Psychological adjustment after stroke

Submitted by

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Declaration

This thesis is submitted for the Doctorate in Clinical Psychology at the University of

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Abstract

Literature Review

The present systematic review critically evaluates and synthesises the available

literature on the effectiveness of psychotherapeutic interventions targeted at reducing

depressive symptomatology following stroke. Studies were identified through electronic

database searches using terms related to 'stroke', 'patient', 'depression', 'intervention',

and 'trial.' Thirteen studies were included in the review. The large amount of

heterogeneity between the reviewed studies precluded the use of meta-analysis.

Nonetheless, the findings support the use of psychotherapy for treatment of post-stroke

depression, with behaviour therapy demonstrating beneficial effects. The

methodological limitations of the reviewed studies and recommendations for clinical

practice and future research are discussed.

Research Report

The study investigated relationships between mindfulness, coping and psychological

outcomes in a stroke population. Using a cross-sectional design, participants ($N = 114$)

completed The Five Facet Mindfulness Questionnaire, The Brief Ways of Coping

Questionnaire, The Mental Adjustment to Stroke Scale, The Patient Health

Questionnaire-9 and The General Anxiety Disorder Questionnaire-7. Mindfulness

explained significant amounts of variance in psychological adjustment to stroke and

post-stroke depression and anxiety. Dysfunctional coping was found to mediate the effect of the mindfulness facet 'acting with awareness' on the adjustment subscale 'helplessness/hopelessness.' This study provides support for the role of mindfulness and coping in recovery following stroke. The clinical implications of these findings are discussed in addition to future research recommendations.

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Section One: Literature Review

Psychotherapeutic interventions for the treatment of depression following

stroke:

A systematic literature review

Abstract

Objectives Depression is a common and serious complication after stroke that impacts on recovery and quality of life, yet remains poorly recognised and inadequately treated. The purpose of this review was to determine the effectiveness of psychotherapy for treatment of depression following stroke.

Methods Studies investigating the effects of psychotherapy for treatment of depression following stroke, published between, January 1967 to January 2016, were identified through electronic searches of Medline, CINAHL, PsycInfo, Web of Knowledge, and the Cochrane Trials Register. Terms selected for searching were related to 'stroke', 'patient', 'depression', 'intervention', and 'trial'. Thirteen studies were included in the review.

Results The reviewed studies (*N*=13) included a wide range of interventions including cognitive behavioural therapy, behavioural therapy, psychoeducation, motivational interviewing and ecosystem focused therapy. The participant inclusion criteria, type of control group and instruments employed to measure depression, varied across studies, precluding meta-analysis. The findings of this review, however, suggest that behaviour therapy may have a beneficial effect on depression following stroke.

Conclusions There is emerging evidence to support the use of behaviour therapy for treatment of post-stroke depression. Further studies addressing therapist effects, long-term outcomes and cost-effectiveness of psychotherapies in large representative samples of stroke survivors, are required before recommendations can be made regarding the routine use of such treatments in clinical practice.

Practitioner Points

- Given the high prevalence and negative impact of depression following stroke, clinicians are encouraged to routinely screen for depression post-stroke, using brief validated measures such as the Patient Health Questionnaire-9.

- The results demonstrate evidence for behavioural therapy but not for other therapies for treatment of depression post-stroke. Clinicians are therefore encouraged to provide behavioural therapy to stroke patients experiencing post-stroke depression.

- Further studies comparing the effectiveness of different psychotherapies, examining cost-effectiveness, therapist and long-term effects, in large representative samples of stroke patients are required.

A stroke occurs when a blood clot or ruptured artery or blood vessel interrupts blood flow to a region of the brain (Department of Health, 2007). Stroke is the leading cause of death in the western world and has the greatest disability impact of any chronic disease (Feigen et al., 2008). Around 50-75% of stroke survivors are left with chronic disabling symptoms affecting speech, mobility, cognition and vision (Sandercock et al., 2001). Such outcomes have been associated with difficulty accepting and adjusting to the effects of stroke, with many stroke survivors reporting psychological problems (Kneebone & Lincoln, 2012). Depression following stroke, also referred to as post-stroke depression (PSD) is considered the most common neuropsychiatric consequence of stroke, with estimates of the frequency ranging from 25% to 79% across studies (Hackett, Yapa, Parag & Anderson, 2004). Such variation in prevalence estimates is due to the complexity in recognition, assessment and diagnosis of depression following stroke, which can be complicated by overlap with the cognitive, language and stroke-related physical symptoms which commonly occur following stroke. Several factors including stroke severity, social support and lesion location have been identified as risk

factors for PSD (Robinson & Spalletta, 2010). PSD is characterised by feelings of sadness and worthlessness, loss of interest, insomnia or hypersomnia, weight loss or weight gain, psychomotor agitation or retardation, concentration and thinking difficulties, and thoughts of self-harm or suicide (Kneebone et al., 2010). PSD has been associated with poorer recovery and rehabilitation response, reduced social functioning and delayed return to work, greater use of healthcare services, increased risk of subsequent cardiac and stroke events, as well as increased mortality from all causes (Donnellan, Hickey, Hevey, & O'Neill, 2010).

Despite the high prevalence and long term impact of PSD, the condition remains poorly recognised and identified, and consequently inadequately treated and managed. This is partly due to the difficulties inherent in diagnosing PSD and lack of available evidence-based treatment. Antidepressants have routinely been prescribed for the treatment of PSD, however, there is growing evidence that their use derive limited, if any benefit (Mast, & Vedrody, 2006). A significant percentage of stroke survivors do not respond to antidepressants, thus remaining depressed (Paul, Dewey, Sturm, Macdonell, & Thrift, 2006). Furthermore, the adverse side effects, including central nervous system and gastrointestinal complications, mean many medical practitioners are often reluctant to prescribe antidepressants for stroke patients (Paul et al., 2006). The standards set by the National Stroke Strategy require the delivery of therapeutic emotional support throughout the clinical stroke pathway (Department of Health, 2007). Evidence suggests that psychotherapeutic interventions are efficacious for the treatment of depression in patients with a range of acquired brain injuries and other neurological conditions (Aniskiewicz, 2010). Such interventions might also be effective for the treatment of PSD.

Four previous reviews have sought to determine whether therapeutic treatment targeting depression in stroke survivors can improve outcomes. Hackett, Anderson, House, and Xia (2008) conducted a systematic review of randomised controlled trials (RCTs) of pharmaceutical agents, electroconvulsive treatment and psychotherapeutic therapies for the treatment of PSD. Efficacy was found to be linked to treatment delivery (trained and supervised therapists using a pre-specified framework for therapy); however, it was not possible to conclude whether there was any overall benefit of psychotherapy for treatment of PSD, given the small number of psychotherapy trials reviewed ($N= 3$) that also had poor methodological quality. The number of trials reviewed may have been compromised by the strict inclusion criteria which was limited to trials of stroke survivors with a clinical diagnosis of depression. Given the difficulties associated with diagnosing PSD, many potentially relevant trials may have been excluded on these grounds. Furthermore, the review excluded trials of cross-over design.

The second systematic review, conducted by Ginkel, Gooskens, Schuurmans, Lindeman and Hafsteinsdottir (2010) sought to identify effective non-pharmacological interventions that nurses could implement in the management of PSD. Life review therapy and physical exercise were found to have positive effects on the occurrence and severity of PSD. The scope of the review, however, was limited to interventions ($N=13$) that could only be facilitated by nurses and not by any other health professional. Lökk and Delbari (2010), conducted a review of the management of depression in elderly stroke survivors and concluded that psychotherapy has no effect for treatment of PSD. However, the review was limited to studies ($N=3$) of samples of elderly stroke survivors, thus limiting generalizability of findings to younger stroke survivors. Furthermore, the review was not systematic in nature; the number of studies reviewed

was not stated, and a systematic or explicit methodology to identify, select and critically evaluate relevant studies was not employed.

Wannagat, Zielasek and Gaebel (2013) conducted a systematic review of pharmacological and non-pharmacological trials (*N*=5) for the treatment PSD. Some evidence was found for the application of non-pharmacological interventions for the treatment of PSD. However, the review was limited to RCTs where the control conditions received interventions of similar intensity, duration or frequency as the intervention condition, limiting the number of eligible studies and consequent scope of the review.

In summary, previous reviews have been unable to draw strong conclusions regarding the efficacy and benefit of psychotherapeutic interventions for the treatment of PSD, given the paucity of studies available with methodological flaws. The restrictive inclusion criteria of previous reviews (reliance on patients with clinical diagnosis of depression, exclusion of trials of cross-over design, therapy interventions delivered by one type of health professional, focus on elderly stroke population) and lack of systematic rigour, has limited the conclusions that can be drawn and recommendations that can be made for clinical practice. In recent years, there has been a growing number of RCTs published in this field. As a consequence, this systematic review provides an update of the literature, to present a comprehensive assessment of the benefits of psychotherapy targeted at improving depressive symptomatology in stroke survivors.

Aims of review

The aims of this review were to (i) provide an updated review and a (ii) critical appraisal of the available literature on psychotherapeutic interventions targeted at

reducing depressive symptomatology following stroke and to (iii) outline the theoretical basis on which such interventions are derived and (iv) determine the effects of such interventions.

Method

Criteria for considering studies for this review

Types of studies. The review was restricted to all relevant RCTs where psychotherapy was used for the treatment of PSD and was compared with placebo, standard care, waiting list for psychotherapy or alternative psychotherapy. Pilot or feasibility trials, in addition to trials using a cross-over design in which two or more interventions were compared with each other, were included. Only studies written in English and published in peer-reviewed journals were included. There was no restriction on eligibility of RCTs on the basis of sample size or duration of follow-up.

Types of Participants. The review included trials of participants with a clinical diagnosis of stroke. There were no restrictions on the basis of age, time post-stroke, gender or other characteristics. Participants were not required to have a clinical diagnosis of depression on recruitment; however, trials that did not measure depression as the primary outcome at follow-up were excluded. Trials that included mixed clinical populations (such as multiple sclerosis, head injury or other central nervous system disorders) or where the intervention had been delivered to both the stroke patient and carer were excluded, unless separate results for the stroke patients could be identified.

Types of interventions. Trials evaluating interventions that involved either direct or indirect patient professional interaction were included. All interventions had to have a clearly defined psychotherapeutic component whereby the treatment was based upon scientific background, using psychotherapeutic techniques to reduce depressive symptoms through modifying motivational, emotional, cognitive, behavioural or

interpersonal processes. There was no exclusion of trials on the basis of delivery of the intervention (group versus individual therapy, or face-to-face versus telephone versus online) or setting (hospital versus community).

Types of outcome measures. From the information provided within included studies, 'standardised mean differences' between groups on outcome measures were analysed to calculate the effect sizes which were reported using Cohen's *d*. Such outcomes included: (1) depression defined by the Diagnostic and Statistical Manual of Mental Disorders (DSM) or similar standard diagnostic criteria; (2) depression measured on self-rating scales including the Hamilton Depression Rating Scale (HDRS; Hamilton, 1960), Montgomery Åsberg Depression Rating Scale (MADRS; Montgomery & Asberg, 1979), Geriatric Depression Scale (GDS; Gompertz, Pound & Ebrahim, 1993), Beck Depression Inventory (BDI; Beck, 1961), and Hospital Anxiety and Depression Scale (HADS; Zigmond & Snaith, 1983), General Health Questionnaire (GHQ-28; Goldberg, 1978), the Yale Depression Screen (YDS; Mahoney et al., 1994), the Visual Analogue Mood Scales (VAMS; Stern, 1997), the Wakefield Depression Inventory (WDI; Snaith, Ahmed, Mehta, & Hamilton, 1971) and the Center for Epidemiological Studies Depression (CES-D; Radloff, 1977).

Search strategy

The list of relevant electronic bibliographic databases searched included: Medline, PsycInfo, Web of Knowledge, CINAHL and The Cochrane Trial Register. Online clinical trials and registers were also searched including www.strokecentre.org/trials and www.clinicalstudyresults.org. The following specific journals were searched by hand: Stroke, Stroke and Cerebrovascular Diseases, International Journal of Stroke, Clinical Rehabilitation, British Medical Journal and Topics in Stroke Research. Existing authors were contacted and asked to provide

articles in press. Finally, the bibliography of identified articles, previous systematic and non-systematic reviews, was searched for studies not identified by the database searches. The literature search was performed for studies published during the period January 1967 (in line with previous reviews) to January 2016. The following search terms were used where MeSH terms were automatically exploded and Boolean operators 'AND' and 'OR' used to combine key words: [*stroke* or *cerebrovascular accident*] AND [*patient**] AND [*depression* or *depress** or *low mood* or *mood disorder* or *mood symptom(s)* or *depressive disorder(s)* or *depressive symptom(s)* or *post stroke depression*] AND [*treatment* or *therapy* or *intervention* or *psychotherapy* or *treatment outcome*] AND [*trial* or *clinical trial* or *randomised controlled trial* or *randomized controlled trial*].

Two raters (psychology postgraduates) reviewed all citations and discarded those that were not relevant based on the title and abstract of the publication. For potentially relevant articles, the full length article was retrieved for further assessment. Any disagreements were resolved by discussion. Figure 1 describes the process and outcome of the search. For data extraction purposes, both raters independently extracted, cross-checked and entered the data on forms.

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Figure 1. PRISMA diagram describing the search strategy

| Records identified through database search (N = 1745) | Additional records identified through other sources (N = 34) |

Records after duplicates removed (N = 1290)

Records screened (N = 1290) → Records excluded following screening by title and abstract (N = 1254)

Full-text articles assessed for eligibility (N = 36) → Full-text articles excluded, with reasons (N = 21) comprise:
Not written in English (N = 2)
Unpublished study (N = 1)
No psychological component in intervention (N = 7)
Not RCT (N = 9)
Depression not main outcome at follow-up (N = 2)

Studies methodological quality assessed (N = 15) → Study excluded due to poor methodological quality (N = 2)

Studies included in the review (N = 13)

Quality assessment and data synthesis

The Downs and Black (1998) checklist was used to score the quality of included studies. This checklist provides an overall methodological quality score for each outcome study from a list of 27 items. The scoring criteria has recently been simplified awarding item 27 with a score of one or zero depending on whether a power calculation was conducted and the study adequately powered to detect a significant treatment effect (Samoocha, Bruinvels, Elbers, Anema, & van der Beek, 2010). In addition to the provision of an overall score, the checklist provides a profile of scores for the quality of reporting, the internal validity, external validity and statistical power. An overall methodological quality score of 17 points or more identifies studies with high methodological quality. Evidence supports the checklist's internal consistency, test-retest and interrater reliability, face and criterion validity (Downs & Black, 1998).

Given that previous reviews in this field have been unable to draw conclusions given the limited and variable quality of studies, this review sought only to comment on studies of high methodological rigour. Therefore, studies that failed to meet a score of 17 points or more on the Downs and Black (1998) checklist were excluded from the final synthesis of findings. Two raters assessed the methodological quality of studies independently with any differences in opinion, resolved by discussion. Interrater reliability analysis using the Kappa statistic was calculated to determine consistency among raters. A substantial level of agreement was found, k=.725 (95% CI, 0.590, 0.860), $p<.001$ (Altman, 1991). Two studies (Chang, Zhang, Xia & Chen, 2011; Wu et al., 2012) were excluded from the review due to low methodological quality.

Data synthesis involved drawing together the main results of each study whilst combining and summarising these findings with the general characteristics and quality evaluation of the trials. Data synthesis proceeded in the form of a narrative approach

given that formal statistical techniques (meta-analyses) were not appropriate given the broad range of study outcomes, types of interventions, study inclusion criteria, type of analysis or type of control group, within trials included in the review.

Results

Table 1 shows a summary of the data extracted and quality appraisal of each study meeting the inclusion criteria (*N*=13).

Participants

Sociodemography. The mean age of participants ranged from 52 to 72 years. Almost all trials (*n*=9) had larger frequencies of males to females (Alexopoulos et al., 2012; Hoffman, Ownsworth, Eames & Shum, 2015; Johnston et al., 2007; Mitchell et al., 2009; Ostwald et al., 2014; Smith, Egbert, Dellman-Jenkins, Nanna & Palmieri, 2012; Thomas, Walker, Macniven, Haworth & Lincoln, 2013; Watkins et al., 2007; Watkins et al., 2011). Diagnosis of depression was a prerequisite of six trials (Alexopoulos et al., 2012; Lincoln & Flammaghan, 2003; Mitchell et al., 2009; Smith et al., 2012; Thomas et al., 2012; Towle et al., 1989). Ten trials included stroke of all subtypes (Hoffman et al., 2015; Johnston et al., 2007; Lincoln et al., 2002; Mitchell et al., 2009; Ostwald et al., 2014; Smith et al., 2012; Thomas et al., 2012; Towle et al., 1989; Watkins et al., 2007; Watkins et al., 2011).

Recruitment time window. The average time from stroke onset to entry into trials ranged from within 48 hours (Hadidi, Lindquist, Buckwalter & Savik, 2014; Johnston et al., 2007) to 39 months (Thomas et al., 2012). Three trials included patients within one month of stroke onset (Hadidi et al., 2014; Watkins et al., 2007; Watkins et al., 2011). Seven trials included patients within one year of stroke onset (Hadidi et al., 2014; Lincoln et al., 2003; Mitchell et al., 2009; Ostwald et al., 2014; Towle et al.,

1989; Watkins et al., 2007; Watkins et al., 2011). One trial specifically excluded patients within one year of stroke onset (Bishop et al., 2014). Details of the time window for entry was uncertain for three trials (Alexopoulos et al., 2012; Hoffman et al., 2015; Smith et al., 2012).

Exclusion criteria. The majority of trials employed criteria which excluded patients with varying degrees of cognitive and/or communication difficulties (Alexopoulos et al., 2012; Bishop et al., 2014; Hadidi et al., 2014; Hoffman et al., 2015; Lincoln et al., 2002, Ostwald et al., 2014; Smith et al., 2012; Thomas et al., 2012; Towle et al., 1989; Watkins et al., 2007; Watkins et al., 2011). Other specific reasons for exclusion included: an inability to communicate in spoken English (Alexopoulos et al., 2012; Bishop et al., 2014; Hadidi et al., 2014; Lincoln et al., 2002; Ostwald et al., 2014; Thomas et al., 2012); or receiving psychotherapy (Thomas et al., 2012; Lincoln et al., 2002; Watkins et al., 2007; Watkins et al., 2011); and residing and/or expectation to be discharged to residential care following hospital discharge (Alexopoulos et al., 2012; Bishop et al., 2014; Hoffman et al., 2015; Ostwald et al., 2014; Towle et al., 1989).

Setting. Seven trials recruited patients from inpatient hospital services (Bishop et al., 2014; Hadidi et al., 2014; Hoffman et al., 2015; Johnston et al., 2007; Mitchell et al., 2009; Watkins et al., 2007; Watkins et al., 2011), five from outpatient services (Alexopoulos et al., 2012; Lincoln et al., 2002; Ostwald et al., 2014; Smith et al., 2012; Towle et al., 1989), and one trial used mixed inpatient and outpatient sources of patients (Thomas et al., 2012).

Depression outcome measures

Twelve assessment scales were used to assess mood or change in mood at the end of treatment across all thirteen trials. The most commonly used measures were the GHQ-28 (Towle, 1989; Watkins, 2007; Watkins, 2011), and the GDS (Bishop, 2014;

Mitchell, 2009; Ostwald, 2014). Eight trials used two or more scales to assess depression (Hoffman, 2015; Lincoln, 2002; Mitchell, 2009; Smith, 2012; Thomas, 2012; Towle, 1989; Watkins, 2007, Watkins, 2011).

