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

AND CLINICAL RESEARCH PORTFOLIO

Volume 1

(Volume 2 bound separately)

Iain N. Campbell MA (Hons), MSc

Submitted in partial fulfilment of the requirements for the degree of Doctorate in

Clinical Psychology (D.Clin.Psy)

Institute of Health and Wellbeing

College of Medical, Veterinary and Life Sciences

University of Glasgow

September 2014



University
of Glasgow

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TABLE OF CONTENTS

Volume One

		<u>Page</u>
Chapter 1:	Systematic Literature Review	6
	Psychological, behavioural and physiological change in healthy adults after compassionate focused meditation training: a systematic review.	
Chapter 2:	Major Research Project Paper	42
	The effect of brief compassionate imagery on empathy following severe head injury.	
Chapter 3:	Advanced Practice I: Reflective Critical Account (Abstract only)	73
	Being brave enough to be a psychologist: Understanding the processes at work when moving from everyday interactions into deliberate therapeutic interactions.	
Chapter 4:	Advanced Practice II: Reflective Critical Account (Abstract only)	75
	New ways of working? The role of experiential learning in shaping attitudes to service design and delivery	

RESEARCH PORTFOLIO APPENDICES

	Page
Appendix 1: Systematic Literature Review	
1.1 Cochrane Libraries risk of bias domains	78
1.2 Guidelines for submission to Clinical Psychology and Psychotherapy	79
Appendix 2: Major Research Project Paper	
2.1 Guidelines for submission to Neuropsychological Rehabilitation	82
2.2 Major Research Project Proposal	85
2.3 Ethics Committee approval letters	95
2.4 Research and Development approval letter	105
2.5 M. Gallagher's MRP abstract	107
2.6 Adaptation of the Empathy Quotient Scale	108
2.7 Adapted Empathy Quotient Scales	109
2.8 Relaxation scale	111
2.9 Development of the imbedded word task	112
2.10 Imbedded word task	113
2.11 Compassionate imagery treatment script	117
2.12 Relaxation imagery treatment script	123
2.13 Patient Information Sheet	129
2.14 Consent Form	132

CHAPTER ONE: SYSTEMATIC LITERATURE REVIEW

Psychological, behavioural and physiological change in healthy adults after compassionate focused meditation training: a systematic review

Iain N. Campbell

Mental Health and Wellbeing

University of Glasgow

1st Floor, Admin Building

Gartnavel Royal Hospital

1055 Great Western Road

Glasgow, G12 0XH

Tel. No: 0141 211 3920

Email: iain.campbell1886@gmail.com

Prepared in accordance with guidelines for submission to Clinical Psychology and
Psychotherapy (Appendix 1.2).

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Abstract

Objective: Evidence suggests that those who regularly experience positive affect derive a range of benefits as a direct result. Ways of increasing and maintaining positive affect are therefore desirable, especially for those who find positive emotion difficult to generate. Compassionate meditation (CM) has begun to attract attention, but there are no reviews of recent controlled trials. The present study systematically reviews the effectiveness of CM in producing durable positive outcomes. Method: Ten databases were systematically searched and a hand search was conducted on relevant journal back issues. Sixteen studies were identified according to specified exclusion criteria. Studies were rated according to Cochrane Library risk of bias and effect sizes were calculated. Results: Lack of reporting made a full assessment of bias difficult and quality varied. Though a range of effects was found for positive psychological, behavioural and physiological change over controls, there were a comparable number of non-significant results, rendering overall outcome equivocal. One study reported follow up, maintaining gains at six and twelve months. Where results were positive, there was some evidence that increased practice related to better outcomes. Conclusions: Clear evidence to support the use of CM has not been established. Future studies should look to improve comparability across studies and explore whether increased practice improves outcomes.

Introduction

Recent years have seen a sharp growth in interest in the principles of compassion (Jazaieri et al., 2014) and how these might be usefully employed in therapeutic contexts (Carson et al., 2005; Gilbert & Irons, 2004; Gilbert & Procter, 2006). Current Western compassionate approaches are largely underpinned by Buddhist philosophies, employing meditative and imagery exercises with the aim of generating positive affect and encouraging long term wellbeing through repeated practice (Buddhagosa, 1975).

Compassion Focused Therapy (CFT)

In the United Kingdom, much of the work in compassion has been advanced by Paul Gilbert through his CFT approach (Gilbert, 2009). The theory behind CFT draws from evolutionary neuroscience and suggests that human development has evolved to recognise the value of social affiliation in ensuring not only the survival of the self, but of kin and of the wider group. From this perspective, the suggestion is that all humans are born with the basic neurophysiological building blocks to seek out, experience and provide nurturing experiences for the self and for important others. CFT further suggests that if this neurophysiological affective system does not develop in childhood, perhaps as a result of typical attachment disruption (Bowlby, 1980), then the individual can experience difficulty in the generation and experience of compassion and may actually develop a fear of this state (Gilbert, McEwan, Matos & Ravis, 2011). A CFT intervention typically employs a number of western therapeutic approaches, but the repeated generation of compassionate affect, based on Buddhist meditative practices, is central to the approach. Change is believed to occur as a result of 'physiotherapy for the brain' (Gilbert, 2009), based on evidence of neuroplasticity arising from meditative practice (Begley, 2009), which suggests that this system can be enhanced if the structures and neurobiological systems are repeatedly stimulated. The question of whether applying compassionate meditation (CM) can bring about durable positive change is yet to be systematically reviewed, however.

The power of positive affect

The benefits of generating positive feeling are neither new nor confined to Buddhist philosophy. Though many studies have identified a correlation between emotional wellbeing and desirable personal resources and social outcomes (Lyubomirsky, King

& Diener, 2005), the assumption is often that the casual direction flows from external success to internal affect. However, a large meta analytic review showed that positive affect often precedes successful outcomes and the development of desirable resources, and more importantly, that positive affect causes a range of behaviours paralleling success (Lyubomirsky, et al., 2005). These outcomes support the 'broaden-and-build' theory of positive emotion advanced by Fredrickson (2001), which is built on the observation that positively valenced mood leads individuals to think, act and feel in a more engaged way, promoting confidence and approach behaviour. When all is going well, an individual can devote time to the enhancement of resources and relationships, developing their repertoire of skills for future use. Fredrickson (2001) views positive emotions as having an adaptive function in motivating the organism into preparing for future challenges by building resource during 'good times'. Given this perspective, finding ways to help individuals who find the every day generation of positive affect difficult (e.g. through major depression; also see Seligman, 2000) is a worthwhile goal.

Meditation in therapy

Meditation has been applied as a clinical intervention across a wide range of populations. A recent systematic review and meta-analysis (Goyal et al., 2014) identified 47 RCT meditation trials, and identified two specific approaches in the literature: mindfulness approaches and mantra approaches. Mantra meditation involves training to reach an effortless state where focused attention is absent (Travis & Shear, 2010), whereas mindfulness meditation (MM) has been defined as involving a) the self-recognition of attention, a metacognitive skill that results in the ability to sustain and switch attention while inhibiting unhelpful elaboration, and b) an orientation to momentary experience, developing insight and decentering the self in order to observe thoughts, feelings and sensations as transitory and subjective (Bishop et al., 2004). Indeed, it is the act of deliberately turning towards internal experiences without becoming caught up in them that has attracted many western therapists, leading to the development of manualised MM approaches such as Mindfulness Based Stress Reduction (MBSR; Kabat-Zinn, 1982) and Mindfulness Based Cognitive Therapy (Teasdale et al., 2000). Goyal et al., (2014) report no evidence for the use of mantra meditation, and comment on poor quality of existing research. Stronger and more numerous studies are reported for MM, reflecting the

level of comparative interest in the field, and MM was found to have small to moderate effects on depression, anxiety and pain, in comparison to controls (depression and anxiety effects maintained to six months). Interestingly, no effects were found for the promotion of positive emotion, however. A narrative review which took a broader approach to the synthesis of MM data, including cross sectional and correlational designs, found that outcomes converged to suggest that MM could be effective in increasing subjective wellbeing (Keng, Smoski & Robins, 2011). A common theme between the two reviews was that the MM research varies widely in terms of quality, making it difficult to place confidence in the benefits frequently attached to it in routine clinical practice. If inducing positive affect is to be a goal, is not therefore clear whether MM is able to achieve this. Compassionate meditation approaches provide an alternative option.

Compassion and compassionate meditation

Despite its presence in the literature, consensus does not yet exist as to the nature of the concept of compassion (see Goetz, Dacher & Simon-Thomas, 2010, for review). A popular definition describes compassion as an affective state in its own right, which consists of two parts: sensitivity to and awareness of suffering and the motivation to alleviate this suffering (Goetz et al., 2010).

In Buddhist traditions, CM and loving-kindness meditation (LKM) represent well-known practices. CM involves techniques to cultivate compassion or genuine sympathy for those experiencing misfortune, together with the wish to see this suffering relieved. Similarly, LKM techniques teach the projection of genuine warmth and kindness to all living things. Both techniques have their roots in Buddhist texts. Specifically, the 'Path of Purification' (Buddhaghosa, 1975) describes the 'four immeasurables': sublime states that are cultivated through meditation, consisting of loving-kindness ('metta' in Pali), compassion ('karuna'), sympathetic joy ('mutida'; joy in the joy of others) and equanimity ('uphekkha', freedom from biased and judgemental approaches to others; Hofmann, Grossman & Hinton, 2011). Even in this brief description, it's clear that the generation of emotion in CM moves beyond compassion to promote combinations of sympathy, love, kindness and joy.

A number of important differences distinguish CM and LKM as alternatives to MM. All begin with the training of mindful attention; however whereas the aim of MM is to maintain that attention on experiential awareness without any intentional influence, CM and LKM actively direct attention towards the generation of positive emotion. In this way CM and LKM are primarily emotion focused and the centre of this focus is not experience, as it is in MM, but on the self as the experiencer (Neff & Germer, 2013).

Compassionate meditation in research

Hofmann et al., (2011) provides a narrative review of CM and LKM. Reflecting the literature at that stage, they drew on studies using different designs, which employ CM and LKM in very different ways. These studies provide evidence that suggest CM and LKM, compared with controls, can induce a number of positive changes, including state affect towards strangers and the self after only a brief session (Hutcherson, Seppala & Gross, 2008), positive affect changes which lead to increased life satisfaction after six weeks training (Fredrickson, Cohn, Coffey, Pek & Finkel, 2008; reviewed in this study), reduced pain, anger and distress in a back pain sample after eight weeks of training (Carson et al., 2005) and reduced stress-induced distress and immune response after six weeks of training (Pace et al., 2009; reviewed in this study). They also draw on cross sectional evidence from Richard Davidson's group (e.g. Lutz, Brefczynski-Lewis, Johnstone & Davidson, 2008) that shows differential activation of brain areas associated with emotional processing and empathy in expert compassion mediators compared with novices. Finally, reference is made to Gilbert's work with CFT, in its early group based guise of Compassionate Mind Training (Gilbert & Procter, 2006; Mayhew & Gilbert, 2008) that reported improvements in anxiety, depression, self-criticism and paranoia in clinical populations. In conclusion, the authors suggest that there is growing evidence to support the use of CM and LKM meditation, but acknowledge that the heterogeneity in design, population and treatment protocols make this comparison premature.

Despite this review being published just three years ago, inspection of the literature revealed that a number of pre to post intervention studies, some adopting a more protocol based approach to the delivery of CM and LKM meditation reminiscent of the structure of the MBSR course (Kabat-Zinn, 1982), have since added to the literature. This recent increase in CM and LKM controlled trials, the potential benefits endowed

by increasing positive emotion and a growing evidence base for another meditation based intervention (MM) suggest that there is value in exploring the evidence base for CM and LKM¹ as it currently stands.

Research Question

Can extended meditation practice that emphasises compassionate principles bring about durable increased positive psychological, behavioural and/or physiological changes in healthy adult volunteers compared with controls? Furthermore, can the same practice bring about durable reduction in negative emotional, behavioural and/or physiological changes in the same population?

Method

Search strategy

An electronic search of the following databases was conducted:

- ERIC (1966 – June 2014), ProQuest;
- EMBASE (1947 – June 2014) and Health Management Information Consortium, (1983 – June 2014), both Ovid;
- Medline (1948 – June 2014), PsycINFO (1800s – June 2014), PsycARTICLES (1894 – June 2014), Psychology & Behavioural Sciences Collection (1965 – June 2014), Health Source: Nursing/Academic Edition (1975 – June 2014) and CINAHL (1981 – June 2014), all EBSCO.

In addition the Cochrane Library was searched (2005 – June 2014) incorporating the Cochrane Database of Systematic Reviews, The Database of Abstracts of Reviews of Effectiveness, Health Technology Assessments, NHS Economic Evaluation Database, The Cochrane Central Register of Controlled Trials and the Cochrane Methodology Register. Where possible duplicates were removed and all searches were limited to journal articles.

The following terms were entered into the aforementioned databases and then combined with the use of the Boolean operator AND:

¹For the remainder of the review LKM will be subsumed under CM.

1. compassion* OR loving kind* OR sympathetic joy OR equanimity OR metta OR karuna
OR mudita OR upekkha
2. mindful* OR meditat* OR theravad*

An initial search returned no clear indication of a concentration of work focusing on a specific clinical group that would facilitate comparison. The decision was taken to limit the review to healthy adult volunteers, which represents the majority of CM studies of this kind. This had the added benefit of improving comparability, albeit at a cost to generalisability to clinical contexts. Similarly, some studies focused on brief interventions to bring about state changes in participants. As this study is concerned with durable change, and with reference to evidence from studies on experienced meditators that suggests that prolonged practice correlates with larger effects (Lutz, Greischar, Rawlings, Matthieu & Davidson, 2004; Lutz et al., 2008), it was decided to limit the review to those interventions which involved repeated practice over time. In the absence of established guidance in the literature, this was arbitrarily set at interventions consisting of five or more repeated practices over no less than five days.

Inclusion and exclusion criteria

Inclusion criteria

- Healthy adult participants
- Studies with a clear description of meditative practice and a specific compassionate focus as the 'active ingredient'.
- Interventions involving repeated practice.
- Qualitative outcome pertaining to psychological, behavioural and/or physiological change post meditation.
- Studies that use a controlled group comparison.

Exclusion criteria

- Studies that are not published in the English language.
- Studies with mixed interventions or which feature a compassionate/mindfulness element only as an adjunct to a broader intervention.
- Single exposure or brief interventions.
- Qualitative research, reviews, dissertations, conference abstracts and book chapters.
- Cross sectional observational and single N designs.

This process resulted in the identification of 16 papers. References for each of these papers were checked. The following journals were hand searched:

- Mindfulness (March 2010 – June 2014)
- Annual Review of Clinical Psychology (March 2010 – March 2014)
- British Journal of Clinical Psychology (March 2010 – June 2014)
- Clinical Psychology and Psychotherapy (Jan/Feb 2010 – May/June 2014)

A total of 16 papers were identified at the end of this process(*Figure 1*).

Assessment of risk of bias

The Cochrane Library approach (Higgins & Green, 2009) was adopted, which advocates judging internal validity based on six domains relating to five types of bias in RCTs:

- Random sequence generation (selection bias)
- Allocation concealment (selection bias)
- Blinding of participants and personnel (performance bias)
- Blinding of outcome assessment (detection bias)
- Incomplete outcome data (attrition bias)
- Selective outcome reporting (reporting bias)

Each domain is assessed without reference to weighting and assigned one of three outcomes: 'high risk' (of bias), 'low risk' or 'unclear risk' according to pre-specified criteria outlined in the Cochrane Handbook (Higgins & Green, 2009; Appendix 1.1). In recognition of difficulties in successful blinding in psychological research design, the criteria for 'blinding of participants and personnel' were modified: 'low risk' was assigned if researchers reported blinding of *either* personnel *or* participants and 'high risk' if no attempt was made.

In order to evaluate the reliability of this approach, four papers (25%) were scored by another reviewer. One paper considered to be comparatively low in overall bias risk (four 'low risk' decisions), two papers considered medium to high risk (three and two 'low risk' decisions) and one considered high risk (one 'low risk' decision) based on the main reviewers opinion, were put forward for this process. Agreement was scored

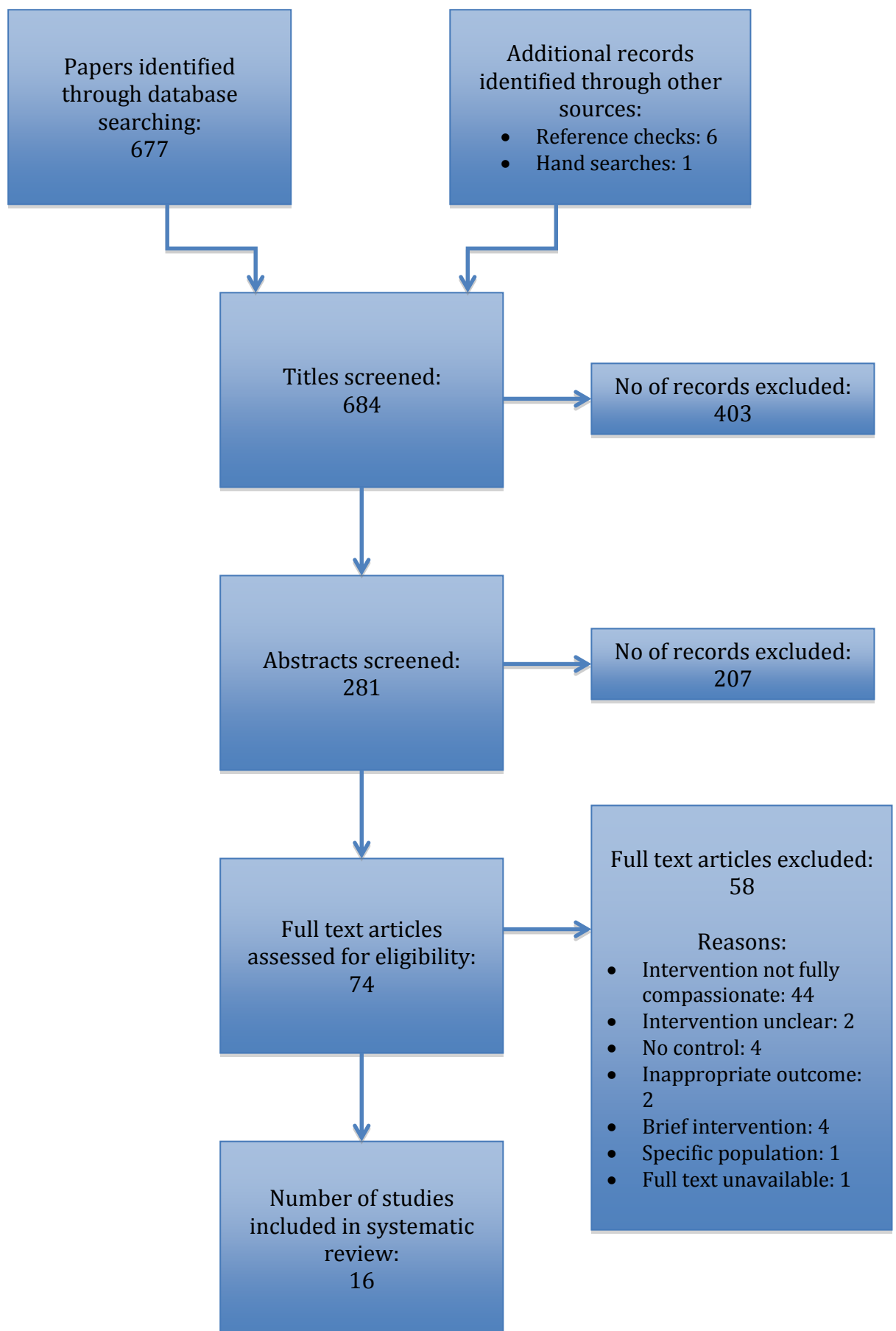


Figure 1: Flow diagram of papers screened

between nought and six for each paper, representing each of the six domains. Agreement was 88% for the sample.

Effect size calculation

Few studies provided either an appropriate between group effect size or the data that would allow this calculation, instead providing pre and post scores in many instances. The approach described by Rohling, Faust, Beverly & Demakis (2009), which used a derivation of Hedges g, was adopted to estimate *between* group ES using the following equation:

$$[(\text{Mean}_{\text{ExpPost}} - \text{Mean}_{\text{ExpPre}})/\text{SD}_{\text{ExpPre}}] - [(\text{Mean}_{\text{ConPost}} - \text{Mean}_{\text{ConPre}})/\text{SD}_{\text{ConPre}}]$$

Because pre-test standard deviations are measured before any intervention has occurred, they will not be influenced by experimental manipulation and are therefore more likely to be consistent across studies (Becker, 1988). Effect sizes for correlation (r) and dichotomous data (odds ratio) were reported when provided by studies.

Results

Included studies

16 papers described 14 controlled trials; *Jazaieri (2013)* and *Jazaieri (2014)* represent two papers from the same study as does *Mascaro (2013a)* and *Mascaro (2013b)*. Fourteen of the 16 papers used randomisation. All but two used pre and post intervention measures (*Condon, 2013* and *Pace, 2009* took measures post intervention only). Seven studies used a waiting list control (WLC) only, three used an active control (AC) only, and six used both. In total, 842 healthy adult volunteers were investigated, of which 595 (71%) were female, and final sample sizes per study ranged from 21 – 139 (n=14, M=60.14, SD=34.25). Seven studies drew on a community population, five from a university population, two from a mix of university and community and one from an information technology workplace. One study did not report sample source. Four studies (*Condon, 2013; Desbordes, 2012; Wallmark, 2013; Weng, 2013*) reported experience of meditation as an exclusion criterion. Attrition from studies ranged from 0 to 42% with an average of 24%.

