and secondly what it would involve if you agreed. We are therefore providing you with the following information. Please read it carefully and be sure to ask any questions you might have and, if you want, discuss it with others including your friends and family. I will do my best to explain the project to you and provide you with any further information you may ask for now or later. You do not have to make an immediate decision.

What is the purpose of the study?

We would like to find out about the effects of a relatively new therapy which could be useful for people who have experienced a head injury. Specifically, we would like to know if 'mental imagery' can help people to feel better about the effects of a head injury.

To do this we will investigate whether one session of mental imagery can influence how people feel after a head injury, and if they can be supported to prepare for this session. If there are signs that mental imagery can be helpful a future study might then look a more intensive treatment. The present study will be submitted as part of a research portfolio for a Doctorate in Clinical Psychology at the University of Glasgow.

What does taking part involve?

Taking part involves coming along for one session. In the first part of this session you will be asked to complete questionnaires and in the second part to participate in a short treatment followed by some more questionnaires. The treatment firstly consists of watching a DVD for 25 minutes. You will then have a 15 minute break before being randomly allocated to one of two treatments, both of which consist of practising breathing techniques and mental imagery for about 1 hour. 'Mental imagery' involves thinking of images in your mind such as a colour, a special place or a feeling, such as relaxation. A device that measures heart rate will be worn throughout the treatment. This is designed to be comfortable for the wearer and is attached using an elasticated band around your chest. This is easy to attach, and you will be able to do this yourself or with assistance from a staff member within your

rehabilitation unit or community group. This session will take place within your rehabilitation unit or community group venue and will last for approximately 3 hours in total.

Why have I been invited?

We will be asking staff who work with potential participants to identify individuals who might be able to agree and who would be willing to take part in the study. This means gathering some information about you beforehand, but this will not be stored without your agreement to take part. If you are invited to take part, it will be because you experienced a head injury more than 3 months ago with some confusion and disorientation that lasted for one day or more.

Who is conducting the research?

Iain Campbell and Melanie Gallagher, two Trainee Clinical Psychologists from the University of Glasgow, are carrying out this study. It is being supervised by Professor Tom McMillan and Dr Hamish McLeod, also from the University of Glasgow.

Do I have to take part?

Participation is voluntary and it is up to you to decide. If you want to take part, you will be asked to sign a consent form to show you have agreed. If you would like to take a break during any part of the study, you would be free to do this. You would also be free to withdraw from the study at any time, and you would not have to give a reason for this. Withdrawing from the study would not affect the standard of care you receive or your future treatment.

What happens to the information?

Your identity and personal information will be completely confidential and known only to the researchers. The information obtained will remain confidential and will be stored within a locked filing cabinet. Data collected will be anonymised and unique codes will be used as identifiers. The data are held in accordance with the Data Protection Act, which means that we will keep it safely and cannot reveal it to other people without your permission.

Will you contact my GP?

With your consent, we will send your GP a short letter to let them know that you are taking part in the study. If you would like to see an example of the letter, please just ask the researchers.

What are the possible effects on me?

The treatment session may generate a number of emotional reactions in you. These emotions may be positive or negative. Should you experience a negative emotional reaction you will be offered the opportunity to discuss this with the researcher or a member of your clinical support staff. Although the study lasts in the region of three hours from beginning to end, there will be plenty of opportunities for comfort breaks provided.

What are the possible benefits of taking part?

By taking part in this research you will be providing valuable information on the development of a psychological therapy that could potentially improve empathy in people who have experienced a head injury.

Who has reviewed the study?

The East of Scotland Research Ethics Committee REC 1, which has responsibility for scrutinising all proposals for medical research on humans in Tayside and beyond, has examined the proposal and has raised no objections from the point of view of medical ethics. It is a requirement that your records in this research, together with any relevant records, be made available for scrutiny by monitors from the University of Glasgow and NHS Greater Glasgow & Clyde, whose role is to check that research is properly conducted and the interests of those taking part are adequately protected.

What do I do now?

If you are interested in taking part in the study, please let a member of staff within your rehabilitation unit or your community group know. We will then contact you by telephone to answer any other questions that you may have about the study and, if you are still interested in taking part following this, we will arrange a time for you to complete the study. When we meet you will be asked to sign a consent form to show that you have read and understood the information provided to you and that you agree to take part in the study.

If you have any further questions?

We will give you a copy of the information sheet and signed consent form to keep. If you would like more information about the study and wish to speak to someone not closely linked to the study, please contact Dr Sue Turnbull, Research Tutor, University of Glasgow, Section of Psychological Medicine, email: <u>s.turnbull@clinmed.gla.ac.uk</u>, Tel no: 0141 211 3927.

If you have a complaint about any aspect of the study?

If you believe that you have been harmed in any way by taking part in this study, you have the right to pursue a complaint and seek any resulting compensation through the University of Glasgow who are acting as the research sponsor. Details about this are available from the research team. Also, as a patient of the NHS, you have the right to pursue a complaint through the usual NHS process. To do so, you can submit a written complaint via email to NHS Greater Glasgow and Clyde at <u>complaints@ggc.scot.nhs.uk</u> (or telephone 0141 201 4500). Note that the NHS has no legal liability for non-negligent harm. However, if you are harmed and this is due to someone's negligence, you may have grounds for a legal action against NHS Greater Glasgow & Clyde but you may have to pay your legal costs.

Contact Details: Main Researchers Melanie Gallagher and Iain Campbell Trainee Clinical Psychologists

Supervisors

Prof Tom McMillan and Dr Hamish McLeod University of Glasgow University of Glasgow Section of Psychological Medicine 1055 Great Western Road Glasgow Glasgow, G12 0XH Email: <u>m.gallagher.1@research.gla.ac.uk</u> <u>i.campbell.2@research.gla.ac.uk</u> Tel: 0141 211 0694 Section of Psychological Medicine 1055 Great Western Road G12 0XH Email: <u>thomas.mcmillan@glasgow.ac.uk</u> <u>hamish.mcleod@glasgow.ac.uk</u> Tel: 0141 211 0694

Thank you for taking the time to read this Information Sheet and for considering taking part in this study.





People's feelings after preparing for and participating in a session using mental imagery

Contact details:	Melanie Galla University of Section of Psy 1055 Great W Glasgow, G12 Email: <u>m.galla</u> <u>i.camp</u>	gher or Iain Campbell Glasgow, ychological Medicine, estern Road, 2 0XH agher.1@research.gla. bbell.2@research.gla.a	<u>ac.uk</u> <u>c.uk</u> Please initial tl	he BOX
I confirm that I have r November 2013 for th	ead and understander above study.	d the information sheet of	dated 22nd of	
I confirm that the rese	archer has answer	ed any queries to my sat	isfaction.	
I understand that my p the project at any time consequences.	participation is volue, without having to	untary and that I am free o give a reason and with	e to withdraw from out any	
I understand that I can	withdraw my data	a from the research data	base at any time.	
I understand that any i confidential and no int	information record formation that idea	led in the investigation we ntifies me will be made	vill remain publicly available.	
I give permission for r	ny G.P. to be info	rmed that I am taking pa	rt in the study.	
I consent to being a pa	articipant in the pro	oject.		
Name of Participant		Date	Signature	
Name of Witness		Date	Signature	

1 copy to the patient, 1 copy to the researcher, 1 original for the patient's notes.

Appendix 2.3 Motivation for intervention measure

Motivation for Intervention

For each of the following statements, please indicate how true it is fo you, using the following scale:

1	2	3	4	5	6	7
Not at			Somev	vhat		Very
all true			true			true

I expect to enjoy doing this activity							
1	2	3	4	5	6	7	
Not at			Somev	vhat		Very	
all true			true			true	

I think I'll be pretty good at this activity

1	2	3	4	5	6	7
Not at			Some	what		Very
all true			true			true

I feel nervous about doing this activity

1	2	3	4	5	6	7
Not at			Some	what		Very
all true			true			true

I believe I have some choice about doing this activity

1	2	3	4	5	6	7
Not at			Some	what		Very
all true			true			true

I believe doing this activity could be beneficial to me							
1	2	3	4	5	6	7	
Not at			Somev	vhat		Very	
all true			true			true	

Appendix 2.4 Attentional bias to compassion/threat measure

(Example of one of the three exercises)

Spatial Awareness (Exercise One)

The grid below contains a number of hidden words. These may be hidden forwards, backwards, up, down or diagonal. You are to find as many words as you can and draw a circle around them when you find one. Write it at the bottom of the page after you have circled it.