Psychotherapy

The forms of psychotherapy included Problem-Solving Therapy (Hadidi et al., 2014; Towle et al., 1989), Cognitive Behavioural Therapy (Hoffman et al., 2015; Lincoln et al., 2002) Behavioural Therapy (Johnston et al., 2007; Mitchell et al., 2009; Thomas et al., 2012), Psychoeducation (Bishop et al., 2014; Ostwald et al., 2014; Smith et al., 2015), Motivational Interviewing (Watkins et al., 2007; Watkins et al., 2014), and Ecosystem Focused Therapy (Alexopoulos et al., 2012). The interventions were delivered by a range of therapists with backgrounds in clinical psychology, neuropsychology, nursing, occupational therapy and social work. The duration of sessions ranged from 30 minutes (Watkins et al., 2007) to 90 minutes (Hadidi et al., 2014), and between a 4-week (Watkins et al., 2007) and 6-month period (Bishop et al., 2015; Ostwald et al., 2014). The majority of interventions were delivered to the stroke patient alone. However, in four studies, the intervention was delivered to both the stroke patient and identified caregiver (Alexopoulos et al., 2012; Bishop et al., 2014; Ostwald et al., 2014; Smith et al., 2014).

In all studies, the intervention was delivered to an individual as opposed to a group. The majority of interventions were delivered face-to-face (N=10). One intervention included a combination of face-to-face and telephone contacts (Johnston et al., 2007), one intervention included telephone contacts alone (Bishop et al., 2014) and another study intervention was delivered via the internet (Smith et al., 2014). Seven trials used standard care as the control comparison condition (Bishop et al., 2014; Hadidi et al., 2014; Johnston et al., 2007; Mitchell et al., 2009; Thomas et al., 2012;

Watkins et al., 2007; Watkins et al., 2011). Two trials used both a standard care control and an alternative therapy group as comparison conditions (Hoffman et al., 2015; Lincoln et al., 2002). Four trials did not have a control comparison group and compared the experimental therapy with alternative therapy (Alexopoulos et al., 2012; Ostwald et al., 2014; Smith et al., 2012; Towle et al., 1989).

Quality of studies

The quality scores of included studies ranged from 18 (Towle et al., 1989) to 25 (Watkins et al., 2007; Watkins et al., 2011). The mean quality of studies was high (M=22.54, SD=1.98). All but two trials (Alexopoulos et al., 2012; Hadidi et al., 2014) used single (assessor) blinded outcome assessments. Only one trial (Lincoln et al., 2002) made an attempt to blind study participants to the intervention they received. Ten trials provided intention-to-treat analyses, (Alexopoulos et al., 2012; Bishop et al., 2014; Hadidi, et al., 2014; Hoffman et al., 2015; Mitchell et al., 2009; Ostwald et al., 2014; Smith et al., 2014; Thomas et al., 2012; Watkins et al., 2007; Watkins et al., 2011). The number of participants ranged from 24 (Alexopoulos et al., 2012) to 411 (Watkins et al., 2007), with dropout rates ranging from 0% (Hadidi et al., 2014) to 22% (Johnston et al., 2007; Watkins et al., 2011). The small number of participants in seven trials compromised statistical power to detect statistically significant treatment effects (Alexopoulos et al., 2012; Bishop et al., 2014; Hadidi et al., 2014; Hoffman et al., 2015; Ostwald et al., 2014; Smith et al., 2012; Towle et al., 1989). Adverse outcomes and therapist effects were not documented in any trial. A correlation analysis indicated that quality of studies was not related to year of publication, r(11) =.31, p=.20.

Main findings

To aid synthesis and comparison, the review findings were grouped by the intervention evaluated. In Table 1, the studies are arranged in order of highest to lowest quality score, under each intervention studied.

Psychoeducation. Three trials evaluated the effectiveness of psychoeducation for treatment of PSD. Treatment effects ranged from small (d=0.13) to medium (d=0.57). None of the effects were significant. Smith et al. (2012) investigated the effectiveness of a web-based psychoeducational intervention. Small treatment effects were reported post-intervention and at one month follow-up. The control condition however received aspects of the evaluated intervention, which may have diluted the effects of the experimental intervention. In comparison, Bishop et al. (2014) found moderate treatment effects of a 6-month psychoeducational intervention delivered via telephone, however, the lack of long term follow-up precludes reliable conclusions to be drawn regarding treatment effectiveness. Similar treatment effects were reported by Ostwald et al. (2014) for a face-to-face 6-month psychoeducational intervention. However, the lack of control group meant it could not be concluded whether the observed treatment effect was directly related to the intervention. Furthermore, the exclusion of participants under 50 years of age, limits generalisability of the findings.

Behavioural Therapy (BT). Three trials evaluated the effectiveness of BT for treatment of PSD. Treatment effects, ranged from small (d=0.03) to large (d=1.40). Two studies reported significant treatment effects. Thomas et al. (2012) reported that a 20 session BT resulted in statistically significant medium to large treatment effects at 3 and 6-month follow-up. Similar findings were reported by Mitchell et al. (2009) who found that a 9 session BT resulted in statistically significant large treatment effects post-intervention and at 12-month follow-up. In contrast, Johnston (2007) reported small

non-significant treatment effects of a 5 session work-book based behavioural intervention. However, the intervention consisted of fewer sessions and was not delivered face-to-face. Furthermore, a large proportion of intervention participants did not complete the workbook tasks, which may have diluted the effects of the experimental intervention. In addition, participants were not required to be presenting with depressive symptomatology on recruitment. These factors may have together contributed to the difference in study findings. However, the lack of an attention placebo group across all studies means that it is not possible to disentangle whether the treatment effects reported resulted from having an interested and supportive therapist available to listen to problems, rather than the specific effects of BT.

Cognitive Behavioural Therapy (CBT). Two three-arm trials evaluated the effectiveness of CBT informed interventions for treatment of PSD. Treatment effects, ranged from small (d= -0.26) to large (d=0.70). Lincoln et al. (2003) reported non-significant small treatment effects of CBT at 3 and 6-month follow-up. In comparison, Hoffman et al. (2015) found large significant treatment effects of CBT on HADS depression subscale but small non-significant treatment effects on MADRS, immediately post-intervention. The size of treatment effect reduced at follow-up, suggesting the intervention has little long term effect.

Problem-Solving Therapy (PST). Two trials evaluated the effectiveness of PST for treatment of PSD. Treatment effect sizes ranged from small (d =0.12) to large (d=0.85), but were non-significant. Towle et al. (1989) found that a 32 session PST delivered more than one year post-stroke, resulted in small treatment effects post-intervention. PST participants reported that the intervention would have been more beneficial if had been delivered earlier post-stroke. In this study, the therapist and data collector was the same person which could have resulted in expectation bias in

participant responses. In contrast, Hadidi et al. (2014) found that a 10 individual session PST, commencing early post-stroke (within 48 hours of stroke onset) resulted in large treatment effects post-intervention. However, the lack of an attention placebo group precludes strong conclusions being drawn regarding the 'active ingredients' of PST, or the role of non-specific attention. Furthermore, the lack of long term follow-up precludes reliable conclusions being drawn regarding treatment effectiveness.

Motivational Interviewing (MI). Two studies commented on the evaluation of a four session MI intervention for treatment of PSD (Watkins et al., 2007; Watkins et al., 2011). Statistically significant small treatment effects were found at 3-months post-stroke on the GHQ-28 (d=0.26) and YDS (d=0.28) and at 12-months post-stroke on the GHQ-28 (d=0.28) and YDS (d=0.05). Interestingly, the effect of MI on self-reported depression (measured by the YDS) compared to mood (GHQ-28) was no longer statistically significant at 12-month follow-up (Watkins et al., 2011). This finding may reflect that the two measures assess different aspects of mood. However, the lack of an attention placebo precludes conclusions being drawn regarding the 'active ingredients' of MI, or the role of non-specific attention.

Ecosystem Focused Therapy (EFT). One study evaluated the effectiveness of 12-week EFT, by comparing EFT with systematic Education on Stroke and Depression (ESD; Alexopoulos et al., 2012). A large but non-significant treatment effect was reported post-intervention (d=0.83). The same therapists delivered both treatments. It is therefore possible that greater therapist allegiance to one of the two treatments may have influenced their performance. Furthermore, the lack of long term follow-up means it is unclear whether the immediate treatment gains reported are sustainable.

Table 1

Characteristics summary of included studies (N=13)

Author(s), Year & Country	Study design	Participants (Sample size, % male, mean age)	Intervention(s) (Delivery, duration & content)	Control condition	Outcome measure(s) (Measure, when administered)	Data analysis	Main findings	Quality Rating
Psychoeducation								
Ostwald et al. (2014), United States	RCT	Mailed Information Intervention plus 6-month home-based psychoeducational intervention: (*N*=80); 69% male; mean age = 67 Mailed Information Intervention only: (*N*=79); 81% male; mean age = 66	Mailed Information Intervention plus 6-month home-based psycho-educational intervention: Home visits for first 6 months post discharge by advance practice nurses, occupational and physical therapists with average of 2 home visits per month of 70 minute duration Patients received mailed monthly personalised letters over 12 month period on signs and symptoms of stroke, stroke prevention, stress management techniques, guidelines around health diet and exercise, links to support groups and advocacy organisations and tips for leisure activities. In addition, patients were provided with support and education, skill training, counselling and linkages to social and community resources Mailed Information Intervention: Patients received mailed monthly personalised letters over 12 months only	No control condition	GDS Completed face-to-face at baseline (pre-intervention), 3, 6, 9 and 12 months (primary end-point) post-discharge	Repeated measures Analysis of Variance (ANOVA) and mixed modelling	No statistically significant benefit of psychoeducation over usual care at any follow-up nor at primary end point (*p*>.05, *d*=0.40)	22

Table 1

Characteristics summary of included studies (N=13)

Smith et al. (2012), United States	RCT	Intervention: (N=19); 100% male; mean age = 60 Control: (N=19); 100% male; mean age = 59	Patients and their carers were provided with computer hardware and internet access and provided with hard copy tutorials. Duration of intervention was not recorded The web-based psychoeducational intervention consisted of 5 components: professional guide, educational videos, online chat sessions, email and message board and a resource room	Received access to resource room component of the web-based intervention	CES-D Completed face-to-face at baseline (pre-intervention), post-intervention, and 1-month follow-up	Analysis of Covariance (ANCOVA)	No statistically significant benefit of psychoeducation over usual care post-intervention (p>.05, d=0.16) or at 1-month follow-up (p>.05, d=0.13)	22
Bishop et al. (2014), United States	Pilot RCT	Intervention: (N=23) Control: (N=26) Only mean age and % male for entire patient sample given: 35% male; mean age = 70	Four therapists with previous clinical experience with family therapy or stroke, provided telephone contacts to stroke survivors and carers during first 6-months post-hospital discharge. Contacts occurred weekly for 6 weeks, bi-weekly for the following 2 months, then monthly for two months Psychoeducational intervention designed to assist stroke survivors in identifying and addressing problems in family functioning, mood, problem-solving, neurocognitive functioning, functional independence and physical health	Received standard medical follow-up	GDS Completed baseline assessments (pre-intervention) face-to-face, and assessments 3 and 6-months post stroke by telephone (47%), proxy (18%) or in person (2%)	Independent group t-tests	No statistically significant benefit of psychoeducation over usual care 3 (p>.05, d=0.50) or 6-months (p>.05, d=0.57) post-stroke	21

Table 1

Characteristics summary of included studies (N=13)

Behavioural Therapy (BT)

Thomas et al. (2012), United Kingdom	RCT	Intervention: (N=51); 57% male; mean age = 69 Control: (N=54); 69% male; mean age = 56	Assistant psychologist delivered 20 individual 1 hour Behavioural Therapy (BT) sessions over 3 months at patients home BT consisted of strategies focused on maximising mood-elevating activities, including education, activity monitoring, activity scheduling and graded task assignments	Received all other services that were available to them as local practice	SADQ and VAMS 'sad' item Completed face-to-face at baseline (pre-intervention), 3 and 6 months post-randomization	Hierarchical multiple linear regression	Statistically significant benefit of BT over usual care on SADQ at 3 *(p=.05, d=0.5)* and 6-months *(p=.05, d=0.7)* Significant benefit of BT over usual care on VAMS 'sad' item at 3-months *(p=.03, d=0.6)* but between group differences no longer significant at 6-months *(p>.05, d=0.49)*	25
Johnston et al. (2007), Scotland	RCT	Intervention: (N=103); 61% male; mean age = 69. Control: (N=100); 61% male; mean age = 69.	Research assistant administered work-book based behavioural intervention of weekly sessions over a 5-week period. First two and last sessions were completed face-to-face. The third and fourth contacts were delivered by telephone The workbook based behavioural intervention included activities designed to allow the patient to attain coping skills and encourage self-management. Information was provided about stroke and recovery, guidance on coping skills and self-management instruction	Not specified	HADS depression subscale Completed face-to-face at baseline (within 2 weeks of hospital discharge), 8 weeks (approximately immediately post-intervention) and 6-months from baseline	Repeated measures ANOVA	No statistically significant benefit of BT over usual care at 8-week *(p>.05, d=0.03)* or 6-month follow-up *(p>.05, d=0.06)*	23

Table 1

Characteristics summary of included studies (N=13)

Mitchell et al. (2009), United States	RCT	Intervention: (*N*=48); 60% male; mean age = 57 Control: (*N*=53); 60% male; mean age = 57	Nurse delivered 9 individual BT sessions delivered over 8 week period at patients home BT intervention involved teaching specific problem-solving approaches & solutions to behavioural changes individualised to each patient	Received regular visits from stroke primary care provider	HRSD Completed face-to-face at baseline (pre-intervention), post intervention (9 weeks) and 12 months post stroke	ANCOVA	Statistically significant benefit of BT over usual care post-intervention (*p*=.02, *d*=1.4) or at follow-up (*p*=.03, *d*=1.17)	23
Cognitive Behavioural Therapy (CBT)								
Lincoln et al. (2003), United Kingdom	Three-arm RCT	CBT Intervention: (*N*=39); 51% male, mean age = 70 Attention placebo: (*N*=43); 51% male; mean age = 66 Control: (*N*=41); 51% male; mean age = 65	CBT intervention: Community psychiatric nurse (CPN) delivered 10 one hour individual CBT sessions over 3 months (location not specified) CBT consisted of cognitive and behavioural techniques including education, graded task assignment, activity scheduling, and identification and modification of unhelpful thoughts and beliefs Attention placebo intervention: CPN delivered 10 one hour individual visits over 3 months CPN had conversation with stroke patients on day-to-day occurrences, physical effects of stroke & life changes. No formal therapeutic intervention offered	Not specified	BDI and WDI Completed face-to-face at baseline (pre-intervention), 3 & 6 months post randomization	Kruskal-Wallis 1-way ANOVA	CBT vs standard care: No statistically significant benefit of CBT over standard care on either WDI (*p*>.05, *d*=-.26) or BDI (*p*>.06, *d*=-.01) at 3-month follow-up or on WDI (*p*>.05, *d*=-.15) or BDI (*p*>.05, *d*=.00) at 6-month follow-up CBT vs attention placebo: No statistically significant benefit of CBT over attention placebo on either WDI (*p*>.05, *d*=-.35) or BDI (*p*>.05, *d*=-.12) at 3-month follow-up or on WDI (*p*>.05, *d*=.02) or on BDI (*p*>.05, *d*=-.15) at 6-month follow-up	24

Table 1

Characteristics summary of included studies (N=13)

Hoffman et al. (2015), Australia	Pilot three-arm RCT	CBT informed coping skills intervention: (*N*=11); 64% male; mean age = 64 Self-management intervention: (*N*=12); 75% male; mean age = 61 Control: (*N*=10); 60% male; mean age = 57	CBT informed coping skills intervention: Clinical Psychologist delivered 8 face-to-face one hour individual weekly sessions at patients home CBT informed coping skills intervention consisted of debriefing & goal setting, psychoeducation, coping skills training, behavioural activation & cognitive therapy, cognitive rehabilitation, family support and involvement, grief work Self-management intervention: Occupational Therapist delivered 8 face-to-face one hour individual weekly sessions at patients home Sessions were tailored to specific individual need. Typical topics covered included: relaxation/stress management training, cognitive & emotional education, fatigue management, goal setting, education about stroke, return to driving and work advice and support, education about communication concerns, and support for activities of daily living concern	Received usual multi-disciplinary assessment and treatment including education and advice throughout discharge process	MADRS and HADS depression subscale Completed face-to-face at baseline (within 1-week of randomization), 1 week post-intervention and 3-months following intervention	ANCOVA	CBT informed coping skills vs standard care: Statistically significant large treatment effect of CBT coping skills over standard care on HADS depression subscale immediately post-intervention (*p*=.03, *d*=.70). Such difference did not remain statistically significant at 3-month follow-up (*p*=.18, *d*=-.30). No statistically significant effects of CBT coping skills over standard care on MADRS immediately post-intervention (*p*=.71, *d*=-.02) or at follow-up (*p*=.26, *d*=-.20) CBT informed coping skills vs self-management: Non-significant effects of CBT over self-management on either HADS depression subscale (*d*=.50) or MADRS (*d*=.02) immediately post-intervention or on HADS depression subscale (*d*=-.30) or MADRS (*d*=-.02) at 3-month follow-up	22

Table 1

Characteristics summary of included studies (N=13)

Problem Solving Therapy (PST)

Study	Design	Participants	Intervention	Control	Measure	Analysis	Results	
Hadidi et al. (2014), United States	Pilot RCT	Intervention: (*N*=11); 45% male; mean age = 73 Control: (*N*=11); 18% male; mean age = 69	Trained nursing doctoral student delivered 10 individual consecutive weekly 1 ½ hour sessions of PST at patients homes PST involved problem identification, goal setting, generating, selecting and implementing solutions, and pleasant activity identification and evaluation	Received usual care, defined as no intervention from the research team	CES-D Completed face-to-face for participants in intervention group, and via telephone for participants in control group at baseline (pre-intervention), & 10 weeks post baseline assessment	ANCOVA and mixed modelling	No statistically significant benefit of PST over usual care at 10-week follow-up (*p*=.08, *d*=0.85)	21
Towle et al. (1989), United Kingdom	RCT	Intervention: (*N*=21); 43% male; mean age = 70 Control: (*N*=23); 30% male; mean age = 69	Social worker provided patients with an information booklet and visited patients twice per week for 16 weeks at patients homes The social worker provided problem solving therapy with counselling in addition to an information booklet covering benefits, aids to daily living, address of stroke clubs and self-help groups, and contact details of local social services	Received one visit by social worker and provided with information booklet	WDI and GHQ-28 Completed face-to-face at baseline (pre-intervention), and 16-weeks post baseline assessment	Independent t-tests	No statistically significant benefit of PST over usual care on the WDI (*p*>.05, *d*=0.12) or GHQ-28 (*p*>.05, *d*=0.37) at 16-weeks post baseline assessment	18

Table 1

Characteristics summary of included studies (N=13)

Motivational Interviewing (MI)

Watkins et al. (2007), United Kingdom	Single centre RCT	Intervention: (*N*=204); 58% male; median age = 70 Control: (*N*=207); 59% male; median age = 70	Trained therapists delivered 4 individual weekly sessions of MI (between 30 and 60 minutes in duration), in a private area MI intervention initially consisted of therapists discussing with patients adjustment to stroke and current concerns. Therapists then elicited patients' goals for recovery and blocks to attainment. This enabled patients to identify their own solutions	Received usual medical, nursing and therapy input	GHQ-28 and Yale depression screen Baseline assessment completed face-to-face between days 5 and 28 at time of randomization. Follow-up assessments were mailed 3 months post stroke	ANCOVA	Statistically significant benefit of MI over usual care on GHQ-28 (*p*=.03; *d*=0.26) and Yale depression screen (*p*=.03; *d*=0.28) 3-months post-stroke	25
Watkins et al. (2011), United Kingdom	As above	As above	As above	As above	GHQ-28 and Yale depression screen Baseline assessment completed face-to-face between days 5 and 28 at time of randomization. Follow-up assessments were mailed 3 and 12-months post-stroke	As above	Statistically significant benefit of MI over usual care seen on GHQ-28 at 3 months (detailed above) remained statistically significant at 12 months (*p*=.02; *d*=0.28). However there was no longer a significant effect of MI on Yale depression screen at 12-months (*p*=.80, *d*=0.05)	25

Table 1

Characteristics summary of included studies (N=13)

Ecosystem Focused Therapy (EFT)

Alexopoulos et al. (2012), United States	RCT	Ecosystem Focused Therapy: (*N*=12); 50% male; mean age = 72 Education on Stroke and Depression: (*N*=12); 58% male; mean age = 69	Ecosystem Focused Therapy: Trained therapists delivered 12 individual 45 minute weekly sessions of EFT at patients home EFT consisted of training in problem solving, and coordination with other therapists to increase patient participation in treatment and rehabilitation and utilization of community resources Education on Stroke and Depression (ESD): Trained therapists delivered 12 individual 45 minute weekly sessions of ESD in patients home. Patients were educated about depression, stroke, and role of available treatments	No control condition	HRS Completed face-to-face at baseline (pre-intervention), 4 and 8 weeks (during intervention) and at 12 weeks (immediately post-intervention), primary end-point	Mann Whitney *U* Tests and mixed modelling	Non-statistically significant large between group effect size found at 12 weeks (*p*=.05, *d*=0.83)	22

Discussion

The purpose of the current systematic review was to determine the effects of psychotherapeutic interventions targeting depression following stroke. The large amount of heterogeneity between the small number of reviewed studies (N=13) precluded statistical analysis (e.g. meta-analysis) of findings across studies. Nonetheless, some conclusions regarding the effectiveness and benefits of psychotherapeutic interventions for treatment of PSD, could be tentatively drawn. Since the release of earlier reviews in this field, a growing number of RCTs had been published. Consequently, this review has provided an update of the literature on the benefits of psychotherapy targeted at improving depressive symptomatology in stroke survivors.