Intervention characteristics

Of the 14 interventions described, length of practice period ranged from 2 – 12 weeks, with an average of 7 – 8 weeks. Most studies included a weekly guided intervention throughout, however two studies (*May, 2013;Weng, 2013*) relied solely on participants' regular home practice. Total taught session time varied between 0 – 16 hours, with an average of 9 – 10 hours. All interventions were based on practices derived from Buddhist meditation and primarily used principles of compassion and loving-kindness. All required participants to practice daily (*Table 1*).

Table 1: Study characteristics in order of low risk of bias

Study	Design	Participants	Intervention	Measures	Outcomes (effect sizes)
Mascaro, (2013a)	RCT, pre-post design comparing effect of CBCT vs AC (health discussion group) on empathic accuracy.	N=29 healthy adults (students and community); 8 dropped out (28%). Final N=21, age M=31.9 (SD=6.70); 13 CBCT, 7F; 8 AC, 2F.	CBCT and AC 8 x 1 session per week (120 mins); 20 mins daily home practice (audio-guided; not AC). Measures taken pre and post intervention	Pre and post: RMET; bilateral inferior frontal gyrus, posterior superior temporal sulcus, dorsomesial prefrontal cortex, temporal poles. fMRI	CBCT group change significantly higher in empathic accuracy (REMT) than AC, but no difference in reaction time (0.72). No change in neural activity pre to post in CBCT. No effect of practice time for changes in brain activity in CBCT
Jazaieri (2013)	RCT, pre-post design comparing CCT and WLC on compassion outcomes	N=149 healthy adults (community) invited; 49 dropped out prior to randomisation (33%). Final N=100: 60 CCT, 39F, age M=41.98 (SD=11.48), 40 WLC, 33F, age M=44.68 (SD=13.05). 9 dropped out of intervention (CCT) and 11 lost to outcome assessment (20% of Final N)	CCT (manualised) 120 mins introduction, 8 x 1 session per week (120 mins); 7 home practice per week (15-30 mins) Measures taken pre and post intervention	Pre and Post: FoC, SCS Mediation time	Significant changes in CCT over WLC: Compassion for others (FoC; 0.72) Compassion from others (FoC; 0.36) Compassion for self (FoC; 0.56 and SCS; 0.55) No of mins in practice only predicted compassion for others
Jazaieri (2014)	RCT, pre-post design comparing CCT and WLC on compassion outcomes	N=149 healthy adults (community) invited; 49 dropped out prior to randomisation (33%). Final N=100: 60 CCT, 39F, age M=41.98 (SD=11.48), 40 WLC, 33F, age M=44.68 (SD=13.05). 9 dropped out of intervention (CCT) and 11 lost to outcome assessment (20% of Final)	CCT (manualised) 120 mins introduction, 8 x 1 session per week (120 mins); 7 home practice per week (15-30 mins) Measures taken pre and post intervention	Pre and Post: KIMS, EQ PSWQ, PSS-4, SHS ERQ Meditation time	Significant changes in CCT over WLC: mindfulness (KIMS; 0.46 and EQ; 0.41), worry (PSWQ; 0.51), emotional regulation (ERQ: emotional suppression; 0.49). No change in self efficacy of cognitive reappraisal, stress (PSS) or happiness (SHS) Amount of practice predicted worry (r=.29) and emotional regulation (expressive suppression; r=.37)

Kang (2014)	RCT, pre-post design, comparing LKM, AC (loving-kindness discussion group) and WLC conditions on improving attitudes. Participants paid.	N=107 healthy adults (community); 6 dropped out (6%) Final N=101, 35 LKM, 20F, age M=25.69 (SD=5.17), 33 AC, 21F, age M=24.42 (SD=5.06), 33 WLC 24F, age M=25.45 (SD=5.45).	LKM and AC 6 x 1 session per week (LKM: 60 mins; AC: 40 mins); 5 x home practice per week (guided recording, at least 20mins, not AC) Measures taken at pre and post intervention.	Pre and Post: IAT 'Feeling thermometer'	Those in LKM showed significantly less implicit bias against black (vs AC 0.66; vs WLC 0.95) and homeless people (vs AC 0.27; vs WLC 0.57). LKM had no effect on explicit attitudes
Neff & Germer (2013)	RCT, pre-post design comparing MSC and WLC on a series of self report outcomes	N=54 adults (community; some meditation experience); 3 excluded (6%) Final N=51; 24 MSC, 19F, age M=51.21 (SD=12.02); 27 WLC, 22F, age M=49.11 (SD=11.59). Follow up (MSC only): 6 months: N=24, 12 months: N= 15.	MSC 8 x 1 session per week (120 mins), incl half day retreat. 7 x 40 mins home practice per week. Measures taken at pre, post intervention with 6 and 12 months follow up (MSC follow up only). SCS taken at week 3 and 6 for MSC group.	Pre and post: SCS, CS, CAMS-R, SoCS, SHS, SLS, BDI, STAI, PSS and AS Meditation time	Compared with WLC, MSC group demonstrated significantly greater gains in self and other compassion (SCS; 1.41 and CS; 0.64), mindfulness (CAMS-R; 0.53), life satisfaction (SLS; 0.49) and greater decreases in depression (BDI; 1.09), anxiety (STAI; 0.75), stress (PSS; 0.39) and avoidance (AS; 0.54). No difference over time between groups in social connectedness (SoCS) or happiness (SHS) Gains were maintained at 6 and 12 months on all measures. Days a week ($r = .42$) and times a day ($r = .43$) practice correlated with self compassion (SCS).
Pace (2009)	Randomised controlled trial, comparing effects of CM vs AC (health discussion group) on stress and behaviour	N=89 healthy adults (students), 28 dropped out (31%) Final N=61; 33 CM, 17F, age M=18.48 (SD=0.62), 28 AC, 15F, age M=18.54 (SD=0.69).	CM and AC 6 x 2 sessions per week (50 mins), home practice (audio guided, length and frequency not specified, not AC) Measures taken post intervention	Pre and post TSST: Cortisol and IL-6 POMS	No main effect of CM on any physiological or distress outcomes. Significant negative correlations between amount of meditation and innate immune (IL-6; $r = -.51$) and distress responses (POMS; $r = .43$).

Condon (2013)	RCT, comparing CM, MM and WLC performance on a behavioural task.	<p>N=67, meditation naïve, healthy adults (community), 26 dropped out, 2 removed by experimenters (42%) information only given on completers.</p> <p>Final N=39 (11 CM, 9 MM, 19 WLC), 29F, age M=25.23 (SD 4.66)</p>	<p>CM and MM 8 x 1 session per week (120 mins); 20 mins daily home practice (audio-guided).</p> <p>Outcome was measured either after 8 weeks of practice or 8 weeks after recruitment</p>	<p>Post intervention behavioural test of helping behaviour: participants were given 2 mins to offer their chair to an injured individual in a waiting area, in the presence of two non-helping study confederates.</p>	<p>Meditators were more likely than controls to offer their chair to an injured individual (odds ratio: 5.33).</p> <p>There was no difference between compassionate and mindfulness meditators</p>
Mascaro (2013b)	RCT, pre-post design comparing effects of CBCT vs AC (health discussion group) on neural responses to witnessing/ experiencing pain	<p>N=29 healthy adults (students and community); 8 dropped out (28%).</p> <p>Final N=21, age M=31.9 (SD=6.70); 13 CBCT, 7F; 8 AC, 2F.</p>	<p>CBCT and AC 8 x 1 session per week (120 mins); 20 mins daily home practice (audio-guided; not AC).</p> <p>fMRI scan taken pre and post intervention</p>	<p>Pre and post: PFE; anterior mid-cingulate cortex, bilateral anterior insula, ventral frontal operculum (pain aversiveness). fMRI</p> <p>IRI</p>	<p>There was no significant group by time interactions in neural responses to self or other pain tasks.</p> <p>State and trait empathy (IRI) change did not differ between groups</p> <p>Practice time did not account for a significant amount of variance on amygdala (self) or anterior insula (others) activity</p>
Wallmark (2013)	RCT, pre-post design comparing FIM and WLC.	<p>N=60 healthy meditation naïve adults (community), 14 dropped out, 4 excluded (30%)</p> <p>Final N=42; 22 FIM, 19F, age M=32 (SD=11), 20 WLC, 17F, age M=35 (SD=15).</p>	<p>FIM 9 x 1 session per week (75 mins), home practice (audio guided, length and frequency not specified)</p>	<p>Pre and post: IRI, PSS, SCS and FFMQ</p>	<p>No significant difference between groups over time for altruistic orientation (IRI).</p> <p>Increase in self compassion (SCS; 0.93), empathy (perspective taking, IRI; 0.34) and mindfulness (FFMQ; 0.75). Stress (PSS; 0.71) decreased compared with WLC</p> <p>Meditation time correlated with decreased stress ($r = -.47$) and increased mindfulness ($r = .45$) and altruistic orientation ($r = .46$).</p>

Weng (2013)	<p>RCT, pre-post design comparing LKM with AC (reappraisal training) on neural responses and a behavioural task (AR)</p> <p>Participants paid</p>	<p>N=63 healthy meditation naïve adults (community), 7 dropped out and 15 were excluded (35%)</p> <p>Final N=41, 20 CM, 12F, age M=21.9 (no SD info), 21 AC, 13F, age M=22.5.</p>	<p>LKM and AC</p> <p>2 weeks daily practice, (30 mins; audioguided self intervention, at least 11 out of 14 days)</p> <p>Measures taken post intervention</p>	<p>Post intervention: AR</p> <p>Pre and post: Images: right inferior parietal cortex, prefrontal cortex, amygdala, anterior insula and nucleus accumbens; fMRI</p>	<p>LKM spent 1.84 times more money to redistribute funds to a 'victim' than AC (0.65).</p> <p>LKM had greater redistribution correlated with greater activation in the IPC and dlPFC than AC.</p> <p>LKM had greater dlPFC-NAcc connectivity associated with greater redistribution than AC. No relationship was found with insula or amygdala.</p>
Desbordes (2012)	<p>RCT, pre-post design comparing MAT, CBCT and AC (health discussion group) brain response to images following intervention</p>	<p>N=51 age M=34.1, (SD=7.7), meditation naïve, healthy adults. 5 dropped out, 10 were excluded (29%)</p> <p>Final N=36; 12 MAT, 8F, age M=34.3 (SD=9.6), 12 CBCT, 8F, age M=32.0 (SD=5.4), 12 AC, 5F, age M=36.0 (SD=7.6).</p>	<p>MAT, CBCT & AC</p> <p>8 x 1 session per week (120 mins); 20 mins daily home practice (audio-guided; not AC).</p> <p>fMRI baseline scan before randomisation repeated after intervention (within 3 weeks on both occasions). Self report measures taken pre and post.</p>	<p>Pre and post: L and R amygdalae activation; fMRI</p>	<p>No effect on L amygdala activation (AA)</p> <p>Between group: R AA in CBCT no different from MAT or AC.</p>
Fredrickson (2008)	<p>RCT, pre-post design, comparing LKM and WLC on emotion, resources, life satisfaction and depression.</p> <p>Participants paid for each level of participation</p>	<p>N=202, age M=41 (no SD) adult employees of an IT company, 102 LKM, 100 WLC. 7 were excluded and 56 dropped out (31%)</p> <p>Final N=139, 91F, age M=41 (SD=9.6); 67 LKM, 72 WLC.</p>	<p>LKM</p> <p>6 x 1 session per week (60 mins); at least 5 home practices per week (guided recording, 15-20 mins)</p> <p>All measures taken electronically. Measures taken pre and post intervention. Daily reporting of emotion and meditation practice.</p>	<p>Pre and post: SLS, CES-DM, various measures of 'personal resources'.</p> <p>Daily: mDES, meditation time</p> <p>Post intervention: DRM</p>	<p>LKM increased positive emotion (not compassion) over time compared with WLC (not significant in ITT analysis).</p> <p>Experimental condition had no direct impact on 'personal resources', life satisfaction, depression or general negative emotions.</p> <p>Time spent in meditation predicted positive emotions on a daily basis and post intervention.</p>

May (2011)	Controlled trial, pre-post design comparing LKM and WLC condition on trait attention	N=27 adults (psychology students), no attrition reported; 13 LKM, 10F, age M=22.08 (no SD reported), 14 WLC, 11F, age M=23.21.	LKM 1 guided meditation session (15 mins); 4 x home practice per week for 8 weeks (at least 15 mins, audio guided) Measures taken at pre and post intervention	Pre and post: ABT HRV FFMQ, PANAS	Trait attention (ABT) did not differ between groups or across time. State attention better in LKM than WLC (0.86) and previous study sample (Burgard & May, 2010; 1.31) directly after meditation. LKM group improved pre to post on two mindfulness subscales (FFMQ). No change in HRV, positive or negative affect in LKM (PANAS) Practice length improved attention.
Sears & Kraus (2009)	Cohort controlled trial, pre-post design comparing four groups	N=61 adults (students), At least 4 dropped out (7%) – unclear. Final N=57; 33F, age M=22.80 (SD=6.86), 19 BMA, 17 BLK, 11 IM, 10 WLC	BMA and BLK: 12 x 1 session per week (10-15 mins) CIM: 7 x 1 session per week (120 mins) Home practice encouraged in three active conditions (length, frequency not specified) Measures taken pre and post intervention	Pre and post: BAI, PANAS, IBS, COPE and HS	BLK (and BMA) had no significant impact on outcomes.
Kok (2013)	RCT, comparing LKM and WLC on emotional, social and physiological change.	N=71 adults (university employees); 5 dropped out, 1 excluded (8%). Final N=65, 43F, age Mdn=37.5.	LKM 6 x 1 session per week (60 mins); home practice (guided recording or self guided, 15-20 mins, frequency optional, but daily recommended) Measures (except HRV) taken daily and electronically. HRV taken pre and post.	Daily: Meditation time, positive emotions, social connections Pre and post: HRV	LKM produced increases in positive emotions, perceived social connections and vagal tone relative to WLC.

Weytens (2014)	RCT, pre-post design comparing PER, LKM and WLC	N=113 adults (students), 26 dropped out (maj. LKM), 8 excluded (30%) Final N=79, 28 PER, 24F, age M=22.5 (SD=3.06), 16 LKM, 13F, age M=22.14 (SD=2.35), 35 WLC, 24F, age M=22.14 (SD=2.35)	PER and LKM 6 x 1 session per week, (120 mins), At least 5 x home practice per week (20 mins) Measures taken pre-post intervention	Pre and post: SHS, SLS, BDI-II, PSS and PILL	Mean difference for PILL better in LKM than WLC (0.75).
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Key:

Interventions

AC: Active Control
BMA: Brief Mindful Attention
CBCT: Cognitively Based Compassion
CCT: Compassion Cultivation Training
CIM: Combined Intensive Meditation
CM: Compassionate Meditation Training
FIM: Four Immeasurables Meditation
LKM: Loving-Kindness Meditation
MAT: Mindful Attention Training
MSC: Mindful Self-Compassion
MM: Mindfulness Meditation
PER: Positive Emotion Regulation
WLC: Waiting List Control

Measures

ABT: Attentional Blink Task
AR: Altruistic Redistribution
AS: Avoidance subscale of IES-R
BAI: Beck Anxiety Inventory
BDI: Beck Depression Inventory
CAMS-R: Cognitive and Affective Mindfulness Scale Revised
CES-DM: Center for Epidemiological Studies – Depression Measure
COPE: Coping Style Questionnaire
CS: Compassion Scale
DAS: Dyadic Adjustment Scale

DRM: Day Reconstruction Method
EFP: Empathy From Pain
EQ: Experiences Questionnaire
ER: Ego Resilience
ERQ: Emotion Regulation Questionnaire
FFMQ: Five-Facet Mindfulness Questionnaire
FoC: Fears of Compassion
fMRI: Functional Magnetic Resonance Imaging
HRV: Heart Rate Variability
HS: Hope Scale
IAT: Implicit Associations Test
IBS: Irrational Beliefs Scale
IRI: Interpersonal Reactivity Index
KIMS: Kentucky Inventory of Mindfulness Skills
mDES: Modified Differential Emotions Scale
PANAS: Positive Affect and Negative Affect Scale
PILL: Pennebaker Inventory of Limbic Languidness
POMS: Profile of Mood States
PSS: Perceived Stress Scale
PSWQ: Penn State Worry Questionnaire
RMET: Reading the Mind in the Eyes Test
SCS: Self Compassion Scale

SoCS: Social Connectedness Scale
SHS: Subjective Happiness Scale
SLS: Satisfaction with Life Scale
STAI: State Trait Anxiety Inventory
TSST: Trier Social Stress Test

Risk of bias in included studies

Table 2: Overall assessment of risk of bias in order of low risk

Mascaro (2013a)						
Jazaieri (2013)						
Jazaieri (2014)						
Kang (2014)						
Neff & Germer (2013)						
Pace (2009)						
Condon (2013)						
Mascaro (2013b)						
Wallmark (2013)						
Weng (2013)						
Desbordes (2012)						
Fredrickson (2008)						
May (2011)						
Sears & Kraus (2009)						
Kok (2013)						
Weytens (2014)						

Key: **Green**= low risk of bias; **Red**= high risk of bias; **Blue** = unclear risk of bias.

Risk of bias overall

On the basis of 96 risk of bias judgements for the sample, 60% resulted in a definite categorisation of low (39%) or high (21%) risk. Studies were ordered to provide an impression of robustness across the review (*Table 2*). In doing so, an inevitably flawed assumption of equal weighting of bias domains is acknowledged. These outcomes are therefore presented for illustrative purposes and should be interpreted with caution. Six papers had 3/6 ($\geq 50\%$) or more low risk of bias ratings (*Mascaro, 2013a; Jazaieri, 2013; Jazaieri, 2014; Kang, 2014; Neff & Germer, 2013; Pace, 2009*). The last of these (*Pace, 2009*) also had two high risk items. Eight papers had two (33%) low risk ratings (*Condon, 2013; Mascaro, 2013b; Wallmark, 2013; Weng, 2013; Desbordes, 2012; Fredrickson, 2008; May, 2011; Sears & Kraus, 2009*). The last four of these had two or more high risk ratings of bias. *Kok (2013)* and *Weytens (2014)* were judged to have fulfilled criteria for one (17%) low risk domain and both had two high risk ratings.

High risk of bias often reflected limitations in blinding, incomplete outcome data and selective outcome reporting. 'Unclear risk' decisions (41%), reflected limited reporting mainly in randomisation procedures, allocation concealment and blinding of outcome assessment (*Table 3*).

Table 3: Assessment of risk of bias by domain

	Random sequence generation	Allocation concealment	Blinding of participants and personnel	Blinding of outcome assessment	Incomplete outcome data	Selective outcome reporting
Mascaro (2013a)	Blue	Blue	Green	Green	Green	Green
Jazaieri (2013)	Green	Blue	Blue	Blue	Green	Green
Jazaieri (2014)	Green	Blue	Blue	Blue	Green	Green
Kang (2014)	Blue	Blue	Green	Blue	Green	Green
Neff & Germer (2013)	Blue	Blue	Blue	Green	Green	Green
Pace (2009)	Green	Green	Red	Blue	Red	Green
Condon (2013)	Blue	Blue	Green	Blue	Red	Green
Mascaro (2013b)	Blue	Blue	Green	Blue	Green	Red
Wallmark (2013)	Green	Blue	Blue	Blue	Red	Green
Weng (2013)	Blue	Blue	Green	Blue	Red	Green
Desbordes (2012)	Blue	Blue	Green	Green	Red	Red
Fredrickson (2008)	Blue	Blue	Red	Green	Green	Red
May (2011)	Red	Red	Green	Blue	Green	Red
Sears & Kraus(2009)	Red	Red	Green	Blue	Red	Green
Kok (2013)	Blue	Blue	Red	Blue	Green	Red
Weytens (2014)	Blue	Blue	Red	Blue	Red	Green

Key: **Green**= low risk of bias; **Red**= high risk of bias; **Blue** = unclear risk of bias.

Allocation

Fourteen of the sixteen studies reported randomisation of some kind, however only four (*Jazaieri, 2013; Jazaieri, 2014; Pace, 2009; Wallmark, 2013*) specified a method and just one of these described concealing allocation (*Pace, 2009*). Two studies stated that they did not use randomisation (*May, 2011; Sears & Kraus, 2009*).

Blinding

Eight studies reported blinding of personnel and participants. One study reported double blinding (*Sears & Kraus, 2009*). Three studies reported single blinding, two of the participants (*Condon, 2013* and *Weng, 2013*) and one of study personnel (*Kang, 2014*). Four further studies were also rated at low risk of bias as their outcome measures were judged to be less open to performance bias (fMRI brain imaging: *Desbordes, 2012; Mascaro, 2013a; 2013b*; and an attentional task: *May, 2011*). Blinding of outcome assessment was reported in four studies; two studies used raters who were blind to the protocol (*Desbordes, 2012; Mascaro, 2013a*), while the others had participants complete measures online (*Fredrickson, 2008; Neff & Germer, 2013*).