Work as quickly as you can. Good luck!



Appendix 2.5 Knowledge of imagery intervention measure

Knowledge of Imagery Intervention

- •Imagining pictures in your mind can:
 - a) Make you win the lottery
 - b) Cause changes in your mood and in your body
 - c) Make other people feel happier
- •If your mind wanders during the exercise you should:
 - a) Start shouting
 - b) Gently try to focus your mind back on the task
 - c) Think about a memory of a time when you were on holiday
- •Compassion involves:
 - a) Caring for someone or something, knowing when they're distressed and wanting to help
 - b) Being attracted to someone
 - c) Having a good sense of humour and telling jokes
- Relaxation involves:
 - a) Running up and down a set of stairs
 - b) Getting really excited about something that's going to happen
 - c) Releasing tension or worries

Appendix 2.6 Preparatory Video script

Script: Preparation for Imagery Task

Online version can be found at: https://vimeo.com/82151402

Introductions

Service user (played by actor): in flat

Psychologist : in office

Service user: Hello my name is Dan and I've been asked to tell you a bit about a new therapy which I hear you're about to take part in. I'm talking to you because I experienced a head injury a couple of years ago *and* I've taken part in this new therapy myself.

I've been asked to tell you some of my ideas about it and what other people have said about it because this new therapy is now being tried with other people who've experienced a head injury. It is thought that it might help people to feel calmer and more connected to the people around them.

Psychologist: We find that people find it easier to engage with a new therapy if they feel prepared for it. To be prepared for Mental Imagery the following points need to be considered:

Shown in text across screen with therapist speaking

- 7. What is this therapy and who does it work for?
- 8. What does the therapy involve? (Iain: and what will happen during the therapy)
- 9. How will I do it? (Iain: what someone would need to do and tips for making it easier)
- 10. What do we mean by compassion? (Iain: there are some words used during the therapy that most people don't tend to use in everyday life so it's worth looking at them. One is 'compassion' and the other is...)
- 11. What do we mean by relaxation? (Iain: ...'relaxation').

What is this therapy called and who does it work for?

Psychologist: This therapy uses something called 'mental imagery.' It involves thinking of pictures in your mind's eye. The idea is that imagining these pictures can cause changes in your mind and body.

In order to show people what I mean by this, I would sometimes ask them to close their eyes and imagine the sight and smell of your favourite meal. Maybe it's a hot roast chicken with roast potatoes or maybe it's a fish supper. I would get them to really imagine how their favourite meal would look on a plate in front of then, and how it would smell. What people tend to find is that they start to produce saliva in their mouth and they actually start to feel hungry, just from imagining something in their mind's eye. This can even stimulate stomach acids, just as they would react if the meal was actually in front of them. That's the key point: imagining pictures in our minds can actually cause changes in how we feel. Imagining pictures in our minds can cause real changes in the mind and in the body.

Psychologists are aware of the power of this approach and have been using this technique to promote real changes with their clients for some time now. The task which I want to prepare people for doesn't involve thinking about food but involves imagining different things. It might involve imagining a peaceful place or asking someone to think about themselves possessing lots of positive qualities, such as being strong, kind and caring toward someone or something.

Imagining this might cause positive changes in the mind and body. Some people who have tried tasks like this in the past have felt more relaxed, less critical of themselves and more able to be warm and kind towards themselves and others. This is a new therapy and but we hope that people who have experienced a head injury will find these positive effects too.

•Text: Imagining pictures and sounds or smells in your mind can cause changes in the mind and body.

What will the therapy involve?

Service user: So what will you need to do? You'll be working one-to-one with a professional therapist, so they'll be there to help if you feel a bit wary or a bit unsure about what to do. The session should last an hour, with a break in the middle for about ten minutes. You'll be sitting down in a room with the therapist and they'll ask you get yourself comfortable and then to breathe in a slow, calm way. That can feel a bit strange at first, but you get used to it with a bit of time and practice. I've found that breathing slowly and calmly has helped to train my body to feel relaxed. You'll also be asked to close your eyes if you feel comfortable with that. I felt a bit funny about that, especially with someone else in the room, but after a while I relaxed into it. The therapist will then read you some information to guide you to imagine different pictures and feelings in your mind's eye.

(Shot of psychologist and service-user sitting down and beginning to do the therapy)

• Text: A therapist will read you some information and help you to form pictures and feelings in your mind.

What images will I be forming in my mind?

Psychologist: There are lots of useful images to imagine which can bring about positive changes in people's minds and bodies. I might ask them to think about pictures, places, memories or feelings. This might be imagining a peaceful place, like a beach. Or it might involve picturing the best version of themselves – by that we mean imagining themself having lots of positive qualities such as being a strong or wise or kind and caring person.

How do you form these images?

Psychologist: Whenever anyone is asked to form pictures in their mind's eye, there are a few things that they tend to find difficult about it. It's important to remember that every single person who completes these tasks will struggle with some of these things and if that happens it's fine – it's normal and doesn't mean that imagery isn't working for you.

1. 'Wandering mind'

Psychologist: It's hard to stay focused on one thing for long. Everyone will find that their mind wanders when they're listening to the radio or watching the television – we all find it hard to keep our attention on one thing. We expect people to find it hard to stay focused when practising imagery, especially if they are new to it. This is completely normal.

Service user: When I was trying to imagine pictures and feelings in my mind, I found that I started thinking about different things and didn't manage to listen to all of it. I thought about what I might have for dinner that night, or a conversation I had had with a mate the night before. I started getting quite annoyed with myself when I noticed I had wandered, but was advised by my therapist to just focus back on the task when I could. Once

I accepted that my mind wanders, just like everyone else's, I stopped getting annoyed at myself for it.

• Text and sound: It's normal for your mind to wander during tasks and this happens to everyone. When you notice this has happened, just gently bring your focus back on to the task and to what the therapist is saying.

2. 'No clear pictures'

Service user: A lot of people have also said that they find it hard to form a really clear picture in their mind when they're trying to imagine something. When I was doing it, I thought the picture in my mind should look like a photograph, but it didn't. I thought I wasn't doing it right. To practise, I tried imagining a picture of an apple in my mind. I could see a bit of colour and an outline of an apple, but it kept changing and it definitely didn't look like a photo of an apple. But I've come to realise that it didn't matter if I couldn't get an exact copy in my mind. I found it was just as helpful to get close to what I was trying to imagine, like getting a sense of the apple, trying to make it red and imagining the stem and the body. Or when I was trying to imagine a place or a feeling I just saw bits of colour and fleeting bits of pictures. I know now that this is what most people see. It's more helpful to think about how it makes me feel, like to really concentrate on a sense of peace and quiet when thinking about an image of the beach or to really think about wanting to help someone when thinking about a kind person.

• Text and sound: It's difficult to form clear images in the mind. Focus on the feelings and just create whatever image you can – all images are ok.

3. Forming feelings

Service user: The therapist kept telling me to focus on my feelings. At one point I thought 'I don't have these feelings, how can I imagine I have them?' But I was asked to *act* as though I had them, to really try to imagine those feelings. Sort of like an actor really tries to feel upset or angry or happy when he is in a film, even if that's not really how he's feeling.

• Text and sound: It can be difficult to form images and feelings; try not to get annoyed at yourself if you're finding this hard. Just focus back on the feelings as best you can.

The therapist used some words I didn't really recognise. I mean, I'd heard these words before but I hadn't ever really used them. To be honest, I wasn't sure I knew what they meant. There were two words in particular that I learned more about after the task with the therapist; one was 'compassion' and the other was 'relaxation.'

What do we mean by compassion?

Service user: In one of the tasks, the therapist might start talking about 'compassion.' I thought 'what are they going on about now, that's not a word I would ever use, compassion.' So the therapist explained it a bit more. They explained that feeling compassion towards someone or something is like the opposite of falling out with them. It's about feeling connected to them, caring about them, thinking about what they're feeling and wanting to help. I thought a bit about when my dog was ill...I loved that wee dog, knew it was hurting and I would have done anything to make him feel better. That's compassion. But I also thought about when my team lost the Scottish cup final. Me and my pals were absolutely gutted. But in a strange way we were all in that moment together.

Do you know what I mean? We were connected and we were there for each other, even though we were greetin' into our pints! I remember looking at one of them and knowing exactly what they were going through. We were connected in the loss of the Cup and I felt what he was feeling. We tried to cheer each other up with a bit of patter afterwards. So even though that was a bit of a sore one, there were also nice feelings and memories attached to it. That's compassion too.