Summary of findings

The results demonstrate evidence for behavioural therapy for treatment of PSD, suggesting that interventions targeted at increasing stroke patients levels of activity, improves depression outcomes following stroke. These findings are consistent with Rizzo, Creed, Goldberg, Meader and Pillings's (2011) review findings of psychotherapies in chronic physical health populations, which found that behaviour therapy resulted in a reduction in depressive symptomatology. The other studies appraised within this literature review, which evaluated the effectiveness of problem-solving, psychoeducation, ecosystem focused therapy, and cognitive behavioural therapy for treatment of PSD produced mixed and inconclusive findings. Some studies demonstrated medium-large treatment effects which were non-significant due to the under-powered study designs (i.e. small sample sizes). In addition these findings were

based on a small number of studies, which therefore required replication before any recommendations can be made for clinical practice.

The review findings suggest that 'timing' of PST may be a crucial factor in terms of effectiveness. Early delivery of PST following stroke may serve as a preventative measure of the further development of mood problems. Depression occurring in the early phase of stroke, where stroke survivors are coping with the consequences of having experienced a life-threatening event and the disabling effects, is different to the type of depression occurring several months or years after the event, where survivors are likely to be adjusting to the prospects of permanent disability and changes in social and financial circumstances (Snow, Lascher, & Mottur-Pilson, 2000). The review findings suggest that PST may be more beneficial for the type of depression occurring in the acute phase of stroke. Unfortunately, the timing of the delivery of interventions post stroke-onset was not always reported in the reviewed trials. This makes it difficult to determine whether the timing of other interventions is a crucial factor in terms of their effectiveness.

The effect of CBT on PSD remains unclear. The short duration and low intensity of CBT delivered in the reviewed trials, may have contributed to the small treatment effects observed. Previous studies of depression in elderly populations have only shown gains when a minimum course of 15 sessions of CBT has been delivered (Koder, Brodaty, Anstey, 1996). Thus, the reviewed CBT studies may have provided insufficient treatment for gains to be made. The effect of EFT on PSD also remains unclear. Although large treatment effects were reported immediately post-intervention in one EFT study, the lack of a control group means that one cannot distinguish whether the effects reported were due to the intervention or other factors. In addition, the lack of follow-up means it is also unclear whether the immediate treatment gains reported can

be sustained over time. Larger treatment effects of BT were reported in studies where the intervention was delivered face-to-face, over a longer duration and where patients presenting with depressive symptoms were criteria for treatment. These findings suggest that patient characteristics, treatment duration and delivery are crucial factors for the effectiveness of BT. Such factors have been associated with psychotherapeutic outcomes in physical health populations (Dale, Adair, & Humpris, 2010; Winkley, Landau, Eisler & Ismail, 2006). One possible explanation regarding the efficacy of treatment delivery via face-to-face as oppose to other means, is that it aids building of therapeutic rapport, which has previously been identified as a predictor of therapeutic outcome (Ardito & Rabellino, 2011). It is likely that being more symptomatic at baseline allows for greater improvement in depressive symptoms as a result of the intervention. The possibilities for improvement when not symptomatic may be limited because of the ceiling effect, which has previously been described in this patient group (Watkins et al., 2007). This explanation might account for why MI resulted in small effects, given participants were on average, not symptomatic, with fairly low baseline depression scores. Nonetheless, psychoeducation resulted in moderate effects for stroke survivors, where being symptomatic of depression at baseline was not a prerequisite for treatment.

The present review findings differed to findings from earlier reviews which suggested minimal or no effect of psychotherapy for treatment of PSD. A possible reason for this discrepancy could be the larger number of studies with greater methodological rigour included within the present review. Nonetheless, many of the reviewed trials included stroke patients with narrow demographic and clinical characteristics. In particular, patients with communication and cognitive problems were commonly excluded from trials, limiting the external validity of the findings. This

reinforces the frequent criticism of depression research that trial participants are not necessarily representative of those requiring treatment in the 'real world' (Zimmerman, Mattia, & Posternak, 2002). Furthermore, many of the reviewed studies lacked an attention control group, which meant that many of the reported treatment effects could have been due to the role of non-specific attention, rather than the active ingredients of psychotherapy. Some studies did not incorporate a control group which means that alternative explanations other than the effect of the treatment being evaluated may account for the variance in patient outcomes. In addition, some studies did not collect follow-up data. This is problematic given that the long-term effectiveness of the interventions, and whether immediate treatment gains are maintained over time, cannot be concluded. Furthermore, given that some anticipated changes may take place over an extended period of time, the lack of follow-up means that it is not possible to assess the full effect of the intervention. Furthermore, the collection of follow-up data is of value in understanding the characteristics of those who adopt, or who adopt and subsequently abandon, the implemented practices for future implementation strategies.

Future research

The review has highlighted a number of specific gaps in the literature for future research to address.

First, the specific characteristics of stroke patients that are at risk of developing depression and the type of stroke patients most likely to benefit from psychotherapy remain unclear. Second, the timing of the delivery of psychotherapy in the stroke clinical pathway, in addition to what is the sufficient duration and intensity of different forms of psychotherapy, requires further investigation. To address these methodological issues, future trials should incorporate more representative samples of stroke patients

with neurological impairments, aphasia and co-morbid medical conditions to enable results to be generalised to a greater proportion of the stroke population. Furthermore, larger samples are required to increase study power to detect between group differences. Third, to enable more reliable conclusions to be drawn regarding treatment effectiveness, future trials should employ both a usual care and attention control condition.

Fourth, the lack of a consistent method to assess depression in trials made comparisons across studies more difficult. In a recent meta-analysis (Cuijpers, van Staten, & Warmerdam, 2007), different self-report and clinician-rated measures of depression resulted in different effect sizes from the same studies (differential effect size: 0.20), which was a similar finding in the present review. There is therefore a need for future studies to investigate the effect of different outcome measures on effect sizes in PSD.

Fifth, in many of the reviewed studies, little was reported regarding therapist effects. Therapist effects are estimated to account for 0% to 50% of change in symptomatic outcomes (Christoph & Mintz, 1991). Thus, such effects should be investigated in future trials to better understand whether outcomes are determined by the specific therapy techniques, or by more general psychological processes such as therapeutic alliance. There was also poor reporting of follow-up data. Long-term follow-up in clinical interventions is of particular importance in stroke survivors where the clinical picture is chronic, fluctuating and complex (McPherson et al., 2005). Further research investigating the longer-term outcomes of psychotherapies would enable rates of relapse or maintenance of remission to be assessed in stroke patients.

Finally, given the current context of health care finance reform initiatives, it would be useful to investigate the cost-effectiveness as well as clinical effectiveness of

different psychotherapies in comparison to one another for treatment of PSD. Research investigating whether the interventions can be delivered via others means, i.e. groups, which allows treatment to be offered to a far greater number of individuals, as well as offering considerable savings in terms of therapist time, is recommended. This may increase the profile, and therefore promotion, of psychotherapy within stroke rehabilitation in the future.

Implications for practice

Given the detrimental effects of PSD on recovery and quality of life, it is essential that clinicians routinely screen for and detect PSD early, using validated and reliable measures such as the PHQ-9. This will enable the identification of individual treatment needs and intervention before the condition worsens. The review findings confirm that psychological treatments are effective for patients with PSD. This finding is reassuring for both patients and clinicians wishing to pursue non-pharmacological options. The preliminary positive benefit of psychoeducation, problem solving, ecosystem focused therapy and behaviour therapy endorses the use of such approaches targeting PSD. As a result, clinicians are advised to consider providing such psychotherapeutic treatments to stroke survivors experiencing mood problems. However, given the sparsity of available evidence, further research is required before recommendations can be made regarding the routine use of such treatments in practice. Clinicians are therefore encouraged to keep up-to-date with the accumulating evidence of the efficacy of different treatments to inform their practice.

Strengths and limitations of review

This review had several major strengths. First, a systematic and comprehensive literature search was performed for relevant studies with a clearly focused research question defined a priori. Second, two review authors independently reviewed all

citations and assessed the quality of included studies, reducing systematic bias. Third, the methodological approach adopted within this review, went beyond earlier review findings given that effect sizes were calculated to compare findings across studies. The review also had some limitations. In particular, the review was limited to English language and published articles which may have precluded the identification of other relevant studies. Despite the limitations, the obtained findings regarding the effectiveness of psychotherapy for depression following stroke deserve consideration.

Conclusions

The present systematic review provides preliminary evidence that behaviour therapy is effective in reducing depression following stroke. However, these conclusions, must be viewed as tentative, given they were based on a small number of studies with a number of methodological limitations. Further research comparing the effectiveness of different psychotherapies, examining cost-effectiveness, therapist and long-term effects, in large representative samples of stroke patients, will provide further empirical evidence upon which to develop recommendations for the use of psychotherapy in the treatment of depression following stroke.

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Appendices

Appendix A: Quality rating tool (Downs & Black, 1998)

Appendix

Checklist for measuring study quality

Reporting

1. *Is the hypothesis/aim/objective of the study clearly described?*

yes	1
no	0

2. *Are the main outcomes to be measured clearly described in the Introduction or Methods section?*
If the main outcomes are first mentioned in the Results section, the question should be answered no.

yes	1
no	0

3. *Are the characteristics of the patients included in the study clearly described ?*
In cohort studies and trials, inclusion and/or exclusion criteria should be given. In case-control studies, a case-definition and the source for controls should be given.

yes	1
no	0

4. *Are the interventions of interest clearly described?*
Treatments and placebo (where relevant) that are to be compared should be clearly described.

yes	1
no	0

5. *Are the distributions of principal confounders in each group of subjects to be compared clearly described?*
A list of principal confounders is provided.

yes	2
partially	1
no	0

6. *Are the main findings of the study clearly described?*
Simple outcome data (including denominators and numerators) should be reported for all major findings so that the reader can check the major analyses and conclusions. (This question does not cover statistical tests which are considered below).

yes	1
no	0

7. *Does the study provide estimates of the random variability in the data for the main outcomes?*
In non normally distributed data the inter-quartile range of results should be reported. In normally distributed data the standard error, standard deviation or confidence intervals should be reported. If the distribution of the data is not described, it must be assumed that the estimates used were appropriate and the question should be answered yes.

yes	1
no	0

8. *Have all important adverse events that may be a consequence of the intervention been reported?*
This should be answered yes if the study demonstrates that there was a comprehensive attempt to measure adverse events. (A list of possible adverse events is provided).

yes	1
no	0

9. *Have the characteristics of patients lost to follow-up been described?*
This should be answered yes where there were no losses to follow-up or where losses to follow-up were so small that findings would be unaffected by their inclusion. This should be answered no where a study does not report the number of patients lost to follow-up.

yes	1
no	0

10. *Have actual probability values been reported (e.g. 0.035 rather than <0.05) for the main outcomes except where the probability value is less than 0.001?*

yes	1
no	0

External validity
All the following criteria attempt to address the representativeness of the findings of the study and whether they may be generalised to the population from which the study subjects were derived.

11. *Were the subjects asked to participate in the study representative of the entire population from which they were recruited?*
The study must identify the source population for patients and describe how the patients were selected. Patients would be representative if they comprised the entire source population, an unselected sample of consecutive patients, or a random sample. Random sampling is only feasible where a list of all members of the relevant

population exists. **Where** a study does not report the proportion of the source population from which the patients are derived, the question should be answered as unable to determine.

yes	1
no	0
unable to determine	0

12. *Were those subjects who were prepared to participate representative of the entire population from which they were recruited?*
The proportion of those asked who agreed should be stated. Validation that the sample was representative would include demonstrating that the distribution of the main confounding factors was the same in the study sample and the source population.

yes	1
no	0
unable to determine	0

13. *Were the staff, places, and facilities where the patients were treated, representative of the treatment the majority of patients receive?*
For the question to be answered yes the study should demonstrate that the intervention was representative of that in use in the source population. The question should be answered no if, for example, the intervention was undertaken in a specialist centre unrepresentative of the hospitals most of the source population would attend.

yes	1
no	0
unable to determine	0

Internal validity - bias

14. *Was an attempt made to blind study subjects to the intervention they have received ?*
For studies where the patients would have no way of knowing which intervention they received, this should be answered yes.

yes	1
no	0
unable to determine	0

15. *Was an attempt made to blind those measuring the main outcomes of the intervention?*

yes	1
no	0
unable to determine	0

16. *If any of the results of the study were based on "data dredging", was this made clear?*
Any analyses that had not been planned at the outset of the study should be clearly indicated. If no retrospective unplanned subgroup analyses were reported, then answer yes.

yes	1
no	0
unable to determine	0

17. *In trials and cohort studies, do the analyses adjust for different lengths of follow-up of patients, or in case-control studies, is the time period between the intervention and outcome the same for cases and controls ?*
Where follow-up was the same for all study patients the answer should yes. If different lengths of follow-up were adjusted for by, for example, survival analysis the answer should be yes. Studies where differences in follow-up are ignored should be answered no.

yes	1
no	0
unable to determine	0

18. *Were the statistical tests used to assess the main outcomes appropriate?*
The statistical techniques used must be appropriate to the data. For example non-parametric methods should be used for small sample sizes. Where little statistical analysis has been undertaken but where there is no evidence of bias, the question should be answered yes. If the distribution of the data (normal or not) is not described it must be assumed that the estimates used were appropriate and the question should be answered yes.

yes	1
no	0
unable to determine	0

19. *Was compliance with the intervention/s reliable?*
Where there was non compliance with the allocated treatment or where there was contamination of one group, the question should be answered no. For studies where the effect of any misclassification was likely to bias any association to the null, the question should be answered yes.

yes	1
no	0
unable to determine	0

20. *Were the main outcome measures used accurate (valid and reliable)?*

For studies where the outcome measures are clearly described, **the question should be answered yes**. For studies which refer to other work or that demonstrates the outcome measures are accurate, the question should be answered as yes.

yes	1
no	0
unable to determine	0

Internal validity - confounding (selection bias)

21. *Were the patients in different intervention groups (trials and cohort studies) or were the cases and controls (case-control studies) recruited from the same population?*
For example, patients for all comparison groups should be selected from the same hospital. The question should be answered unable to determine for cohort and case-control studies where there is no information concerning the source of patients included in the study.

yes	1
no	0
unable to determine	0

22. *Were study subjects in different intervention groups (trials and cohort studies) or were the cases and controls (case-control studies) recruited over the same period of time?*
For a study which does not specify the time period over which patients were recruited, the question should be answered as unable to determine.

yes	1
no	0
unable to determine	0

23. *Were study subjects randomised to intervention groups?*
Studies which state that subjects wererandomised should be answered yes except where method of randomisation would not ensure random allocation. For example alternate allocation would score no because it is predictable.

yes	1
no	0
unable to determine	0

24. *Was the randomised intervention assignment concealed from both patients and health care staff until recruitment was complete and irrevocable?*

All non-randomised studies should be answered no. If assignment was concealed from patients but not from staff, it should be answered no.

yes	1
no	0
unable to determine	0

25. *Was there adequate adjustment for confounding in the analyses from which the main findings were drawn?*
This question should be answered no for trials if: the main conclusions of the study were based on analyses of treatment rather than intention to treat; the distribution of known confounders in the different treatment groups was not described; or the distribution of known confounders differed between the treatment groups but was not taken into account in the analyses. In non-randomised studies if the effect of the main confounders was not investigated or confounding was demonstrated but no adjustment was made in the final analyses the question should be answered as no.

yes	1
no	0
unable to determine	0

26. *Were losses of patients to follow-up taken into account?*
If the numbers of patients lost to follow-up are not reported, the question should be answered as unable to determine. If the proportion lost to follow-up was too small to affect the main findings, the question should be answered yes.

yes	1
no	0
unable to determine	0

Power

27. *Did the study have sufficient power to detect a clinically important effect where the probability value for a difference being due to chance is less than 5%?*
Sample sizes have been calculated to detect a difference of x% and y%.

	Size of *smallest* intervention group	
A	$<n_1$	0
B	n_1-n_2	1
C	n_3-n_4	2
D	n_5-n_6	3
E	n_7-n_8	4
F	n_8+	5

Appendix B: Item level breakdown of quality assessment

Item level assessment of methodological quality of psychotherapeutic interventions, using the adapted checklist (Downs & Black, 1998)

Author, date	1. Description of hypothesis	2. Description of outcomes	3. Description of participants	4. Description of intervention	5. Description of confounders	6. Description of findings	7. Are estimates of random variability provided?	8. Reporting of adverse events	9. Attrition at follow up described?	10. Have probability values been reported appropriately?	11. Representativeness of source population	12. Representativeness of the recruited population	13. Representativeness of staff & facilities	14. Participants blinded?	15. Evaluators blinded?	16. Any unplanned analyses should be stated	17. Consistent time points for all groups	18. Appropriate statistical tests?	19. Was there any non-compliance with intervention	20. Accuracy of measures – outcome measures clearly described?	21. Groups from same population	22. Time period groups recruited should be stated	23. Randomised sample, stated and appropriate	24. Randomised assignment concealed from both patients and staff until completion of recruitment	25. Adjustment for confounders?	26. Losses at follow-up reported?	27. Power - stated & study not underpowered	Quality Rating Score
Alexopoulos et al. (2012)	1	1	1	1	1	1	1	0	1	1	1	1	1	0	0	1	1	1	1	1	1	1	1	0	1	1	0	22
Bishop et al. (2014)	1	1	1	1	1	1	0	0	1	1	1	1	1	0	1	1	0	1	1	1	1	1	0	1	1	1	0	21
Chang et al. (2011)	1	1	1	1	0	1	0	0	0	0	1	0	1	0	0	0	1	1	1	1	1	1	1	0	0	0	0	14
Hadidi et al. (2014)	1	1	1	1	1	1	1	0	1	1	1	0	1	0	0	1	1	1	1	1	1	1	1	0	1	1	0	21

Appendix B cont.