Incomplete data reported

Six studies reported high attrition rates without an indication in their analyses of any intent to treat (ITT) procedure that would account for this (*Condon, 2013; Desbordes, 2012; Pace, 2009; Wallmark, 2013; Weng, 2014*). A seventh study was judged high risk, as reporting around drop out was vague and no ITT was apparent in analyses. Two studies (*Kang, 2014; Neff & Germer, 2013*) reported no ITT, but attrition was low (6% in both) and profiles of drop outs suggested this was unlikely to influence outcome. Similarly, though reporting a high attrition rate (28%) in two trials, *Mascaro (2013a, 2013b)* also reported drop out analyses that suggested this was unlikely to bias outcome. The remaining five studies reported appropriate ITT analyses.

Selective outcome reporting

The majority of studies (eleven) provided sufficient detail on their primary outcomes in relation to pre stated hypotheses. Two studies did not provide data on at least one primary non-significant outcome (*Desbordes, 2012; Mascaro, 2013b*) and two did not provide sufficient data to allow for calculation of between group effect size (*Fredrickson, 2008; Kok, 2013*). One study (*May, 2011*) omitted an outcome and did not provide sufficient data for effect size calculation of all outcomes.

Table 4: *Standardised mean difference effect size between groups by outcome*

Study	Waiting list control	Active control
Jazaieri (2013)	FoC for others: 0.72 From others: 0.36 For self: 0.56 SCS: 0.55	
Jazaieri (2014)	KIMS: 0.46 EQ: 0.41 PSWQ: 0.51 ERQ (ES): 0.49	
Kang (2014)	Black people implicit bias: 0.95 Homeless people implicit bias: 0.57	Black people implicit bias: 0.66 Homeless people implicit bias: 0.27
Mascaro (2013a)		RMET accuracy: 0.72
May (2011)	ABT: 0.86	ABT: 1.31
Neff & Germer (2013)	SCS: 1.41 CS: 0.64 CAMS-R: 0.53 SLS: 0.49 BDI: 1.09 STAI: 0.75 PSS: 0.39 AS of IES-R: 0.54	
Wallmark (2013)	PSS: 0.71 IRI (PT): 0.34 FFMQ: 0.75 SCS: 0.93	
Weng (2013)		AR: 0.65
Weytens (2014)	PILL: 0.75	

Study Findings

Between group effect size

Between group, standardised mean difference effect sizes for significant outcomes were calculated from nine studies yielding 29 effects (*Table 4*): 24 effects vs WLC and 5 effects vs AC (see *Table 4*). Seven studies had effects calculated comparing CM to WLC: effect sizes ranged from 0.34 – 1.41. Eight effects were small (≥ 0.2 ; Cohen, 1988), ten effects were medium (≥ 0.5) and six effects were large (≥ 0.8). Four studies had five effects calculated comparing CM to AC groups: 0.27 (small), 0.65, 0.66, 0.72 (medium) and 1.31 (large).

Table 5: Increased positive psychological outcomes identified, study and between group effect size

Outcome	Study	Effect size (control)
Emotional outcomes		
Positive emotion	Fredrickson, 2008	- (WLC)**
	Kok, 2013	- (WLC)**
Self compassion	Jazaieri, 2013	0.55 (WLC)**
	Neff & Germer, 2013	1.41 (WLC)**
	Wallmark, 2013	0.93 (WLC)**
Compassion for others	Neff & Germer, 2013	0.64 (WLC)**
Cognitive outcomes		
Mindfulness	Jazaieri, 2014	0.46 (WLC)** 0.41 (WLC)**
	May, 2011	- (WLC)*
	Neff & Germer, 2013	0.53 (WLC)**
	Wallmark, 2013	0.75 (WLC)**
Perspective taking (empathy)	Wallmark, 2013	0.34 (WLC)*
Attention (state)	May, 2011	0.86 (WLC)* 1.31 (AC)*
Empathic accuracy	Mascaro, 2013a	0.72 (AC)*
Other psychological outcomes		
Life satisfaction	Neff & Germer, 2013	0.49 (WLC)**
Perceived social connections	Kok, 2013	- (WLC)**

* $p < 0.05$ ** $p < 0.01$

Psychological outcome change

The majority of outcomes represented self-report assessed psychological outcomes, consisting of increases in positive affect, cognition and other psychological outcomes (Table 5) and reduced negative affect, cognition and other psychological outcomes (Table 6). Only three of the studies reporting psychological outcome change did not use self-report (Kang, 2014; Mascaro, 2013; May, 2014), using behavioural measures to identify cognitive change. The majority of psychological outcome changes were found in comparison to WLCs, with three studies reporting change in comparison to ACs (Kang, 2014; Mascaro, 2013; May, 2014).

Table 6: Decreased negative psychological outcomes identified, study and between group effect size

Outcome	Study	Effect size (control)
Emotional outcomes		
Fears of Compassion <ul style="list-style-type: none"> • For others • From others • For self 	Jazaieri, 2013	0.72 (WLC)** 0.36 (WLC)* 0.56 (WLC)**
Depression	Neff & Germer, 2013	1.09 (WLC)**
Anxiety	Neff & Germer, 2013	0.75 (WLC)**
Stress	Neff & Germer, 2013	0.39 (WLC)*
	Wallmark, 2013	0.71 (WLC)*
Cognitive outcomes		
Worry	Jazaieri, 2014	0.51 (WLC)**
Emotional suppression	Jazaieri, 2014	0.49 (WLC)*
Implicit bias (towards a minority group) <ul style="list-style-type: none"> • Black people • Homeless people • Black people • Homeless people 	Kang, 2014	0.95 (WLC)* 0.57 (WLC)* 0.66 (AC)* 0.27 (AC)*
Other psychological outcomes		
Avoidance	Neff & Germer, 2013	0.54 (WLC)*

* $p < 0.05$ ** $p < 0.01$

Psychological outcomes with no change

All psychological outcomes that did not reach significance were also based mainly on self-report measures. While the majority of significant psychological outcomes changes were found in comparison to WLCs, psychological outcomes that showed *no* change occurred in a much higher proportion of comparisons with ACs, as well as WLCs (Table 7).

Table 7: *Psychological outcomes with no change, study and control*

Outcome	Study	Control
<i>Emotional outcomes</i>		
Positive emotion	May, 2011	WLC
	Sears & Kraus, 2009	AC & WLC
Happiness	Jazaieri, 2014	WLC
	Neff & Germer	WLC
Empathy	Mascaro, 2013b	AC
Compassion	Fredrickson, 2008	WLC
Hope	Sears & Kraus, 2009	AC & WLC
Altruistic orientation	Wallmark, 2013	WLC
Negative emotion	May, 2011	WLC
	Fredrickson, 2008	WLC
	Sears & Kraus, 2009	AC & WLC
Depression	Fredrickson, 2008	WLC
Stress	Jazaieri, 2014	WLC
Distress	Pace, 2009	AC
Anxiety	Sears & Kraus, 2009	AC & WLC
<i>Cognitive outcomes</i>		
Cognitive reappraisal	Jazaieri, 2014	WLC
Explicit attitudes (towards a minority group)	Kang, 2014	AC & WLC
Irrational beliefs	Sears & Kraus, 2009	AC & WLC
Coping	Sears & Kraus, 2009	AC & WLC
Attention (trait)	May, 2011	WLC
<i>Other psychological outcomes</i>		
Life satisfaction	Fredrickson, 2008	WLC
‘Personal resources’ (mindfulness, pathways thinking, environmental mastery, self-acceptance, purpose in life, social support received, positive relations with others and illness symptoms)	Fredrickson, 2008	WLC
Social connectedness	Neff & Germer	WLC

Behavioural outcome change

Two studies examined participants' behaviour by placing them naively into pre-arranged scenarios and studying their response. *Condon (2013)* found that experimental participants were more likely to behave compassionately towards a stranger in pain than WLC (OR=5.33, $p<0.05$). This result was not significantly different from a mindfulness AC. *Weng (2013)* found that CM meditators were more likely to act altruistically towards a stranger than WLC (between groups effect: 0.65, $p<0.05$).

Physiological outcome change

Eight studies reported physiological change as an outcome. Four studies reported fMRI data in the study of neural activation and two studies looked at nervous system balance using the heart rate variability (HRV) metric. One study considered changes in the endocrine system and another self-report of physical symptoms.

Functional MRI studies looked for activation change in the amygdalae (*Desbordes, 2012; Weng, 2013*), bilateral inferior frontal gyrus, posterior superior temporal sulcus, temporal poles (*Mascaro, 2013a*), right inferior parietal cortex (IPC), anterior insula, nucleus accumbens (NAcc; *Weng, 2013*) anterior mid-cingulate cortex, bilateral anterior insula, ventral frontal operculum (*Mascaro, 2013b*) and the prefrontal cortex (PFC; *Mascaro, 2013a; Weng, 2013*). Three studies (*Desbordes, 2012, Mascaro, 2013a; Mascaro, 2013b*) identified no difference in neural activation between groups. One study (*Weng, 2013*) found that, compared with AC, a CM group evidenced greater activity in the IPC ($p<0.01$), dlPFC ($p<0.01$) and in the connections between the dlPFC and the NAcc ($p<0.01$) associated with increased altruistic behaviour. No relationship between altruistic behaviour and either insula or amygdala activation was found.

One study found that those trained in CM evidenced positive change in HRV ($p<0.05$) in comparison to WLC (*Kok, 2013*). A second study found no such difference in the same comparison (*May, 2011*). *Pace (2009)* found no main effect of their CM condition compared with an AC on cortisol (a physiological stress response) or IL-6 (an immune system response) change following exposure to a social stressor. Finally, *Weytens (2014)* found that self-report of physical symptoms improved more in their CM condition compared with WLC.

Long term effects of compassionate meditation

Only one study reported follow up. *Neff and Germer (2013)* found that post intervention outcomes were maintained at similar levels at both six and twelve month follow-ups (self compassion, mindfulness, compassion for others, social connectedness, life satisfaction, happiness, depression, anxiety, stress or avoidance: $p > 0.05$ at six months; all outcomes except life satisfaction: $p > 0.05$ at twelve months; life satisfaction increased $p < 0.05$).

Effect of amount of practice on outcomes

Eight studies reported on the effect of amount of personal practice on outcome. Six studies suggested increased positive outcomes and reduced negative outcomes correlated with increased practice time, including positive emotion (*Fredrickson, 2008*), compassion for the self ($r = .42$ and $.43$, both $p < 0.05$; *Neff & Germer, 2013*) and others ($r = .24$, $p < 0.05$; *Jazaieri, 2013*), emotional suppression, worry ($r = -.37$, $p < 0.01$ and $r = -.29$, $p < 0.05$; *Jazaieri, 2014*), immune response, distress ($r = .51$ and $-.46$, both $p < 0.01$; *Pace, 2009*), stress, mindfulness and altruistic orientation ($r = -.49$, $.45$, and $.46$, all $p \leq 0.05$; *Wallmark, 2013*). In a post hoc analysis, *Pace (2009)* found that high practice meditators in their sample had a significantly reduced immune response to a social stressor compared with low practice participants (Cohen's $d = 0.89$, $p < 0.05$).

Two studies (*Mascaro, 2013a, 2013b*), representing the same sample, reported that practice time did not correlate with fMRI neural activation.

Discussion

This review considered whether the use of compassionate meditation (CM) interventions with healthy adults can bring about durable positive change in psychological, behavioural and physiological outcomes. This is the first systematic review of the literature, in an area that has seen a sharp increase in interest in recent years (*Jazaieri et al., 2014*).

Can compassionate meditation bring about positive change in psychological, behavioural and physiological outcomes in healthy adults?

The majority of studies found significant effects supporting the use of CM, reporting a spread of small, medium and large effects. In the main, these results addressed emotional and cognitive change.

Psychological outcomes

Evidence is presented that suggests CM increases mindfulness and reduces worry, fears of compassion, emotional suppression and implicit bias towards two minority groups. The evidence did not reach agreement on whether CM can impact on positive emotion, compassion, empathy, life satisfaction, social connectedness, depression, anxiety or stress, with the evidence found in some studies not replicated in others. Furthermore, there was no evidence for CM's direct ability to alter happiness, hope, altruism, negative emotion, distress, cognitive reappraisal, explicit attitudes towards minority groups, irrational beliefs, coping, trait attention or personal resources (as defined by Fredrickson, 2008; see Table 7). If theories underpinning the use of CM rely on the generation of positive emotion, either to promote neuroplasticity (Gilbert, 2009) or to build personal resource (Fredrickson, 2001) then the failure to establish change in some of the central associated emotions represents something of a threat.

Further, almost all of the reported improvements occurred in comparison to waiting list controls (WLCs), even though nine studies used ACs. Some ACs included alternative mindfulness approaches, so this may indicate that these outcomes do not improve on existing interventions, which would be consistent with the conclusion from a recent meditation systematic review (Goyal et al., 2014). Given that other ACs consisted of education groups matched for time however, a more damaging assessment would be that change might simply reflect non-specific group effects.

Behavioural and physiological outcomes

There are fewer studies documenting the impact of CM on behaviour and physiological change, and the evidence that exists is, like psychological outcomes, equivocal. Evidence shows that, following CM, individuals are more likely to act altruistically, although CM may be no better than MM in promoting this.

Physiologically, CM's impact on dynamic nervous system balance (HRV) is undecided, with one study apiece falling on either side of significance. CM had no impact on immune system response, although only one study has examined this thus far.

Finally, despite the evidence of increased neural activation in areas of the brain associated with affective processing in experienced meditators (Lutz et al., 2004, 2008), CM training was unable to produce enhanced activation in brain areas associated with emotional processing, empathy and altruism, except in one study (Weng, 2013). This study reported increased activation in the inferior parietal cortex, dorsolateral prefrontal cortex (dlPFC) and the circuits linking the dlPFC and the nucleus accumbens (NAcc), in the context of increased altruistic behaviour. Though an isolated finding, it is relevant as the frontal cortex is implicated in emotional regulation (Ochsner & Gross, 2005), while the NAcc has been associated with charitable giving (Harbaugh, Mayr & Burghart, 2007). It should also be noted that two of the three studies that identified no neural activation change (Mascaro, 2013a, 2013b) reported from one trial, which experienced considerable attrition (28%) resulting in the smallest sample of all included studies (n=21).

Are the effects of compassionate meditation durable?

Compassion Focused Therapy uses CM and imagery in an attempt to 'exercise' the mind/brain and produce lasting change (Gilbert, 2009), so the question of whether repeated generation of positive feelings will lead to this lasting change, is pertinent. Follow up of gains were reported in only one of the 16 studies included. *Neff & Germer (2013)* reported strong post intervention outcomes, and found that all positive changes were maintained for at least twelve months after training. However, a significant proportion of their sample had prior meditation experience limiting the generalisability of these findings.

Does time spent in practice influence outcome?

Expert meditators generating loving-kindness states showed a greater activation in areas of the brain associated with empathy in the context of emotive stimuli (Lutz et al., 2008), suggesting that neural development may increase with practice. The cross sectional design of this study prevents assumptions about direction of causality however, as it is possible that individuals who have increased activation in these areas

of the brain are more likely to be drawn to CM. Studies that utilise a baseline as a control are perhaps better placed to answer this question. There was considerable support in the included studies to support this assertion, with relationships between amount of practice relating to increased positive emotion, compassion, mindfulness and altruism and reduced emotional suppression, worry, immune response, distress and stress. Interestingly, given the Lutz et al., (2008) study, fMRI activation of areas of the brain associated with empathy and altruism did not increase with practice time, though again, the small sample size in *Mascaro (2013a, 2013b)* is a possible contributor to this outcome.

If increased practice increases response, equivocal outcomes would be explained if some interventions did not provide enough practice. If this is true, then the included studies with longer interventions in terms of length of overall practice period (*Sears & Kraus, 2009* – 12 weeks) or total length of taught sessions (*Cordon, 2013; Desbordes, 2012; Jazaieri, 2013; Jazaieri, 2014; Mascaro, 2013a, 2013b* and *Neff & Germer, 2013* – 16 hours) should show more positive results than those with briefer interventions (e.g. *Weng, 2013* – 2 weeks) and less taught practice (*Weng, 2013* – 0 hours). This does not hold up in this admittedly simplified comparison however, as four of the longer interventions found few relevant effects, whereas *Weng (2013)* was the only study in the sample to report neural activation changes. More research would aid an understanding of the length of practice required to effect noticeable change and to establish if this equates to clinical relevance for meditation in routine practice.

Risk of bias within studies

Assessment of bias was carried out according to the Cochrane Reviews method. There were problems verifying methods of randomisation and concealment of allocation, as the majority of studies considered it sufficient to simply state that they had ‘randomised’ and inappropriate methods (e.g. using date of birth) could not be ruled out. Issues were also found in the judgement of blinding which again was only possible to assess if the study chose to explicitly describe it. One study (*Sears & Kraus, 2009*) managed to achieve double blinding however, suggesting that while this may be challenging or onerous, it is a standard that is not unachievable in intervention studies. Regardless, reporting on blinding approach is always achievable. By contrast, the judgement of data handling and reporting was more transparent. Though assessed

in the absence of access to pre study protocols, this was more open to educated assessment based on a comparisons of study hypotheses and reported results. Generally, the included studies reported fully on their outcomes, however there was a tendency in just under half to base results on completer data, which is a concern in an area where attrition rates meant an average of a quarter of the study sample was lost. Taken together, the variable study quality appears to reflect that found in the wider meditation intervention literature (Goyal et al., 2014; Keng et al., 2011).

Study Limitations

The decision to limit the review to healthy adult volunteers limits the generalisability of outcomes to potential clinical populations. Furthermore, the recruitment centres (e.g. universities, a professional workplace) and the procedures used to find participants (e.g. recruitment from meditation centres) resulted in a participant profile that was female, motivated, educated and likely to have an interest or experience in meditation (only four studies reported explicitly excluding participants with meditation experience). We can say very little about how men, those from less educated backgrounds and those whose state of mind undermines confidence and motivation may engage with this approach (i.e. clinical populations). This is the first systematic review in this area however, and the included studies and their samples represent the first steps in understanding the utility of CM.

Another potential limitation was the choice of evaluation tool. Cochrane methodology is normally employed to assess large-scale drug trials, where the preservation of the RCT is paramount and usually relatively achievable. While the principles of bias control are just as important to psychological research, in practice they can be problematic. This study involves early trials of a new approach, and it is perhaps the case that pilot studies should not be judged in the same way that large scale pharmacological RCTs are. Furthermore, to concentrate purely on bias is to overlook other important factors affecting outcome including sample sizes and attrition or intervention characteristics. Despite these shortcomings however, the Cochrane approach provides a recognised and reliable one, and though achieving the standards fully is a challenge the performance of the included studies across the six domains suggests that it can be done. Furthermore, alternative methods of using checklist

summary scores present their own difficulties (Higgins & Green, 2009), so the approach was considered acceptable in this context.

Further study

Compassion meditation does not yet have a standardised approach, and the subsequent variation makes comparisons across trials difficult. A number of standardised protocols are presented within the included studies and future research might usefully promote one of these approaches more widely, in the way that mindfulness research has adopted Kabat Zinn's MBSR (1982). Applying this to different populations and against established interventions would build a more reliable view of any evidence for CM. Particularly, establishing whether positive effects are possible in the relative short term, (e.g. 6-8 weeks) or whether benefit is confined to expert level, would be of interest given that compassionate meditative principles are already being used as a clinical tool. Finally, future studies should include follow-ups to establish pervasiveness of any effect.

The included studies rely heavily on self-report. Other physiological or behavioural measures such as heart rate variability, which has been found to distinguish cortisol activity in response to compassionate imagery (Rockliff, Gilbert, McEwan, Lightman & Glover, 2008), provide measures less vulnerable to performance bias and socially driven responding and could help reinforce self report outcomes.

Conclusion

The evidence for CM producing positive change in healthy participants is equivocal. There is also little available evidence to say whether any gains are maintained long term. Finally, increased practice may lead to greater gains, and some non-significant outcomes may be a result of insufficient practice. The development of a manualised approach would allow for more widespread research and improve comparability to help establish if CM can produce durable positive change. Improved reporting of potential bias would help improve the quality of literature in meditation studies. At the present time however, there is not enough evidence to support its use as a clinical intervention.

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CHAPTER TWO: MAJOR RESEARCH PROJECT PAPER

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

Iain N. Campbell

Mental Health and Wellbeing

University of Glasgow

1st Floor, Admin Building

Gartnavel Royal Hospital

1055 Great Western Road

Glasgow, G12 0XH

Tel. No: 0141 211 3920

Email: iain.campbell1886@gmail.com

Prepared in accordance with guidelines for submission to Clinical Psychology and
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Clinical Psychology (D.Clin.Psy)*

Lay Summary

Families often report a loss of empathy (the ability to feel what someone else is feeling) in relatives who have sustained a severe head injury (SHI). At the moment there are no effective treatments for this. A recent study reported the use of a brief compassionate imagery intervention with people with SHI, but was unable to increase levels of empathy or compassion. The present study builds on this research. After watching a DVD about imagery interventions, participants with SHI were split into two groups. One group underwent an enhanced version of compassionate imagery (the experimental group) and the other underwent relaxation imagery (the comparison group). All completed questionnaires measuring empathy, self-compassion, relaxation and anxiety before and after the intervention. In addition, a wordsearch task designed to measure sensitivity to threatening and compassionate words was completed before and after the intervention. Participants' heart rate was monitored throughout the intervention. No differences were found between groups on any measure. Results from the compassionate and relaxation imagery groups were then combined; at the end of the interventions relaxation had increased and anxiety decreased with no significant change in empathy or compassion. The outcome of this brief intervention does not indicate that compassionate focused imagery is effective in increasing empathy and compassion. Further research using a more intensive treatment and a larger group of participants is recommended.