My sister also said she felt compassion towards her friend when her husband was ill. It's about caring for someone or something, knowing when they're upset or distressed or in pain and *wanting to help them*.

• Text and sound: Compassion is caring for someone or something, knowing when they're suffering and wanting to help.

(Pause DVD here. Indicate to the participant that in the imagery task, they may be asked to think of a time when they have:

1. Felt connected to someone or something or a group

2. Cared for someone or something and wanted to help if they were distressed/upset/in pain.

Discuss any part of this which the participants does not understand)

Psychologist: Feeling compassion towards other people is usually a very positive thing. But research has also built on this to show that if people are able to practice feeling compassion towards *themselves* that this can help them to feel much better about themselves.

Service user: At first, I felt a bit uncomfortable when talking about compassion in relation to *me*. I was asked to think about 'me at my best' and was told to think about being compassionate towards someone else. Where I come from, you don't show your feelings for anyone else, at least not when it's caring about someone. I've spent my whole life hiding that. So to be honest I wasn't sure what to do during parts of the task, and it made me a bit uneasy. But I've since learned that it can be a strength, to care about other people and want to help them out.

I started to think of myself as a strong, caring person who wanted to help people out when they were distressed. It was a bit weird but after I had gotten used to it, I started to feel quite good.

The therapist helped me to stick with the feeling, and to get used to it, even develop it. If you're uncomfortable with that feeling too, then you can talk to the therapist about it; they reminded me that being honest about feeling kind and caring was new to me and it was normal that I might not be that comfortable with it. But sticking with it has been worth it to help me feel better about myself and other people. The therapist told me to really concentrate on *feeling* strong, kind and caring, even if I didn't *think* I was at the time.

• Text and sound: Some of the feelings may be uncomfortable or new. Try to stick with imagining the feelings if you can, and to remind yourself that it will feel more comfortable with more practise.

What do we mean by relaxation?

Psychologist: When using imagery, one of the words commonly used is 'relaxation.' Relaxation is about releasing tension and worries. If people imagine a place where they think they would feel relaxed, such as a beach with the sun warming their face, or a sitting beside a flowing river,

they might actually find that their mind and body feels relaxed and calm. Imagining some relaxing images can help with this. Breathing in a relaxed and soothing way can help too.

(Pause DVD here. Indicate to the participant that in the imagery task, they may be asked to think of a time when they have:

- 1. Felt very relaxed
- 2. Consider the place in which they have felt relaxed e.g. beach, forest Discuss any part of this which the participants does not understand)

• Text and sound: Relaxation is about releasing tension or worries

Summary

Service user: Well I hope you feel you know more about the therapy now. You're about to get a taste of imagery yourself. But before you do, it will be worthwhile to try to remember some key things:

• Imagining pictures and sounds or smells in your mind can cause changes in the mind and body.

•A therapist will read you some information and help you to form pictures and feelings in your mind.

• It's normal for your mind to wander during imagery tasks and this happens to everyone. Just try to focus on the task when you notice this has happened.

• It's difficult to form clear images in the mind. Focus on the feelings and just create whatever image you can – all images are ok.

•It can be difficult to form images and feelings; try not to criticise yourself if you're finding this hard.

•Compassion involves caring for someone or something, knowing when they're distressed and wanting to help.

•Some of the feelings may be uncomfortable or new. Try to stick with the feelings if you can, and to remind yourself that it will feel more comfortable with more practise.

• Relaxation is about releasing tension or worries

Appendix 2.7 Development of preparatory video and compassionate imagery script

Introduction O'Neill and McMillan, (2012) used a controlled trial to examine the effectiveness of a short 30-minute compassionate imagery exercise in individuals with SHI. Although the intervention had no effect on empathy, a near-significant increase in self-compassion was found in compassionate imagery treated patients and relaxation treated controls. This trend suggests that improvements in the provision of the intervention and other modifications to the study design may allow detection of significant effects of a short intervention on self compassion; an effect which could potentially enable patients to self-soothe and reduce anxiety or threat focussed thoughts and behaviours. O'Neill and McMillan (2012) found a high fear of compassion amongst participants in their study and also remarked that the language used in the CFI intervention may not have been acceptable within the demographic group most commonly affected by SHI, namely, younger men from lower socio-economic backgrounds. As the second most common cause of SHI in Glasgow is assault (Thornhill et al, 2000), it is possible that such a sample of individuals who have experienced SHI may be more likely to have experienced violence within their past relationships, and so may be more likely to activate threatening memories when asked to take part in CFI. Therefore the language of CFI and fears of compassion could have contributed to finding a non-significant result within the O'Neill and McMillan (2012) study, and attempts to alter this may improve outcome in future CFI studies. The present study was therefore concerned with determining whether the imagery script used within O'Neill and McMillan (2012) should be altered, and if so, in what way, and also to consider what information might be used to adequately prepare participants for a compassion focused imagery exercise.

Methods

1. Focus Group

A consultant psychologist working within a local brain injury inpatient rehabilitation unit approached potential participants to take part in a focus group to determine their opinions on a short compassion focused imagery exercise. Two Trainee Clinical Psychologists led this focus group session, in which an excerpt of the CFI script used by O'Neill and McMillan (2012) was read aloud and participants' opinions were sought on:

- a. Initial thoughts on the experience:
 - What do/don't you like about it? Were you comfortable/uncomfortable with any parts of it?
 - What did you think about the language used?

- Who do you think would benefit from this (e.g. people with/without head injury or people may speak about specific groups of people such as age, gender groups?)
- c. What would you want to know about this therapy before you decided whether to take part in it or not?
- *d.* What would make this therapy more appealing to you?

This session lasted for 1 hour 15 minutes and was held within the brain injury rehabilitation unit.

Participants in Focus Group A group of 8 participants took part in this; 6 of these participants were patients within a brain injury rehabilitation unit in Glasgow (4 males; mean age 46.4 years (SD 10.57); all British nationals; 4 individuals had been affected by TBI [2 as a result of RTA, 2 as a result of a Fall] and 2 individuals by another form of ABI; 2 were from the most deprived 'band 1' of Scottish Index of Multiple deprivation, 2 from 'band 3', 1 from 'band 8' and 1 from least deprived 'band 10') and 2 were members of staff in the inpatient rehabilitation unit (1 consultant clinical psychologist, 1 assistant psychologist).

2. Recent literature was consulted

On preparation for CFI: from Gilbert (2009;2010); the only single case study of the use of CFT following TBI known to the author (Ashworth, Gracey & Gilbert, 2011); and review articles relating to the adaptation of therapy following ABI (Block & West, 2013; also see systematic literature review within this thesis).

3. Expert in field consulted

Finally, once drafts of the preparatory video script and CFI script had been constructed, Dr Ashworth, a Clinical Psychologist with an expressed interest in CFT and TBI who had conducted the above mentioned single case study was contacted for feedback. The scripts were altered following this feedback.

Information from Focus Group The focus group suggested that individuals were familiar with controlled breathing from relaxation groups. Three participants indicated that they found it difficult to keep their mind on the imagery exercise, but all participants indicated that they enjoyed the exercise. In relation to the language used, one individual indicated that there were many words that they wouldn't routinely use "I was wondering what you first meant, I was

thinking 'I don't speak like that." With respect to compassion, most members indicated that they could connect with this word, and one person described it as 'caring and sharing.' The consultant clinical psychologist questioned whether it could be seen as 'the opposite of falling out with someone' and also indicated that in preparation, he would want to know who this worked for and whether it would be likely to work for him. Generally, participants indicated that the exercise was not shocking to them and this seemed familiar due to experience in relaxation classes. The consultant psychologist reported that it would be good to take longer over the exercise, to include more pauses, and more repetition, perhaps with breaks for reflection. Also, he indicated that in relation to the language used, it would be good to use concrete examples, rather than the abstract ones used in the exercise.

Information from literature From a short review of literature into adaptations to facilitate treatment of those affected by TBI, a review article by Block and West (2013) provided useful information, some of which was based on Folzer (2001) and other studies. See systematic review within the present thesis for this information.