Item level assessment of methodological quality of psychotherapeutic interventions, using the adapted checklist (Downs & Black, 1998)

Author, date	1. Description of hypothesis	2. Description of outcomes	3. Description of participants	4. Description of intervention	5. Description of confounders	6. Description of findings	7. Are estimates of random variability provided?	8. Reporting of adverse events	9. Attrition at follow up described?	10. Have probability values been reported appropriately?	11. Representativeness of source population	12. Representativeness of the recruited population	13. Representativeness of staff & facilities	14. Participants blinded?	15. Evaluators blinded?	16. Any unplanned analyses should be stated	17. Consistent time points for all groups	18. Appropriate statistical tests?	19. Was there any non-compliance with intervention	20. Accuracy of measures – outcome measures clearly described?	21. Groups from same population	22. Time period groups recruited should be stated	23. Randomised sample, stated and appropriate	24. Randomised assignment concealed from both patients and staff until completion of recruitment	25. Adjustment for confounders?	26. Losses at follow-up reported?	27. Power - stated & study not underpowered	Quality Rating Score
Hoffman et al. (2015)	1	1	1	1	1	1	1	0	1	1	1	0	1	0	1	1	1	1	1	1	1	1	1	0	1	1	0	22
Johnston et al. (2007)	1	1	1	1	1	1	1	0	1	1	1	1	1	0	1	1	1	1	0	1	1	1	1	0	1	1	1	23
Lincoln et al. (2003)	1	1	1	1	1	1	1	0	1	1	1	1	1	1	1	1	1	1	1	1	1	1	1	0	0	1	1	24
Mitchell et al. (2009)	1	1	1	1	1	1	1	0	1	1	1	0	1	0	1	1	1	1	1	1	1	1	1	0	1	1	1	23

Appendix B cont.

Item level assessment of methodological quality of psychotherapeutic interventions, using the adapted checklist (Downs & Black, 1998)

Author, date	1. Description of hypothesis	2. Description of outcomes	3. Description of participants	4. Description of intervention	5. Description of confounders	6. Description of findings	7. Are estimates of random variability provided?	8. Reporting of adverse events	9. Attrition at follow up described?	10. Have probability values been reported appropriately?	11. Representativeness of source population	12. Representativeness of the recruited population	13. Representativeness of staff & facilities	14. Participants blinded?	15. Evaluators blinded?	16. Any unplanned analyses should be stated	17. Consistent time points for all groups	18. Appropriate statistical tests?	19. Was there any non-compliance with intervention	20. Accuracy of measures – outcome measures clearly described?	21. Groups from same population	22. Time period groups recruited should be stated	23. Randomised sample, stated and appropriate	24. Randomised assignment concealed from both patients and staff until completion of recruitment	25. Adjustment for confounders?	26. Losses at follow-up reported?	27. Power - stated & study not underpowered	Quality Rating Score
Ostwald et al. (2014)	1	1	1	1	1	1	1	0	1	1	1	0	1	0	1	1	1	0	1	1	1	1	1	1	1	1	0	22
Smith et al. (2012)	1	1	1	1	1	1	1	0	1	1	0	1	1	0	1	1	1	1	1	1	1	1	1	0	1	1	0	22
Thomas et al. (2012)	1	1	1	1	1	1	1	0	1	1	1	1	1	0	1	1	1	1	1	1	1	1	1	1	1	1	1	25
Towle et al. (1989)	1	1	1	1	1	1	1	0	1	1	1	1	1	0	0	1	0	0	1	1	1	1	1	0	0	0	0	18

Appendix B cont.

Item level assessment of methodological quality of psychotherapeutic interventions, using the adapted checklist (Downs & Black, 1998)

Author, date	1. Description of hypothesis	2. Description of outcomes	3. Description of participants	4. Description of intervention	5. Description of confounders	6. Description of findings	7. Are estimates of random variability provided?	8. Reporting of adverse events	9. Attrition at follow up described?	10. Have probability values been reported appropriately?	11. Representativeness of source population	12. Representativeness of the recruited population	13. Representativeness of staff & facilities	14. Participants blinded?	15. Evaluators blinded?	16. Any unplanned analyses should be stated	17. Consistent time points for all groups	18. Appropriate statistical tests?	19. Was there any non-compliance with intervention	20. Accuracy of measures – outcome measures clearly described?	21. Groups from same population	22. Time period groups recruited should be stated	23. Randomised sample, stated and appropriate	24. Randomised assignment concealed from both patients and staff until completion of recruitment	25. Adjustment for confounders?	26. Losses at follow-up reported?	27. Power - stated & study not underpowered	Quality Rating Score
Watkins et al. (2007)	1	1	1	1	1	1	1	0	1	1	1	1	1	0	1	1	1	1	1	1	1	1	1	1	1	1	1	25
Watkins et al. (2011)	1	1	1	1	1	1	1	0	1	1	1	1	1	0	1	1	1	1	1	1	1	1	1	1	1	1	1	25
Wu et al. (2012)	1	1	1	1	0	1	0	0	0	0	1	0	1	0	0	0	0	0	0	0	1	1	0	0	0	0	0	9

Section Two: Research Report

Associations between mindfulness, coping and psychological outcomes in

stroke survivors

Abstract

Objectives Emotional disturbances are common following stroke and can impede rehabilitation and quality of life. Limited knowledge of the determinants of emotional distress post-stroke has prevented and constrained the development and delivery of effective psychological interventions throughout the stroke clinical care pathway. The aim of the present study was to examine whether mindfulness and coping behaviours were associated with psychological outcomes in stroke patients.

Design A questionnaire-based cross-sectional study.

Methods A sample of stroke patients ($N = 114$) completed The Five Facet Mindfulness Questionnaire, The Brief Ways of Coping Questionnaire, The Mental Adjustment to Stroke Scale, The Patient Health Questionnaire-9 and The General Anxiety Disorder Questionnaire-7.

Results Mindfulness explained significant amounts of variance in depression ($\Delta R^2 = .68$), anxiety ($\Delta R^2 = .60$), helplessness/hopelessness ($\Delta R^2 = .49$), denial/avoidance ($\Delta R^2 = .26$), fatalism ($\Delta R^2 = .25$), anxious preoccupation ($\Delta R^2 = .19$) and fighting spirit ($\Delta R^2 = .08$). The mindfulness facet 'acting with awareness' was the most consistent predictor of psychological outcomes. After controlling for significant demographic variables, dysfunctional coping was found to mediate the effect of 'acting with awareness' on 'helplessness/hopelessness.' Coping behaviours were not found to mediate the effects of mindfulness on any other psychological outcome.

Conclusions This study provides support for the role of mindfulness and coping in recovery following stroke. There is a need for stroke services to routinely screen for psychological distress in stroke patients throughout the clinical stroke pathway. Stroke patients identified as experiencing elevated levels of psychological distress, might benefit from being offered a psychological intervention designed to cultivate mindful

awareness and modification of dysfunctional coping behaviours to maximise post-stroke recovery and quality of life.

Practitioner Points

- Inpatient and community stroke services may benefit from routinely screening levels of psychological distress in stroke patients (using measures such as The Patient Health Questionnaire-9 and The General Anxiety Disorder-7). It is highly likely stroke patients experiencing elevated levels of psychological distress might also be experiencing low levels of mindfulness and employing dysfunctional coping styles (including self-criticism, denial and substance misuse). These particular stroke patients may benefit from further psychological assessment and intervention.

- Interventions where a key component is the cultivation of mindfulness may be of particular benefit for stroke patients experiencing psychological distress. Equipping stroke patients with such skills and styles might also represent important secondary prevention. Such interventions however require further research and evaluation in a stroke population, prior to application to clinical practice.

- Further research is required to examine the role of mindfulness on psychological outcomes using longitudinal designs, to enable firmer conclusions regarding the likely direction of relationships to be drawn.

- The replication of the study findings in more ethnically and geographically diverse samples of stroke patients is required before the findings can be generalised.

A stroke is defined as a focal or global disturbance in cerebral functioning, lasting more than 24 hours (or until death) of presumed vascular origin (Department of Health, 2007). In the United Kingdom, 150,000 people have a stroke each year, and stroke is considered the third most common cause of death and single largest cause of adult disability, worldwide (Feigen et al., 2008). The number of individuals experiencing a first ever stroke is estimated to increase by approximately 30% by 2023 compared with 1983 (Maheswaran et al., 2006). Stroke is estimated to cost the English economy approximately seven billion pounds per annum, comprising direct costs, costs of informal care, and costs incurred because of lost productivity and disability (Saka, Mcguire & Wolfe, 2009).

Approximately one third of those affected by stroke die within a month (Sandercock et al., 2001). In those who survive, the deprivation of blood supply results in brain damage, the consequences of which can include impairments in speech, vision, movement and cognition (Sandercock et al., 2001). Approximately one third of those affected, remain moderately to severely disabled five years following their stroke (Hoff & Mobbs, 2001). It is not surprising therefore, that many stroke patients experience great difficulty adjusting to changed circumstances and life after stroke (Donnellan, Hevey, Hickey, & O'Neill, 2006). Emotional disturbances are common following stroke, with depression being the most frequently assessed psychological outcome (Hackett, 2008). Prevalence rates for depression are around 31% (Hackett, Yapa, Parag & Anderson, 2005) and between 20-25% for anxiety in the stroke population (Aström, 1996). Post-traumatic stress reactions arise for 10-30% of stroke patients (Gangstad, Norman & Barton, 2009) and up to 60% of stroke patients develop a fear of falling (Watanabe, 2005). Emotional disturbances following stroke can impact rehabilitation outcome, and result in longer hospital stays, reduced participation in rehabilitation,

greater physical impairment and handicap, and increased risk of further stroke and mortality (Morris, Raphael, & Robinson, 1992).

There is widespread agreement that early recognition and active management of psychological difficulties following stroke is desirable (Turner-Stokes & Hassan, 2002). Routine assessment and treatment of emotional difficulties throughout the stroke clinical pathway has been recommended (Royal College of Physicians of London, 2012). To date, however, the psychological impact of surviving a stroke has not received the same empirical attention as physical aspects. As detailed in Section 1 of this thesis, current treatment of emotional difficulties following stroke has therefore been constrained by an incomplete knowledge of the determinants of emotional disturbances following stroke.

Models that can help make sense of the emotional trajectories experienced by stroke patients may assist clinicians in identifying and treating those at risk of, or experiencing, psychological distress. A starting point in identifying and treating those at risk of, or experiencing, psychological distress, is to develop a better understanding of the predictors of psychological distress following stroke. Previous research has failed to identify consistent relationships between factors including stroke severity, lesion location, social support and psychological distress, which has led researchers to propose that other psychosocial factors may be important in understanding the aetiology of psychological distress in patients following a stroke (Thomas & Lincoln, 2012). In particular, mindful awareness and coping behaviours might be associated with psychological outcomes (including adjustment, anxiety and depression) in stroke patients, given that such associations have been found in other chronic and neurological conditions (de Ridder & Schreurs, 2001; Keng, Smoski, & Robins, 2011).

Mindfulness or mindful awareness, derived from Buddhist tradition, concerns the self-regulation process of attending towards present-moment experiences in a non-judgemental manner (Kabat-Zinn, 1990). Mindfulness has been theorised to consist of a number of distinct skills and capacities including the ability to direct attention and notice experiences as they are occurring in present moment, the ability to refrain from judging experiences, and the ability to tolerate and accept positive and negative experiences without avoidance or reactivity (Baer, Smith, & Allen, 2004). Previous studies exploring the factor structure of mindfulness, have described the concept as multidimensional, consisting of five different facets including describing, observing, acting with awareness, non-judging and non-reactivity (Baer, Smith, Hopkins, Krietemeyer, & Toney, 2006).

Mindfulness theory proposes that mindfulness is both a basic human capacity occurring at variable levels and an ability that can be accomplished by practising various forms of meditation.. To date, the majority of research on the effects of mindfulness on mood and other indicators of mental health has been conducted within the context of treatment interventions, whereby the primary aim is to cultivate mindful presence. Controlled studies of mindfulness-based interventions have demonstrated positive effects for the treatment of psychological disorders, particularly anxiety and depression (Hofmann, Sawyer, Witt, & Oh, 2010). There is a growing body of evidence to suggest that greater cultivation of mindful awareness, improves psychological outcomes in patients with a range of physical and mental health problems (Evans et al., 2008; Xie, Zhoe, Gong, Iennaco, & Ding, 2014). A meta-analysis of 39 studies reported large effect sizes for anxiety (Hedges' $g = 0.97$) and depression (Hedges' $g = 0.63$) in a range of conditions including cancer, chronic fatigue syndrome, chronic pain and traumatic brain injury (Chiesa, & Serretti, 2010). A systematic review of 15

mindfulness-based studies of people with long-term neurological conditions found

significant benefits, including enhanced ability to cope with symptoms, improved

wellbeing and quality of life and reduction in anxiety and depression (Hoffman et al.,

2010). There is now emerging evidence arising from four single case experimental

designs, to suggest mindfulness improves psychological outcomes following stroke

(Lawrence, Booth, Mercer & Crawford, 2013). In particular, mindfulness-based stress

reduction and mindfulness-based cognitive therapy were found to lead to a reduction in

symptoms of anxiety and depression in stroke patients (Lawrence, Booth, Mercer &

Crawford, 2013). Although previous research has demonstrated the enhancement of

mindfulness through specific intervention programmes and therapies facilitates a variety

of well-being outcomes, little work has examined this attribute as a naturally occurring

characteristic. Recognising that almost everyone has the capacity to attend and to be

aware, examining mindfulness as an individual difference characteristic allows

examination of the role of this phenomenon in psychological experience. Mindfulness

as a human capacity (i.e. dispositional mindfulness) has been found to be associated

with better well-being and positive mood, and lower levels of depression, anxiety and

stress in student and community adult samples (Brown & Ryan, 2003; Carlson &

Brown, 2005). Higher levels of dispositional mindfulness have previously been

associated with lesser use of avoidance coping strategies and better psychological well-

being in college students (Weinstein, Brown & Ryan, 2009). Branstrom, Duncan and

Moskowitz (2011) found dispositional mindfulness to be associated with psychological

well-being in a Swedish population-based sample. Additionally, the study found that

heightened mindful awareness was associated with increased coping ability during

stressful conditions. Together, these studies examining dispositional mindfulness,

demonstrate individual differences in the dispositional tendency to be mindful and

significant associations with well-being (Baer et al., 2006). In this study, we wanted to specifically examine how dispositional mindfulness, was related to different psychological outcomes in stroke patients. Additionally, previous studies provide no information on how the different facets of mindfulness are related to psychological outcomes. Furthermore, the process through which mindfulness has salutary effects on psychological outcomes in stroke patients has received no empirical attention to date. Thus, the precise mechanisms by which such benefits accrue in a stroke population, remain unclear.

Coping is one mechanism through which mindfulness may attenuate levels of psychological distress in stroke patients (Thomas et al., 2012). Lazarus and Folkman (1984; p.141) define coping as "the constantly changing cognitive and behavioural efforts to manage the specific external or internal demands that are appraised as taxing or exceeding the resources of the person." Coping has broadly been classified into emotion-focused, problem-focused and dysfunctional coping styles. Emotion-focused coping styles reflect efforts to regulate the emotional consequences of stressful or potentially stressful events. Problem-focused coping styles involve efforts to do something active to alleviate the stressful circumstances. Dysfunctional coping behaviours reflect efforts to ignore, distort or escape the stressful situation by seeking out people, or by engaging in a substitute task. Whilst dysfunctional coping can reduce stress in the short-term, it is ultimately ineffective in supporting overall mental well-being in the long-term (Carr, 2011). In contrast, emotion-focused and problem-focused coping are generally considered adaptive, in that effort is directed towards resolving the stressful situation, or overcoming the stress associated with them. A meta-analysis of 5 studies examining coping after stroke, found greater use of adaptive coping, to be associated with lower levels of anxiety and depression (Donnellan et al., 2006).

However, stroke studies have failed to distinguish between problem-focused and emotion-focused coping behaviours, instead, combining them under 'adaptive coping.' Thus, it remains unclear whether problem-focused or emotion-focused coping is of greater benefit for reducing psychological distress in stroke patients. In the chronic illness literature, greater use of problem-focused coping in contrast to emotion-focused coping has been associated with better adjustment and lower levels of anxiety and depression (Rabinowitz & Arnett, 2009).

There is a theoretical argument to suggest mindfulness supports adaptive (emotion-focused and problem-focused) coping. Specifically, if more mindful individuals are better able to observe internal thoughts, feelings and emotions, as they occur in the present moment, rather than engaging in past or future problematic thinking patterns (i.e. ruminating or catastrophizing) they may be more likely to cope in adaptive ways, rather than in ways that perpetuate their distress (Kabatt-Zinn, 1990; McCullough, Orsulak, Brandon & Akers, 2007). Mindfulness might help support psychological wellbeing through the greater use of adaptive coping styles and lesser use of dysfunctional coping styles (Baer et al., 2006). Thus, it is a plausible argument that coping may serve as a common pathway through which mindfulness leads to improved psychological outcomes (Shapiro, Carlson, Astin, & Freedman, 2007). Despite such studies' contributions, the effects of mindfulness on coping and psychological outcomes including adjustment, depression and anxiety in a stroke population, remains unknown. Furthermore, the mechanisms (coping behaviours) that might mediate the relationship between mindfulness and psychological wellbeing in a stroke population has yet to be determined.

Aims

The main aim of the present study was to examine the associations between mindfulness, coping, and psychological outcomes (anxiety, depression and mental adjustment) in a stroke population. The present study also afforded the opportunity to test the mediating role of coping on the relationship between mindfulness and psychological outcomes. On the basis of previous research, a number of hypotheses were made.

Hypotheses

1. Higher levels of mindfulness would be associated with lower levels of anxiety and depression, and better adjustment to stroke.

2. Greater use of adaptive coping (emotion-focused and problem-focused styles) would be associated with lower levels of anxiety and depression, and better adjustment to stroke.

3. Greater use of dysfunctional coping would be associated with elevated levels of anxiety and depression, and poorer adjustment to stroke.

4. Higher levels of mindfulness would be associated with greater use of adaptive coping styles (emotion-focused and problem-focused).

5. Greater use of adaptive coping styles (emotion-focused and problem-focused), would mediate relations between mindfulness and better psychological wellbeing.

6. Dysfunctional coping would mediate relations between mindfulness and poorer psychological wellbeing.

Method

Participants and procedure

The study employed a cross-sectional design. Participants were a convenience sample recruited between 1 May 2015 and 31 December 2015 via the stroke clinical care pathway of a National Health Service Trust in Northern England. Participants were recruited from either a stroke outpatient clinic, which is a service offered to stroke patients approximately six weeks following discharge from the acute hospital setting, or from an assessment and rehabilitation centre, a service designed to improve patients' ability to perform their daily activities and prevent further decline, at any time point following their stroke.

Adult stroke patients (≥ 18 years old) with a clinically confirmed diagnosis of stroke, able to complete questionnaires themselves or with the assistance of a researcher, friend or relative, and fluent in English, were recruited from the outpatient follow-up stroke clinic and the outpatient assessment and rehabilitation centre. Participants were excluded if they were deemed to lack capacity to provide informed consent, or had significant cognitive impairment resulting from stroke that would hinder their ability to complete the questionnaires.