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. **Aims:** 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. **Methods:** Participants were randomised to a 50-minute compassionate focused imagery (CFI) or relaxation imagery (RI) control condition. Self-report 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 non-significant 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 suggest 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.

Introduction

The incidence of head injury in Europe is estimated to be 235 per 100,000 of the population (Tagliaferri, Compagnone, Korsic, Servadei, & Kraus, 2006). In one year in Glasgow, there were 2962 admissions with head injury to hospital wards (Thornhill et al., 2000). Persistent disability is found in a high proportion of those experiencing head injury, and shows a stronger association with psychosocial sequelae than with injury severity (Whitnall, McMillan, Murray, & Teasdale, 2006; McMillan, Teasdale, & Stewart, 2012). This highlights the importance of addressing the psychological needs of head injury survivors. While interventions for physical disability can improve outcome, personality changes such as egocentrism, impulsivity, disinhibition and poor temper control often persist, causing difficulties with social relationships and resulting in social isolation and poorer recovery (Tate, Lulham, Broe, Strettles, & Pfaff, 1989; Wood & Yurdakul, 1997). Wood and Williams (2008) suggest that egocentrism and insensitivity to the needs of others may explain why many relationships fail post head injury, and why isolation persists in a high proportion of survivors. Empathy has emerged as a variable of interest, where the ability to recognise and respond to the emotional state of others is reduced (DeSousa et al., 2011). Despite the apparent need for interventions to improve the ability to empathise, there is little evidence to support the use of psychological therapy in this context (McMillan, 2013; O'Neill & McMillan, 2012).

Compassion is defined as sensitivity to the suffering of others and a commitment to alleviate suffering, a description that links it closely to the construct of empathy. Compassion Focused Therapy (CFT; Gilbert, 2009) is a recently developed intervention that seeks to enhance the capacity for compassionate experience to improve psychological wellbeing. The underpinning theory draws on evolutionary, neurophysiological and attachment perspectives, and proposes three interacting affective regulatory systems:

1. *Threat and protection*, reflecting the typically referred to 'fight or flight' sympathetic response.
2. *Drive and resource seeking*, characterised by pleasure or satisfaction that is derived from active attainment.
3. *Affiliative*, a system that is recognised as promoting a sense of rest, soothing and social connectedness.

Through work with people who experience high levels of shame and self-criticism, Gilbert and Procter (2006) noted that some individuals experience an imbalance in the activation of these three systems that correlated with increased psychopathology. CFT is designed to help individuals balance the three systems using principles that combine Western clinical psychology and Buddhist philosophy and practice to promote self-nurturing. Central to this intervention is the repeated generation of compassionate feelings towards the self and others, a practice believed to increase capacity within the affiliation system through a proposed process of neuroplasticity, in what Gilbert refers to less formally as 'physiotherapy for the brain' (Gilbert, 2009).

The prefrontal cortex is implicated in the generation of empathy (Damasio, 2003), via its thalamo-cingulate connections with the limbic system, which in turn plays a central role in the generation of affiliative emotions, motives and behaviours (MacLean, 1990). These circuits and their associated neurotransmitter and hormonal support (Wang, 2005) may be 'exercised' by rehearsal of compassionate experience during CFT. Evidence for this process is not established, however in recent years there has been increasing interest in CFT, and in the application of compassionate principles generally (Hofmann, Grossman, & Hinton, 2011). Damage resulting from head injury is often diffuse with focal injury in the frontal and temporal lobes (Adams et al., 1985). Given that those who have suffered severe head injury (SHI) are likely to have sustained damage to an integral part of the proposed affiliative system, the question of whether CFT's neuroplasticity process will extend to enable them to develop not only compassion for themselves, but for other people, is compelling.

O'Neill and McMillan (2012) reported the effects of a single session of compassion-focused imagery (CFI) on people with SHI who also had low empathy. The aim was to explore whether increased empathy could be achieved, even transiently, and whether this translated into improved self-reports of empathy. No significant effect was found with regard to empathy; however, higher self-report scores for self-compassion approached significance in both the CFI and relaxation imagery (RI) control group. The authors suggest that a longer intervention period might enhance the treatment effect and that the language used in compassion might be a barrier to participants (largely young males) who are unfamiliar with it. The present study examines a longer exposure to CFI in participants who have attended a short pre-treatment intervention

aimed at reducing difficulties with compassionate language and imagery. This latter approach is outlined in a separate study (Gallagher, 2014; Appendix 2.5).

A further consideration is that the self-report measures used by O'Neill and McMillan (2012) may not have been sensitive enough to detect a change in a single-session. Bradley and Lang (2000) assert that any measure of emotion should include at least one measure from three key systems: language, behaviour and physiological events. Self-report satisfies only the language criterion. To meet these requirements a behavioural dimension represented by a measure of information processing bias ('The Imbedded Word Task') was developed with the aim of including a measure that was potentially sensitive to less consciously driven responding. Physiological responses were also assessed using Heart Rate Variability (HRV). HRV is an indicator of central nervous system activity that may differentiate those in an 'affiliative state' from those in a 'threatened state' (Rockcliff, Gilbert, McEwan, Lightman, & Glover, 2008), and therefore provided a potentially objective measure of an active compassionate state. HRV's role in affiliation is explained by the polyvagal theory (Porges, 2006), which describes how the phylogenetically advanced ventral-vagal complex has evolved to actively facilitate sympathetic and parasympathetic activity, representing a flexible balance between social engagement and threat reactions in response to environmental cues (Porges, 2006). HRV was accepted as a measure of vagal influence, with low HRV representing low vagal activity, reduced reactivity in the autonomic nervous system and a decreased ability to respond flexibly to environmental conditions other than threat (and vice versa), reflecting Gilbert's (2009) threat and compassion systems. Rockcliff et al. (2008) found that brief CFI promoted predicted change in HRV associated with self-criticism and attachment style. This preliminary study supports the use of HRV as a measure of activation of a prosocial affiliative system in response to CFI, as well as utilising Fears of Compassion measures to highlight the importance of distinguishing those who are high in fears of compassion and therefore unlikely to react adaptively to CFI.

A relaxation imagery control was chosen as it provided a clinically established intervention that was comparable in length and delivery to the experimental condition (CFI). Given the assumption that increased HRV is considered to represent an increase in relaxed emotional state (Porges, 2006), it was anticipated that the RI

condition would have a similar impact on HRV to CFI. For this reason, HRV changes were only considered meaningful in the presence of corresponding self-report changes in empathy and compassion.

Aims and hypotheses

This study explored whether increased duration of CFI following an intervention to increase familiarity with compassionate language would translate the non-significant and non-specific trend reported by O'Neill and McMillan (2012) into a significant and specific increase in empathy and compassion. In an attempt to ensure detection of any change, the present study also considered whether additional measures would increase sensitivity.

An associated study, not reported here, examined the effect of preparing a group of SHI participants for CFI in anticipation of this intervention (Appendix 2.5).

Hypotheses:

1. Following a single session of CFI intervention, severe head injury participants will evidence greater changes from baseline on self-report of self-compassion and empathy, a greater reduction in sensitivity to threat words and a greater increase in sensitivity to empathy and compassion words in an information processing task compared to a RI control group.
2. Changes in compassion and empathy self-report and reduced ANS markers of stress and arousal as measured by HRV will be associated with the CFI and not RI intervention.
3. There will be a significant negative correlation between scores on the Fears of Compassion Scale and the magnitude of change across all outcomes in the CFI condition. No significant correlation will be found in the RI condition.

Methods

Ethics

Approval was obtained from NHS East of Scotland Research Ethics Committee (Appendix 2.3). Management approval for the protocol was granted by NHS Greater Glasgow and Clyde Research and Development Directorate (Appendix 2.4),

Huntercombe Group, the Brain Injury Rehabilitation Trust and Headway Glasgow (Appendix 2.3).

Design

The study consisted of two phases: an initial preparatory intervention reported elsewhere (Appendix 2.5) and an imagery intervention reported here. All who completed the preparatory intervention went on to complete the imagery intervention.

The imagery intervention employed a mixed factorial design, with a between groups comparison using repeated measures within subjects to ascertain change pre to post intervention. There were two levels of the intervention independent variable: compassion focused imagery (CFI) and relaxation imagery (RI). The latter condition formed the control group, an established intervention in head injury that matched the experimental intervention in terms of time and level of therapeutic input. RI was not expected to directly impact on empathy and compassion self-report and attention outcomes.

Dependent variables were:

- Self report:
 - Compassion
 - Empathy
 - Stress level
 - Relaxation
- Behavioural:
 - Compassion and threat word identification (information processing bias)
- Physiological:
 - Heart rate variability (HRV)

Scores on the Fears of Compassion scale were included as a covariate to allow an examination of the impact of pre existing attitudes towards compassion on outcome.

Sample Size Considerations

O'Neill and McMillan's (2012) study represented the first study to use brief compassionate imagery with a head injured sample. Though a trend towards

increased empathy of borderline significance was found when the treatment groups were combined (i.e. within groups), there were no significant between group effects produced by the reported intervention, and effect sizes were small. The aim of the current study was to develop an intervention that reduces the limitations noted by O'Neill and McMillan (2012) and increases the chance of finding an effect of CFI. In addition a preparatory exercise (Appendix 2.5) was introduced prior to the imagery part of the intervention. These significant alterations to, and the small between group effect sizes reported by, the original intervention, meant that the O'Neill and McMillan (2012) study was not appropriate as a basis for sample size calculation.

Shapiro, Brown and Biegel (2007) using a mindfulness intervention, reported significant outcomes on the Self Compassion Scale, a primary measure in the current study. Notably, however, Shapiro et al. (2007) adopted a different design (within subjects) and longer intervention. Nonetheless, this was considered a reasonable starting point for a sample size calculation for what is essentially a pilot intervention looking for minimal state change. Based on their data, a sample size of 24 was estimated (GPower; Erdfelder et al., 1996) with $d_z=0.8$, $\alpha=0.05$ and power=0.8.

Participants

Participants were recruited from a brain injury community service in East Dumbarton, two inpatient rehabilitation services (Glasgow and Lanarkshire) and a voluntary community group based in Glasgow.

Inclusion criteria: Participants were aged between 18 and 65 years old, with a history of SHI (defined as post traumatic amnesia > 1 day; Russell, 1935) that occurred at least three months prior to testing. Participants had capacity to consent as verified by staff known to them. Participants underwent a preparatory intervention prior to commencing with the imagery intervention (Appendix 2.5).

Exclusion criteria: Individuals with a learning disability, a diagnosed degenerating neurological condition, current substance abuse, sensory and/or communication difficulties which may affect their ability to consent and/or fully engage with the study, or severe and active mental illness that would prevent participation were not included in the study.

Twenty-six participants met the criteria and consented. Data for two participants were excluded: in one it later emerged that stroke was the primary cause of brain injury and in the second sensory difficulties prevented full engagement. Twenty-four participants ($n=24$) were therefore included; five were women. All identified themselves as white British, Irish or Scottish. Mean age was 46.95 ($SD=8.89$) and a severe head injury was sustained at least three months prior to participation ($Mdn=112.50$, $IQR=30.50-211.75$). Cause of injury was a fall ($n=11$), road traffic accident ($n=9$) or assault ($n=4$). Median age for leaving education was 16.00 ($IQR=16.00-17.00$) and mean premorbid full scale IQ estimated by the Test of Premorbid Functioning (Wechsler, 2011) was 91.92 ($SD=9.83$). Deprivation was derived from postcodes using the Scottish Index of Multiple Deprivation 2012 (SIMD; Scottish Government, 2012), which ranks geographical areas from 1 (most deprived) to 6,505 (least deprived). The median in the current sample was 1189 ($IQR=577.50-3204.25$). The majority of participants (75%) live in areas within the bottom four SIMD deciles (i.e. most deprived). This compared with just 54% of the general population of the Greater Glasgow and Clyde population as a whole (Scottish Government, 2012). Finally, the Glasgow Outcome Scale-Extended (Wilson, Pettigrew, & Teasdale 1997) rated disability outcome as 'lower severe' in four participants (16.67%), 'upper severe' in three (12.5%), 'lower moderate severe' in ten (41.67%), 'upper moderate' in five (20.83%) and two (8.33%) as 'lower good recovery'.

Measures

Descriptive measures

- Test of Premorbid Functioning (TOPF; Wechsler, 2011): a premorbid measure of IQ. 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 (SDMT; Smith, 1982): a brief measure of executive function, reliant on attention, visual scanning and motor/psychomotor speed. Tests-retest reliability in a non-brain injured population was found to be good (>0.76) and it is considered to be an effective test of 'general' brain impairment.
- Glasgow Outcome Scale-Extended (GOS-E; Wilson et al., 1997): a highly cited measure of disability following TBI, the GOS-E uses eight categories to record disability outcome.

Pre intervention measure

- Fears of Compassion (FoC; Gilbert McEwan, Matos, & Ravis, 2011): it has been noted that pre-existing attitudes towards compassion can impact on the ability to access the affiliative system. This self-report measure contains three scales designed to estimate fears of compassion for others (10 items), compassion from others (13 items) and compassion from self (15 items). Items are rated on a five point Likert scale ranging from 0 ('don't agree at all') to 4 ('completely agree'). The measure has good reliability (0.76 – 0.92).

Pre and post intervention measures: self-report

Primary outcome measures

- Empathy Quotient (EQ; Baron-Cohen & Wheelwright, 2004; Appendix 2.7): the original measure contains 60 items, 40 empathy and 20 control items. Empathy in the context of this measure is conceptualised along both cognitive and affective components. Concerns about the length of this measure and the impact on participant attention and fatigue led to the decision to adopt the approach described by O'Neill & McMillan (2012). The EQ was reduced to 26 items (10 cognitive, 10 affective and 6 social skills items), randomly split in two and administered pre and post-intervention (Appendix 2.6). Responses are given on a 4-point Likert scale ranging from 'strongly agree' to 'strongly disagree', possible outcome ranges from 0-26 and higher scores indicate higher levels of empathy. The EQ has been found to be reliable over time and across samples and displays reasonable concurrent and construct validity (Lawrence, Shaw, Baker, Baron-Cohen, & David, 2004).
- The Self Compassion Scale – short form (SCS; Neff, 2003): measures self-kindness and self-judgement, common humanity versus isolation and mindfulness against over identification. Twelve items are rated on a five point Likert scale ranging from 1 ('almost never') to 5 ('almost always'), possible outcome ranges from 12-60 and higher scores indicate higher levels of self empathy. The full version of this measure (26 items) has shown good reliability (0.75 – 0.81), though again for reasons of brevity in the context of head injury, the short version of the scale was used. This version has evidenced a near perfect correlation with the long form (≥ 0.97 ; Raes, Pommier, Neff, & Van Gucht, 2010).

Secondary outcome measures

- Relaxation Scale (RS; O'Neill & McMillan, 2012; Appendix 2.8): the brief measure designed and used by O'Neill and McMillan in their 2012 study was adopted. Three

measures of relaxation were derived via a 7-point Likert scale; possible outcome ranges from 3-21 and higher scores indicate higher levels of relaxation.

- The State-Trait Anxiety Inventory, Short form (STAI; Marteau & Bekkers, 1992): sensitive to fluctuations in state anxiety, this six-item version offers a more brief and acceptably reliable alternative (0.82) to the original 40-item measure. All items are rated on a Likert scale from 1 ('not at all') to 4 ('very much'), possible outcome ranges from 6-24 and higher scores indicate higher levels of anxiety.

Pre and post intervention measures: behavioural (secondary outcome measures)

- Imbedded word task (Appendix 2.10): Based on the procedure described by Wenzlaff, Rude, Taylor, Stultz, and Sweatt (2001), a wordsearch task was developed, with the aim of measuring state mediated effects on information processing bias towards compassionate and threat based words before and after intervention (Appendix 2.9). Each wordsearch was 13 x 13 letters and contained five compassion rated words (e.g. 'calm'), five threat-rated words (e.g. 'hurt') and five neutral-rated words (e.g. 'rice'). Words were matched in terms of length, frequency of use (Francis & Kucera, 1982) and emotional valence (Averill, 1975). Neutral words were intended to divert participants from what would otherwise be only compassionate or threat based words. Participants were rated according to how many compassionate words they identified (range 0-5, higher scores indicating an increased compassionate state) and how many threat words they identified (range 0-5, higher scores indicating an increased threatened state) in four minutes. The validity and reliability of the wordsearches were not established prior to their inclusion in the study and therefore are considered to be a pilot measure.

Pre and post intervention measures: physiological (secondary outcome measures)

- Heart Rate Variability (HRV): inter beat interval (R-R) was recorded using the Polar RS800CX training computer via the Polar H3 heart sensor. The standard deviation of the interbeat intervals (SDNN) within a 95% confidence interval around the mean to filter out outliers and artifacts, was calculated using a Microsoft Excel spreadsheet. This reflected the metric used by Rockliff et al., (2008) who in turn selected it on the recommendation of the Task Force of the European Society of Cardiology and the North American Society of Pacing and Electrophysiology (1996).

Intervention

A focus group of individuals with severe head injury and professionals involved in their care helped shape the interventions. As a result, emphasis was placed on pacing

and reducing demands on memory, attention and executive function difficulties by limiting content and making use of repetition. Both interventions lasted 50 minutes and contained elements of breathing, relaxation and mental imagery. The following structure was used:

- 15-minute breathing and imagery exercise focused on compassion (CFI condition) or relaxation (RI condition) based imagery.
- 5-minute guided reflection; the experimenter and participant discussed the exercise to enhance the experience and mitigate difficulties.
- 10-minute break to guard against fatigue; the participant and experimenter remained in the room to minimise participant distraction and arousal.
- 15-further minutes of breathing and imagery exercises identical to the first exercise (except for introductions).
- 5-minute debrief to consolidate new experiences or answer questions.

A script for each intervention was used to ensure standardisation of content (Appendices 2.11 and 2.12).

Procedure

Staff in the brain injury services approached potential participants and provided them with the study Information Sheet (Appendix 2.13). If an individual indicated interest, they were contacted by a researcher who answered any further questions and arranged a meeting.

One researcher administered all measures pre and post intervention and was blind to intervention group. A separate researcher randomised participants to CFI or RI, carried out the intervention and was blind to scores on all measures. After written consent was obtained (Appendix 2.14), demographic information and descriptive measures were gathered. Each participant was then fitted with a chest band heart rate monitor and underwent a preparatory intervention (a DVD about 'mental imagery') that was designed to acclimatise them to the nature of imagery as an intervention and to the language of compassion and relaxation used in the interventions (Appendix 2.5). The first 15 minutes of this 20-minute activity was largely passive, and served as the baseline for HRV measurement. Pre-intervention measures were then taken. Each participant was then randomised to CFI or RI. Randomisation was achieved using a randomisation code generator (Randomisation Code Website: Harr, 2010; retrieved

December 2013, seed no. 6378). Each 15-minute imagery section allowed for HRV comparison to each other and to the baseline. Upon completion of the intervention, the heart rate monitor was removed and the participant completed the post intervention measures. To test 'blinding' both the researcher administering outcome measures and the participant were asked to guess which intervention the participant had received. The researcher correctly identified 50% of the condition allocation, while 67% of participants identified the correct intervention (Fisher's exact test indicated that received intervention was not associated with participant intervention speculation ($p=0.193$)). The participant was then debriefed.

Results

Demographic Variables

Continuous demographic data was checked regarding parametric assumptions. Normality was ascertained from plot inspection and homogeneity of variance was tested using the Levene Test. Age, Full Scale IQ (FSIQ) and SDMT followed a normal distribution. Months since injury, age on leaving education and SIMD rank did not (*Table 1*).

There were no significant differences between groups in age ($t(22)=-1.083$, $p=0.291$), gender (Fisher's exact test, $p=0.590$), cause of accident (Fisher's exact test, $p=1.00$), FSIQ ($t(22)=0.408$, $p=0.687$), SDMT ($t(22)=-0.290$, $p=0.775$), age in years since education was completed (Mann Whitney $U=69$, $p=0.867$), SIMD rank ($U=46$, $p=0.133$) or GOS-E (Fisher's exact test, $p=1.00$). Time since injury was significantly longer in individuals in the RI group (Mdn=194.50, IQR=98.25-216.25) compared with the CFI group (Mdn=38.00, IQR=6.50-133.00; $U=35$, $p=0.032$).

Table 1: Participant characteristics by group.

	Treatment Group	
	Compassion Focused Imagery (CFI) n=12	Relaxation Imagery (RI) n=12
Age (M (SD))	45.00 (8.32)	48.92 (9.37)
Gender (n (%)): Male Female	9 (75.00) 3 (25.00)	11 (91.67) 1 (8.33)
Ethnicity (n (%)): White Scottish/British/Irish	12 (100)	12 (100)
Cause of HI (n (%)): Road traffic accident Assault Fall	2 (16.67) 3 (25.00) 7 (58.33)	7 (58.33) 1 (8.33) 4 (33.33)
Months since HI (Mdn; IQR):	38.00 (6.50-133.00)	194.50 (98.25-216.25)
Age left education (years; Mdn; (IQR):	16.00 (15.25-18.50)	16.00 (16.00-17.00)
SIMD Rank (Mdn ; IQR):	760.00 (276.25-2150.25)	1505.00 (920.00-4624.25)
ToPF Full Scale IQ (M; SD):	92.75 (10.09)	91.08 (9.93)
Symbol-Digit Modalities Test (M; SD):	29.00 (9.49)	27.67 (12.82)
GOS-E (n (%)): Severe disability Moderate disability Good recovery	3 (25.00) 7 (58.33) 2 (16.67)	4 (33.33) 8 (66.67) 0 (0.00)

Experimental analysis

Between group impact of intervention on self-report scores

Pre to post-intervention scores (*Table 2*) were translated into a single change variable for each self-report dependent variable: Empathy Quotient (EQ), Self Compassion Scale (SCS), Relaxation Scale (RS) and the State Trait Anxiety Inventory (STAI). Frequency data were plotted and inspected for the assumption of normality. Change in EQ, SCS and RS were normally distributed. Studentised residual Q-Q plots were inspected post analysis and no deviations were apparent. The STAI change scores were not normally distributed. Change in EQ, SCS and RS had homogeneity of error variance.