Information from experts in field Dr Ashworth indicated that using concrete examples which participants can relate to is generally useful within CFI exercises within a TBI population. Football was suggested as a good example, used with many men in clinical practice, to consider a sense of belonging and empathy with friends. Particularly with males, it was indicated the 'you at your best' imagery exercise in CFT would be likely to be the least threatening type of imagery initially, and that focusing on strength and courage prior to love and warmth may be more comfortable for some. In relation to the preparatory video, it was suggested that this referred to scenarios which people may be able to relate to (e.g. football) and that this referenced the exercises which participants would be asked to do within the imagery session. Dr Ashworth indicated that three principles of (1) shortening the material, (2) going at a slow pace, and (3) repetition, should be borne in mind within both the video and imagery exercises. She also emphasised the importance of reducing cognitive load and allowing time for reflection in order to account for slowed processing and to provide the opportunity for reinforcement. A timing outline for the imagery exercise was outlined as: 15 mins imagery, 5 minute reflection, 10 minute complete break, 15 mins imagery, 5 minute reflection.

Development of video The preparatory video utilised 'preparing for compassionate exercises' and 'introducing imagery' (Gilbert 2010; p.32-47) as a framework. Considering information from literature and experts in the field, concrete examples of compassionate imagery and relaxation imagery were added, repetition was used through short summaries at the end of each section and a longer summary at the end. Information was also presented in oral and a written format on screen in order to aid processing. Furthermore, two short pauses were added in
order to aid reflection, processing, and for participants to consider images which they may utilise in the imagery task, to link the video with the imagery task. As the purpose of the video was to prepare individuals for either the relaxation imagery task *and* the compassionate imagery task (as all participants would watch the same video), the definitions of relaxation and compassion were introduced. It was determined that the primary aim of the video was to introduce concepts which individuals were likely to find difficult (e.g. 'wandering mind,' or not experiencing 'clear images' as discussed by the focus group and Gilbert, 2010) and offer information relating to this. Furthermore, it was to introduce concepts which would be discussed within the imagery task. A copy of the script for this video and a link to the online version can be found in Appendix 2.6.

Alteration to script for Imagery tasks In O'Neill and McMillan (2012), the imagery task had a duration of 30 minutes, which included some information relating to controlled breathing, and then the imagery task. This was increased to 50 minutes within the present study, and was split according to the timings recommended by Dr Ashworth, meaning that participants were able to complete imagery, reflect on this and then *repeat the same imagery* and reflect on this again. It was considered that this covered several points outlined in the information gathered from the literature review.

Other considerations for study preparation A visual timetable of the study was constructed, to be kept on the table throughout the study. Furthermore, it was determined that all questionnaires would be read aloud by the researcher to aid processing.

Short discussion of outcome Information was gathered from a small focus group, experts working in the field of CFT and TBI and also through a small review of relevant CFT literature and TBI literature. Clear limitations are that the focus group was small and therefore may not be representative of a TBI sample, and also participants in this group may have been keen to provide positive feedback on the experience of CFI. Furthermore, alterations made to the CFI, relaxation and preparatory scripts were based on some anecdotal evidence from an expert in the field, and this information has not been scientifically tested. However, information from experts in the field did mirror that from published literature. Given the resources available to this preliminary part of the study, alterations were made which were found to be acceptable to experts in the field, and which took relevant literature into account. In future research, it may be useful to complete qualitative interviews on an individual basis to consider participants' reactions to compassion focused imagery; such interviews may be less affected by social desirability bias.

Appendix 2.8 Research Proposal

MAJOR RESEARCH PROJECT PROPOSAL

EFFECT OF PREPARATORY INFORMATION ON FEAR OF COMPASSION AND EXPECTATIONS OF A COMPASSIONATE IMAGERY EXERCISE

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DATE OF SUBMISSION: 09/08/13

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ABSTRACT

Background Previous research has indicated that a single session of compassion-focussed imagery (CFI) or relaxation was related to a trend toward improvement in self-compassion amongst a group of individuals with Severe Head Injury (SHI) (O'Neill & McMillan, 2012). Other research has also suggested that preparing individuals for therapy can promote beneficial effects, such as lowering anxiety about therapy. There is a need to determine whether the previous CFI intervention can be improved through the addition of preparing participants, amongst other changes. Aims The main aim of the present study is to determine whether providing preparatory information about interventions which aim to reduce response to threat, such as CFI or relaxation, will reduce fear of compassion. Secondary aims are to determine whether this preparatory information will make a compassion-focussed imagery intervention more effective overall, and whether it will alter mood, fear of compassion and motivation for the imagery intervention. Methods Participants will be shown a video containing information which will prepare them to take part in the CFI exercise. Pre- and post- information measures of mood, motivation for an intervention, fear of compassion and an attentional measure to threat will be taken. Participants will then proceed to a linked study where they will take part in a compassion-focussed or relaxation based imagery exercise, and separate outcome measures will then be taken. Applications Together with the linked study, this research should improve upon the methodology of a previous CFI single-session trial, and should indicate whether this is an effective treatment for individuals who have experienced SHI. If successful, it should also improve evidence base for and reduce barriers to accessing psychological therapy in people with SHI.

INTRODUCTION

Severe head injury (SHI) often has a significant impact on personality, resulting in disinhibition, aggression, irritability, and impairments in empathy and executive function (Howitt, 2002). These change in emotional processing and personality can have a profound impact on an individual's life, and has been described by family members of those affected by SHI to be the most stressful effect of the injury (Brooks & McKinlay, 1983).

A recent single case study suggested that Compassion Focussed Therapy (CFT) can be adapted for use with those who have experienced severe head injury (SHI) in order to aid emotional adjustment to their injury (Ashworth, Gracey & Gilbert, 2011). They explain Gilbert's (2009) model, that CFT is based on a neurophysiological model of affect regulation which predicts that 'threat-focused' emotions can be regulated through the development and use of 'affiliative' soothing emotions. On the basis of this neurophysiological model, Ashworth et al. suggest that CFT may be particularly useful in conceptualising emotional responses to SHI and developing interventions in rehabilitation after SHI. 'Threat-focused' emotions include anxiety, anger and disgust (Gilbert, 2009). The 'threat system' outlined in CFT may therefore be particularly salient when considering the changes in emotion after SHI, particularly aggression and irritability, and the subtle but significant effects of misinterpretations arising from interactions which may require empathy and/or compassion. Within the present study, participant's compassion towards themselves and others will be a main focus, but empathy will also be measured, and so the distinction between both constructs is an important one. 'Empathy' is defined as the ability to understand and share the feelings of another, whereas the meaning of 'compassion' is having an awareness of the suffering of another with the wish to relieve it. Therefore, although both terms relate to an understanding of emotion, compassion is considered to be more active, and empathy relatively passive.

Short compassionate imagery exercises produce an increase in soothing emotions in a student sample (Rockliff et al. 2008). Furthermore, O'Neill and McMillan, (2012) used a controlled trial to examine the effectiveness of a short 30-minute compassionate imagery exercise in individuals with SHI. Although the intervention had no effect on empathy, a near-significant increase in self-compassion was found in compassionate imagery treated patients and relaxation treated controls. This trend suggests that improvements in the provision of the intervention and other modifications to the study design may allow detection of significant effects of a short intervention on self compassion; an effect which could potentially enable patients to self-soothe and reduce anxiety or threat focussed thoughts and behaviours.

Gilbert (2011) has indicated that people who are self-critical and fearful of compassion, may require preparation for CFT in order to find this therapy more acceptable and less threatening. Indeed, it is thought that fears of compassion can develop because compassion itself can become the focus of the threat system. Gilbert (2011) suggests that asking participants to feel kindness and compassion for themselves or others can activate their attachment system, which can activate negative memories of feeling alone, abused, shamed or vulnerable within their past relationships. This can then activate learned defences within individuals, which stimulates the production of cortisol and the fight-or-flight response. Thus, fears of compassion and defences against compassion may develop, and people who are more likely to block emotions associated with safeness and warmth may replace these with fear and aggression. O'Neill and McMillan (2012) found a high fear of compassion amongst participants in their study; as the present

study aims to use a sample of participants from the same population, it is likely that fears of compassion will be reported by this sample. O'Neill and McMillan (2012) also remarked that the language used in the CFI intervention may not have been acceptable within the demographic group most commonly affected by SHI, namely, younger men from lower socio-economic backgrounds. As the second most common cause of SHI in Glasgow is assault (Thornhill et al, 2000), it is possible that such a sample of individuals who have experienced SHI *may* be more likely to have experienced violence within their past relationships, and so may be more likely to activate threatening memories when asked to take part in CFI. Therefore the language of CFI and fears of compassion could have contributed to finding a non-significant result within the O'Neill and McMillan (2012) study, and attempts to alter this may improve outcome in future CFI studies.