Potentially eligible study participants (i.e. those who met the study inclusion criteria) attending the outpatient clinic were identified and initially advised about the research study by the staff member conducting the outpatient appointment, the Stroke Physician or the Consultant Nurse Specialist. At the assessment and rehabilitation centre, the Staff Nurse identified and informed potentially eligible study participants about the research. Participants were then given an opt-in form (see Appendix A) by the staff member, providing them with the opportunity to decide whether they wished to be approached by the researcher to discuss the nature of the study in further detail. Those

who expressed an interest in participating in the research, were then approached by the researcher and provided with an information sheet (see Appendix B). Those who subsequently agreed to participate in the study were provided with a consent form (see Appendix C) and the questionnaires to complete. All participants were offered the assistance of the researcher to complete the questionnaires. All 114 eligible participants who were approached by the researcher, agreed to take part in the study.

Sample characteristics

The characteristics of the participants recruited are shown in Table 1. The sample comprised 114 individuals (61 men, 53 women) aged between 38 and 91 years ($M = 68.55$, $SD = 13.16$). The majority of the sample were White British ($n = 104$) and retired ($n = 75$). More than half of the sample were married ($n = 61$), with the remaining participants being either widowed ($n = 29$), divorced ($n = 8$), or single ($n = 16$). Approximately two-thirds of the sample had experienced an ischemic stroke ($n = 76$), whilst the remaining had experienced a haemorrhagic stroke ($n = 38$). Participants had experienced a stroke in the previous one to eighty-four months ($M = 12.82$ months, $SD = 13.85$). For the majority of participants, this was their first stroke ($n = 86$). The mean score of 65.12 ($SD = 24.85$) on the Barthel Index (Mahoney & Barthel, 1965) reflects moderate level of dependence.

Table 1

Participant demographic and clinical variables (N=114)

Variable	N	(%)
Gender		
Female (%)	53	(46.5)
Male (%)	61	(53.5)
Ethnicity		
White British (%)	104	(91.2)
Afro-Caribbean (%)	3	(2.6)
Asian (%)	2	(1.8)
Other (%)	5	(4.4)
Marital Status		
Married (%)	61	(53.5)
Widowed (%)	29	(25.4)
Single (%)	16	(14.0)
Divorced (%)	8	(7.0)
Employment		
Employed (%)	15	(13.2)
Unemployed (%)	24	(21.1)
Retired (%)	75	(65.8)
Age at leaving full time education		
< 16 years (%)	84	(73.7)
≥16 years (%)	30	(26.3)
Previous history of stroke		
Yes (%)	28	(24.6)
No (%)	86	(75.4)
Stroke type		
Ischaemic (%)	76	(66.7)
Haemorrhagic (%)	38	(33.3)
	M	SD
Age	68.55	13.16
Time since stroke onset (months)	12.82	13.85
Barthel Index Score	65.12	24.85

Power analysis

Abbott et al. (2014), in their meta-analyses, reported significant associations between mindfulness and measures of emotional wellbeing, with the majority of these correlations approximating medium effect sizes. A medium effect size was therefore

used for the power analysis for the present study ($f^2 = 0.15$). Using G*Power 3.1 (Faul, Erdfelder, Buchner, & Lang, 2009) it was estimated that a minimum of 109 participants would need to be recruited to detect a medium effect size in a regression analysis with eight predictor variables (i.e. five mindfulness subscales and three coping subscales) with power set at 0.80 and alpha set at 0.05 (Cohen, 1988).

Ethical considerations

Ethical approval for this study was obtained from the South Yorkshire Research Ethics Committee (see Appendix D). The participating National Health Service Trust's Research and Development department also gave approval for this study (see Appendix E). With consideration of potential adverse events, any participant who experienced the content of the questionnaires as distressing, or wished to discuss more about the nature of their stroke, was advised to consult with staff members based within the stroke services, or with their General Practitioner. For individuals scoring above the recommended clinical cut-off on The General Anxiety Disorder-7 (Spitzer, Kroenke, Williams, & Löwe, 2006) or The Patient Health Questionnaire-9 (Kroenke, Spitzer, & Williams, 2001), or expressing self-harm or suicidal ideation, this information was fed back to the stroke service clinicians. Participants were offered reimbursement of the car parking charges incurred whilst participating in the study (completion of questionnaires). No other financial incentives were offered for taking part in the study.

Measures

Mindfulness. The Five Facet Mindfulness Questionnaire (FFMQ; Baer et al., 2006) is a widely used measure designed to assess the tendency to be mindful in daily life (see Appendix F). The instrument is a 39-item self-report measure with responses made on a 5-point Likert scale, ranging from 1 (never or rarely true) to 5 (very often or always true), with higher scores indicating higher mindfulness. The measure is

composed of 5 subscales: observing, which refers to a process of noticing both internal and external experiences (e.g. when I'm walking, I deliberately notice the sensations of my body moving), describing, which involves the capacity and ability to label internal experiences with words (e.g. I'm good at finding words to describe my feelings), acting with awareness, which involves attending to current activities in the present moment, (e.g. when I do things, my mind wanders off and I'm easily distracted), non-judging of inner experiences, which refers to adopting a non-judgmental perspective towards thoughts and feelings (e.g. I criticize myself for having irrational or inappropriate emotions) and non-reactivity to inner experiences, which consists of allowing thoughts and feelings to pass without reacting or fixating onto them (e.g. I perceive my feelings and emotions without having to react to them). In the original validation study (Baer et al, 2006) the five subscales demonstrated adequate to good levels of internal consistency with Cronbach alpha values ranging from α =.75 (non-reactivity subscale) to α =.91 (describing subscale). The measure has also shown good test-retest reliability in patients with fibromyalgia (Veehof, ten Klooster, Taal, Westerhof, & Bohlmeijer, 2011), and construct validity in patients with depression (Bergomi, Tschacher, & Kupper, 2012). The measure has demonstrated adequate predictive validity, with significant correlations with anxiety and depression in patients with neurological conditions (de Bruin, Topper, Muskens, Bögels, & Kamphuis, 2012). However, the measure has yet to be normed and validated in a stroke population.

Coping. The Brief Ways of Coping Questionnaire (Brief COPE; Carver, 1997) is a 28-item self-report measure, designed to assess a broad range of coping styles (see Appendix G). Participants are asked to rate the extent to which they engage in various coping behaviours on a Likert scale ranging from 1 (I have not been doing this at all) to 4 (I have been doing this a lot). The measures consists of 14 distinct subscales that are

commonly categorised into three scales; problem-focused coping (e.g. I've been getting help and advice from other people), emotion-focused coping (e.g. I've been praying or meditating) and dysfunctional coping (e.g. I've been using alcohol or other drugs to help me get through it) (Snell, Siegert, Hay-Smith & Surgenor, 2011). For each subscale, higher scores indicate greater use of the coping behaviour. The Brief COPE subscales have demonstrated adequate levels of test-retest reliability, internal consistency and content validity in patients following an acquired brain injury (Carver, 1997).

Adjustment. The Mental Adjustment to Stroke Scale (MASS; Watson, Greer, & Bliss, 1989) is a 40-item self-report instrument, assessing adjustment to stroke at the present moment (see Appendix H). The measure consists of five subscales: fighting spirit (e.g. I try to fight the illness), helplessness/hopelessness (e.g. I feel like giving up), anxious preoccupation (e.g. I suffer great anxiety about it), fatalism (e.g. I feel fatalistic about it) and denial/avoidance (e.g. I do not really believe I have had a stroke). Patients with 'fighting spirit' are determined to get better and remain optimistic, having had their stroke. Patients with feelings of 'helplessness/hopelessness' feel overwhelmed with having had a stroke and preoccupied with death and dying. Patients with 'anxious preoccupation' worry excessively about their condition, continually seeking further information about their symptoms. Patients with a 'fatalistic' attitude are able to adjust to having had their stroke and able to continue with their lives, and patients with 'denial/avoidance,' typically deny having had a stroke, and/or minimise the seriousness of their condition. For all subscales, with the exception of fighting spirit, higher scores indicate a more negative attitude. The subscales have good internal consistency with Cronbach's alpha values ranging from $\alpha = .62$ (anxious preoccupied subscale) to $\alpha = .81$ (fighting spirit subscale). The measure has also demonstrated good test-retest reliability

(Kappa value = 0.89) in a stroke population (Lewis, Dennis, O'Rourke, & Sharpe, 2001).

Depression. The Patient Health Questionnaire-9 (PHQ-9; Kroenke et al., 2001) is a 9-item measure of the severity of depression (see Appendix I). Items are rated on a four-point Likert scale ranging from 0 (not at all) to 3 (nearly every day). Higher scores indicate higher levels of depression. The measure has excellent internal consistency (α =.89) and excellent test re-test reliability. The measure has strong criterion validity for identifying probable cases of depression, with a cut off score $\geq$10 representing reasonable cut-off for identifying cases of major depression with sensitivity of 91% and a specificity of 88% for depression in a post-stroke population (Williams et al., 2005).

Anxiety. The General Anxiety Disorder-7 (GAD-7; Spitzer et al., 2006) is a 7-item measure of anxiety (see Appendix J). Items are rated on a four-point Likert scale ranging from 0 (not at all) to 3 (nearly every day). Higher scores indicate higher levels of anxiety. The measure has excellent internal consistency (α =.92) and good test-retest reliability (intraclass coefficient =.83). The measure also has good criterion validity with a cut off score $\geq$10 representing reasonable cut off for identifying cases of generalised anxiety disorder with 89% sensitivity and 82% specificity in a post-stroke population (Spitzer et al., 2006).

Demographic and clinical variables

Information on a range of socio-demographic and clinical variables was collected including age, gender, ethnicity, employment status, marital status, education, time since stroke onset, previous stroke history and type of stroke (see Appendix K). Information pertaining to the stroke was extracted from participants' medical records following their consent.

Data analysis

Descriptive statistics were calculated to describe the demographics of the sample. T-tests, Analysis of Variance (ANOVA), chi-square tests and Pearson Product-Moment correlations were conducted as appropriate to test the associations between demographic, clinical and main outcome variables (anxiety, depression, mindfulness, coping, and adjustment).

Hierarchical regression analyses were performed to examine the amount of variance explained by mindfulness variables, when controlling for significant clinical and demographic variables, and the contribution of coping styles, when mindfulness, clinical and demographic variables were controlled for. To reduce the number of independent variables (socio-demographic and clinical variables, mindfulness and coping variables) in the regression analyses, only those independent variables which were significantly associated with the dependent variables (anxiety, depression and adjustment) were entered into the regression models. For each dependent variable, the following method was used to conduct the regression analysis. At step one, any significantly correlated socio-demographic or clinical variables associated with the dependent variable were entered into the model. At step two, any significantly correlated mindfulness subscales were entered into the model. At step three, any significant coping variables were entered into the model. Analyses were also conducted to check the assumptions of normality, linearity multicollinearity and homoscedasticity in the regression analyses.

To examine whether coping mediated the relationship between mindfulness and the dependent variables, Preaches and Hayes (2008) Boot Strapping Method was applied. The mindfulness variables that were significant predictors for anxiety, depression, and adjustment, were entered into the mediation analyses, together with

potential mediators (i.e. any coping style that significantly correlated with the dependent variable). Any additional predictor variables that significantly correlated with the dependent variable(s) were entered into the analysis as covariates. The paths from mindfulness to coping (path a), coping to the dependent variable (path b) and mindfulness to the dependent variable were checked for significance (path c). If the path between mindfulness and the dependent variable became non-significant (path c'), when controlling for coping variables, a mediation effect was indicated. If this occurred, bootstrapping analyses were conducted to establish whether indirect effects through individual potential mediators were significant.

Results

Data screening

The data were examined for the assumptions of multivariate analyses (Tabachnick, & Fidell, 2007). Assessment of skewness and kurtosis did not reveal any significant violations for the dependent outcome variables (anxiety, depression and adjustment). Multicollinearity among the independent variables was investigated by examining the correlations between independent variables and by computing collinearity statistics inspecting the tolerance, variance inflation factors and variance proportions for all regression analyses. None of the tests indicated multicollinearity was a cause for concern. The residual plots of all regression analyses data indicated no violations of the assumptions of normality, linearity and homoscedasticity.

Demographic and clinical variables

Associations between demographic and clinical variables and the dependent outcome variables (anxiety, depression and adjustment) were calculated. Age at leaving education was coded as 0 (<16 years) and 1 (≥16 years). Associations between

dichotomous participant variables (gender, stroke type and education), with the dependent outcome variables were calculated using t-tests. No significant associations were found.

Correlational analyses were conducted to examine the relationship between continuous demographic variables (age, time post stroke onset and Barthel Index score) with the dependent outcome variables. Younger participants scored significantly higher on the adjustment subscale 'helplessness/hopelessness' [r (112) = -0.257, p =.01]. Associations between categorical variables with more than two categories (marital status, ethnicity and employment status) with the dependent outcome variables were analysed using one-way Analysis of Variance. There was a statistically significant difference between marital status groups on the adjustment 'helplessness/hopelessness' subscale [F (3,110) = 3.93, p =.01], the adjustment 'anxious preoccupation' subscale [F (3,110) = 4.73, p =.00], the adjustment 'denial/avoidance' subscale [F (3,110) = 3.70, p =.01], the GAD-7 [F (3,110) = 3.54, p =.02], and the PHQ-9 [F (3,110) = 2.70, p =.05].

Post hoc analyses using Tukey's honestly significant difference, were calculated to identify which specific Marital Status group(s) differed on each dependent outcome variable. The post hoc analyses showed that marital and widowed groups differed significantly (p<.05) from the single and divorced groups for all dependent variables, with the exception of the depression variable which showed that married participants differed significantly to all others (p<.05). For all regression analyses, the marital status variable was re-coded as 0 (married and widowed) versus 1 (divorced and single) for all dependent variables, except depression, where marital status was dichotomised as 0 (married) and 1 (divorced, single and widowed). Table 2 illustrates the means and standard deviations for the outcome variables by marital status. No other clinical variables correlated significantly with the outcome variables.

Table 2

Means and Standard Deviations for the outcome variable by Marital Status

	Marital Status			
	Married (*n*=61)	Widowed (*n*=29)	Single (*n*=16)	Divorced (*n*=8)
Variable				
MASS (Adjustment)				
Fighting Spirit	46.34 a(7.37)	45.03a (6.19)	47.06b (3.55)	43.63b (10.38)
Helplessness/Hopelessness	10.85a (3.71)	11.93a (3.84)	13.69b (3.93)	14.63b (5.04)
Anxious Preoccupation	22.75a (3.57)	22.62a (3.53)	25.13b (3.58)	27.00b (5.35)
Fatalism	16.10a (2.89)	17.07a (2.93)	17.81b (2.59)	16.50b (2.33)
Denial/Avoidance	2.20a (1.06)	2.41a (1.12)	2.75b (1.00)	3.38b (0.52)
PHQ-9 (Depression)	5.79a (5.13)	7.48b (7.11)	6.5b (4.84)	11.75b (7.23)
GAD-7 (Anxiety)	4.20a (4.18)	4.66a (4.95)	6.75b (6.10)	9.38b (5.85)

Psychological variables

Descriptive statistics for the mindfulness, coping and dependent outcome variables are presented in Table 3. The statistics on the mood measures indicate that, 28 participants (24.6%) exceeded the clinical cut-off scores for depression and 19 participants (16.7%) exceeded the clinical cut-off scores for anxiety. The emotion-focused coping subscale was found to have poor internal reliability (α=.55). To improve

the internal reliability of this subscale, item number 5 was deleted. The dysfunctional

coping subscale was also found to have poor internal reliability (α=.39). To improve the

internal reliability of this subscale, items number 9, 19 and 21 were deleted. The

adjustment subscales 'fatalism' and 'anxious preoccupation' also demonstrated poor

internal consistency. However given that these are established subscales, and dependent

variables within this study, items were not removed from the scales. The remaining

measures and their subscales, demonstrated good internal consistency.

Table 3

Means, Standard Deviations, and Internal Consistencies for Mindfulness, Coping and Outcome Variables (N = 114)

Variable	Mean	SD	Number of Items	α
FMMQ (Mindfulness)				
Observing	26.20	8.41	8	.91
Describing	26.61	6.92	8	.82
Acting with Awareness	27.23	7.14	8	.82
Non Judging of Inner Experiences	28.89	7.86	8	.90
Non Reacting to Inner Experiences	22.40	7.08	7	.89
Brief Cope (Coping Styles)				
Problem-focused Coping	16.87	4.41	6	.81
Emotion-focused Coping	22.66	5.59	9	.70
Dysfunctional Coping	15.21	4.05	9	.64
MASS (Adjustment)				
Fighting Spirit	45.92	6.89	16	.77
Helplessness/Hopelessness	11.79	4.01	6	.83
Anxious Preoccupation	22.35	3.88	9	.46
Fatalism	16.61	2.86	8	.42
Denial/Avoidance	2.41	1.08	1	-
PHQ-9 (Depression)	6.74	5.94	9	.86
GAD-7 (Anxiety)	5.04	4.96	7	.88

Correlational analyses

Correlational analyses were conducted to examine the relationships between mindfulness, coping styles and the outcome variables (see Tables 4, 5 and 6). Significant correlations were found between all mindfulness facets and the problem-focused and emotion-focused coping styles (Table 4). Thus, stroke patients who reported higher levels of mindfulness also reported greater use of problem-focused and emotion-focused coping. Negative correlations were found between all mindfulness facets and the dysfunctional coping style. Thus, stroke patients who reported lower levels of mindfulness also reported greater use of dysfunctional coping behaviours.

Table 4

Correlations between Mindfulness and Coping Styles (N = 114)

Coping Behaviours

	Problem-focused Coping	Emotion-focused Coping	Dysfunctional Coping
Mindfulness Facets			
Observing	.62**	.50**	-.54**
Describing	.53**	.50**	-.52**
Acting with awareness	.53**	.49**	-.55**
Non-judging to inner experiences	.60**	.54**	-.54**
Non-reactivity to inner experiences	.64**	.48**	-.54**

Note. $N = 114$. **$p<.01$.

Strong and significant negative correlations were found between depression and anxiety with all mindfulness facets (Table 5). Thus, stroke patients who reported lower levels of mindfulness also reported higher levels of anxiety and depression. Significant positive correlations were found between the mindfulness facets and 'fighting spirit' adjustment subscale. Negative associations were found between mindfulness and the

remaining adjustment subscales. Thus, individuals reporting higher levels of

mindfulness reported better adjustment to their stroke.

Table 5

Correlations between Mindfulness and Outcome Variables (N = 114)

	Mindfulness Facets				
			Acting with	Non-judging of inner	Non-reactivity to inner
	Observing	Describing	Awareness	experiences	experiences
Outcome Variables					
MASS (Adjustment)					
Fighting Spirit	.56**	.49**	.50**	.53**	.49**
Helplessness/ Hopelessness	-.67**	-.68**	-.71**	-.72*	-.59**
Anxious Preoccupation	-.32**	-.38**	-.42**	-.40**	-.22*
Fatalism	-.42**	-.42**	-.43**	-.50**	-.42**
Denial/Avoidance	-.50**	-.44**	-.50**	-.53**	-.42**
PHQ-9 (Depression)	-.77*	-.67**	-.72**	-.75**	-.74**
GAD-7 (Anxiety)	-.77**	-.71**	-.78**	-.77**	-.78**

Note. $N = 114$. **$p<.01$.

Significant negative correlations were found between problem-focused and

emotion-focused coping with depression and anxiety (Table 6). Thus, stroke patients

reporting greater use of problem-focused and emotion-focused coping behaviours, also

reported lower levels of depression and anxiety. Significant positive associations were

found between dysfunctional coping and depression and anxiety. Thus, individuals who reported greater use of dysfunctional coping behaviours also reported higher levels of anxiety and depression. Significant positive correlations were found between problem-focused and emotion-focused coping behaviours and the 'fighting spirit' adjustment subscale. Negative associations were found between problem-focused and emotion-focused coping behaviours with the remaining adjustment subscales. Thus, individuals reporting greater use of problem-focused and emotion-focused coping behaviours also reported better adjustment to their stroke.