Table 2: Selfreport outcomes pre and post intervention and change by group

	Empathy Quotient (M; SD)		Self Compassion (M; SD)		Relaxation Scale (Mdn; IQR)		STAI (Mdn; IQR)	
	Pre	Post	Pre	Post	Pre	Post	Pre	Post
CFI (n=12)	12.92 (5.00)	13.83 (5.57)	36.08 (5.98)	35.92 (7.00)	14.00 (12.00 - 17.75)	18.00 (16.50 - 19.75)	11.00 (8.00 - 13.75)	8.00 (6.25 - 13.00)
CFI change	0.92 (4.94)		-0.17 (6.26)		3.33 (3.68)*		-0.5 (-3.50-0.00)	
RI (n=12)	12.50 (3.55)	14.75 (4.00)	36.67 (8.72)	37.25 (9.80)	18.50 (15.00 - 20.00)	19.50 (15.75 - 21.00)	7.50 (7.00 - 11.75)	8.50 (6.00 - 9.75)
RI change	2.25 (2.80)		0.58 (4.66)		1.17 (2.62)*		-1.0 (-2.00-0.00)	
CFI and RI combined (n=24)	12.71 (4.25)	14.29 (4.77)	36.38 (7.32)	36.58 (8.36)	15.00 (12.00 - 19.75)	19.00 (16.50 - 21.00)	10.00 (7.00 - 12.75)	8.00 (6.00 - 10.00)

* mean change scores (and standard deviation)

To compare change in EQ, SCS and RS scores across groups, ANCOVAs using pre-intervention scores as a covariate were used. Independence of the covariates and treatment effects and the assumption of homogeneity of regression slopes were met for all three analyses. Change scores for EQ and SCS were not significantly predicted by their respective pre-scores ($F(1,21)=2.524$, $p=0.127$; $F(1,21)=0.609$, $p=0.444$), but RS change was predicted by its pre-scores ($F(1,21)=14.907$, $p<0.01$). The effect of intervention was not significant after controlling for respective pre-intervention scores for change in EQ ($F(1,21)=0.577$, $p=0.456$), change in SCS ($F(1,21)=0.131$, $p=0.721$) or change in RS ($F(1,21)=0.426$, $p=0.521$). A Mann Whitney test was carried out on change in STAI scores across the two groups. No significant difference between the conditions was found ($U= 67.50$, $p=0.346$).

Between group impact of intervention on sensitivity to compassionate and threat based words

Compassionate and threat words identified from pre to post intervention were translated into two change categories (*Table 3*): *reduction/no change* (less words identified post-intervention/same number identified) or *increase* (more words identified post-intervention). Change was then compared between groups for identification of compassion based and then again for threat based words. Fisher's exact test revealed no differences between CFI and RI groups in change in identification of words, either in the identification of compassionate ($p=1.0$) or threat words ($p=1.0$).

Table 3: Pre to post change in compassionate and threat word identification by group

	Compassionate words		Threat words	
	Reduction/no change	Increase	Reduction/no change	Increase
CFI	7	5	8	4
RI	8	4	9	3
Total	15	9	17	7

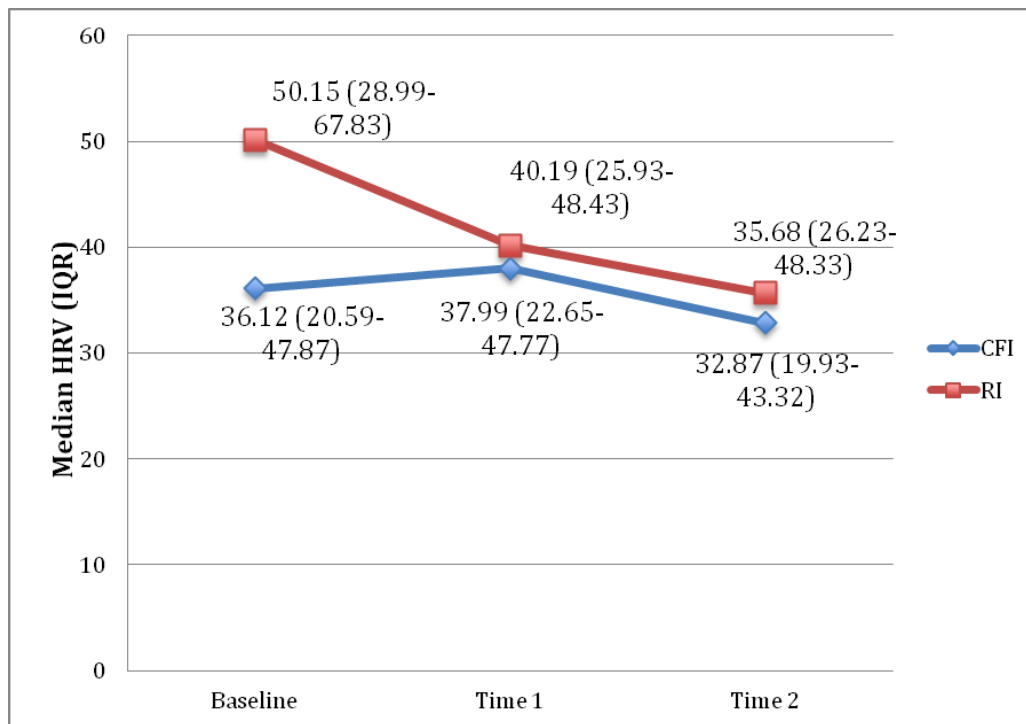


Figure 1: Median HRV scores by intervention group

Changes in HRV in relation to changes in compassion and empathy self report

Median HRV (SDNN) at each time point (baseline, time 1 and time 2) are presented in *Figure 1*. As HRV shows less reactivity in individuals with low HRV (Porges, 2006) HRV change was expressed as a percentage of the baseline, making the magnitude of HRV change comparable between individuals (*Table 4*). Where change was a negative outcome, this was retained in the percentage value in order to indicate direction of change. HRV change from baseline to time 1 and from baseline to time 2 were inspected for normality. Inspection of Q-Q plots of studentised residuals suggested enough deviation from normality in both distributions to preclude the use of parametric analysis.

Table 4: Median (and interquartile range) HRV % change by group

	Baseline to Time 1	Baseline to Time 2
CFI Group (n=12)	-3.03 (-17.72-40.07)	-12.29 (-18.45-14.04)
RI Group (n=12)	-9.93 (-19.24 - -2.91)	-16.55 (-29.64-11.66)

Table 5: Spearman's rho correlations (and p-value) by group and timepoint.

	CFI Group (n=12)		RI Group (n=12)	
	Empathy Quotient Change	Self-Compassion Change	Empathy Quotient Change	Self-Compassion Change
HRV Change Baseline to time 1	-.309 (0.329)	-.039 (0.905)	-.167 (0.604)	-.235 (0.462)
HRV Change Baseline to time 2	-.277 (.383)	-.322 (0.313)	-.215 (0.502)	-.380 (0.224)

Spearman's rho was used to examine correlations between EQ change and HRV change, and SCS change and HRV change. No significant relationships were found (Table 5).

Fears of Compassion in relation to change in empathy and self-compassion self report and HRV

Fears of Compassion scores (FoC; M=64.71, SD=23.44) were plotted and followed a normal distribution. Pearson's r was used to examine correlations with EQ and SCS. Spearman's rho was used to assess the relationship with HRV change (Table 6). All but one of the outcomes reflected the predicted direction. No correlations were significant, however.

Table 6: Fear of Compassion correlated with empathy, self-compassion and HRV outcome by group.

	CFI Group (n=12)	RI Group (n=12)
Empathy Quotient Change	-.16 (0.63)	.06 (0.84)
Self-Compassion Change	-.27 (0.39)	-.15 (0.64)
HRV Change Baseline to time 1	-.21* (0.51)	-.08* (0.80)
HRV Change Baseline to time 2	-.10* (0.76)	-.35* (0.26)

NB: Where data met assumptions of normality Pearson's r and (p) are quoted. Otherwise, Spearman's rho* and (p) are quoted.

Supplementary analyses: Brief non-specific imagery (CFI and RI combined)

The CFI and RI group data were combined and analysed to explore the impact of a non-specific imagery intervention on self-report and HRV outcomes.

Within group impact of brief non-specific imagery on self report

Distributions for both the EQ and the SCS scores, pre and post intervention, followed a normal distribution. Distributions for RS and the STAI were not normally distributed, and transformation of the data did not improve this. Differences in EQ and SCS scores were compared pre and post-intervention using paired samples t-tests. There was no significant difference pre and post intervention on the SCS ($t(23)=-0.189$, $p=0.852$). On the EQ, there was a non-significant trend towards increased empathy post intervention ($t(23)=-1.945$, $p=0.064$, $d_z=0.40$). There was a significant increase in RS scores pre (Mdn=15.00, IQR=12.00-19.75) to post (19.00, IQR=16.50-21.00) intervention (Wilcoxon signed ranks; $T=28.50$, $p<0.01$, $r=.41$) and a significant decrease in state anxiety pre (Mdn=10.00, IQR=7.00-12.75) to post (Mdn=8.00, IQR=6.00-10.00) on the STAI ($T=40$, $p<0.05$, $r=.29$).

Within group impact of brief non-specific imagery on HRV outcomes

HRV data at baseline, time 1 and time 2 were plotted and checked for normality. The data did not follow a normal distribution. Change in HRV from baseline to time 1 (Wilcoxon signed ranks tests; $T=110$, $p=0.253$) and from baseline to time 2 was not significant ($T=100$, $p=0.153$).

Supplementary analyses: HRV

Between group impact of intervention on HRV outcomes

Mann Whitney U-tests found no significant differences in HRV change between groups from baseline to time 1 ($U=58.00$, $p=0.443$) or baseline to time 2 ($U=62.00$, $p=0.590$).

HRV increase group vs decrease group: impact on self-report outcomes

In a process similar to that adopted by Rockliff et al., (2008), regardless of CFI or RI intervention, those with an increase in HRV, defined as an increase in SDNN from baseline to time 2, were compared with those with a decrease in HRV, using EQ and

SCS change outcomes. FoC pre-intervention scores were also examined to establish if they predicted membership of either HRV change group. This resulted in a group of $n=8$ HRV increases and a group of $n=16$ HRV decreases.

When split into HRV increase and decrease groups, EQ change and SCS change were found to be of similar variance as adjudged by a Levene procedure. FoC showed unequal variance. Independent samples t-tests found no differences between the HRV increase and decrease groups for EQ change ($t(22)=-0.939$, $p=0.358$), SCS change ($t(22)=0.340$, $p=0.737$) or FoC pre interventions scores ($t(9.517)=-0.706$, $p=0.497$, equal variances not assumed).

Discussion

This study compared brief CFI and RI in individuals with SHI on self-report, behavioural and physiological measures primarily of empathy and self-compassion.

The primary hypothesis predicted that, compared to the RI control group, CFI would promote greater increases in self-compassion and empathy, evidenced by increases in self report, a reduction in sensitivity to threat words and a greater increase in sensitivity to empathy and compassion words. However, type of intervention had no differential impact on change in empathy, self-compassion, relaxation, anxiety or sensitivity to either type of words. The second hypothesis stated that an association between changes in self-report compassion and empathy and changes in HRV would be found in the CFI condition and not in the RI condition. Once more, group effects were non-significant. Finally, it was predicted that Fears of Compassion would negatively correlate with change across the main outcomes in the CFI condition only. This hypothesis is also rejected; participants' reports of Fears of Compassion were not associated with empathy, self-compassion or HRV.

Supplementary analyses confirmed that HRV response did not differ between groups. Indeed, instead of the overall increase in HRV predicted by polyvagal theory (Porges, 2006), HRV not only showed no significant change over time, but also tended towards a drop in both conditions, suggesting that the experience of imagery may have promoted a move away from a prosocial state in proportion of participants. Rockliff et

al.'s (2008) procedure of sub-dividing the sample into those with increased and decreased HRV responses across the intervention did not distinguish EQ or SCS change across the study on FoC scores prior to the study.

Combining the CFI and RI groups to form a single group was associated with improved general feelings of relaxation and reduced state anxiety across the intervention. There was a non-significant trend towards an increase in empathy across the intervention ($p=0.06$, $d_z=0.40$). These outcomes were not reflected in self-compassion or HRV however, neither of which showed any significant change over time.

The use of compassionate interventions with a SBI sample

O'Neill and McMillan (2012) reported no between group differences and an increase in self-compassion that approached significance ($p=0.07$) when groups were combined. Noting high levels of Fears of Compassion in their sample, they recommended a longer intervention following an opportunity for participants to familiarise themselves with the nature of compassionate imagery. In the present study, participants viewed a DVD and discussed this with a researcher before undergoing a more intensive imagery exercise (Appendix 2.5). However these adaptations did not lead to a significant group effect on the primary outcomes investigated by O'Neill & McMillan. Two studies have shown that brief compassionate interventions can produce significant effects, however. Rockliff et al., (2008) used a five-minute compassionate imagery intervention with 184 students and found a change in HRV relative to self-report self-criticism and attachment style. Hutcherson, Seppala, & Gross (2008), using a seven minute brief loving-kindness meditation intervention, increased positive emotional responses towards strangers in 45 healthy volunteers, with small to medium effects. Given the changes in these healthy samples, it may be that, for those who have sustained a SHI, the generation of compassion and empathy is inherently problematic.

In the theory underpinning CFT, reference is made to the co-existence of a 'new brain' and an 'old brain' in humans, with quality of communication between the two predicting experience of distress (Gilbert, 2009). Drawing on neurobiological and evolutionary perspectives, this theory refers to relationships between primitive limbic systems, thought to be the seat of emotion in mammals (Panksepp, 1998), and the

phylogenetically advanced neocortex, which is both influenced by emotion and, crucially in this context, influences emotion through appraisal processes (Panksepp, 1998; MacLean, 1990). The use of imagery in CFT is believed to make use of 'new brain' abilities to promote affiliative responses within 'old brain' emotional systems. Given the role of the prefrontal cortex in the generation of affiliative emotion (Damasio, 2003), the high incidence of damage to this area of the brain following SHI and reduced empathy in the SHI population (Williams & Wood, 2009; Wood & Williams, 2008), the ability to generate empathy and compassion through the process proposed by CFT is likely to be compromised in this population.

As well as damage to the structures thought to be primarily associated with affiliative responding, there are other cognitive impairments strongly associated with SHI that may undermine an individual's capacity to engage with compassionate imagery. All participants were either in rehabilitation or were attached to support services following this process. Ratings on the GOS-E generally indicated a moderate level of disability and therefore a degree of neuropsychological impairment within the sample is likely. Sustained attention, regarded as central in meditative practices (e.g. Bishop et al., 2004), memory, for both task instructions and for retrieving compassionate experiences, and motivation to engage in a sustained exercise with little stimulation, are examples of functions that are commonly compromised following head injury (Ponsford, Sloan, & Snow 2013). If the participants in this study found the sustained nature of the intervention too difficult and became frustrated or concerned, this may help explain why HRV reduced in twice as many participants as it increased.

A final consideration is the socio-economic context in which many of these individuals were raised. A higher proportion of this sample lived in deprived areas compared with the general population of the Greater Glasgow and Clyde NHS area. It is therefore likely that some will have faced premorbid early and prolonged adversity that may inhibit the ability to experience, recognise and embrace affiliative affect (Gilbert, 2009), regardless of head injury. If this were the case, then accessing compassionate imagery would not only be difficult but could be potentially anxiety provoking. Some evidence for this comes from the much larger proportion of participants whose HRV dropped across the study, suggesting increased sympathetic arousal. Furthermore, FoC scores appeared to be slightly higher than that reported in a healthy adult sample

elsewhere (Gilbert et al., 2011). However, despite previous findings that empathy is generally impaired in those with SBI (e.g. Wood & Williams, 2008), self-report scores in this sample were broadly comparable with a number of healthy adults samples (Baron-Cohen, 2006) and were higher than those in the O'Neill and McMillan study (which excluded those with higher empathy scores). Pre-intervention self-compassion was also similar to that found in a healthy sample with a high proportion of meditators (Neff & Germer, 2011). This may suggest that non-significant outcomes relate more to the effects of damage to the brain than to participants' pre-intervention empathy levels.

Study effect sizes

The Rockliff and Hutcherson studies not only investigated on healthy samples, but also report sample sizes that were considerably larger ($n=184$ and $n=93$, respectively) than both O'Neill and McMillan (2012) and this study. In the current study, the small effect sizes (Cohen, 1992) between groups for EQ change ($d=0.33$) and SCS change ($d=0.17$) suggest that the study may be underpowered. Similarly, effect sizes for the interventions combined, within groups, for EQ and HRV (B-T1 and B-T2) were small ($d_z=0.40$ and $r=.16$ and $.21$ respectively). So while the groups could not be separated in terms of their impact, it is possible that a significant effect required a larger sample size to find. By combining the groups, a larger effect on empathy that approaches significance was found, providing some evidence that imagery can be a viable intervention in SHI, despite the challenges of damage to key areas of the brain. However, HRV change tended towards the opposite direction from that expected if the SHI group had experienced increased empathy and casts some doubt over the validity of the empathy finding. Again however, the HRV change was not significant and effects were small; it may be that a larger sample size will help clarify if these findings have any meaning.

Intervention

Prior to taking part in this intervention, all participants viewed a preparatory DVD and discussed this with the researcher afterwards. Though information retention after the DVD was good, the preparatory intervention had no effect on FoC, state anxiety or negative affect. However, motivation for the imagery intervention increased ($p<0.01$;

$r=.50$) as did sensitivity to compassionate words ($p<0.001$; $r=.52$; Gallagher, personal communication; see Appendix 2.5).

Generally, compliance with the imagery interventions was good; post-intervention feedback regarding participants' experience was positive and none expressed distress or chose to disengage. Extended imagery practice is thought to be difficult for inexperienced individuals, so time was set aside during the intervention to discuss any issues that arose. No participants took advantage of this opportunity, however. This may indicate that participants were simply comfortable with the imagery approach, though emotional outcomes from the preparatory intervention do not provide strong evidence for this. Alternatively then, it could equally be an indication of reduced engagement, though further exploration of the participants' subjective experience would be required to establish this.

Strengths and limitations

This study made use of language, behaviour and physiology based measures (Bradley & Lang, 2000) and in doing so provides added protection against performance bias. The use of randomisation and blinding (of a researcher and participants) insulated against selection and outcome biases, and further strengthened internal validity. Finally, the use of a clinically relevant and closely analogous control group provided an appropriate comparator.

Small effect sizes across all primary outcomes, suggested that the study may have been underpowered, however. Also, the imbedded word task developed for this study was not validated before use, meaning that while the results of this measure were broadly in line with other outcomes, it cannot be assumed to be valid or reliable. Its inclusion was justified on the basis of it being considered safe and brief in its completion, but it would benefit from validation in both a healthy and a head injured population. A final consideration is the impact of an extended research procedure on participants. This study was directly preceded by a separate study (Appendix 2.5) designed to prepare the participant for an imagery task. Although questionnaires were chosen to be as brief as possible and numerous breaks were provided, the entire study took a participant three and a half hours to complete and fatigue may have therefore influenced engagement.

Further study

This is the first study to use HRV as a measure of affiliative response. This method was chosen based on Porges' (2006) Polyvagal Theory and on evidence from a previous study that showed that HRV could reliably differentiate positive and negative response to compassionate imagery (Rockliff et al., 2008). This latter study was based on a healthy population, however. No studies have looked at what impact, if any, severe injury to the brain has on the typical vagal response and by extension HRV. Establishing HRV as a valid measure of affiliative responding in a SHI population would help provide a useful adjunct to the more commonly used self-report measure.

The obstructive role that adverse reactions to the experience of compassion and kindness have on individuals' ability to engage in therapeutic work has already been reported (Gilbert et al., 2011). Similarly to O'Neill & McMillan (2012), the sample described here includes a high proportion of individuals who live in deprived areas. Further research would inform on what impact such an environment has on an individual with a brain injury and their ability to experience, understand and express affiliative emotions. This would then have implications for therapeutic interventions based on the generation of positive affect.

Finally, evidence is accumulating that brief compassionate imagery does not promote positive changes in individuals with a SHI. However, small between group effects suggest that this sample size may be insufficient, so future research should recruit larger samples to establish whether meaningful change exists, before compassionate imagery is incorporated into larger scale interventions (such as CFT) for those with SHI.

Conclusions

Compassion focused interventions aimed at effecting change through the generation of positive emotion are gathering interest in other clinical populations, though their effectiveness is not yet established. The results from this study confirm the outcomes of a previous study in finding that a brief compassionate imagery intervention promotes no clear changes attributable to the proposed affiliative system in a severe head injured sample. Even if compassionate approaches are proven as effective, it may yet be that structural damage, associated neuropsychological and emotional

impairment and high levels of premorbid adversity combine to form barriers that make this approach inaccessible following severe brain injury. There is reason to believe that both studies have been underpowered however, and replication using a larger sample is recommended.