Providing preparatory information prior to psychological therapy can improve treatment engagement, reduce anxiety and provide patients with more accurate therapy expectations (e.g. Deane et al., 1992). Furthermore, Johansen et al. (2011) found that different types of video preparation material (e.g. focussing on therapeutic alliance or experiential acceptance) are related to different changes in affect and therapist-rated alliance after one session of therapy. Such preparatory information has not yet been utilised within a trial of CFT or CFI interventions; it remains to be tested whether a short recorded preparation for compassion focussed imagery could result in reduction in anxiety regarding the intervention and of fears of compassion.

In response to the potential problems noted in previous research about the acceptability of CFI language for the demographic profile of people most affected by head injury, the present study aims to firstly obtain qualitative information on attitudes towards compassion focussed imagery (CFI) interventions from a small sample of individuals affected by head injury. This information will then be used to inform the creation of a CFI preparatory intervention and to tailor the language used within a CFI intervention. Given the results of previous research, it seems likely that participants will report some fears of compassion (O'Neill & McMillan, 2012), therefore a second aim of this study is to explore characteristics of FoC in people with SHI. Related to this, a third aim will be to determine the patterns of change in FoC, following preparatory information and whether this change correlates with the subsequent magnitude of response following CFI within Iain Campbell's linked study (see Appendix E for abstract of this study).

The fourth, and main, aim of this study is to determine whether providing pre-therapy preparatory information augments the effect of CFI on fear of compassion, affect and motivation to engage in treatment. The present study is linked to another Trainee MRP which is a one session treatment trial comparing compassion based imagery with a relaxation exercise. The outcome variables are changes in empathy and self-compassion and the participants are people who have experienced a severe head injury. As such, the fifth aim of the present study is to provide all participants for the linked study with preparatory information, rather than to contrast the effect of preparatory information with a control group. This should provide an equivalent experience for both CFI and relaxation group in the linked study, and may help to provide conditions conducive to an effective one-session CFI intervention. Finally, the sixth aim of the present study is to use an attentional measure to access subtle changes arousal of the threat versus affiliative systems. This will therefore aim to reduce the sole reliance on having questionnaire measures of change in these 'biopsychosocial' systems. The present study will

aim to explore the relationship between questionnaire indices of threat from compassion and this attentional measure.

HYPOTHESES

•A reduction in fears of compassion, negative affect and anxiety will occur following compassion focussed preparatory information.

•An increase in motivation for CFI and relaxation imagery interventions will occur following preparatory information.

•Those participants who show a greater reduction in fears of compassion following preparatory information will show a greater response to a CFI intervention within a linked study.

PLAN OF INVESTIGATION

Participants

Inclusion and exclusion criteria

Participant recruitment is based on the procedure outlined by O'Neill and McMillan (2012).

Inclusion criteria

Participants will be aged 18 to 65 years old, with a history of serious head injury (defined as post traumatic amnesia > 1 day; Russell, 1935) that occurred at least three months prior to testing. They will also have capacity to consent, as defined by professional staff members responsible for their care.

Exclusion criteria

Individuals with a learning disability, deteriorating neurological condition; ongoing alcohol and/or drug abuse; visual, hearing or communication difficulties that might affect ability to consent or understand/comply with test procedures, or severe mental illness that would prevent effective participation in the study will be excluded from the study.

Participant recruitment

Participants for an initial focus group will be approached through Headway, a registered brain injury charity. Subsequently, participants for the preparation/ information study will be identified and approached through inpatient brain injury rehabilitation services in the West of Scotland, primarily Graham Anderson House and the Murdostoun Unit, and also community groups such as Headway and West Dunbartonshire Brain Injury Project

Measures

The following assessments will be conducted prior to preparatory information. A description of each measure, including psychometric properties where appropriate, can be found in Appendix A.

• **Balanced Emotional Empathy Scale (BEES) (Mehrabian, 2000).** A baseline measure of empathy, to examine this as a covariate.

• **Test of Premorbid Functioning (Wechsler, 2011).** A measure to estimate pre-injury IQ and memory abilities, to examine this as a co-variate.

• The Symbol-Digit Modalities Test. (Smith, 2010). To detect cognitive impairment, to examine this as a covariate.

• The Self Compassion Scale (Neff, 2003). A measure of compassion towards self, this will be an outcome variable within the linked study, to measure changes in this before and after CFI/relaxation intervention.

Pre and post-preparatory information assessments will include:

• Positive and negative affect schedule (PANAS) (Watson, Clark, & Tellegen, 1988). This will be a measure of outcome, measuring change in positive and negative affect before and after preparatory information.

• Fears of Compassion Scales (Gilbert, McEwan, Matos & Rivis, 2011). This will be repeated and will measure change in fears of compassion before and after preparatory information. It will measure fears of expressing compassion towards others, responding to compassion from others and expressing compassion towards oneself.

• Motivation for intervention scale. This will be adapted from the Intrinsic Motivation Inventory (IMI) (Ryan, 1982). This will measure change in motivation for the CFI or relaxation intervention before and after preparatory information.

• State-Trait- Anxiety Inventory, Short form (STAI, six item version) (Marteau & Bekker, 1992). The key measure from this will be change in state anxiety before and after preparatory information.

• Measure of attentional bias to threat. This will be an adaptation of the Imbedded Work Task (Wenzlaff et al., 2001), which involves identification of words embedded in a letter grid or 'word search' to measure attentional bias of depression-prone individuals to positively/negatively valenced words. This will measure change in attentional bias towards threat words before and after preparatory information.

Post- preparatory information assessment:

•Measure of knowledge of imagery interventions (constructed by researcher, can be found in Appendix B).

DESIGN

A repeated measures design will be used with the pre-post intervention difference on measure of fears of compassion, PANAS and motivation for intervention as the main outcome variables.

Research procedures

The present study will form the 'preparatory phase' which will then lead on to a linked study containing the 'intervention phase,' meaning that two researchers are involved in the study as a whole. Within both parts of the study, one researcher will complete all assessments and the other researcher will complete the preparatory information and CFI/relaxation information. The researcher responsible for intervention will randomly allocate participants to treatment, thus blinding the researcher involved in assessment to treatment type.

Preparatory Phase

Part one of the present study will involve a focus group, where qualitative information will be sought to inform the construction of preparatory information and the delivery of CFI intervention.

Preparatory Information Production. The short preparatory DVD will be produced and shown to all participants. In order to reduce expectation bias relating to the specific intervention, the DVD will inform patients about procedures involved in a general 'imagery exercise' which aims to help individuals with 'management of the threat response,' and it will contain information on themes central to compassion focussed theory. An outline for this has been based on Gilbert (2009), and the final information will be altered by the results of the focus group (see Appendix C).

Part two of the present study will constitute the main data collection phase. Within an inpatient unit, each participant will be asked to complete all baseline measures with the support of the researcher. They will then be asked to watch the preparatory DVD within a quiet room, with a Trainee Psychologist present. There will be a break for a five-minute discussion in the middle of this DVD in order to reduce the likelihood of fatigue and to maintain attention. Following the DVD presentation, the participant will again be asked to complete the specified post-preparatory information measures.

Intervention Phase This phase will be conducted as part of another study, and will involve participants being randomly assigned to a CFI or relaxation intervention. Full details of this study can be found in Iain Campbell's MRP Proposal. Figure 1 shows the overall procedure of the two studies.

Settings and Equipment

Participants will be asked to take part in the study within the inpatient unit or community group from which they had been recruited. Necessary equipment will be neuropsychological assessments, psychometric measures, attentional measures, and an encrypted laptop.

Qualitative analysis of focus group information informs the production of preparatory information DVD and compassion focussed imagery intervention.

Participants recruited from inpatient brain injury units and community groups



- •Balanced Emotional Empathy Scale (BEES) Test of Premorbid Functioning
- •The Symbol Digit Modalities Test Self Compassion Scale

Heart rate monitoring equipment will be attached and participant will have 10 mins to sit in room alone for baseline measure

- Participant will then complete repeated measures for preparatory phase:
- PANAS •Intrinsic Motivation Inventory •Fears of Compassion Scale •STAI-short form •Attentional bias to threat
- And the repeated measures for the intervention phase:
- Self Compassion Scale Relaxation Measure The Empathy Quotient



Figure 1. Procedure for preparatory phase (present study, in black) and intervention phase (linked study, in red)

DATA ANALYSIS

Descriptive analysis will indicate whether participants report fears of compassion, and if so, the types of fears they reported. Subsequently, paired samples t -tests will be used to assess change

in pre-post information measures (fears of compassion, PANAS, STAI, motivation for intervention). Pearson correlations will examine the relationships between knowledge of the CFI intervention following information and the overall effect of the intervention. A split-half comparison will determine whether changes on fears of compassion within the present study are related to outcome after intervention in the linked CFI study.