Table 6

Correlations between Coping Styles and Outcome Variables (N = 114)

	Coping Behaviours		
	Problem-focused Coping	Emotion-focused Coping	Dysfunctional Coping
Outcome Variables			
MASS (Adjustment)			
Fighting Spirit	.48**	.47**	-.49**
Helplessness/ Hopelessness	-.48**	-.47**	.60**
Anxious Preoccupation	-.22*	-.21*	.44**
Fatalism	-.36**	-.26**	.38**
Denial/Avoidance	-.43**	-.36**	.52**
PHQ-9(Depression)	-.58**	-.47**	.54**
GAD-7(Anxiety)	-.58**	-.46**	.55**

Note. $N = 114$. **$p<.01$.

Regression and mediation analyses

Regression analyses were conducted to examine the extent to which mindfulness and coping styles explained variance in anxiety, depression and psychological adjustment. Clinical and demographic variables that significantly correlated with dependent outcome variables were entered in the first block, mindfulness in the second block, and coping styles in the third block. In order to keep the number of independent variables in the regression analyses to a minimum, only variables that were found to be significantly associated with depression, anxiety, and adjustment, were entered into each regression analyses.

Depression. Considering depression, marital status explained 3.0% of the variance in depression at step one, $R^2 = .03$, $F(1,112) = 3.43$, $p = .07$. The addition of the mindfulness facets at step two, explained an additional 68% of the variance in depression, $\Delta R^2 = .68$, $F(5,107) = 51.02$, $p < .001$, with 'acting with awareness' and 'non-reactivity to inner experiences' explaining unique amounts of variance in depression. At step three, the addition of the coping behaviours led to a non-significant increment in the variance explained in depression, $\Delta R^2 = .01$, $F(3,104) = 0.66$, $p = .58$. The variables included in the final regression equation explained 72% of the variance in depression, $R^2 = .72$, $F(9,104) = 29.50$, $p < .001$, with 'acting with awareness' and 'non-reactivity to inner experiences' explaining unique amounts of variance in depression[1]. There was no evidence to suggest that coping mediated the relationship between the mindfulness variables and depression (Table 7).

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[1] Further analysis indicated that when coping behaviours were entered at step two, prior to the mindfulness facets, they accounted for 45% of the variance in depression, $\Delta R^2 = .45$, $F(3,109) = 30.47$, $p < .001$, with 'acting with awareness' and 'non-reactivity to inner experiences' making significant contributions to the regression equation.

Table 7

Summary of Regression Analyses to Assess Factors Predicting Depression (N = 114)

Step	Variable	B	SE(B)	β
1	Marital status	2.04	1.10	.17
2	Marital status	.19	.63	.02
	Observing	-.09	.10	-.13
	Describing	.08	.10	.09
	Acting with Awareness	-.31	.08	-.38***
	Non-judging of inner experiences	-.11	.09	-.14
	Non-reactivity to inner experiences	-.29	.10	-.34**
3	Marital status	.13	.65	.01
	Observing	-.08	.10	-.11
	Describing	.06	.10	.07
	Acting with Awareness	-.30	.09	-.36**
	Non-judging of inner experiences	-.090	.09	-.12
	Non-reactivity to inner experiences	-.25	.10	-.30*
	Problem-focused coping	-.10	.10	-.07
	Emotion-focused coping	.00	.07	.00
	Dysfunctional coping	.09	.10	.06

Note. $N = 114$. Step 1 $\Delta R^2 = .03$, Step 2 $\Delta R^2 = .68***$, Step 3 $\Delta R^2 = .01$.

$*p < .05, **p < .01, *** p<.001$.

Anxiety. Considering anxiety, marital status explained 7% of variance at step one, $R = .07$, $F(1,112) = 8.87$, $p < .001$. The addition of mindfulness facets at step two, explained an additional 60% in the variance in anxiety, $\Delta R^2 = .60$, $F(5,107) = 39.84$, $p < .001$, with 'observing' and 'acting with awareness' making a significant contribution to the regression equation. At step three, the addition of the coping behaviours led to a non-significant increment in the variance explained in anxiety, $\Delta R^2 = .01$, $F(3,104) = 1.27$, $p = .29$. The variables in the final regression equation explained 68% of the

variance, $R^2 = .68$, $F(9,104) = 25.43$, $p < .001$, with 'observing' explaining a unique

amount of variance in anxiety[2]. Although the effect of 'acting with awareness' on

anxiety became non-significant when the coping variables were controlled for, the

decrease in the size of the beta weight was minimal. As a result, further mediation

analyses were not conducted (Table 8).

Table 8

Summary of Regression Analyses to Assess Factors Predicting Anxiety (N = 114)

Step	Variable	B	SE(B)	β
1	Marital status	3.28	1.10	.27**
2	Marital status	1.20	0.69	.10
	Observing	-0.23	0.08	-.38**
	Describing	0.16	0.00	.22
	Acting with Awareness	-0.15	0.07	-.22*
	Non-judging of inner experiences	-0.15	0.08	-.24
	Non-reactivity to inner experiences	-0.15	0.09	-.22
3	Marital status	1.22	0.69	.10
	Observing	-0.21	0.08	-.36*
	Describing	0.15	0.09	.21
	Acting with Awareness	-0.13	0.07	-.19
	Non-judging of inner experiences	-0.13	0.08	-.21
	Non-reactivity to inner experiences	-0.12	0.09	-.17
	Problem-focused coping	-0.08	-0.09	-.07
	Emotion-focused coping	-0.00	0.10	-.00
	Dysfunctional coping	0.14	0.08	.11

Note. $N = 114$. Step 1 $\Delta R^2 = .07**$, Step 2 $\Delta R^2 = .60***$, Step 3 $\Delta R^2 = .01$.

*$p < .05$, **$p < .01$, *** $p < .001$.

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[2] Further analysis indicated that when coping behaviours were entered at step two, prior to the mindfulness facets, they accounted for 41% of the variance in anxiety, $\Delta R^2 = .41$, $F(3,109) = 29.34$, $p < .001$ with 'observing' making a significant contribution to the regression equation.

Adjustment subscale 'helplessness/hopelessness.' Considering the adjustment subscale 'helplessness/hopelessness,' marital status and age explained 11% of variance at step one, $R^2 = .11$, $F(2,111) = 6.77$, $p < .01$. The addition of mindfulness facets at step two, explained an additional 49% in the variance in helplessness/hopelessness, $\Delta R^2 = .49$, $F(5,106) = 25.48$, $p < .001$, with 'acting with awareness' making a significant contribution to the regression equation. At step three, the addition of the coping behaviours explained an additional 5% of the variance in helplessness/hopelessness, $\Delta R^2 = .05$, $F(3,103) = 4.60$, $p <.01$. The variables in the final regression equation explained 65% of the variance, $R^2 = .65$, $F(10,103) = 18.55$, $p < .001$, with 'non-reactivity to inner experiences' and 'dysfunctional coping behaviour' explaining unique amounts of variance in helplessness/hopelessness[3]. It is noteworthy that the previously significant effect for 'acting with awareness' became non-significant after the addition of dysfunctional coping, suggesting mediation (Table 9).

As recommended by Preacher and Hayes (2008), further analyses were conducted to test whether dysfunctional coping mediated the effect of 'acting with awareness' on 'helplessness/hopelessness.' Acting with awareness was entered with potential mediator, dysfunctional coping, as well as marital status, age, describing, observing, non-reactivity to inner experiences, non-judging of inner experiences, emotion-focused and problem-focused coping as covariates. The direct effect of acting with awareness on helplessness/hopelessness was significant, $B = -0.15$, $SE = 0.07$, $p =.023$, but became non-significant when the proposed mediator was controlled for, $B = -0.12$, $SE = 0.07$, $p =.07$. Using bootstrapping procedures, the indirect effect of 'acting with awareness' on 'helplessness/hopelessness' through dysfunctional coping, was

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[3] Further analysis indicated that when coping behaviours were entered at step two, prior to the mindfulness facets, they accounted for 39% of the variance in helplessness/hopelessness, $\Delta R^2 = .39$, $F(3,108) = 28.30$, $p < .001$, with 'non-reactivity to inner experiences' and 'dysfunctional coping behaviour' making significant contributions to the regression equation.

found to be significant, $B = -0.04$, $SE = 0.02$, CI [-.09, -.01], suggesting that dysfunctional coping behaviour mediates the relationship between 'acting with awareness' on 'helplessness/hopelessness.'

Table 9

Summary of Regression Analyses to Assess Factors Predicting 'Helplessness/Hopelessness' subscale of MASS (N = 114)

Step	Variable	B	SE(B)	β
1	Marital status	2.17	0.94	.22*
	Age	-0.05	0.03	-.18
2	Marital status	0.77	0.67	.08
	Age	-0.03	0.02	-.09
	Observing	-0.15	0.08	-.30
	Describing	-0.08	0.08	-.14
	Acting with Awareness	-0.16	0.07	-.28*
	Non-judging of inner experiences	-0.13	0.07	-.25
	Non-reactivity to inner experiences	0.13	0.08	.22
3	Marital status	0.86	0.64	.09
	Age	-0.02	0.02	-.08
	Observing	-0.13	0.07	-.28
	Describing	-0.08	0.07	-.14
	Acting with Awareness	-0.12	0.07	-.21
	Non-judging of inner experiences	-0.11	0.07	-.21
	Non-reactivity to inner experiences	0.17	0.07	.30*
	Problem-focused coping	-0.04	0.07	-.04
	Emotion-focused coping	-0.04	0.05	-.06
	Dysfunctional coping	0.25	0.07	.25**

Note. $N = 114$. Step 1 $\Delta R^2 = .11$**, Step 2 $\Delta R^2 = .49$***, Step 3 $\Delta R^2 = .05$.**

*$p < .05$, **$p < .01$, *** $p < .001$.

Adjustment subscale 'anxious preoccupation.' Considering the adjustment subscale 'anxious preoccupation,' marital status explained 10% of variance at step one, $R^2 = .10$, $F(1,112) = 12.87$, $p < .001$. The addition of mindfulness facets at step two, explained an additional 19% in the variance in anxious preoccupation, $\Delta R^2 = .19$, $F(5,107) = 5.72$, $p < .001$, with 'non-reactivity to inner experiences' and marital status making significant contributions to the regression equation. At step three, the addition of the coping behaviours explained an additional 8% of the variance in anxious preoccupation, $\Delta R^2 = .08$, $F(3,104) = 4.35$, $p < .01$. The variables in the final regression equation explained 37% of the variance, $R^2 = .35$, $F(9,104) = 6.82$, $p < .001$, with marital status, 'non-reactivity to inner experiences' and 'dysfunctional coping behaviour' explaining unique amounts of variance in anxious preoccupation (Table 10)[4].

Table 10

Summary of Regression Analyses to Assess Factors Predicting 'Anxious Preoccupation' (N = 114)

Step	Variable	B	SE(B)	β
1	Marital status	3.04	0.85	.32***
2	Marital status	2.17	0.80	.30**
	Observing	-0.08	0.10	-.17
	Describing	-0.13	0.10	-.23
	Acting with Awareness	-0.17	0.09	-.31
	Non-judging of inner experiences	-0.07	0.09	-.15
	Non-reactivity to inner experiences	0.28	0.10	.51**
3	Marital status	2.26	0.77	.24**

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[4] Further analysis indicated that when coping behaviours were entered at step two, prior to the mindfulness facets, they accounted for 16% of the variance in anxious preoccupation, $\Delta R^2 = .16$, $F(3,109) = 8.14$, $p < .001$, with marital status, 'non-reactivity to inner experiences' and 'dysfunctional coping behaviour' making significant contributions to the regression equation.

Observing	-0.07	0.09	-.15
Describing	-0.13	0.10	-.22
Acting with Awareness	-0.12	0.08	-.22
Non-judging of inner experiences	-0.06	0.09	-.13
Non-reactivity to inner experiences	0.32	0.10	.59**
Problem-focused coping	-0.03	0.10	-.04
Emotion-focused coping	0.03	0.07	.05
Dysfunctional coping	0.33	0.09	.35**

Note. $N = 114$. Step 1 $\Delta R^2 = .10$***, Step 2 $\Delta R^2 = .19$***, Step 3 $\Delta R^2 = .35$.**

*$p < .05$, **$p < .01$, *** $p < .001$.

Adjustment subscale 'denial/avoidance.' Considering the adjustment subscale 'denial/avoidance,' marital status explained 7% of variance at step one, $R^2 = .07$, $F(1,112) = 8.28$, $p < .01$. The addition of mindfulness facets at step two, explained an additional 26% in the variance in denial/avoidance, $\Delta R^2 = .26$, $F(5,107) = 8.26$, $p < .001$. At step three, the addition of the coping behaviours explained an additional 9% of the variance in denial/avoidance, $\Delta R^2 = .09$, $F(3,104) = 5.10$, $p < .01$. The variables in the final regression equation explained 41% of the variance, $R^2 = .41$, $F(9,104) = 8.18$, $p < .001$, with dysfunctional coping behaviour explaining a unique amount of variance in denial/avoidance (Table 11)[5].

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[5] Further analysis indicated that when coping behaviours were entered at step two, prior to the mindfulness facets, they accounted for 29% of the variance in denial/avoidance, $\Delta R^2 = .29$, $F(3,109) = 16.44$, $p < .001$, with 'dysfunctional coping behaviour' making a significant contribution to the regression equation.

Table 11

Summary of Regression Analyses to Assess Factors Predicting 'Denial/Avoidance' (N = 114)

Step	Variable	*B*	*SE(B)*	*β*
1	Marital status	0.69	0.24	.26**
2	Marital status	0.39	0.22	.15
	Observing	-0.05	0.03	-.38
	Describing	0.02	0.03	.12
	Acting with Awareness	-0.02	0.02	-.14
	Non-judging of inner experiences	-0.04	0.03	-.32
	Non-reactivity to inner experiences	0.03	0.03	.21
3	Marital status	0.40	0.20	.15
	Observing	-0.04	0.03	-.33
	Describing	0.02	0.03	.11
	Acting with Awareness	-0.01	0.02	-.06
	Non-judging of inner experiences	-0.03	0.02	-.25
	Non-reactivity to inner experiences	0.05	0.03	.33
	Problem-focused coping	-0.03	0.03	-.14
	Emotion-focused coping	-0.01	0.02	-.03
	Dysfunctional coping	0.09	0.03	.33**

Note. $N = 114$. Step 1 $\Delta R^2 = .70$**, for Step 2 $\Delta R^2 = .26$**, Step 3 $\Delta R^2 = .09$.**

*$p < .05$, **$p < .01$, *** $p<.001$.

Adjustment subscale 'fatalism.' Considering the adjustment subscale 'fatalism,' mindfulness facets explained 25% of the variance in fatalism at step one, $R^2 = .25$, $F(5,108) = 7.18$, $p < .001$ with 'non-judging of inner experiences' emerging as the sole significant independent predictor. At step two, the addition of the coping behaviours led to a non-significant increment in the variance explained in fatalism, $\Delta R^2 = .02$, $F(3,105) = .662$, $p = .577$. The variables included in the final regression equation

explained 27% of the variance in fatalism, $R^2 = .27$, $F(8,105) = 4.82$, $p < .001$, with

'non-judging of inner experiences' explaining a unique amount of variance in fatalism

[6]. There was no evidence to suggest coping to be a mediator (Table 12).

Table 12

Summary of Regression Analyses to Assess Factors Predicting Fatalism (N =114)

Step	Variable	*B*	*SE(B)*	*β*
1	Observing	0.01	0.07	.02
	Describing	0.00	0.07	.00
	Acting with Awareness	-0.01	0.06	-.02
	Non-judging of inner experiences	-0.16	0.07	-.43*
	Non-reactivity to inner experiences	-0.04	0.08	-.09
2	Observing	0.02	0.07	.05
	Describing	-0.01	0.08	-.02
	Acting with Awareness	0.01	0.07	.01
	Non-judging of inner experiences	-0.15	0.07	-.40*
	Non-reactivity to inner experiences	-0.01	0.08	-.02
	Problem-focused coping	-0.06	0.08	-.10
	Emotion-focused coping	0.02	0.05	.04
	Dysfunctional coping	0.10	0.07	.15

Note. $N = 114$. Step 1 $\Delta R^2 = .25$***, Step 2 $\Delta R^2 = .02$.

*$p < .05$, **$p < .01$, *** $p<.001$.

Adjustment subscale 'fighting spirit.' Considering the adjustment subscale

'fighting spirit,' mindfulness facets explained 33% of the variance in fighting spirit at

step one, $R^2 = .33$, $F(5,108) = 10.8$, $p < .001$; only 'observing' made a significant

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[6] Further analysis indicated that when coping behaviours were entered at step one, prior to the mindfulness facets, they accounted for 19% of the variance in fatalism, $\Delta R^2 = .19$, $F(3,110) = 8.81$, $p < .001$, with 'non-judging of inner experiences' making a significant contribution to the regression equation.

contribution to the regression equation. At step two, the addition of the coping behaviours explained an additional 7% of the variance explained in fighting spirit, $\Delta R^2 = .07$, $F(3,105) = 4.95$, $p < .01$. The variables included in the final regression equation explained 40% of the variance in fighting spirit, $R^2 = .40$, $F(8,105) = 9.03$, $p < .001$, with 'observing,' emotion-focused and dysfunctional coping explaining unique amounts of variance in fighting spirit (Table 13)[7].

Table 13

Summary of Regression Analyses to Assess Factors Predicting Fighting Spirit (N = 114)

Step	Variable	B	SE(B)	β
1	Observing	0.36	0.17	.44*
	Describing	-0.05	0.17	-.05
	Acting with Awareness	0.12	0.15	.12
	Non-judging of inner experiences	0.17	0.16	.19
	Non-reactivity to inner experiences	-0.10	0.18	-.10
2	Observing	0.31	0.16	.39*
	Describing	-0.05	0.16	-.08
	Acting with Awareness	0.04	0.14	.07
	Non-judging of inner experiences	0.08	0.15	.09
	Non-reactivity to inner experiences	-0.20	0.17	-.13
	Problem-focused coping	0.21	0.16	.23
	Emotion-focused coping	0.23	0.12	.10*
	Dysfunctional coping	-0.39	0.16	-.23*

Note. $N = 114$. Step 1 $\Delta R^2 = .33$***, Step 2 $\Delta R^2 = .07$.**

*$p < .05$, **$p < .01$, *** $p < .001$.

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[7] Further analysis indicated that when coping behaviours were entered at step one, prior to the mindfulness facets, they accounted for 37% of the variance in fighting spirit, $\Delta R^2 = .37$, $F(3,110) = 21.60$, $p < .001$ with, 'observing,' 'emotion-focused' and 'dysfunctional coping' making significant contributions to the regression equation.

Discussion

The current study sought to investigate the unique associations between five facets of mindfulness (describing, observing, acting with awareness, non-judging, and non-reactivity), and coping with psychological outcomes in stroke patients. In line with hypotheses, correlational analyses revealed that each mindfulness facet had significant negative associations with anxiety, depression, and all adjustment subscales, with the exception of fighting spirit, where significant positive correlations were found. These findings suggest that elevated levels of mindfulness are associated with lower levels of anxiety and depression, and better psychological adjustment to stroke. Thus, attending to internal and external experiences occurring in the present moment is associated with better psychological wellbeing in stroke patients. Similar findings have been reported from studies of a range of clinical populations including cancer (Monti et al., 2006), cardiac disease (Loucks et al., 2015), rheumatoid arthritis (Pradhan et al., 2007) and fibromyalgia (Cash et al., 2015), whereby elevated levels of mindfulness have been associated with lower levels of anxiety and depression and better global adjustment to the chronic condition. The study findings are also congruent with studies that have found associations between higher levels of dispositional mindfulness and better psychological outcomes in student and community adult samples (Branstrom et al., 2011; Brown et al., 2003; Carlson et al., 2005).