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**CHAPTER THREE:
ADVANCED PRACTICE I: REFLECTIVE CRITICAL ACCOUNT**

**Being brave enough to be a psychologist: Understanding the processes at work
when moving from everyday interactions into deliberate therapeutic
interactions**

Iain N. Campbell

Mental Health and Wellbeing

University of Glasgow

1st Floor, Admin Building

Gartnavel Royal Hospital

1055 Great Western Road

Glasgow, G12 0XH

Tel. No: 0141 211 3920

Email: iain.campbell1886@gmail.com

*Submitted in partial fulfilment of the requirements for the degree of Doctorate in
Clinical Psychology (D.Clin.Psy)*

Abstract

Introduction

The novice psychologist enters the clinic with textbooks full of theories. Armed only with their knowledge of normal social interactions however, they must learn how to apply these theories by first learning how to interact in a therapeutically effective way. Fears about contravening the 'do no harm' principle interact with a lack of experience and can result in an increased tendency to err on the side of caution, a realisation that occurred to me when observing an experienced clinician engaged in this process.

Gibbs' (1988) model of reflection is used to formally structure the resultant reflection, while language from Carper's (1978) 'ways of knowing' facilitates a fuller exploration of the knowledge that influences therapeutic decisions.

Reflection

Reflecting on what I know of myself and on the theories, the ethics and the client dynamics that influence decisions, uncovers a set of personal fears that follow a similar theme: that to move interactions too quickly beyond the polite into potentially upsetting therapeutic ones, is to be cavalier. Furthermore, to do so may threaten the relationship and ultimately the wellbeing of the client.

I acknowledge that assumptions that have made my practice overly 'safe' lack grounds, but their removal does not make me accomplished yet; however, my awareness of what knowledge *is* important is heightened. I conclude that being a braver psychologist takes a synthesis of knowledge of the self, theory and experience.

Reflective Review

A meta-reflection allows me to recognise that my initial frustration at being 'restricted' by structure in fact highlights the inadequacy of informal, mental reflection in exploiting the full extent of a learning experience.

**CHAPTER FOUR:
ADVANCED PRACTICE II: REFLECTIVE CRITICAL ACCOUNT**

**New ways of working? The role of experiential learning in shaping attitudes to
service design and delivery**

Iain N. Campbell

Mental Health and Wellbeing

University of Glasgow

1st Floor, Admin Building

Gartnavel Royal Hospital

1055 Great Western Road

Glasgow, G12 0XH

Tel. No: 0141 211 3920

Email: iain.campbell1886@gmail.com

*Submitted in partial fulfilment of the requirements for the degree of Doctorate in
Clinical Psychology (D.Clin.Psy)*

Introduction

Clinical psychologists often experience tension between maintaining high quality of service to clients and meeting governmental targets in the context of receding resources. To meet the increasing demand for psychological therapy, one option has been for services to adopt a stepped care design delivered by multidisciplinary teams. This review ponders whether clinical psychology is sacrificing autonomy and identity in the name of efficiency or whether it has moved towards a modern mode of service that ultimately means a better deal for clinicians and clients alike.

Kolb's (1984) four stage experiential learning cycle is described, which places experience at the heart of the process of new learning.

Reflection

Two differing approaches to the delivery of psychological therapy are presented, one traditional using a one to one approach and the other multidisciplinary with a stepped design. A positive personal reaction to the latter is considered alongside concerns about loss of identity and specialised skills.

I consider whether my initial positive reaction to working in a stepped care service design is naïve to threats to the profession. The reflective process guides me to place confidence in my experience of these new ways of working, without losing sight of what service changes mean to the profession as a whole.

Reflective review

The central importance of experience in challenging, augmenting and/or replacing previous assumptions, and in the process of encouraging development of knowledge has been a valuable learning focus throughout this account.

RESEARCH PORTFOLIO APPENDICES

	Page
Appendix 1: Systematic Literature Review	
1.1 Cochrane Libraries risk of bias domains	78
1.2 Guidelines for submission to Clinical Psychology and Psychotherapy	79
Appendix 2: Major Research Project Paper	
2.1 Guidelines for submission to Neuropsychological Rehabilitation	82
2.2 Major Research Project Proposal	85
2.3 Ethics Committee approval letters	95
2.4 Research and Development approval letter	105
2.5 M. Gallagher's MRP abstract	107
2.6 Adaptation of the Empathy Quotient Scale	108
2.7 Adapted Empathy Quotient Scale	109
2.8 Relaxation scale	111
2.9 Development of the imbedded word task	112
2.10 Imbedded word task	113
2.11 Compassionate imagery treatment script	117
2.12 Relaxation imagery treatment script	123
2.13 Participant Information Sheet	129
2.14 Consent Form	132

Risk of bias		
Study identification (author, title, year of publication, journal title)		
Domain	Judgement	Support for judgement
Random sequence generation (selection bias)		
Allocation concealment (selection bias)		
Blinding of participants and personnel (performance bias)		
Blinding of outcome assessment (detection bias)		
Incomplete outcome data (attrition bias)		
Selective outcome reporting (response bias)		

Appendix 1.2

Guidelines for submission to Clinical Psychology and Psychotherapy

Author Guidelines

MANUSCRIPT STYLE

The language of the journal is English. 12-point type in one of the standard fonts: Times, Helvetica, or Courier is preferred. It is not necessary to double-line space your manuscript. Tables must be on separate pages after the reference list, and not be incorporated into the main text. Figures should be uploaded as separate figure files.

Enter an **abstract** of up to 250 words for all articles [except book reviews]. An abstract is a concise summary of the whole paper, not just the conclusions, and is understandable without reference to the rest of the paper. It should contain no citation to other published work.

Reference style . The APA system of citing sources indicates the author's last name and the date, in parentheses, within the text of the paper.

A. A typical citation of an entire work consists of the author's name and the year of publication .

Example: Charlotte and Emily Bronte were polar opposites, not only in their personalities but in their sources of inspiration for writing (Taylor, 1990). Use the last name only in both first and subsequent citations, except when there is more than one author with the same last name. In that case, use the last name and the first initial.

B. If the author is named in the text, only the year is cited .

Example: According to Irene Taylor (1990), the personalities of Charlotte. . .

C. If both the name of the author and the date are used in the text, parenthetical reference is not necessary .

Example: In a 1989 article, Gould explains Darwin's most successful. . .

D. Specific citations of pages or chapters follow the year .

Example: Emily Bronte "expressed increasing hostility for the world of human relationships, whether sexual or social" (Taylor, 1988, p. 11).

E. When the reference is to a work by two authors, cite both names each time the reference appears .

Example: Sexual-selection theory often has been used to explore patters of various insect matings (Alcock & Thornhill, 1983) . . . Alcock and Thornhill (1983) also demonstrate. . .

F. When the reference is to a work by three to five authors, cite all the authors the first time the reference appears. In a subsequent reference, use the first author's last name followed by *et al* . (meaning "and others") .

Example: Patterns of byzantine intrigue have long plagued the internal politics of community college administration in Texas (Douglas *et al* ., 1997) When the reference is to a work by six or more authors, use only the first author's name followed by *et al* . in the first and all subsequent references. The only exceptions to this rule are when some confusion might result because of similar names or the same author being cited. In that case, cite enough authors so that the distinction is clear.

G. When the reference is to a work by a corporate author, use the name of the organization as the author .

Example: Retired officers retain access to all of the university's educational and recreational facilities (Columbia University, 1987, p. 54).

H. Personal letters, telephone calls, and other material that cannot be retrieved are not listed in References but are cited in the text .

Example: Jesse Moore (telephone conversation, April 17, 1989) confirmed that the ideas. . .

I. Parenthetical references may mention more than one work, particularly when ideas have been summarized after drawing from several sources. Multiple citations should be arranged as follows .

Examples:

- List two or more works by the same author in order of the date of publication: (Gould, 1987, 1989)
- Differentiate works by the same author and with the same publication date by adding an identifying letter to each date: (Bloom, 1987a, 1987b)
- List works by different authors in alphabetical order by last name, and use semicolons to separate the references: (Gould, 1989; Smith, 1983; Tutwiler, 1989).

All references must be complete and accurate. Where possible the DOI for the reference should be included at the end of the reference. Online citations should include date of access. If necessary, cite unpublished or personal work in the text but do not include it in the reference list. References should be listed in the following style:

Journal Article

Gardikiotis, A., Martin, R., & Hewstone, M. (2004). The representation of majorities and minorities in the British press: A content analytic approach. *European Journal of Social Psychology*, 34 , 637-646. DOI: 10.1002/ejsp.221

Book

Paloutzian, R. F. (1996). *Invitation to the psychology of religion* (2nd ed.). Boston: Allyn and Bacon.

Book with More than One Author

Natarajan, R., & Chaturvedi, R. (1983). *Geology of the Indian Ocean* . Hartford, CT: University of Hartford Press. Heslen, J., Carpenter, K., Moriber, H., & Milsop, A. (1983). *Computers in the business world* . Hartford, CT: Capital Press. and so on. The abbreviation *et al.* is not used in the reference list, regardless of the number of authors, although it can be used in the text citation of material with three to five authors (after the initial citation, when all are listed) and in all parenthetical citations of material with six or more authors.

Web Document on University Program or Department Web Site

Degelman, D., & Harris, M. L. (2000). *APA style essentials* . Retrieved May 18, 2000, from Vanguard University, Department of Psychology Website:
http://www.vanguard.edu/faculty/ddegelman/index.cfm?doc_id=796

Stand-alone Web Document (no date)

Nielsen, M. E. (n.d.). *Notable people in psychology of religion* . Retrieved August 3, 2001, from

<http://www.psywww.com/psyrelig/psyrelpr.htm>

Journal Article from Database

Hien, D., & Honeyman, T. (2000). A closer look at the drug abuse-maternal aggression link. *Journal of Interpersonal Violence*, 15, 503-522. Retrieved May 20, 2000, from ProQuest database.

Abstract from Secondary Database

Garrity, K., & Degelman, D. (1990). Effect of server introduction on restaurant tipping. *Journal of Applied Social Psychology*, 20, 168-172. Abstract retrieved July 23, 2001, from PsycINFO database.

Article or Chapter in an Edited Book

Shea, J. D. (1992). Religion and sexual adjustment. In J. F. Schumaker (Ed.), *Religion and mental health* (pp. 70-84). New York: Oxford University Press.

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Illustrations. Upload each figure as a separate file in either .tiff or .eps format, the figure number and the top of the figure indicated. Compound figures e.g. 1a, b, c should be uploaded as one figure. Grey shading and tints are not acceptable. Lettering must be of a reasonable size that would still be clearly legible upon reduction, and consistent within each figure and set of figures. Where a key to symbols is required, please include this in the artwork itself, not in the figure legend. All illustrations must be supplied at the correct resolution:

- Black and white and colour photos - 300 dpi
- Graphs, drawings, etc - 800 dpi preferred; 600 dpi minimum
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Placement: References are cited in the text by the author's surname, the publication date of the work cited, and a page number if necessary. Full details are given in the reference list. Place them at the appropriate point in the text. If they appear within parenthetical material, put the year within commas: see Table 3 of National Institute of Mental Health, 2012, for more details)

Within the same parentheses: Order alphabetically and then by year for repeated authors, with in-press citations last.

Repeat mentions in the same paragraph: If name and year are in parentheses, include the year in subsequent citations. Within a quotation: This is the text, and Smith (2012) says "quoted text" (p. 1), which supports my argument. This is the text, and this is supported by "quoted text" (Smith, 2012, p. 1). This is a displayed quotation. (Smith, 2012, p. 1)

One author: Smith (2012) or (Smith, 2012)

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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Reference list

Order: Alphabetical letter by letter, by surname of first author followed by initials.

References by the same single author are ordered by date, from oldest to most recent.

References by more than one author with the same first author are ordered after all references by the first author alone, by surname of second author, or if they are the same, the third author, and so on. References by the same author with the same date are arranged alphabetically by title excluding 'A' or 'The', unless they are parts of a series, in which case order them by part number. Put a lower-case letter after the year: Smith, J. (2012a). Smith, J. (2012b). For organizations or groups, alphabetize by the first significant word of their name. If there is no author, put the title in the author position and alphabetize by the first significant word.

Form of author name: Use the authors' surnames and initials unless you have two authors with the same surname and initial, in which case the full name can be given:

Smith, J. [Jane]. (2012). Smith, J. [Joel]. (2012). If a first name includes a hyphen, add a full stop (period) after each letter: Jones, J.-P.

Books

One author: Author, A. A. (2012). *This is a book title: And subtitle*. Abingdon: Routledge.

Two authors: Author, A. A., & Author, B. B. (2012). *This is a book title: And subtitle*. Abingdon: Routledge.

Three authors: Author, A. A., Author, B. B., & Author, C. C. (2012). *This is a book title: And subtitle*. Abingdon: Routledge.

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).

Chapter: Author, A. A. (2012). This is a chapter. In J. J. Editor (Ed.), *Book title: And subtitle* (pp. 300–316). Abingdon: Routledge.

Journals

One author: Author, A. A. (2011). Title of article. *Title of Journal*, 22, 123–231. doi:xx.xxxxxxxx Provide the issue number ONLY if each issue of the journal begins on page 1. In such cases it goes in parentheses: *Journal*, 8(1), pp–pp. Page numbers should always be provided. If there is no DOI and the reference was retrieved from an online database, give the database name and accession number or the database URL (no retrieval date is needed): Author, A. A. (2011). Title of article. *Title of Journal*, 22, 123–231. Retrieved from <http://www.xxxxx> If there is no DOI and the reference was retrieved from a journal homepage, give the full URL or site's homepage URL: Author, A. A. (2011). Title of article. *Title of Journal*, 22, 123–231. Retrieved from <http://www.xxxxx>

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

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

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).

Figures

- Please provide the highest quality figure format possible. Please be sure that all imported scanned material is scanned at the appropriate resolution: 1200 dpi for line art, 600 dpi for grayscale and 300 dpi for colour.
- Figures must be saved separate to text. Please do not embed figures in the manuscript file.
- Files should be saved as one of the following formats: TIFF (tagged image file format), PostScript or EPS (encapsulated PostScript), and should contain all the necessary font information and the source file of the application (e.g. CorelDraw/Mac, CorelDraw/PC).

- All figures must be numbered in the order in which they appear in the manuscript (e.g. Figure 1, Figure 2). In multi-part figures, each part should be labelled (e.g. Figure 1(a), Figure 1(b)).
- Figure captions must be saved separately, as part of the file containing the complete text of the manuscript, and numbered correspondingly.
- The filename for a graphic should be descriptive of the graphic, e.g. Figure1, Figure2a.

APA guidelines for reporting numbers

- Use figures for numbers 10 and above (12 of the subjects); for numbers above and below 10 grouped for comparison (2 of 16 responses); for numbers representing time, dates, and age (3 years ago, 2 hr 15 min); for numbers denoting a specific place in a series, book, or table (Table 3, Group 3, page 32).
- Use words for numbers below 10 that do not represent precise measurements (eight items, nine pages); for numbers beginning a sentence, title, or heading (Forty-eight percent responded; Ten subjects improved, and 4 subjects did not.).

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MRP Proposal

**Promoting empathy and compassion in a brain injured population
using compassionate imagery**

2nd of August 2013

Introduction

The incidence of head injury is estimated to be 235 per 100,000 of the population (Tagliaferri, et al., 2006). In one year, there were 2962 admissions with head injury to hospital wards in Glasgow (Thornhill et al, 2000). There is persistent disability in a high proportion of those experiencing head injury, which shows a stronger association with psychosocial sequelae than with severity of original injury (Whitnall et al, 2006; McMillan et al., 2012) and highlights the importance of addressing psychological needs of survivors of head injury alongside the rehabilitation of their physical difficulties. While interventions aimed at physical disability often result in improved outcome, personality changes such as egocentrism, impulsivity, disinhibition and poor temper control can persist, provoking strain in relationships (Wood & Yurdakul, 1997). Negative psychosocial outcomes in this group such as marital breakdown (Wood & Yurdakul, 1997) and difficulty establishing new and maintaining previous social relationships (Tate et al., 1989) contribute to increased social isolation and therefore poorer recovery. In trying to understand relationship difficulties, there has been research interest in deficits in empathy, when people are no longer able to respond to the emotional state of those they are with (DeSousa et al., 2011). Woods and Williams (2008) suggest that such egocentrism and insensitivity to the needs of others may explain why so many relationships fail post head injury, and why isolation persists in such a high proportion of survivors. Despite the apparent need for interventions to improve the ability to empathise, there is little evidence to support the use of psychological therapy in this context.

Compassion Focused Therapy (CFT; Gilbert, 2009) is a recently developed intervention that seeks to enhance compassion and empathy in order to bring about improved psychological wellbeing. The underpinning theory draws on evolutionary, neurophysiological and attachment perspectives and proposes the existence of three broad affective regulatory systems:

4. *threat and protection*, reflecting the typically referred to fight or flight sympathetic response;
5. *drive and resource seeking*, characterised by pleasure that is derived from active attainment; and
6. *affiliative*, a system that is recognised as promoting a sense of rest, calm and connectedness.

It was through his work with people with mental health problems who experience high levels of shame and self-criticism that Gilbert noted that certain individuals seem to experience an imbalance in the activation of these three systems that correlated with increased psychopathology. CFT was developed to aid individuals in finding balance in these three systems using principles heavily influenced by Buddhist philosophy and practice (Gilbert, 2009) to promote self-nurturing.

Gilbert (2005) suggests that a physiological system that specifically enables and promotes adaptive social interactions has evolved in humans and that early attachment experiences predict the ability of an individual to activate the appropriate elements of this system in response to environmental cues. In support of this assertion, the neuropeptide oxytocin has been found to promote caring-affiliation (Wang, 2005), with emerging evidence that it reduces sensitivity, especially to socially threatening stimuli, in the fear circuits of the amygdala (Kirsch et al., 2005). The prefrontal cortex with its role in the regulation of emotion, prosocial and moral behaviour and in inhibiting amygdala activity (Wang, 2005) is also relevant to a physiological understanding of affiliative responding, with injury to this region often associated with the types of emotional deficits reported after head injury. Damasio (2003) reported social deficits in individuals with lesions in the frontal cortex and argued that this represented a social emotion problem. The question of whether deficits in empathy attributable to neurological trauma and damage can be mediated by psychological intervention seems an important one.

In 2012, O'Neill and McMillan reported the effects of a single session abbreviated form of CFT, compassion-focused imagery (CFI), with a group of head injured individuals with low empathy. The aim was to explore whether increased empathy could be achieved and whether this translated into improved self-reports of empathy. No significant result was reported with regard to empathy, however the authors noted that higher self-report scores for self-compassion approached significance, although this was found in both the CFI and relaxation control groups. The authors suggested that a longer intervention period might enhance the treatment effect and that the language used in compassion might be a barrier to participants who are unfamiliar with it. This present study aims to address these issues by substantially increasing exposure to CFI and including a short preparatory intervention preceding treatment

aimed at reducing difficulties with compassionate language. This latter approach is outlined in a separate trainee study (Gallagher, 2013; see Appendix 4).

A further consideration is that the self-report measures used by O'Neill and McMillan (2012) may not be sensitive enough to detect a change in a single-session intervention. Bradley and Lang (2000) assert that any study seeking to measure emotion should include at least one measure from three key systems identified as language, behaviour and physiological events. Self-report satisfies only the language criteria. To meet the requirements of a behavioural dimension a measure of attention will be employed. Physiological responses pertaining to prosocial emotion will be assessed using Heart Rate Variability (HRV).

Polyvagal theory describes how the vagal nerve has evolved to actively facilitate sympathetic response and threat versus social engagement behaviour in response to environmental cues (Porges, 2006), and this is consistent with Gilbert's (2009) three-component compassion system. HRV is an accepted measure of vagal influence, with low HRV representing low vagal activity, reduced reactivity in the ANS and a decreased ability to respond adaptively to environmental stressors (and vice versa). Rockcliff et al., (2008) found that brief CFI brought about HRV change pre to post exposure in a student population, with half of their group displaying a marked increase in HRV (increased vagal influence) and the other half showing a reduction in HRV (reduced vagal influence). Non-significant trends in the data suggest that those higher in self-criticism and anxious attachment styles are more likely to display reduced HRV and vice versa. This study supports HRV as a reliable measure for the activation of the prosocial affiliative system in response to CFI, and also highlights the importance of retaining a measure of self-criticism to distinguish those who are high in fears of compassion and therefore unlikely to react adaptively to compassionate imagery.

Inducing relaxation of the ANS (e.g. through relaxation exercises) is likely to have a similar effect on HRV to stimulation of the compassionate system (e.g. via imagery), rendering a straight HRV comparison of these approaches unhelpful. Instead a change in HRV attributable to compassionate imagery might be more meaningfully identified if it can be associated with changes in compassionate self-report and attentional task

outcomes. At the time of writing this study represents the first use of HRV in this way and with a head injury population, and is therefore treated as a preliminary exploration.

Aims and hypotheses

The present study will explore whether increased duration of a CFI intervention and inclusion of an intervention to increase familiarity with compassionate language translates the general non-significant trend reported by O'Neill and McMillan (2012) into a significant and specific increase in empathy and compassion. In an attempt to ensure detection of any change, the present study also aims to consider whether alternative measures beyond self-report, will prove more sensitive.

A related study, not reported here, will look at the effectiveness of preparing a group of head injury participants in anticipation of this intervention (Gallagher, 2013; see Appendix 4).