Sample size estimation

As there have been no studies of this kind with this population, the likely effect size and required sample size are difficult to estimate. Previous studies have used the Fears of Compassion Scale as a baseline rather than as an outcome measure, therefore it would be inappropriate to use such research to perform a power calculation. However, Deane et al. (1992) utilised the STAI-Y (Spielberger, 1983) to measure differences in anxiety prior to and following video-based preparatory information in a sample of adults preparing for outpatient psychotherapy. The present study aims to examine repeated measures effects, therefore a repeated measures analysis of the data from Deane et al. (1992) (mean pre-preparatory information score= 48.47, SD=12.02; mean post score=43.67, SD=12.27; sample size=36) would indicate a medium effect size (dz=0.40) as defined by Cohen (1992), with power of 0.75. This result was reached using the default correlation setting of 0.5 within G*Power3 (Faul, et al., 2007).

Although the present study will be conducted using a sample of patients who have experienced a head injury, it seems reasonable to consider that a similar effect size could be found, considering the similar format of preparatory information presentation and sparse research within a head injured population. With an 80% power to detect a medium effect size (dz=0.4), and an alpha set at .05, it is estimated that a total sample size of 41 participants would be required to find a significant effect.

All participants within the present study will be offered the imagery intervention within the wider study. Naturally, sample size will be dependent upon the availability and willingness of patients to participate in the present study.

HEALTH AND SAFETY ISSUES

Participant health and safety

Participants may become uncomfortable due to the length of intervention and testing, or the content of the intervention. The author, a Trainee Psychologist, will be present throughout the study which will be conducted on a one-one basis, therefore discomfort should be noted and attended to. Regular breaks will be offered, and participants will also be able to break at any point. The researchers will liaise closely with professionals involved in patient's care to ensure they are physically and psychologically able to take part.

Researcher health and safety

There is a risk that, following head injury, some participants may find it difficult to control emotional expression, which might include aggression. Researchers will liaise closely with inpatient unit staff to ensure a safe room for researchers and participants is chosen, and personal alarms may be worn if necessary.

ETHICAL ISSUES

Ethical approval will be sought from the West of Scotland Research Ethics Committee. Length of intervention will be balanced to consider least possible disruption and fatigue to patients and maximum likelihood of effectiveness of the interventions. To this aim, participants will be informed that they are able to stop or break the intervention or measurements. Participants will be blinded to the type of intervention they will receive following preparatory information, which may impact on informed consent. However, they will be provided with information on the content of 'an imagery intervention' and will be debriefed following the study. It is not anticipated that fears of compassion will cause significant distress during the CFI intervention phase, as it is possible that fears of compassion may lead participants to avoid connecting with compassionate imagery, thus avoiding distress. However, the CFI and relaxation interventions will be conducted by a Trainee Clinical Psychologist who will monitor for signs of distress during the intervention, and all participants will be informed that they can withdraw from the study at any point. If the preparatory course and CFI intervention are shown to be effective, it may be possible to offer this to participants who completed the relaxation intervention following the study.

FINANCIAL ISSUES

Neuropsychological measures will need to be bought, and most costs aside from this are likely to be administrative (please see Appendix D).

TIMETABLE

April 2013 – Submit proposal for blind marking

July: August 2013 - Make amendments to proposal, submit to R&D then Ethics

September 2013 – Amendments made as outlined by Ethics Board

September 2013 – Focus Group and film DVD

November 2013: April 2014 – Recruitment

May: June 2014 – Analyse data

July 2014 - Submit

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Appendix A: Description of Measures

• **Balanced Emotional Empathy Scale (BEES)**. This is a measure of emotional empathy. Mehrabian (2000) states that the trait of Emotional Empathy can be used to help distinguish persons who typically experience more of others' feelings from those who are generally less responsive to the emotional expressions and experiences of others. Respondents use a 9-point scale to report their degree of agreement or disagreement with each item. There are 30 items, 15 positively worded and 15 negatively worded. The coefficient alpha internal consistency for the Balanced Emotional Empathy Scale (BEES) is .87 (Mehrabian, 2000).

• **Test of Premorbid Functioning** (Wechsler, 2011). This provides an estimate of pre-injury intellectual functioning. The TOPF is based on a reading paradigm, requiring the reading and pronunciation of words that have irregular grapheme-to-phoneme translation.

• **The Symbol-Digit Modalities Test**. This provides a measure of executive function by requiring attention, visual scanning and motor and psychomotor speed. The test allows written or verbal responding. It involves the conversion of meaningless geometric designs into written and/or oral number responses and can be used for screening for cerebral dysfunction (Smith, 2010). Test-retest reliability was tested within a sample of adults without brain injury for the written and oral form. The test-retest correlation was found to be .80 for the written SDMT and .76 for the oral SDMT. The SDMT has been shown to be effective as a test of "general" brain impairment (Smith, 2010).

• **The Self-Compassion Scale** (Neff, 2003). This scale measures the degree to which individuals display self-kindness against self-judgement, common humanity versus isolation, and mindfulness versus over-identification. Participants rate each item on a Likert scale ranging from 1 (almost never) to 5 (almost always). This measure has good reliability (Cronbach's alphas ranging from .75 to .81).

Pre and post- preparatory information assessments will include:

• **Positive and negative affect schedule (PANAS)** (Watson, Clark, & Tellegen, 1988). This 20item schedule assesses positive affect (PA), such as feeling enthusiastic, active, and alert; and negative affect (NA), such as feeling anger, contempt, disgust, fear, and nervousness. Items are rated from 1 to 5 and totalled, yielding a positive affect summary score and a negative affect summary score. The PANAS scales have good validity and are sensitive to mood changes when used with short-term instructions (Watson et al., 1988).

• Fears of Compassion Scales (Gilbert, McEwan, Matos & Rivis, 2011). These three scales measure fears of: compassion for others (10 items), compassion from others (13 items), and compassion from self (15 items). The items are rated on a 5-point Likert scale (0 = Don't agree at all, 4 = Completely agree). A fear of compassion may inhibit the capacity of compassionate imagery to increase self-compassion and empathy. This measure has been shown to have good reliability (Cronbach's alphas ranging from .76 to .92)

•Motivation for intervention scale. This will be adapted from the Intrinsic Motivation Inventory (IMI) (Ryan, 1982), a 45-item measurement intended to assess participants' interest/enjoyment, perceived competence, effort, value/usefulness, felt pressure and tension, and perceived choice while performing a given activity, yielding six subscale scores. Intrinsic motivation has been described as a measure of 'state' motivation, and should therefore be appropriate for the present study (Choi et al., 2012). The IMI was designed to be adapted by researchers to answer their specific question, therefore different versions have been created. Appendix A shows the original 45 item version and the adapted version for the present study.

• **State-Trait- Anxiety Inventory, Short form** (STAI, six item version.) This six item version shows a reliability coefficient of .82, indicating good reliability. Tests of validity also showed similar concurrent validity for the 20 item and 6-item version of STAI (Marteau & Bekker, 1992).

• **Measure of attentional bias to threat**. This may be an adaptation of the Imbedded Word Task (Wenzlaff et al., 2001), which involves identification of words embedded in a letter grid or 'word search' to measure attentional bias of depression-prone individuals to positively/negatively valenced words. Wenzlaff et al. (2001) indicated that such individuals may be more likely to try to suppress negative thoughts in daily life in order to maintain a neutral or positive mood state. Therefore, they indicated that people may be likely to suppress a bias to negative words within this task, and so introduced a cognitive load designed to disrupt thought suppression (through Ironic Processes Theory, Wegner, 1994) of negatively valenced words. This may be relevant to the particular study, where it is hypothesised that certain individuals might be likely to supress feelings of safeness and warmth, as they are associated with fear (Gilbert, 2011).

Appendix B: Adapted full scales which will be used in this study

Suggested Version of IMI to use in present study and adapted to use pre-intervention Interest/Enjoyment

I expect to enjoy doing this activity very much This activity will be fun to do. I think this will be a boring activity. (R) This activity won't hold my attention at all. (R) I would describe this activity as very interesting. I think this activity will be quite enjoyable.