The regression analyses revealed that mindfulness explained large amounts of variance in depression, anxiety and adjustment. The mindfulness facet 'acting with awareness' emerged as a significant unique predictor of depression, anxiety and 'helplessness/hopelessness.' Thus, staying focused on present-moment experiences in contrast to operating on "auto-pilot" mode and ruminating over past events or catastrophizing about future events, was associated with lower feelings of depression

and anxiety and feeling less overwhelmed with having had a stroke. These present findings are supported by literature which suggests greater mindful 'acting with awareness' and thereby greater awareness to moment to moment experiences, is strongly associated with lower global depression, anxiety and worry in community samples (Bohlmeijer, ten Klooster, Fledderus, Veehof, & Baer 2011; de Bruin et al., 2012).

Mindful 'non-reactivity to inner experiences' emerged as a unique significant predictor of depression, 'anxious preoccupation' and 'helplessness/hopelessness.' Thus, allowing thoughts and feelings to pass through awareness without reacting or fixating on them, was associated with lower feelings of depression, feeling less overwhelmed with having had a stroke and feeling less worried about stroke related symptoms. Non-reactivity cultivated through mindfulness may target and reduce cognitive and emotional reactivity to repetitive intrusive thoughts in stroke patients. The findings of the current study are convergent with previous research that has found higher non-reactivity to be associated with lower overall global symptoms of depression in community samples (Delgado et al., 2010).

Mindful 'observing' was a significant unique predictor of anxiety and 'fighting spirit.' Thus, greater capacity for noticing and attending to internal and external stimuli was associated with lower levels of anxiety and greater determination to get well and remain optimistic in a stroke population. The findings of the current study are convergent with previous research that has found thatgreater levels of mindful 'observing' to be associated with lower overall global symptoms of anxiety in community samples (Cash & Whittingham, 2010). Mindful 'non-judging of inner experiences' emerged as a significant unique predictor of 'fatalism.' Thus, cultivating non-judgement and compassion towards the self was associated with a fatalistic attitude

towards stroke, whereby patients acknowledge their stroke but seek no further information and carry on with their lives.

Considering the impact of coping on psychological outcomes, correlational analyses revealed that greater use of problem-focused and emotion-focused coping behaviours was associated with lower levels of anxiety and depression and greater psychological adjustment to stroke. As hypothesised, greater use of dysfunctional coping behaviours was associated with elevated levels of anxiety and depression and poorer adjustment following stroke. Thus, efforts directed towards resolving the stressful situation, or overcoming the stress associated with them, is associated with greater psychological wellbeing in stroke patients. The present findings are convergent with previous work, indicating that greater use of emotion-focused and problem-focused coping styles is associated with greater adjustment to chronic conditions (Rabinowitz & Arnett, 2009) and lower levels of depression and anxiety post-stroke (Donnellan et al., 2006).

The regression analyses revealed that coping behaviours explained very small amounts of additional variance in depression, anxiety and adjustment, although dysfunctional coping emerged as a significant predictor of four adjustment subscales, including: 'fighting spirit,' 'helplessness/hopelessness,' 'anxious preoccupation' and 'denial/avoidance.' Thus, greater use of dysfunctional coping behaviours (efforts to ignore, distort or escape the stressful situation by seeking out people or by engaging in a substitute task) was strongly associated with lesser determination to get well and remain pessimistic, feeling overwhelmed with having had a stroke, feeling worried about stroke related symptoms and denial around having had a stroke or minimising its seriousness. This finding, is in line with predictions based on the extant literature, that dysfunctional coping behaviours are associated withpoorer psychological wellbeing and adjustment to

conditions including epilepsy (Kemp, Morley, & Anderson, 1999), chronic fatigue syndrome (Moss-Morris, Petrie, & Weinman, 1996) and multiple sclerosis (Dennison, Moss-Morris, & Chalder, 2009).

The relationship between coping behaviours and mindfulness facets was as expected. Positive correlations were found between mindfulness facets and problem-focused and emotion-focused coping and negative correlations between mindfulness facets and dysfunctional coping behaviours. These findings are congruent with the conceptualization of mindfulness as being in opposition to avoiding one's experiences (Kabat-Zinn, 1990). Such findings are consistent with previous research that has shown an inverse relationship between dispositional mindfulness and dysfunctional coping behaviours in college students (Weinstein, Brown & Ryan, 2009).

The present study also examined coping as a mediator of the effects of mindfulness on psychological outcomes, which has previously not been tested. However, dysfunctional coping was the only coping strategy found to mediate the relationship between mindfulness and psychological outcomes. Specifically, dysfunctional coping behaviour was found to mediate the relationships between mindful 'acting with awareness' on helplessness/hopelessness. Thus, as mindful 'acting with awareness' decreased, dysfunctional coping increased, as was associated with greater helplessness/hopelessness. This finding suggests that engaging in problematic ways of thinking (i.e. ruminating and catastrophizing) is associated with maladaptive coping, perpetuating feelings of helplessness. In this study, coping behaviours were not found to mediate the relationships between any other mindfulness facet with any other psychological outcome variable. Thus the influence of mindfulness facets on all other psychological outcome variables (depression, anxiety and anxious preoccupation, fighting spirit, denial/avoidance, and fatalism) is independent of the style of coping

behaviours adopted in stroke patients. This indicates that the cultivation of acceptance, attention and awareness, self-regulation, kindness, non-judging, non-striving and patience, through mindfulness is associated with better psychological outcomes following stroke, independent of coping behaviours.

Particular subscales (dysfunctional coping, emotion-focused coping, anxious preoccupation and fatalism) were found to have low internal reliabilities. Given that the adjustment subscales are published and widely used scales, items were not deleted from the individual subscales. Lewis et al. (2001) found all the individual adjustment subscales of the MASS to have good internal reliabilities in patients within 30 days of stroke onset. It is possible that the different samples of stroke patients studied may account for the differing internal reliabilities reported across studies. Although utilising the adjustment subscales in their whole form enabled direct comparison with results of other studies using such measures, using adjustment subscales with poor internal consistency may have compromised the power of statistical analyses using these measures. For these reasons, the conclusions drawn regarding these variables must be regarded as tentative. The dysfunctional and emotion-focused coping subscales are widely used but not published subscales. Thus items were deleted from these subscales to improve the internal reliability of the subscales. This in turn compromised the ability to directly compare the study results with results of other studies using similar coping measures.

Theoretical implications

The present study has a number of important theoretical implications. There are several possible pathways through which mindfulness might be associated with better psychological outcomes in stroke patients. Being mindful may lead to the view of thoughts and feelings as being transient, perceiving and experiencing cognitions as 'just

thoughts' and affects as 'just feelings,' passing through awareness without reacting or fixating on them (Cho, 2013). This may in turn, lead to a reduction in negative or distorted thinking patterns (i.e. rumination about past events or catastrophizing and worrying about future events), and reduced reactivity to unpleasant states (i.e. stressors) and thus, better overall psychological wellbeing. Another process through which mindfulness might be associated with better psychological outcomes in stroke patients, is through the cultivation of acceptance rather than avoidance of being with what is, that is, feeling content with the current situation, rather than continuously striving towards future possible states or goals, or having the need to alter current unpleasant states (Cho, 2013). Receptive attention and awareness are considered core characteristics of mindfulness, and in accordance with theories of self-regulation, are valuable in the maintenance and enhancement of psychological wellbeing (Brown & Ryan, 2003). The self-determination theory (Deci & Ryan, 1985) is one theory of self-regulation, which proposes that greater awareness and attention is essential in facilitating and regulating behaviours in a way that is congruent with and fulfils one's needs and values, and thus beneficial for overall psychological wellbeing.

Second, the finding that greater use of adaptive coping behaviour is associated with better psychological outcomes in stroke patients also has theoretical implications. In accordance with Lazarus et al. (1984) theory of coping, choice of coping strategy is influenced by appraisal and perceived controllability of the stressful situation. Individuals who appraise the stressor as threatening as opposed to challenging, and individuals who perceive themselves as having little control over the stressor, are more likely to employ maladaptive dysfunctional coping styles. Dysfunctional coping behaviours such as increased alcohol use may be perceived as a stress reliever, but may actually make the individual's stress worse, conversely prolonging recovery from the

stressor. In contrast, individuals who appraise the stressor as challenging and having controllability over the stressor are more likely to adopt styles whereby effort is directed towards resolving stressful situations, or by overcoming the stress associated with them. This in turn, facilitates the assimilation and transcendence of stress in a way that ultimately enhances psychological wellbeing.

Third, the finding that mindfulness is associated with more adaptive coping behaviours also has important theoretical implications. Mindfulness might be associated with greater use of more adaptive coping behaviours in stroke patients by increasing self-awareness. Increased self-awareness enables the individual to become much less controlled by their thoughts and emotions, by directing them away from automatic behavioural patterns and allowing them to more clearly and objectively observe their internal events, thoughts and feelings as they occur in the present moment, rather than engaging in past-or future-oriented negative distorted thinking patterns (Weinstein, Brown, & Ryan, 2007). Thus instead of getting caught up in a fixed and rigid thought-emotion behaviour pattern, individuals are more able to be flexible in their thinking and behaviours, freely choosing their responses and reactions, thereby selecting more adaptive healthier ways of coping, rather than ways that will perpetuate their stress and ill health. Initial evidence suggests, mindfulness may be associated with lower use of dysfunctional (avoidant) coping, given that mindfulness has been associated with lower levels of negative thinking styles (rumination, thought suppression), related to poorer outcomes (Shapiro, Brown, & Biegel, 2007).

Clinical implications

The present findings have a number of clinical implications. Given the prevalence and detrimental effects of psychological distress on stroke recovery and quality of life, it is essential that clinicians routinely screen for and identify stroke

patients whom are experiencing mood problems using validated and reliable measures such as the PHQ-9 and GAD-7, so that these patients can be referred for appropriate psychological support and intervention. The findings suggest that mindfulness plays a key role in supporting psychological wellbeing in stroke patients, with mindfulness emerging as a significant predictor of psychological outcomes following stroke. These findings highlight the potential utility of targeting mindful awareness in psychological interventions following stroke to improve psychological outcomes. Such treatments might include mindfulness based interventions which are designed to reduce rumination and emotional avoidance and increase behavioural self-regulation, through a range of techniques including mindful breathing, body scan and meditation practice (Segal, Williams, & Teasdale, 2002). The study findings also suggest the possibility that some techniques maybe especially important for stroke patients presenting with particular symptoms. For example, stroke patients presenting with depression may benefit more from techniques that focus on cultivating 'non-reactivity', such as breath awareness (Linehan, 1993). Whereas stroke patients presenting with high anxious arousal, may benefit more from techniques focusing on 'observing' such as mindful eating or body scan (Linehan, 1993). Encouragingly, such interventions have already produced promising results including reductions in depression and anxiety in a range of conditions including diabetes, cardiac disease and cancer (Hoffman et al., 2010). Mindfulness based interventions can be delivered across a range of settings including community based locations. Such interventions require minimal resources and therefore inexpensive to deliver which is of particular importance in stroke, given that recent economic trends mean that health providers are looking for innovative ways to deliver clinically effective stroke services that are cost-effective (Saka et al., 2009).

Based on the study findings, another potentially appropriate psychotherapeutic intervention for stroke patients experiencing elevated levels of psychological distress, would be Acceptance and Commitment Therapy (ACT), designed to encourage individuals to accept, rather than resign themselves to their current situation (Hayes, Strosahl, & Wilson, 1999). ACT is a 'third wave' cognitive behavioural therapy, designed to facilitate individuals' progress towards attaining a more fulfilling and valued life by increasing psychological flexibility. ACT utilises six core principles (connection, defusion, expansion, the observing self, committed action and values) in conjunction with one another, to help the individual develop psychological flexibility. ACT also targets maladaptive coping styles, such as denial and avoidance, in order to stimulate action to improve individuals' situation (Moore & Seeney, 2007). Thus ACT might be of particular value and importance for stroke patients experiencing high levels of psychological distress and employing dysfunctional coping styles. ACT has proven to be effective in patients with a range of neurological and chronic conditions and might be of particular benefit for individuals experiencing difficulty adjusting to their stroke (Hayes, Follette, & Linehan, 2004). Such interventions however, require empirical evaluation in a stroke population prior to routine application and implementation in clinical practice.

Strengths and limitations

One of the strengths of this study is the large cohort of stroke patients recruited. The use of standardised measures allowed for a level of rigor necessary to confidently draw conclusions about the relationships between the variables. Furthermore, this is the first time the relationship between mindfulness, coping and psychological outcomes in stroke patients has been investigated. Whilst this study contributed to our understanding of the associations between mindfulness, coping and psychological outcomes in stroke

patients, the study has a number of limitations that should be noted. First, given that the majority of participants characterised themselves as White British and given that patients were only recruited from two stroke centres based in Northern England, UK, the generalisability of the present findings may be limited. Second, although statistical analyses were sufficiently powered to detect significant effects, it is important for future work to replicate the findings using larger samples. Third, the internal reliability of the coping scales was low which required deleting items from subscales. Furthermore, the 'anxious preoccupation' and 'fatalism' adjustment subscales had low internal consistencies which may have compromised the statistical power of tests involved in using such measures. Fourth, the study employed a cross-sectional design, and as a consequence, the direction of the relationships and inferences regarding causality could be questioned. For example, low levels of psychological distress, may promote mindfulness or alternatively, mindfulness, may lead to reduced psychological distress. Further longitudinal studies are required to disentangle the direction of the relationships between mindfulness, coping, depression, anxiety and adjustment in a stroke population. Furthermore, although analyses controlled for several potential confounders, the degree to which the presence of unknown and unmeasured variables might have influenced the findings is unknown.

This study also suffers from the limitations associated with self-report, including common method variance and socially desirable responding. There has also been some controversy regarding use of self-report measures to assess mindfulness (Grossman, 2008). Some of the intractable problems associated with the psychometric assessment of self-reported mindfulness include the conceptual difficulties and differences in experts' understanding and operationalization of mindfulness, and the potentially significant discrepancies in how mindful individuals believe themselves to be, versus how mindful

they really are (Grossman, 2008). Nonetheless, the FFMQ employed within this study has demonstrated adequate psychometric properties. Despite these limitations, findings from this study contribute to the developing literature on psychological wellbeing following stroke.

Recommendations for future research

The current findings support the need for future studies to elucidate the precise nature of the relationship between mindfulness, coping and psychological outcome variables using longitudinal designs to enable firmer conclusions to be drawn regarding the causality of the relationships between such variables. Replication of the study findings in a larger more ethnically and geographically diverse sample of stroke patients is required before the findings can be generalised. Previous research has identified factors including social support and stroke severity to be related to psychological outcomes in stroke patients. Such variables were not measured within the present study and may have served as unknown potential confounders and therefore mediators between mindfulness and psychological outcomes. Furthermore, given that mindfulness appears to serve a protective factor for maintaining emotional wellbeing in stroke patients, the evaluation of mindfulness based interventions including acceptance and commitment therapy where the cultivation of mindfulness is a key component, warrants evaluation in a stroke population. This would also provide stronger experimental evidence on the causal role of mindfulness in helping psychological adjustment to stroke.

Conclusions

This study represents the first application of mindfulness to the association of depression, anxiety, and psychological adjustment in stroke patients, assessing coping

as a mediator of the effects of mindfulness on psychological outcomes. This investigation has shown that mindfulness and coping are associated with psychological outcomes, but that coping does not mediate the relationship between mindfulness and psychological outcomes (with the exception of dysfunctional coping which mediates the relationship between 'acting with awareness' on helplessness/hopelessness). These findings also bolster support for mindfulness as a state that may foster resilience against mental anguish and distress, in particular as it relates to the aftermath and adjustment following stroke. The current study contributes to the evidence base that conceptualises mindfulness as a state and practice associated with improved health and psychological wellbeing in stroke patients. Interventions designed to cultivate mindfulness and modify dysfunctional coping behaviours, and support better psychological outcomes in a stroke population should be empirically developed and evaluated. However, key conceptual and empirical questions remain to be answered prior to the development of large-scale interventions among stroke patients. Future research should aim to explore the direction of the relationships between mindfulness and psychological outcomes to enable firmer conclusions regarding causality to be drawn. In addition, before the findings can be generalised, it is imperative that the study be replicated in a larger, more ethically and geographically diverse sample of stroke patients.

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Appendices

Appendix A: Participant opt-in form

The University Of Sheffield.	Department Of Psychology. **Clinical Psychology Unit.**

Doctor of Clinical Psychology (DClin Psy) Programme
Clinical supervision training and NHS research training & consultancy.

Clinical Psychology Unit	Telephone:	0114 2226650
Department of Psychology	Fax:	0114 2226610
University of Sheffield	Email:	pcp12tg@sheffield.ac.uk
Western Bank		
Sheffield S10 2TN UK		

Clinical Psychology
Unit
Department of
Psychology
University of Sheffield
Western Bank
Sheffield S10 2TN   UK

<u>**Research Project**</u>

Mindfulness, adjustment, coping and psychological outcome after stroke

A Trainee Clinical Psychologist (Christine Cobley) is undertaking a piece of research to better understand the relationship between adjustment (dealing with a new situation), mindfulness (awareness of the present moment), coping strategies and emotional wellbeing (mood) following stroke. If relationships are found, this could assist in the development of interventions that could help individuals who have experienced a stroke in the future.

Please take as much time as you wish to think about participating in the above study and discuss with your family should you wish. Please have a read through the attached Information Sheet to decide whether or not you would be interested in participating in this research. If you would be interested in obtaining further information on the study (with no obligation to participate) you can contact Christine through the Research Support Officer at The University of Sheffield (telephone 0114 2226650). Alternatively if you would like Christine to contact you, please let a member of the clinical staff team who are caring for you know, and they will pass your details onto Christine who will be in contact with you shortly.

Thank you,

Christine Cobley

Appendix B: Participant information sheet

The University Of Sheffield.	Department Of Psychology. **Clinical Psychology Unit.**
	Doctor of Clinical Psychology (DClin Psy) Programme Clinical supervision training and NHS research training & consultancy.

Clinical Psychology Unit **Department of Psychology** **University of Sheffield** **Western Bank** **Sheffield S10 2TN UK**	Telephone: 0114 2226650 Fax: 0114 2226610 Email: pcp12tg@sheffield.ac.uk

PARTICIPANT INFORMATION SHEET

The role of beliefs and coping in recovery from stroke

We would like to invite you to take part in a research study. Before you decide, you need to understand why the research is being done and what it would involve for you.

Please take time to read the following information carefully. Talk to others about the study if you wish.

Take time to decide whether or not you wish to take part.

What is the purpose of the study?

The main purpose of this study is to understand if there is a link between your adjustment (dealing with a new situation), mindfulness (awareness of the present moment), coping strategies and emotional wellbeing (mood) following stroke. If there is a link then this may help us develop interventions to help individuals who have experienced a stroke in the future.

Why have I been invited?

It is important that we recruit participants who have recently had a stroke and therefore we have chosen to recruit participants who are currently under the care of the stroke services in Sheffield.

Do I have to take part?

Participation within the study is completely voluntary and you are not obliged to take part. Deciding not to take part in the study will not affect your treatment. Your treatment will continue as normal. If you decide to take part we will describe the study and go through the information sheet, which we will then give you to keep. We will then ask you to sign a consent form to show that you have agreed to take part in the following study. You are free to withdraw at any time, without giving reason. This will not affect the standard of care you receive.

What will happen if I take part?

If you decide to take part in this study, the researcher will meet with you to explain in more detail and answer any questions you have. She will then go through the questionnaires with you, which should take about 30 minutes to complete. The researcher will access your medical records to collect details relating to your stroke. If you need additional support reading or writing, the researcher can provide assistance.