Hypotheses:

4. Following a single session CFI intervention, head injury participants will evidence greater increases from baseline on self reported measures of self-compassion and empathy and a greater reduction in sensitivity to threat stimuli and a greater increase in sensitivity to empathy and compassion stimuli in an attentional task compared to a relaxation control group.
5. An association between changes in compassion and empathy self report and reduced ANS markers of stress and arousal as measured by HRV will be found in the CFI condition and not in the relaxation condition.
6. There will be a significant negative correlation between scores on fears of compassion and the magnitude of change across all outcomes in the CFI condition. No significant correlation will be evident in the relaxation condition.

Plan of investigation

Participants

Inclusion criteria

Participants will be aged between 18 and 65 years old, with a history of severe head injury (defined as post traumatic amnesia > 1 day; Russell, 1935) that occurred at

least three months prior to testing. Participants will have capacity to consent. Participants will have undergone a preparatory intervention prior to commencing with this intervention.

Exclusion criteria

Individuals with a learning disability, diagnosis of a degenerating neurological condition, current substance abuse, sensory and/or communication difficulties which may affect their ability to consent and/or fully engage with the study or severe and active mental illness that would prevent participation will be excluded from the study.

Recruitment procedures

Participants will be identified and approached primarily through inpatient brain rehabilitation services (Graham Anderson House, Glasgow and the Murdostoun Unit, Wishaw). If further participants are required, community groups will then be approached, including Headway (Glasgow and Ayrshire). Consent to participate in both preparatory and CFI intervention studies will be gained at the same time and participants will proceed to the CFI intervention after attending the preparatory session.

Measures

Attitudes towards compassion will be measured preintervention using the Fears of Compassion Scales (Gilbert et al., 2011).

Descriptive measures include:

- Test of Premorbid Functioning (Wechsler, 2011); estimates pre-injury IQ and memory abilities.
- The Symbol-Digit Modalities Test. (Smith, 2010); measures cognitive impairment.
- The Glasgow Outcome Scale (Jennett et al., 1981); measures scale of brain injury.
- Socio economic status; postcodes will be used to ascertain a broad impression.

Pre and post intervention measures include:

- The Self-Compassion Scale (Neff, 2003); measures self-kindness against self-judgement, common humanity versus isolation and mindfulness against over identification, total scores pre and post intervention will be compared.
- The Empathy Quotient (Baron-Cohen & Wheelwright, 2004); measures cognitive and affective components of empathy, total scores will measure any change in total empathy scores.
- Relaxation measure (O'Neill & McMillan, 2012) a self-report measure of relaxation taken on a likert scale will measure change in feelings of relaxation over pre and post intervention.
- State-Trait Anxiety Inventory, Short form (STAI; Marteau & Bekkers, 1992); sensitive to fluctuations in state anxiety, this measure will be used to measure changes in participant anxiety across the intervention.

A behavioural test to assess any state mediated effects on attention and/or bias in processing towards compassion-based words will be adapted from the Imbedded Word Task, described by Wenzlaff et al. (2001). This will consist of a word search containing three lists of ten compassionate, threat and neutral words, between 3 and 7 letters long. The outcome measure will consist of the ratio of compassion vs threat words.

Finally, HRV will be measured throughout the CFI intervention, based on the Rockliff et al., (2008) approach, using a heart monitor to yield a measure of the standard deviation of interbeat intervals (SDNN), a common metric used in HRV measurement (Task Force, 1996).

Design

This study consists of two phases, an initial preparatory intervention followed by the CFI intervention described herein. The current study will use a between-groups, repeated measures design. There is one independent variable at two levels: an experimental condition using compassionate imagery and a control condition using an intervention which involves the same amount of time and therapy input, but which would not be expected to have any impact on compassion or empathy. O'Neill and McMillan (2012) used a relaxation group for this purpose. Self reported empathy, self-compassion, stress level, relaxation, word-search task performance and HRV change will form the dependent variables and a measure of 'fear of compassion' represents a

covariate. This is a single blind randomised trial as participants will not be made aware of which condition they are to be assigned. Success of blinding will be assessed by asking each participant to speculate about which intervention they believe they've undertaken. One experimenter will carry out all assessments (pre and post) for both preparatory and CFI interventions, and another will carry out randomisation and interventions.

Research Procedures

All participants who have completed the preparatory intervention(see Appendix 4) will be asked to complete pre-intervention measures and will be randomised to either the CFI or relaxation control groups, using a true random number generator (e.g. random.org; Haahr, 2010). All participants will be fitted with a chest monitor and a period of ten minutes will precede the intervention, when a recording of a series of neutral stories will be played to the participant. This will provide a baseline HRV measure across both conditions and is designed to mimic normal waking state levels of arousal. Both groups will then undergo a 50-minute session (one CFI, one relaxation focused) involving practising breathing techniques, relaxation and mental imagery, using a session script to ensure consistency across interventions; this length of time has been chosen as it is considered long enough to provide an increased therapy dose compared to O'Neill and McMillan, but lessens the risk of participant fatigue compared with longer sessions. A break of 10 minutes will take place in the middle of the 50-minute intervention to maximise attention and guard against fatigue. Participants will be asked to remain within the room throughout this period.

Self-report measures, the word-search task and HRV measures will be taken from all participants before and after intervention. In order to control for heart rate artefacts, a protocol that will establish each step of the intervention will be devised in advance, so that each participant's experience will be identical.

Data analysis

Paired samples t-tests will examine the overall effect of intervention and within-groups effects. ANCOVA will be used to explore the differential effect of compassionate imagery and relaxation on self-compassion, empathy, relaxation, anxiety, attentional bias and HRV, with the baseline score (pre-intervention) as the

covariate for the outcome measures (post-intervention). Pearson's correlation coefficients will be used to examine the relationship between fear of compassion, pre-intervention level of empathy and responsiveness to intervention. Non-parametric alternatives will be employed wherever parametric assumptions cannot be met.

Estimate of sample size

O'Neill and McMillan's (2012) preliminary study which was the first in this area, showed no significant effect, and there are no related studies from which an effect size can be derived. Similarly, a literature search suggested an absence of research using the Self Compassion Scale or Empathy Quotient in single session interventions.

Shapiro et al., (2007) compared performance on the Self Compassion Scale before and after an eight week mindfulness based stress reduction intervention. Using this data (pre-int M=18.06, SD=3.97; post-int M=20.92, SD=3.84), the effect size was large (dz=0.73; dz representing the Cohen effect size for a repeated measures design). From these figures we can estimate how many participants are required to detect a change on this outcome measure. For a large effect size (dz=0.8), with alpha set at 0.05 and power set to detect change at 0.8 a total sample size of 12 (GPower; Erdfelder et al., 1996) per group is needed.

Settings and equipment

Participants will undergo the study at the site of the service from which they are recruited. Equipment required includes an encrypted laptop PC, heart rate monitor and accompanying software, neuropsychological and attentional assessments, psychometric questionnaires and baseline and intervention scripts.

Health and safety issues

See appendix for Health and Safety considerations.

Ethical issues

The client group is potentially vulnerable. Participants will only be recruited to the study if they have capacity to consent and do so freely. Staff involved in their care will obtain the initial consent. An information sheet will be provided beforehand and a full debrief will be provided after testing. Ethical approval for both the preparatory and

CFI interventions will be sought jointly from the NHS West of Scotland Research Ethics Committee.

Financial issues

See appendix for Financial considerations.

Timetable

2013

April	Proposal submitted for blind marking
May – June	Meet with proposal supervisor; amendments made and approval sought from Research Director
June – Sept	Proposal submitted to Ethics and R&D Amendments made as outlined by Ethics
October	Ethics approval
November	Begin recruitment

2014

April	Recruitment/data collection completed
May – June	Data analysis
June – July	Drafts written and amended
July	Report finalised and submitted

Practical applications

There is little evidence to support the use of psychological interventions in addressing emotional deficits after head injury at this time. This study may elucidate the potential of CFI for treatment of certain emotional changes associated with head injury.

References

References can be found in the Major Research Project Paper (Chapter 2).

ToSRES

Research Ethics Service

East of Scotland Research Ethics Service (EoSRES) REC 1

Tayside Medical Sciences Centre (TASC)
Residency Block C, Level 3
Ninewells Hospital & Medical School
George Pinfir Way
Dundee DD1 9SY

Professor Thomas M McMillan
Professor of Clinical Neuropsychology
University of Glasgow
Mental Health and Wellbeing, MVLS,
Garnavel Royal Hospital
105b Great Western Road,
Glasgow G12 0XL

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

26 November 2013
13/ES/0139
Mrs Lorraine Reilly
01382 383878
lorraine.reilly@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
IRAS project ID:	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/ISC 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 <http://www.rdforum.nhs.uk>.

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 (catherineblewett@nhs.net), 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:	<i>Please quote this number on all correspondence</i>
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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



pp
Dr Lynda Cochrane
Alternate Vice-chair

ecosres.tayside@nhs.net

Enclosures: "After ethical review – guidance for researchers"

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 Prie Way
 Dundee DD1 9SY

Professor Thomas M McMillan
 Professor of Clinical Neuropsychology
 University of Glasgow
 Mental Health and Wellbeing, MVLS,
 Gartnavel Royal Hospital
 105b Great Western Road,
 Glasgow G12 0X11

Date: 16 January 2014
 Your Ref.:
 Our Ref: 13/ES/0138 (SSA 14/ES/0014)
 Enquiries to: Mrs Lorraine Reilly
 Direct Line: 01382 383878
 Email: lorraine.reilly@nhs.uk

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/0138
SSA reference: 14/ES/0014
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
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.



Yours sincerely



Mrs Lorraine Reilly
Senior REC Co-ordinator

ecosres.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: 16 January 2014
Your Ref:
Our Ref: LR/13/ES/0139 (SSA 14/ES/0009)
Enquiries to: Mrs Lorraine Reilly
Direct Line: 01382 383878
Email: 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/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.



Yours sincerely



Mrs Lorraine Reilly
Senior REC Co-ordinator

anora.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 Prie Way
 Dundee DD1 9SY

Professor Thomas M McMillan
 Professor of Clinical Neuropsychology
 University of Glasgow
 Mental Health and Wellbeing, MVLS,
 Gartnavel Royal Hospital
 105b Great Western Road,
 Glasgow G12 0X11

Date: 16 January 2014
 Your Ref.:
 Our Ref: 13/ES/0138 (SSA 14/ES/0010)
 Enquiries to: Mrs Lorraine Reilly
 Direct Line: 01382 383878
 Email: lorraine.reilly@eths.scot.nhs.uk

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/0138
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
Murdochson 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.



Yours sincerely



Mrs Lorraine Reilly
Senior REC Co-ordinator

ecosres.tayside@nhs.net

Copy to:

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



Appendix 2.4 Research and Development approval letter



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

R&D Management Office
Western Infirmary
Tennent Institute
1st Floor 38 Church Street
Glasgow, G11 6NT,

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 (www.nhs.gov.uk/content/default.asp?page=a1411), 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,



Dr Erica Packard
Research Co-ordinator

Cc: Mr Iain Campbell
Prof Tom McMillan

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

Objective Head injury can result in problems in 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.

Appendix 2.6 Adaptation of the Empathy Quotient Scale

The following describes the process carried out by O'Neill and McMillan (2012) to arrive at the Empathy Quotient measure adopted in this study:

'Reduction of the Empathy Quotient

The Empathy Quotient (Baron-Cohen & Wheelwright, 2004) contains 60 items; 40 empathy items and 20 control items. Using only the empathy items, Lawrence et al. (2004) removed the items that correlated with socially desirable responding and conducted a principal components analysis that reduced the scale to 28 items divided across three factors: cognitive empathy (11 items), emotional reactivity (11 items), and social skills (6 items). This model was adopted for the current study. Furthermore, to ensure that each factor could be equally split and balanced between the pre- and post-intervention measures, item 36 ("Other people tell me I am good at understanding how they are feeling and what they are thinking") was removed from the cognitive empathy scale as it had one of the lowest factor loadings (0.559) and also loaded on the emotional reactivity scale (0.315). Item 43 ("Friends usually talk to me about their problems as they say I am very understanding") was removed from the emotional reactivity scale as it had one of the lowest factor loadings (0.452) and also loaded on the cognitive empathy scale (0.442).'

Appendix 2.7 Adapted Empathy Quotient Scale

THE EMPATHY QUOTIENT - A

How to Fill Out the Questionnaire

Below is a list of statements. Please read each statement *carefully* and rate how strongly you agree or disagree with it by circling your answer. There are no right or wrong answers, or trick questions.

IN ORDER FOR THE SCALE TO BE VALID, YOU MUST ANSWER EVERY QUESTION.

- | | | | | |
|---|-------------------|-------------------|----------------------|----------------------|
| 1. I really enjoy caring for other people. | strongly
agree | slightly
agree | slightly
disagree | strongly
disagree |
| 2. I find it hard to know what to do in a social situation. | strongly
agree | slightly
agree | slightly
disagree | strongly
disagree |
| 3. I can pick up quickly if someone says one thing but means another. | strongly
agree | slightly
agree | slightly
disagree | strongly
disagree |
| 4. It is hard for me to see why some things upset people so much. | strongly
agree | slightly
agree | slightly
disagree | strongly
disagree |
| 5. I find it easy to put myself in somebody else's shoes. | strongly
agree | slightly
agree | slightly
disagree | strongly
disagree |
| 6. Seeing people cry doesn't really upset me. | strongly
agree | slightly
agree | slightly
disagree | strongly
disagree |
| 7. I don't tend to find social situations confusing. | strongly
agree | slightly
agree | slightly
disagree | strongly
disagree |
| 8. I can sense if I am intruding, even if the other person doesn't tell me. | strongly
agree | slightly
agree | slightly
disagree | strongly
disagree |
| 9. I usually stay emotionally detached when watching a film. | strongly
agree | slightly
agree | slightly
disagree | strongly
disagree |
| 10. I can tune into how someone else feels rapidly and intuitively. | strongly
agree | slightly
agree | slightly
disagree | strongly
disagree |
| 11. I can easily work out what another person might want to talk about. | strongly
agree | slightly
agree | slightly
disagree | strongly
disagree |
| 12. I don't consciously work out the rules of social situations. | strongly
agree | slightly
agree | slightly
disagree | strongly
disagree |
| 13. I am good at predicting what someone will do. | strongly
agree | slightly
agree | slightly
disagree | strongly
disagree |

THE EMPATHY QUOTIENT - B

How to Fill Out the Questionnaire

Below is a list of statements. Please read each statement *carefully* and rate how strongly you agree or disagree with it by circling your answer. There are no right or wrong answers, or trick questions.

IN ORDER FOR THE SCALE TO BE VALID, YOU MUST ANSWER EVERY QUESTION.

- | | | | | |
|--|-------------------|-------------------|----------------------|----------------------|
| 1. I can easily tell if someone else wants to enter a conversation. | strongly
agree | slightly
agree | slightly
disagree | strongly
disagree |
| 2. I find it difficult to explain to others things that I understand easily, when they don't understand it first time. | strongly
agree | slightly
agree | slightly
disagree | strongly
disagree |
| 3. Friendships and relationships are just too difficult, so I tend not to bother with them. | strongly
agree | slightly
agree | slightly
disagree | strongly
disagree |
| 4. I often find it difficult to judge if something is rude or polite. | strongly
agree | slightly
agree | slightly
disagree | strongly
disagree |
| 5. I am good at predicting how someone will feel. | strongly
agree | slightly
agree | slightly
disagree | strongly
disagree |
| 6. I am quick to spot when someone in a group is feeling awkward or uncomfortable. | strongly
agree | slightly
agree | slightly
disagree | strongly
disagree |
| 7. If I say something that someone else is offended by, I think that that's their problem, not mine. | strongly
agree | slightly
agree | slightly
disagree | strongly
disagree |
| 8. I can't always see why someone should have felt offended by a remark. | strongly
agree | slightly
agree | slightly
disagree | strongly
disagree |
| 9. I can easily tell if someone else is interested or bored with what I am saying. | strongly
agree | slightly
agree | slightly
disagree | strongly
disagree |
| 10. I get upset if I see people suffering on news programmes. | strongly
agree | slightly
agree | slightly
disagree | strongly
disagree |
| 11. Other people, often say that I am insensitive, though I don't always see why. | strongly
agree | slightly
agree | slightly
disagree | strongly
disagree |
| 12. I can tell if someone is masking their true emotion. | strongly
agree | slightly
agree | slightly
disagree | strongly
disagree |
| 13. I tend to get emotionally involved with a friend's problems. | strongly
agree | slightly
agree | slightly
disagree | strongly
disagree |

Appendix 2.8 Relaxation scale

Relaxation Likert Scale

1. Overall, how relaxed do you feel?

1	2	3	4	5	6	7
Not relaxed at all						Very relaxed

2. Take a moment to focus on your body. How tense do you feel physically?

1	2	3	4	5	6	7
Not tense all						Very tense at

3. Take a moment to focus on your thoughts. How calm do you feel?

1	2	3	4	5	6	7
Not calm at all						Very calm

Note: - Item 2 will be reverse scored.

Appendix 2.9 Development of the imbedded word task

The approach adopted here was based on that described by Wenzlaff et al. (2001). Two researchers used Averill's Semantic Atlas (1975) to aid generation of a list of compassion based and threat based words. Words were ordered in length and the top 60 (i.e. the shortest) words in each group were retained. An online random word generator (www.wordgenerator.net) provided 60 neutral words and all words were combined to provide a list of 180.

The full word list was ordered alphabetically to achieve a quasi-randomised list. An experienced clinical psychologist and four 'non-psychologists' were asked to categorise each word as either threat, compassion or neutral related. A word was admitted into the final list if there was agreement from **four** or more of the five participants, resulting in a list of:

- 49 threat words
- 36 compassionate words
- 39 neutral words

All words were rated using MRC Psycholinguistic Database (www.psych.rl.ac.uk), which provides ratings of written word frequency (based on the work of Francis & Kucera, 1982). Averill's Semantic Atlas (1975) provided a rating of emotionality. Threat and compassion words with no emotionality rating were removed. The three word lists (compassion, threat and neutral) were matched based on length (first order), then written word frequency (second order) and then emotionality (third order). This process generated sixteen word matches. A nine letter match was removed, based on excessive length.

Ordered in length, triplets of words were assigned in order into crossword one, two and three. Word lists were entered into an online wordsearch generator (tools.atozteacherstuff.com/word-search-maker) and 13x13 grids were required to accommodate all words.

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!

I	J	C	F	V	L	U	F	Y	A	L	P	R
D	E	F	E	S	W	X	D	Z	R	D	N	C
D	J	L	L	B	E	B	I	I	B	V	N	T
M	V	U	C	I	D	R	C	I	Z	E	Y	R
L	Z	G	N	T	G	E	E	G	O	R	L	U
A	I	R	U	T	I	T	T	N	T	U	D	H
C	D	A	L	E	C	A	I	A	E	L	N	F
H	M	N	U	R	E	M	R	B	E	V	I	N
X	K	I	F	K	O	I	U	T	X	F	K	J
Q	A	T	E	D	C	T	Q	R	R	I	E	T
Q	X	E	T	N	C	N	Z	B	V	O	B	D
D	E	R	A	C	S	I	D	U	U	U	P	S
K	T	U	H	Y	R	F	R	G	U	W	B	J

Spatial Awareness (Exercise Two)

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!

I	I	A	D	E	R	U	T	R	O	T	D	K
M	O	N	I	D	E	V	O	T	E	D	T	H
Q	A	G	I	E	B	K	K	I	A	G	N	C
O	K	R	I	T	H	V	I	F	P	P	E	O
Y	K	Y	X	C	N	P	T	T	I	Q	L	N
O	I	T	C	E	E	N	R	R	C	N	O	C
B	Q	I	J	J	E	H	A	A	T	H	I	R
W	D	X	P	E	R	I	G	C	U	A	V	E
H	B	P	T	R	G	E	I	K	R	P	A	T
D	X	P	L	U	F	E	C	A	E	P	C	E
M	T	H	A	N	K	F	U	L	Z	Y	I	M
E	R	C	I	X	R	O	L	E	H	C	A	B
I	T	E	N	D	E	R	C	H	T	Z	D	N

Spatial Awareness (Exercise Three)

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!

X	Y	C	N	G	G	L	O	N	E	L	Y	T
S	L	L	C	O	N	S	O	L	E	D	C	C
T	U	U	L	X	T	E	B	A	H	P	L	A
O	F	F	A	N	N	O	Y	E	D	N	G	Q
R	S	E	O	M	C	G	U	T	L	J	A	F
E	S	T	G	L	R	A	G	D	U	R	D	B
R	I	A	I	N	O	N	R	V	F	I	G	A
V	L	R	B	I	I	A	E	I	A	N	E	N
Z	B	G	P	V	J	N	T	R	N	M	T	Q
P	W	Z	O	Y	I	B	F	H	U	G	O	U
F	S	L	O	L	Q	A	A	U	I	B	Q	E
A	Y	P	E	Q	X	F	I	R	Q	N	H	T
X	D	T	S	S	E	L	P	L	E	H	G	Y

Complete word matches for the imbedded word task

Wordsearch One		
Hurt	Calm	Rice
Bitter	Serene	Uncle
Scared	Kindly	Domino
Hateful	Playful	Granite
Defeated	Intimate	Portrait
Wordsearch Two		
Angry	Happy	Green
Tragic	Tender	Track
Violent	Devoted	Picture
Rejected	Peaceful	Concrete
Tortured	Thankful	Bachelor
Wordsearch Three		
Afraid	Loving	Store
Lonely	Caring	Gadget
Annoyed	Blissful	Banquet
Helpless	Grateful	Juvenile
Loathing	Consoled	Alphabet

Compassionate Imagery Script – Version 4

Baseline measurement (10 mins)

Imagery Part One (15 mins)

Introduction

“Thank you for taking part in our research. As you will have learned from the DVD we’re going to guide you through an imagery exercise, and to make sure everyone hears the same thing, I’ll be reading it from this sheet. This session will be split into five different sections. First I’ll guide you through an imagery exercise. Then we’ll stop and talk a little about it. After this you will have a ten-minute break, and when you finish your break I’ll guide you through the same imagery exercise again. We’ll finish by talking some more about your experience.”