Perceived Competence

I think I will be pretty good at this activity.

I'll be pretty skilled at this activity.

This is an activity that I won't do very well. (R)

Pressure/Tension

I don't feel nervous at all about doing this. (R)

I feel very tense while doing this activity.

I will be very relaxed when doing this. (R)

I'm anxious about this task.

Perceived Choice

I believe I have some choice about doing this activity.

I feel like it is not my own choice to do this task. (R)

I feel like I have to do this. (R)

Value/Usefulness

I believe this activity could be of some value to me

I think that doing this activity will be useful for helping me to stay calm

I think doing this activity could help me to be in control of my emotions

I believe doing this activity could be beneficial to me.

I think this is an important activity

Knowledge of Imagery Intervention (to determine if people remembered preparatory information)

What are the names of the three systems?

- a) Threat, drive and soothing
- b) Threat, punishing and growth
- c) Spiritual, intellectual and emotional

Which system will you aim to practise using during the imagery exercise?

- a) Threat system
- b) Soothing system
- c) Drive system

How will you complete the imagery exercise?

- a) I'll listen to a tape and do what it tells me
- b) A family member will be trained and will show me what to do
- c) A trained professional will go through the exercise with me

What should you do if you feel uncomfortable during the exercise?

- a) Press a buzzer
- b) Start shouting
- c) Tell a therapist

Appendix C : Example of a preparatory information script

Hello, my name is Frank and I've been asked to talk about what it's like to go through an imagery intervention, much like the one you're about to practise today. I experienced a head injury five years ago after I was involved in a car accident, and my treatment centre suggested that using imagery could help me to manage 'my response to threat'. I thought 'what are they trying to get me to do now? What does that even mean?' But, then I needed some help at the time and thought 'if they think it can make a difference then I'll give it a shot.' And once I got over the strange feeling of it, I actually found it really helpful.

I'm going to talk a bit about this 'threat response' that they told me about, and why imagery can help. Then I'm going to talk a bit about what the imagery task will involve for you.

1. What is the 'threat response?'

So you might be wondering what this 'threat response' is and why I wanted to do something to change it. When I learned about it I was told that our 'threat response' is a natural reaction to any kind of stressful experiences; this reaction hasn't changed much through all of the years of evolution. I was told to think back thousands of years to when men and women lived in the wild; since that time, our bodies and brains haven't changed much at all. At that time, if humans saw an animal, say a lion, running towards them they would need something that would help them get away from that danger; either they would need the strength to fight or to run away. They would need to get their heart pumping quickly and would need lots of hormones like adrenaline to help them to do that. If you didn't act fast enough then you didn't survive.

But since that time our societies have changed a lot, we don't tend to get lions running around near our homes but we do have to deal with a lot of situations which can trigger the same response. This could be things we see, hear or even think about. Yesterday I passed by a bunch of teenagers outside the shops and they were shouting at everyone who went past; I could feel my heart rate picking up then. Even with my family, my daughter spilled a cup of tea in my house the other day and I lost my temper really quickly; I know she didn't mean it but when I start to feel angry there's no logical thinking behind it, just this quick reaction. I guess this 'threat' reaction has to be quick – if it wasn't in the past then humans wouldn't have been able to protect themselves and survive. Just after my head injury I even found it really hard to go out at all, I avoided it because I was convinced that I wouldn't be able to cope with what was out there. At all of these times my threat system would have been kicking in, when I felt anxious or angry. But of course in these situations I didn't fight or run; my body was trying to protect me or prepare me for danger but I didn't really need it. Usually it was my mind that went into overdrive instead, thinking later about what I should have done or what I should have said rather than getting angry. Overall, my threat system was taking over at times and making it difficult for me to feel like I was in control. It was really having an effect on what I did, what I avoided and my relationships with my family.

2. Other systems

I learned that the 'threat system' is one of the three main systems that humans have. The second system, our 'drive system' is focussed on getting the things we want. It drives us to do things, and in our evolution this would have been things that would help us survive like getting food, having sex, maybe getting status. Now, in our complicated societies we can be driven to reach loads of different goals, like gaining status through wearing certain clothes, getting a certain car or trying to get a promotion. Or setting our minds to building something, or training to become good at a sport. It can keep us motivated and give us a great feeling when we achieve something.

But, if our drive system takes over then this could cause us some problems; we might be constantly working or it could lead us to seek food all of the time and overeat, or for us to set ourselves goals that we can never achieve.

The last system is called the 'soothing system.' This helps us to feel safe and calm and is also involved when we feel connected to friends and family. It can help us to feel calm, safe and secure in ourselves. I was told that a lot of people aren't used to using this system, most people are either walking around with a really active 'threat system' or 'drive system' or both.

If you can learn to use your soothing system more it has been shown to be able to balance out an overactive threat or drive system. It can help you to feel calm in your body, which then has a real effect on your mind and your mood. But it can also help you to accept yourself and other people, without feeling that you need to change or they need to change. I can say that living my life with my threat system going off all the time was really hard work, the imagery exercise that you'll do should help you to build up your soothing system and put these three systems into balance. It can help you to feel more able to control your mood and to work towards goals that are achievable for you.

BREAK FOR SHORT DISCUSSION BETWEEN THERAPIST AND PARTICIPANT

3. What happens?

You'll be working one-to-one with a professional therapist who has had specialist training in the imagery technique, so you'll be in safe hands. It goes without saying that if you feel uncomfortable throughout any part of it you can just let them know. The session should last an hour (?) and you'll do a few different imagery exercises in that time.

You'll be asked to breathe in a slow, calm way which can feel a bit strange at first, but you get used to it with a bit of time and practice. That'll help you to train your body to feel relaxed. You'll also be asked to close your eyes if you feel comfortable with that, and will be asked to notice what happens to your thoughts. I try to concentrate on my breathing but my brain often goes all over the place thinking things like "what's for tea tonight?" But you learn that it's ok for your mind to do that, you just need to keep bringing it back to your breathing when you can . Then they also asked me to imagine different pictures in my head- I found it quite hard to do this, especially in the beginning. All I could see was a bit of colour. But they told me that that was fine, I just had to concentrate on the feeling they were asking me to create. I found in time that the pictures I was imagining became a bit clearer. The key thing I learned was to not beat myself up if I wasn't doing it 'right,' but to just try my best and see what happened.

Some of these exercises should help you to build up your soothing system, so that you can learn to balance out times when you feel threatened or under pressure.

With one of the exercises which you might do, I began to feel quite uncomfortable because they were asking me to imagine feeling safe and secure and calm, and to imagine people being kind to me.

They also used some words in some exercises that put me off a bit, like 'compassion,' 'gentleness' and 'nurture.' All of those things made me think this might not be for me. I was used to looking after myself; I wasn't used to thinking about 'kindness' and 'warmth,' especially not in relation to me! It was actually quite overwhelming, trying to feel safe and secure and I

guess I wasn't really expecting that. It made me want to push against it and stop doing the exercise; I told the therapist at the time and they said that was the way a lot of people feel. They helped me to stick with the feeling, and to get used to it. If you feel that way too, then just let the therapist know; they helped me to remind myself that this was all new to me so it was normal that I might not be that comfortable with it.

4. I stuck with it, because I wanted to see if I could find a way to balance out my mood a bit. It made me think about how to do things that are helpful for me and other people, rather than losing my temper a lot of the time or avoiding things I felt uncomfortable about doing. What will happen afterwards?

After the imagery exercise, you'll have some time to talk with the therapist about anything that you found good or bad about it. Hopefully you'll feel calm and relaxed, and that you've got some new skills that you can use too. After completing the imagery task for the first time, I felt quite strange, a bit unsettled. I wasn't used to it, but now I can use it to help me when I feel anger coming on, or when I feel anxious. I tell myself, your body's designed to want to protect itself through getting frustrated or anxious, but it doesn't help me when I do. So I try bringing in that other soothing system using the imagery, and it helps me to keep things running more smoothly.