Soothing Breathing Rhythm

“Before we begin with our imagery exercise it will help if you can get your breathing right. This will help you with the imagery. It can help you become more at peace with yourself.

Okay so when you’re ready, take up a comfortable seating position with your feet on the floor about a shoulder width apart with your back straight and your head in line with this. Let your hands rest comfortably in your lap.

When you’re in a comfortable position close your eyes, or fix your eyes on a spot on the floor if you prefer. Allow yourself to have a gentle facial expression, with a slight smile.

Now, gently focus on your breathing. As you breathe try to allow the air to come in through your nose and then down into the bottom of your lungs. Feel your stomach move as you breathe in and out. Just notice your breathing and play with it: try breathing a little faster (break) and now breathe slower. Try to find a breathing rhythm that for you seems to be your own soothing, comforting rhythm. Just notice that for a little while, the cool air coming in through your nose, down into the bottom of your lungs and then the air moving out through your mouth.

As you continue to focus on your breathing, notice how you have a sense of slowing down. Experience yourself becoming heavier in the chair. Sense the weight of your body resting on the chair.

When your mind wanders remind yourself that this is normal and okay. Simply notice it happening and then gently guide your attention back to an awareness of your breathing as best you can.

Focus on the flow of air coming in and out of your nostrils. Just gently observing. No need to change anything. Just allow things to be as they are. Before we move onto the imagery work, remember that your mind will wander during this exercise; this is completely normal and expected, so when it happens, simply notice it and bring your

focus back to the image we are working on. Also remember that you may not be able to bring to mind clear images. This doesn't mean you're doing it wrong; it is completely normal. Don't try to create a photograph in your mind, impressions work just as well and it's more important that you focus on any feelings that are created with your images.

So while we continue to breathe, let's start the imagery. Again, we're not going to worry about our mind wandering nor are we going to worry about not getting clear images in our mind."

Creating the 'felt sense' of compassion

"Let's try to remember a time when you experienced a sense of closeness to somebody or something else. Perhaps it was a time when you were with a group of your friends or at a family get together or even when spending time with your pet. A time when it felt good to be with others, when being close to others felt nice. Try to hold that time in your mind as best you can.

Short pause

Try to remember how it felt to be close to someone, to feel connected, contented and comforted. Focus on what this feels like. Notice any nice feelings in your mind and body. Spend some time picturing this in your mind. "

Pause (30 secs)

Compassionate self

"Now you have some idea of how it feels to be connected and comforted, let's build on this through focusing on the feelings of being compassionate inside you. Remember in the DVD compassion was described as caring for someone or something and wanting to help when they are in pain or in distress. Let's think a bit more about that. I'd like you to try to imagine a compassionate you. To do this, I'd like you to imagine you at your best.

Soften the expression on your face and make a slight smile. Try to remember a time when you cared for someone else or you were particularly kind to somebody. A time when you felt calm and wise and wanted to help. Try to hold that time in your mind as best you can.

Try to imagine what you were like when you were **at your best**, when you felt strong, sensitive and kind towards someone, when you were being deeply compassionate. It doesn't matter if you don't think you have these qualities now, just imagine that you do have them. Think and feel all of the qualities you might have been displaying at that time."

Strength: "Imagine yourself being calm and having wisdom. Imagine yourself expanding and becoming more powerful, mature and wise. Imagine yourself having inner strength. Think of someone you know that has inner strength, perhaps someone famous who you would consider to be strong and wise. (*Pause*). Imagine you felt strong like them. Just spend a moment just feeling this expansion and warmth in your body, paying attention to your body as you imagine this part of you. Calm and wise. Powerful, mature and wise.

Pause (30 secs)

Now continue to think of yourself at your best, being the best person you can be to others and to yourself, a time when you were being deeply compassionate. Think and feel all of the qualities you were displaying at that time. Strong, sensitive and kind to others.”

Sensitive: “Imagine yourself being sensitive with the ability to tolerate any difficulties. Think about yourself being open to the suffering of those around you, and being able to handle anything that might come your way. Really taking the time to understand how others are feeling, caring about how they feel. Just take a moment to feel this. Pay attention to your body as you imagine this part of you. Feel sensitive and confident. Sensitive and tolerant.

Pause (30 secs)

Again, let’s go back to thinking of yourself at your best, being the best person you can be to others and to yourself, a time when you were being deeply compassionate. Think and feel all of the qualities you were displaying at that time. Strong, sensitive and kind to others.”

Kind: “Now imagine yourself being kind and warm. Think about you trying to help someone else and the kinds of things you might say if you were trying to be kind and warm. (*Pause*). Imagine wanting to help, wanting to make someone feel better, someone that needs you. Imagine watching them get better. Just take a moment to feel this. Pay attention to your body as you imagine this part of you. Kind and warm. Kind and helpful and caring for others.

Pause (30 secs)

When you feel ready, slowly open your eyes and bring yourself back to the present moment. If you want, you can have a gentle stretch or deep breath. Take as long as you need.”

Reflection (5 minutes)

- How did you feel during your imagery exercise?
- Describe your favourite bit of the exercise?
- Were you able to bring compassionate situations to mind?
- What could you do differently next time to make it even better?

Break (10 mins – participant to remain within the room)

Imagery Part Two (15mins)

Soothing Breathing Rhythm

“Before we begin another imagery exercise it will help if you can get your breathing right again. Remember, this will help you with the imagery. It can help you become more at peace with yourself.

Okay so when you're ready, get back into a comfortable seating position with your feet on the floor about a shoulder width apart with your back straight and your head in line with this. Let your hands rest comfortably in your lap.

When you're in a comfortable position close your eyes, or fix your eyes on a spot on the floor if you prefer, just as you did before. Allow yourself to have a gentle facial expression, with a slight smile.

Now, gently focus on your breathing. As you breathe try to allow the air to come in through your nose and then down into the bottom of your lungs. Feel your stomach move as you breathe in and out. Just notice your breathing and play with it: try breathing a little faster (break) and now breathe slower. Try to find a breathing rhythm that for you seems to be your own soothing, comforting rhythm. Just notice that for a little while, the cool air coming in through your nose, down into the bottom of your lungs and then the air moving out through your mouth.

As you continue to focus on your breathing, notice how you have a sense of slowing down. Experience yourself becoming heavier in the chair. Sense the weight of your body resting on the chair.

When your mind wanders remind yourself that this is normal and okay. Simply notice it happening and then gently guide your attention back to an awareness of your breathing as best you can.

Focus on the flow of air coming in and out of your nostrils. Just gently observing. No need to change anything. Just allow things to be as they are. Before we move onto the imagery work, remember that your mind will wander during this exercise; this is completely normal and expected, so when it happens, simply notice it and bring your focus back to the image we are working on. Also remember that you may not be able to bring to mind clear images. This doesn't mean you're doing it wrong; it is completely normal. Don't try to create a photograph in your mind, impressions work just as well and it's more important that you focus on any feelings that are created with your images.

So while we continue to breathe, let's start the imagery again. Remember, we're not going to worry about our mind wandering nor are we going to worry about not getting clear images in our mind."

Creating the 'felt sense' of compassion

"Let's go back to the time when you experienced a sense of closeness to somebody or something else. Perhaps it was a time when you were with a group of your friends or at a family get together or even when spending time with your pet. A time when it felt good to be with others, when being close to others felt nice. Try to hold that time in your mind as best you can.

Short Pause

Try to remember how it felt to be close to someone, to feel connected, contented and comforted. Focus on what this feels like. Notice any nice feelings in your mind and body. Spend some time picturing this in your mind."

Pause (30 secs)

Compassionate self

“Now you have some idea of how it feels to be connected and comforted, let’s build on this again through focusing on the feelings of being compassionate inside you. Remember in the DVD compassion was described as caring for someone or something and wanting to help when they are in pain or in distress. Let’s think a bit more about that. I’d like you to try to imagine a compassionate you. To do this, I’d like you to imagine you at your best.

Soften the expression on your face and make a slight smile. Try to remember a time when you cared for someone else or you were particularly kind to somebody. A time when you felt calm and wise and wanted to help. Try to hold that time in your mind as best you can.

Try to imagine what you were like when you were **at your best**, when you felt strong, sensitive and kind towards someone, when you were being deeply compassionate. It doesn’t matter if you don’t think you have these qualities now, just imagine that you do have them. Think and feel all of the qualities you might have been displaying at that time.”

Strength: “Imagine yourself being calm and having wisdom. Imagine yourself expanding and becoming more powerful, mature and wise. Imagine yourself having inner strength. Think of someone you know that has inner strength, perhaps someone famous who you would consider to be strong and wise. *(Pause)*. Imagine you felt strong like them. Just spend a moment just feeling this expansion and warmth in your body, paying attention to your body as you imagine this part of you. Calm and wise. Powerful, mature and wise.

Pause (30 secs)

Now continue to think of yourself at your best, being the best person you can be to others and to yourself, a time when you were being deeply compassionate. Think and feel all of the qualities you were displaying at that time. Strong, sensitive and kind to others.”

Sensitive: “Imagine yourself being sensitive with the ability to tolerate any difficulties. Think about yourself being open to the suffering of those around you, and being able to handle anything that might come your way. Really taking the time to understand how others are feeling, caring about how they feel. Just take a moment to feel this. Pay attention to your body as you imagine this part of you. Feel sensitive and confident. Sensitive and tolerant.

Pause (30 secs)

Again, let’s go back to thinking of yourself at your best, being the best person you can be to others and to yourself, a time when you were being deeply compassionate. Think and feel all of the qualities you were displaying at that time. Strong, sensitive and kind to others.”

Kind: “Now imagine yourself being kind and warm. Think about you trying to help someone else and the kinds of things you might say if you were trying to be kind and warm. *(Pause)*. Imagine wanting to help, wanting to make someone feel better, someone that needs you. Imagine watching them get better. Just take a moment to feel this. Pay attention to your body as you imagine this part of you. Kind and warm. Kind and helpful and caring for others.

Pause (30 secs)

When you feel ready, slowly open your eyes and bring yourself back to the present moment. If you want, you can have a gentle stretch or deep breath. Take as long as you need.”

Reflection (5 minutes)

- How did you feel during your imagery exercise this time?
- Describe your favourite bit of the exercise?
- Were you able to bring compassionate situations to mind?
- What are you going to try to remember after you leave today?

Total session time: 60 mins

Relaxation Imagery Script – Version 2

Baseline measurement (10 mins)

Imagery Part One (15 mins)

Introduction

“Thank you for taking part in our research. As you will have learned from the DVD we’re going to guide you through an imagery exercise, and to make sure everyone hears the same thing, I’ll be reading it from this sheet. This session will be split into five different sections. First I’ll guide you through an imagery exercise. Then we’ll stop and talk a little about it. After this you will have a ten-minute break, and when you finish your break I’ll guide you through the same imagery exercise again. We’ll finish by talking some more about your experience.”

Soothing Breathing Rhythm

“Before we begin with our imagery exercise it will help if you can get your breathing right. This will help you with the imagery. It can help you become more at peace with yourself.

Okay, so when you’re ready, take up a comfortable seating position with your feet on the floor about a shoulder width apart, and with your back straight and your head in line with this. Let your hands rest comfortably in your lap.

When you’re in a comfortable position close your eyes, or fix your eyes on a spot on the floor if you prefer. Allow yourself to have a gentle facial expression, with a slight smile.

Now, gently focus on your breathing. As you breathe try to allow the air to come in through your nose and then down into the bottom of your lungs. Feel your stomach move as you breathe in and out. Just notice your breathing and play with it: try breathing a little faster (break) and now breathe slower. Try to find a breathing rhythm that for you seems to be your own relaxing, calming rhythm. Just notice that for a little while, the cool air coming in through your nose, down into the bottom of your lungs and then the air moving out through your mouth.

As you continue to focus on your breathing, notice how you have a sense of slowing down. Experience yourself becoming heavier in the chair. Sense the weight of your body resting on the chair.

When your mind wanders on to other things remind yourself that this is normal and okay. Simply notice it happening and then gently guide your attention back to an awareness of your breathing as best you can.

Focus on the flow of air coming in and out of your nostrils. Just gently observing. No need to change anything. Just allow things to be as they are. Before we move onto the imagery work, remember that your mind will wander during this exercise; this is completely normal and expected, so when it happens, simply notice it and bring your focus back to the image we are working on. Also remember that you may not be able to bring to mind clear images. This doesn’t mean you’re doing it wrong; it is

completely normal. Don't try to create a photograph in your mind, impressions work just as well and it's more important that you focus on any feelings that are created with your images.

So while we continue to breathe, let's start the imagery. Again, we're not going to worry about our mind wandering nor are we going to worry about not getting clear images in our mind."

Imagining and becoming the calm self

"Let's try to remember a time when you felt calm and relaxed. Perhaps it was a time when you were on holiday, spending time with family or maybe it's when you're doing something you find relaxing, like listening to music. A time when it felt good just to feel relaxed in yourself, when all you felt was calmness. Try to hold that time in your mind as best you can.

Short pause

Imagine that you are that very deeply calm and relaxed person. Remember how it felt to feel those calm, relaxed feelings. Focus on what this feels like. Notice any nice feelings in your mind and body. Spend some time picturing this in your mind."

Pause (30 secs)

Imagining that special place

"Now you have some idea of how it feels to be relaxed, let's build on this through thinking about your special relaxing place. Remember in the DVD relaxation was described as releasing tension and worries. Let's think a bit more about that. I'd like you to imagine yourself in your most relaxed state of mind, in a place where you feel calm and still.

Soften the expression on your face and make a slight smile. As you focus on breathing slowly and the feelings of relaxation flowing through your body, try to imagine a special place where you feel calm and relaxed. A place that you would go if you wanted to feel calm and relaxed.

Try to imagine what this place needs to be like in order for you to feel calm and relaxed. Perhaps you will imagine yourself at the coast or on a beach... maybe your calm and relaxed place is on a hillside or on a mountain. Or maybe your relaxed place is in a forest or a wood. It doesn't matter where you choose as long as you choose somewhere that feels relaxing and calming.

Let's start with the general layout of the place you are imagining. Are you picturing somewhere outdoors... or indoors.*(Pause)*. It may be a small cozy place... or a large, vast open space... create an image of this calm and relaxing place and focus on that for a while.

Pause (30 secs)

Continue to think about yourself at a time when you felt calm and relaxed. The most calm and relaxed you could possibly be. Focus on what this feels like. Notice any nice feelings in your mind and body. Calm and relaxed.

Now picture some more details about your peaceful place. Who is in this place? Are you alone? Or perhaps you are with a certain person who helps you relax? Are there other people present, people you know or don't know? Think about where they are in relation to you... Perhaps there are animals or birds, maybe a pet that helps you to feel calm. Imagine who is in your calm and relaxing place, anyone or anything you like, whether it is you alone, or if you have company.

Pause (30 secs)

Again, continue to think about yourself at a time when you felt calm and relaxed. The most calm and relaxed you could possibly be. Focus on what this feels like. Notice any nice feelings in your mind and body. Calm and relaxed.

Now let's try to imagine even more detail about your surroundings. Focus now on the relaxing sounds around you in your peaceful place. What can you hear? Or is it completely silent? Listen to the calm and relaxing sounds. *(Pause)*. Next, imagine what you can touch. Can you imagine what the temperature is like, any soft breeze, the surface you are on.... imagine the details of this calming place in your mind. Now focus on the sights of your place - colours, shapes... objects... plants... water... all of the beautiful things that make your place enjoyable.

Enjoy being in your peaceful place for a few moments. Memorize the sights, sounds, and sensations around you. The feeling of calmness and of deep relaxation.

Pause (30 secs)

When you feel ready, slowly open your eyes and bring yourself back to the present moment. If you want, you can have a gentle stretch or deep breath. Take as long as you need."

Reflection (5 minutes)

- How did you feel during your imagery exercise?
- Describe your favourite bit of the exercise?
- Were you able to bring relaxing situations to mind?
- What could you do differently next time to make it even better?

Break (10 mins – participant to remain within the room)

Imagery Part Two (15mins)

Soothing Breathing Rhythm

"Before we begin with another imagery exercise it will help if you can get your breathing right again. Remember, this will help you with the imagery. It can help you become more at peace with yourself.

Okay, so when you're ready, get back into a comfortable seating position with your feet on the floor about a shoulder width apart, and with your back straight and your head in line with this. Let your hands rest comfortably in your lap.

When you're in a comfortable position close your eyes, or fix your eyes on a spot on the floor if you prefer, just as you did before. Allow yourself to have a gentle facial expression, with a slight smile.

Now, gently focus on your breathing. As you breathe try to allow the air to come in through your nose and then down into the bottom of your lungs. Feel your stomach move as you breathe in and out. Just notice your breathing and play with it: try breathing a little faster (break) and now breathe slower. Try to find a breathing rhythm that for you seems to be your own relaxing, calming rhythm. Just notice that for a little while, the cool air coming in through your nose, down into the bottom of your lungs and then the air moving out through your mouth.

As you continue to focus on your breathing, notice how you have a sense of slowing down. Experience yourself becoming heavier in the chair. Sense the weight of your body resting on the chair.

When your mind wanders on to other things remind yourself that this is normal and okay. Simply notice it happening and then gently guide your attention back to an awareness of your breathing as best you can.

Focus on the flow of air coming in and out of your nostrils. Just gently observing. No need to change anything. Just allow things to be as they are. Before we move onto the imagery work, remember that your mind will wander during this exercise; this is completely normal and expected, so when it happens, simply notice it and bring your focus back to the image we are working on. Also remember that you may not be able to bring to mind clear images. This doesn't mean you're doing it wrong; it is completely normal. Don't try to create a photograph in your mind, impressions work just as well and it's more important that you focus on any feelings that are created with your images.

So while we continue to breathe, let's start the imagery again. Remember, we're not going to worry about our mind wandering nor are we going to worry about not getting clear images in our mind."

Imagining and becoming the calm self

"Let's go back to the time when you felt calm and relaxed. Perhaps it was a time when you were on holiday, spending time with family or maybe it's when you're doing something you find relaxing, like listening to music. A time when it felt good just to feel relaxed in yourself, when all you felt was calmness. Try to hold that time in your mind as best you can.

Short pause

Imagine that you are that very deeply calm and relaxed person. Remember how it felt to feel those calm, relaxed feelings. Focus on what this feels like. Notice any nice feelings in your mind and body. Spend some time picturing this in your mind."

Pause (30 secs)

Imagining that special place

"Now you have some idea of how it feels to be relaxed, let's build on this through

thinking about your special relaxing place. Remember in the DVD relaxation was described as releasing tension and worries. Let's think a bit more about that. I'd like you to imagine yourself in your most relaxed state of mind, in a place where you feel calm and still.

Soften the expression on your face and make a slight smile. As you focus on breathing slowly and the feelings of relaxation flowing through your body, try to imagine a special place where you feel calm and relaxed. A place that you would go if you wanted to feel calm and relaxed.

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Enjoy being in your peaceful place for a few moments. Memorize the sights, sounds, and sensations around you. The feeling of calmness and of deep relaxation.

Pause (30 secs)

When you feel ready, slowly open your eyes and bring yourself back to the present moment. If you want, you can have a gentle stretch or deep breath. Take as long as you need.”

Reflection (5 minutes)

- How did you feel during your imagery exercise this time?
- Describe your favourite bit of the exercise?
- What are you going to try to remember after you leave today?
- Was there anything you’d like help with?

Total session time: 60 mins



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 at 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: s.turnbull@clinmed.gla.ac.uk, 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 complaints@ggc.scot.nhs.uk (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
University of Glasgow
Section of Psychological Medicine
1055 Great Western Road Glasgow
Glasgow, G12 0XH
Email: m.gallagher.1@research.gla.ac.uk
i.campbell.2@research.gla.ac.uk
Tel: 0141 211 0694

Supervisors

Prof Tom McMillan and Dr Hamish McLeod
University of Glasgow
Section of Psychological Medicine
1055 Great Western Road
G12 0XH
Email: thomas.mcmillan@glasgow.ac.uk
hamish.mcleod@glasgow.ac.uk
Tel: 0141 211 0694

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



University
of Glasgow



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

Contact details: Melanie Gallagher or Iain Campbell
University of Glasgow,
Section of Psychological Medicine,
1055 Great Western Road,
Glasgow, G12 0XH
Email: m.gallagher.1@research.gla.ac.uk
i.campbell.2@research.gla.ac.uk

Please initial the BOX

I confirm that I have read and understand the information sheet dated 22nd of November 2013 for the above study.

☐

I confirm that the researcher has answered any queries to my satisfaction.

☐

I understand that my participation is voluntary and that I am free to withdraw from the project at any time, without having to give a reason and without any consequences.

☐

I understand that I can withdraw my data from the research database at any time.

☐

I understand that any information recorded in the investigation will remain confidential and no information that identifies me will be made publicly available.

☐☐

I give permission for my G.P. to be informed that I am taking part in the study.

☐

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