Appendix D: Health and Safety Form, Expenses Form, Plain English Summary (Anonymised)

WEST OF SCOTLAND/ UNIVERSITY OF GLASGOW

DOCTORATE IN CLINICAL PSYCHOLOGY

1. Title of Project	Effect of preparatory information on fear of compassion and motivation for a compassion focussed imagery exercise.
2. Trainee	-
3. University Supervisor	-
4. Other Supervisor(s)	-
5. Local Lead Clinician	-
6. Participants: (age, group or sub- group, pre- or post-treatment, etc)	Participants will be aged 18 to 65 years old, with a history of serious head injury (defined as post traumatic amnesia > 1 day; Russell, 1935) that occurred at least three months prior to testing. They will also have capacity to consent, as defined by professional staff members responsible for their care. Participants for the preparation/ information study will be identified and approached through inpatient brain injury rehabilitation services in the West of Scotland, primarily Graham Anderson House and the Murdostoun Unit, and also through a community group.
7. Procedures to be applied (eg, questionnaire, interview, etc)	The procedure will involve the use of questionnaires pre and post preparatory information. The preparatory information will involve participants watching a DVD for approximately 20 minutes, which contains information on imagery exercises which aim to reduce 'response to threat'

HEALTH AND SAFETY FOR RESEARCHERS

	(such as relaxation or compassion focussed imagery). A short break in the middle of this DVD (aprox. 5 mins) will allow time for discussion about this DVD and aims to maintain attention on the information.
8. Setting (where will procedures be carried out?)i) General	These procedures will be carried out in the setting from which participants have been recruited: either within their inpatient unit or community group setting. This should allow research to be conducted in a setting familiar to participants, with the support of staff familiar to them.
ii) Are home visits involved	No

9. Potential Risk Factors Identified (see chart)	 1.Due to brain injury, the present sample of participants may be more likely to be associated with impulsive, irrational or unpredictable behaviour, and/or poor emotional control than the general population. 2. It is anticipated that some participants may have fears concerning feeling compassion towards themselves, which might cause them to become another size about tractment.
. 10. Actions to minimise risk (refer to 9)	 1. This research will be conducted within a setting which is familiar for patients. This will either be an inpatient or community setting, whereby staff working in these settings will already have procedures in place to minimise risk to staff, such as possession of personal alarms and location in a visible setting. Researchers will also liaise closely with staff involved in participant's care prior to the study to determine whether impulsive behaviour is likely to occur. 2. The proparatory information will aim to reduce
	2. The preparatory information will aim to reduce fears of compassion, and all participants will be made aware that they can take a break from the study or withdraw from the study at any point. The compassion focussed imagery procedure is of a type which has been utilised with a similar sample in the past, and it is not anticipated that it should cause distress.



Please complete the list below to the best of your ability

Item	Details and Amount Required	Cost or Specify if to Request to Borrow from Department
Stationary	N/A	
		Subtotal: £0
Postage	N/A	Subtotal: £0
Photocopying and Laser Printing (includes cost of white paper)	17 sheets x 41 photocopies At £0.05 per photocopy	
		Subtotal: £34.85
Equipment and Software	Heart Rate Variability (HRV)Equipment	HRV equipment to be borrowed from Physiology Dept., University of Glasgow.
	Laptop to view preparatory information Equipment for filming preparatory information	Laptop to be borrowed from Clinical Psychology dept., University of Glasgow.
		Filming equipment should be borrowed from Film dept., University of Glasgow.
Measures	Weschler Test of Premorbid Functioning x 41	Pack of 50 forms= £109, should be able to gain

	Symbol-Digit Modalities Test x 41	access to test pack through department. Pack of 50 forms=£88, should be able to gain access to test pack through department.
		Subtotal: £197
Miscellaneous	Actor in preparatory video	It is likely to be that no expenses will be necessary for this.
Total		£231.85 Please note that the above neuropsychological measures will be utilised within this study and a linked study. The expected cost of the two studies combined = £277.80



Plain English Summary

Title Effect of preparatory information on fear of compassion and expectations of an imagery exercise.

Background It has been found that 'imagery' exercises can have an effect on the mind and body; for example, visualising an image of eating food can cause a person to produce saliva. Initial research with people who have experienced a head injury suggests that an 'imagery exercise' which involves visualising compassionate, kind and caring feelings can produce some positive effects, such as feeling kinder towards oneself. More research is needed to see whether such exercises could be improved and made more effective. In order to improve the outcome of therapy, some research suggests that showing people with a short DVD about therapy before they begin can help people to feel less anxious and more able to engage in therapy. The present study aims to find out whether showing people a short 'preparatory' DVD about an imagery exercise will have an effect on the overall effect of the exercise, their mood, motivation for the exercise, and fears relating to feeling compassion towards themselves or others.

Methods

- Participants. People invited to take part in the study will have experienced: post traumatic amnesia of one day or more and a head injury more than 3 months ago.
 All will be recruited within the west of Scotland, from an inpatient Brain Injury Rehabilitation unit or community group for those who have experienced a head injury. People who are approached can choose not to take part in the study.
- ii) Design of study: In a quiet room with the researcher, each participant will be asked to fill out a series of questionnaires for approximately 30 minutes; they will be supported by the researcher and/or a friend/family member to do this. They will then watch a DVD for 30 minutes, with a 5 minute break in the middle. This DVD will inform participants about the content of the 'imagery intervention,' and the ways in which it might be useful for them. Participants will be asked to complete questionnaires after this, lasting for approximately ten minutes. Following a break

they will then proceed to another study where they will be able to take part in the imagery intervention.

iii) Key ethical issues: Preparatory information is designed to tell people about the imagery intervention, and therefore to ease anxiety. However, some people may feel uncomfortable about the imagery exercise. They will be able to discuss any concerns with the researcher or a member of their clinical team, and to withdraw from the study at any time. All information collected will be treated as confidential. It will be held in accordance to the Data Protection Act, meaning it cannot be shared without the participant's consent.

Practical Applications

- i) The information collected within this study should show whether it is useful to prepare someone for an imagery intervention, including whether this can make people less anxious about feeling compassion towards themselves or others, and whether providing patients with preparatory information should make treatment more effective.
- ii) If interested, all participants will be informed of the overall outcome of this study.Findings will also be distributed among the inpatient units and community groups involved, and results will be published if possible to distribute findings widely

Appendix E: Abstract from Iain Campbell's linked study

Abstract

Background

Loss of empathy is one of the personality changes that can result from head injury and many clients and their families report that such changes are more challenging than comorbid physical sequelae. In an attempt to increase empathy using a brief psychological intervention (compassion focused imagery), O'Neill and McMillan (2012) found a non-significant trend towards increased self-compassion within a group of head injured individuals.

Aims

This study seeks to explore whether preparation, modifications to the intervention and alternative measures can detect a change in empathy and/or compassion in a head injured population.

Methods

All participants will undergo a preparatory intervention as part of a separate study detailed elsewhere in Melanie Gallagher's MRP proposal. Participants will then be randomised to a 50minute compassionate focused imagery or relaxation control condition. Self-report empathy, compassion, relaxation and anxiety outcomes, a wordsearch style task designed to detect processing bias and heart rate variability changes will serve as dependent variables. Pre intervention fear of compassion will be treated as a covariate.

Applications

There is little to support the use of psychological interventions in addressing emotional deficits post head injury at this time. Positive outcomes may lead to the development of more substantial psychological interventions in the future.

Appendix 2.9 Abstract from follow-on treatment study

Title: The effect of brief compassionate imagery on empathy following severe head injury

Abstract

Background: Loss of empathy is part of the personality change commonly observed following head injury. In a preliminary study that attempted to increase empathy after head injury, O'Neill and McMillan (2012) found a non-significant trend towards increased self-compassion using a brief compassionate imagery intervention. <u>Aims:</u> This study explores whether modifications to the design used by O'Neill and McMillan will result in a positive change in empathy and/or compassion in a severe head injury sample. <u>Methods</u>: Participants were randomised to a 50minute compassionate focused imagery (CFI) or relaxation imagery (RI) control condition. Selfreport of empathy, compassion, relaxation and anxiety, a wordsearch task designed to detect information processing bias and heart rate variability changes (HRV) were the dependent variables. Pre-intervention Fears of Compassion (FoC) scores were treated as a covariate. Results: Differences post-intervention were not significant between CFI and RI conditions. No correlations between outcome change and HRV change were found. No correlations between outcome change and FoC were found. Data from both conditions combined revealed a nonsignificant trend towards increased empathy post-intervention. This change was not reflected in HRV outcomes. Conclusion: Evidence to support the use of brief compassionate imagery for people with head injury was not found. Smaller than predicted between group effect sizes suggests that the study may be underpowered, and hence conclusions are tentative. A more intensive intervention programme in studies with a larger sample size is recommended.