What are the possible benefits of taking part?

The main benefit of taking part in this study is that it may help us to identify those patients who may be at risk of developing emotional difficulties such as anxiety or depression and/or may have difficulties adjusting and coping with the consequences following stroke. We cannot promise that the study will help you but the information we get from this study may help us in understanding the factors which affect others who have a stroke in the future.

What if there is a problem?

If answering the questionnaires raises any distressing feelings, you will be asked to discuss this with the stroke nurse or consultant at the clinic or to contact your GP for further help.

Will my taking part in the study be kept confidential?

We have a duty of confidentiality to you as a research participant. If you join the study, some parts of your medical records and the data collected for the study will be looked at by authorised persons from the research team.

All information which is collected about you during the course of the research will be anonymised and kept strictly confidential, and any information about you which leaves the hospital will have your name and address removed so that you cannot be recognised.

What will happen to the results of the research study?

The results of this study may be published in the scientific literature and may also be presented at scientific meetings. All such data will be presented anonymously, that is with no personal details that could identify any of the participants.

What if you want to complain?

Any complaints can be addressed to: Professor Paul Norman at the Department of Psychology, The University of Sheffield, Western Bank, Sheffield, S10 2TN.

If you feel that your complaint has not been handled to your satisfaction following this, you can contact the University's Registrar and Secretary Dr Philip Harvey, Email: registrar@sheffield.ac.uk and Tel: 0114 222 1101.

You can also make a complaint via your local hospital. To do this, please contact the Patient Advice and Liaison Service (PALS) at: 722 Prince of Wales Road, Sheffield S9 4EU, Tel: 0800 085 7539 and provide information about the project.

Contact Information

This research is being conducted by Christine Cobley, Trainee Clinical Psychologist. This research will be used to write a thesis which fulfils part of her doctoral training. If you have any questions about the research, you can leave a telephone message with the Research Support Officer on: 0114 222 6650 and she will ask Christine to contact you.

Appendix C: Participant consent form

The University Of Sheffield.	Department Of Psychology. ## Clinical Psychology Unit. Doctor of Clinical Psychology (DClin Psy) Programme Clinical supervision training and NHS research training & consultancy.

Clinical Psychology Unit　　Telephone:　0114 2226650
Department of Psychology　Fax:　　　　0114 2226610
University of Sheffield　　　Email:　　　pcp12tg@sheffield.ac.uk
Western Bank
Sheffield S10 2TN   UK

Consent form
Mindfulness, adjustment, coping and psychological outcome after stroke

Participant

name...

Participant

address..

I confirm that I have read and understand the information sheet for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	

I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected.	
I understand that relevant sections of my medical notes and data collected during the study may be looked at by individuals from University of Sheffield, from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.	
I agree to take part in the above study.	

_____   _____   _____
Name of Participant   Date   Signature

_____   _____   _____
Name of Person taking consent   Date   Signature

3 copies: 1 for participant, 1 for the project notes and 1 for the medical notes

Appendix D: NHS Research Ethics approval letter

NHS
Health Research Authority

NRES Committee Yorkshire & The Humber - South Yorkshire

Unit 001
Jarrow Business Centre
Rolling Mill Road
Jarrow
Tyne and Wear
NE32 3DT

Telephone: 0191 4283563

17 April 2015

Miss Christine Cobley
Trainee Clinical Psychologist
Sheffield Health and Social Care NHS Trust
Clinical Psychology Unit, Department of Psychology
Western Bank
Sheffield
S10 2TN

Dear Miss Cobley

Study title:	**Associations between dispositional mindfulness, coping, psychological adjustment and wellbeing in stroke survivors**
REC reference:	**15/YH/0075**
IRAS project ID:	**172740**

Thank you for your letter dated 10 April 2015, 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.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this favourable opinion letter. The expectation is that this information will be published for all studies that receive an ethical opinion but should you wish to provide a substitute contact point, wish to make a request to defer, or require further information, please contact the REC Manager, Mrs Helen Wilson, nrescommittee.yorkandhumber-southyorks@nhs.net . Under very limited circumstances (e.g. for student research which has received an unfavourable opinion), it may be possible to grant an exemption to the publication of the study.

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

A Research Ethics Committee established by the Health Research Authority

documentation [as revised], subject to the conditions specified below.

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. This should be before the first participant is recruited but no later than 6 weeks after recruitment of the first participant.

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 request a deferral for study registration within the required timeframe, they should contact hra.studyregistration@nhs.net. The expectation is that all clinical trials will be registered, however, in exceptional circumstances non registration may be permissible with prior agreement from NRES. Guidance on where to register is provided on the HRA website.

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).

Ethical review of research sites

NHS sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management

permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Approved documents

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

Document	Version	Date
Covering letter on headed paper [Cover Letter]		
Covering letter on headed paper [Cover Letter]	2a	10 April 2015
IRAS Checklist XML [Checklist_14042015]		14 April 2015
Letters of invitation to participant [Participant Opt-in Form]	2a	10 April 2015
Non-validated questionnaire [Demographic Data Collection Form]	1	29 January 2015
Participant consent form [Participant Consent Form]	2	06 March 2015
Participant information sheet (PIS) [Participant Information Sheet]	2	06 March 2015
REC Application Form [REC_Form_14042015]		14 April 2015
Referee's report or other scientific critique report [Scientific Approval Letter]	1	29 January 2015
Research protocol or project proposal [Protocol]	1	29 January 2015
Summary CV for Chief Investigator (CI) [Curriculum Vitae]	1	03 February 2015
Summary CV for supervisor (student research) [PN Short CV]	1	03 February 2015
Validated questionnaire [Brief Cope Scale]	1	29 January 2015
Validated questionnaire [Rosenberg Self Esteem Scale]	1	29 January 2015
Validated questionnaire [GAD-7]	1	29 January 2015
Validated questionnaire [Mental Adjustment to Stroke Scale]	1	29 January 2015
Validated questionnaire [PHQ-9]	1	29 January 2015
Validated questionnaire [Five Facet Mindfulness Questionnaire]	2	06 March 2015

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

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website:
http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/

HRA Training

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

15/YH/0075	Please quote this number on all correspondence

With the Committee's best wishes for the success of this project.

Yours sincerely

██████████████████

pp
Dr Ian Woollands
Chair

Email: nrescommittee.yorkandhumber-southyorks@nhs.net

Enclosures: "After ethical review – guidance for researchers"

Copy to: Miss Samantha Heaton, Sheffield Teaching Hospital NHS Foundation
                    Trust

Appendix E: NHS Trust site R & D approval letter

Sheffield Teaching Hospitals NHS

NHS Foundation Trust

7th May 2015

Christine Cobley
Clinical Psychology Unit
Department of Psychology
University of Sheffield
Western Bank
Sheffield
S10 2TN

Dear Christine,

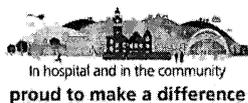### Project Authorisation

NHS Permission for Research to Commence

STH ref:	STH18796	
NIHR CSP ref:	Not applicable	
REC ref:	Not applicable	
MHRA ref:	CTA No: Not applicable	EudraCT No: Not applicable
Clinical Trial reg no:	Not applicable	
Study title:	Associations between dispositional mindfulness, coping, psychological adjustment and wellbeing in stroke survivors	
Chief Investigator:	C Cobley	
Principal Investigator:	C Cobley	
Sponsor:	Sheffield Teaching Hospital NHS Foundation Trust	
Funder:	Not applicable	
NIHR TARGET FPFV RECRUITMENT DATE	16 Jul 15	

MANDATORY REPORTING OF RECRUITMENT
The Research Department is obliged to report study set up and recruitment performance for the Trust to NIHR and to report research activity for all studies to Trust Board. In order to meet these reporting requirements please be advised that it is now a *mandatory* condition of STH project authorisation that recruitment to *all* research studies* at STH is reported into EDGE (the Accrual Collation and Reporting Database). It is essential that recruitment is entered into EDGE *real-time* to enable directorates to accurately monitor performance. Please see item 2 of the 'Conditions of R&D Authorisation' for further details.

Please be informed that failure to report recruitment to EDGE may result in loss or delay in funding to the Trust and to the Directorate.

*Information regarding EDGE eligibility for reporting is detailed in the 'Conditions of R&D Authorisation'

Ref: STH18796/SH

The Research Department has received the required documentation as listed below:

1.	Sponsorship Agreement	Not applicable
	Clinical Trial Agreement	Not applicable
	Material Transfer Agreement	Not applicable
	Funding Award Letter	Not applicable
2.	Monitoring Arrangements	Not Applicable
3.	STH registration document	R & D Form 23 Apr 15
4.	Evidence of favourable scientific review	Not applicable
5.	Protocol – final version	Version 1, 29 Jan 15
6.	Participant Information sheet	Version 2, 06 Mar 15
7.	Consent form	Version 2, 06 Mar 15
8.	Letter of indemnity arrangements	NHS Indemnity applies
9.	ARSAC certificate / IRMER assessment	Not applicable
10.	Ethical review- Letter of approval from NHS REC or UREC	NRES Committee Yorkshire & The Humber - South Yorkshire 17 Apr 15
11.	Site Specific Assessment	SSI 23 Apr 15
12.	Clinical Trial Authorisation from MHRA	Not applicable
13.	Evidence of hosting approvals	
	- STH Principal Investigator	C Cobley, 05 Mar 15
	- Clinical Director	R Grunewald, 04 Mar 15
	- Research Finance	E Fraser, 06 May 15
	- Data Protection Officer	P Wilson, 17 Mar 15
14.	Honorary Contract/Letter of Access	Not applicable
15.	Associated documents	
	- Five facet Mindfulness questionnaire	Version 2, 06 Mar 15
	- PHQ9	29 Jan 15
	- Mental Adjustment to Stroke Scale	29 Jan 15
	- GAD-7	29 Jan 15
	- Rosenberg Self Esteem Scale	29 Jan 15
	- Brief Cope Scale	29 Jan 15
	- Demographic Data Collection form	Version 1, 29 Jan 15
	- Patient Opt in letter	Version 2a, 10 Apr 15

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Ref: STH18796/SH
This project has been reviewed by the Research Department. NHS permission for the above research to commence has been granted on the basis described in the application form, protocol and supporting documentation on the understanding that the study is conducted in accordance with the Research Governance Framework, GCP and Sheffield Teaching Hospitals policies and procedures (see attached appendix).

Yours sincerely

Professor S Heller
Director of R&D, Sheffield Teaching Hospitals NHS Foundation Trust
Telephone +44 (0) 114 2265934
Fax +44 (0) 114 2265937

Ref: STH18796/SH

Sheffield Teaching Hospitals NHS Foundation Trust

Conditions of R&D Authorisation

Please note the following requirements that must be adhered to by the investigator when embarking on a research project at Sheffield Teaching Hospitals NHS Foundation Trust (STH). The investigator must update the Research Department of the following:

1. Safety reporting

Investigators should ensure that they elicit information regarding adverse events from participants at each study visit. If a Serious Adverse Event (SAE) is discovered the Investigator must alert the Sponsor immediately (within 24 hours) and must comply with sponsor requests for further information to ensure that events are reported to ethics and regulatory bodies within the timelines laid down in the Medicines for Human Use (Clinical Trials) Regulations 2004. Investigators should refer to the STH Research Department SOPs available by request or on the Department website http://www.sheffieldclinicalresearch.org for further guidance.

2. Recruitment reporting in EDGE

It is now a *mandatory* requirement of STH NHS Permission that recruitment to research studies at STH is reported using the EDGE and essential that recruitment is entered into EDGE *real-time*.

EDGE Exempt Studies

Not all studies are required to use the EDGE Accrual Collation and Reporting Database. Your CRO Research Coordinator will confirm during the set-up phase of your study whether you are required to record recruitment into EDGE.

Those studies which are EDGE exempt:

Studies conducted in a STH Clinical Research Facility (CRF)* - These studies will be under the management of the CRF where accrual will be captured in the CRF Manager database.

*Recruitment for CRF Link studies (where the CRF provides the research environment for the PI and their team) will require reporting into EDGE as data for these studies are not captured in CRF Manager.

Definition of Recruited Participant: Eligible participant recruited onto the trial.

Note: Screen failures do not count as a recruited participant.

Once you have been issued with a login for EDGE, please refer to the training materials at the link below to use the system:
http://www.sheffieldclinicalresearch.org/clinical-research-office/setting-up-running-your-study

For further information regarding the use of EDGE or training provision please contact your local STH EDGE Administrator Gaurika Kapoor (gaurika.kapoor@sth.nhs.uk).

3. Protocol Amendments

Investigators should alert the Research Department if there is a protocol amendment subsequent to initial Trust Research Governance authorisation. An amendment includes any changes which affect the conduct of the study. This may include for example any changes to study documentation e.g. a patient information sheet, a decision to use advertising, changes to staff or revisions to study timelines. Where studies are sponsored by STH, changes to the protocol and/or other study documents must be submitted to the Research Department for review prior to ethics submission to ensure that they are appropriately categorised as substantial or non-substantial amendments and that appropriate scientific review is carried out. Where studies are not sponsored by STH, the revised documentation accompanied by a REC approval letter should be submitted to your Research Coordinator in order for Trust Authorisation to be issued before implementation of the amendment.

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4. Training
In accordance with the principle of Good Clinical Practice, investigators should ensure that all persons assisting with the trial are adequately informed about the protocol, the investigational product(s), and their trial related duties and functions. The investigator is responsible for ensuring that the research team have the requisite study-specific/GCP training. If anyone joins the team after authorisation has been granted, their GCP status should be checked by the Principal Investigator and notified to the Research Department who will arrange access to our on-line GCP training programme if required.

5. Study status
Under the Research Governance Framework, STH has a responsibility to maintain an accurate record of all research undertaken within the organisation or involving participants, organ, tissue or data obtained through the organisation. A requirement of Research Governance authorisation is that the Investigator provides ongoing information on study progress. The investigator should inform their Research Coordinator on an ongoing basis of the dates where major milestones are reached as defined below. Equally an investigator should inform their Research Coordinator of any revisions to timelines for example, if the study fails to recruit as originally forecast.

Milestone	Definition
Registered	Project is registered with STH Research Department
Withdrawn (before authorisation)	PI has withdrawn the study application before Research Governance Authorisation
Authorised	Project has received STH Research Governance Authorisation
Open to recruitment	Research team are actively identifying/screening/recruiting participants and/or collecting data
First patient First visit (FPFV)	Date of first visit at which data (e.g., medical history) is collected from the first study subject to determine eligibility to participate in a given clinical study
Abandoned (after authorisation)	Study previously given Research Governance Authorisation has been abandoned by the PI prior to recruitment
On hold	Study is delayed/not active but plans to continue at some point. This delay could be resource issues such as finance, research team personnel etc or a decision of Sponsor for safety concerns, business issues etc.
Recruitment ended	All participants/data sources identified. Participants are currently actively involved in research process. Questionnaires/interviews/interventions are being undertaken. Data collection from identified sources is ongoing
Last patient Last visit (LPLV)	For IMP studies, if not otherwise defined in protocol, this is the end of trial and MHRA can be informed of end of study at this point as per clinical trials toolkit advice http://www.ct-toolkit.ac.uk/_db/_documents/Protocol.pdf. For STH sponsored studies we expect safety data to be collected for a minimum of 30 days post last patient last dose.
Long-term follow up	For studies where last on-site patient visit has occurred and patients are followed to final outcome e.g. mortality/morbidity at X years post project
Database Lock	All data collected and cleaned. No further changes of data expected/allowed
Close out at site	No further research project activity expected at site. All study material has been removed/disposed.
Published	Research project results have been published (May occur after archiving)
Archived	All research documentation has been archived (on or off site). Project results may not have been published at this stage.

PI: Principal investigator.

Ref: STH18796/SH

6. Standard Operating Procedures (SOPs)

Investigators should familiarise themselves with any STH SOPs which are relevant to the study they are undertaking. Evidence of training in these SOPs should be recorded in your individual SOP training log, a template log can be found at http://www.sheffieldclinicalresearch.org/clinical-research-office/useful-documents. Investigators may also wish to develop study specific SOPs, if appropriate. Copies should be kept in the Investigator Site File. Investigators should ensure that they use the most current SOPs or file note why this is not the case. A full list of STH Research Department SOPs can be found on the departmental website http://www.sheffieldclinicalresearch.org

7. Progress reports

A copy of all interim, annual or final reports sent to the Research Ethics Committee, Regulatory Authority or Sponsor must be sent to your Research Coordinator in the Research Department. This may include annual progress, end of study, expedited SUSAR or safety reports.

8. Archiving of Essential Documentation at the End of a Study

The lead investigator is responsible, according to the principles of Good Clinical Practice, for arranging for the archiving of their research data whether they are taking part in a commercial trial, a non-commercial trial or one that is funded from their own account. The UK Medicines for Human Use (Clinical Trials) Amendment Regulations 2006 cover the maintenance of a trial master file and the archiving of essential documentation. Investigators must adhere to these Regulations and ensure that facilities used to archive essential documents are compliant with the requirements of the Regulations. The Sponsor of a study will advise the investigator as to when documents may be destroyed.

9. Audit & Inspection

It is a requirement of STH Healthcare Governance that an investigator alerts their Research Coordinator within the Research Department as soon as they receive notification that an external body will be entering STH premises to carry out an audit or inspection of any aspect of their research.

10. The Use of Human Tissue Samples in Research

Investigators should familiarise themselves with the provisions of the Human Tissue Act 2004, a framework for regulating the storage and use of human organs and tissue from the living, and the removal storage and use of tissue and organs from the deceased for specified purposes. All investigators intending to collect/use human tissue samples in the course of their study must advise the Research Department of this intention upon registering the study. Similarly, the intention to create and maintain a tissue bank must be registered with the Research Department as the storage of tissue for unspecified research purposes is licensable under the HT Act.

Appendix F: Five Facet Mindfulness Questionnaire

This instrument is based on a factor analytic study of five independently developed mindfulness questionnaires. The analysis yielded five factors that appear to represent elements of mindfulness as it is currently conceptualized. The five facets are observing, describing, acting with awareness, non-judging of inner experience, and non-reactivity to inner experience.

Please rate each of the following statements using the scale provided. Write the number in the blank that best describes your own opinion of what is generally true for you.

1	2	3	4	5
Never of very rarely true	Rarely true	Sometimes true	Often true	Very often or always true

_____ 1. When I'm walking, I deliberately notice the sensations of my body moving.

_____ 2. I'm good at finding words to describe my feelings.

_____ 3. I criticize myself for having irrational or inappropriate emotions.

_____ 4. I perceive my feelings and emotions without having to react to them.

_____ 5. When I do things, my mind wanders off and I'm easily distracted.

_____ 6. When I take a shower or bath, I stay alert to the sensations of water on my body.

_____ 7. I can easily put my beliefs, opinions, and expectations into words.

_____ 8. I don't pay attention to what I'm doing because I'm daydreaming, worrying, or   otherwise distracted.

_____ 9. I watch my feelings without getting lost in them.

_____ 10. I tell myself I shouldn't be feeling the way I'm feeling.

_____ 11. I notice how foods and drinks affect my thoughts, bodily sensations, and emotions.

_____ 12. It's hard for me to find the words to describe what I'm thinking.

_____ 13. I am easily distracted.

_____ 14. I believe some of my thoughts are abnormal or bad and I shouldn't think that way.

_____ 15. I pay attention to sensations, such as the wind in my hair or sun on my face.

_____ 16. I have trouble thinking of the right words to express how I feel about things

_____ 17. I make judgments about whether my thoughts are good or bad.

_____ 18. I find it difficult to stay focused on what's happening in the present.

_____ 19. When I have distressing thoughts or images, I "step back" and am aware of the   thought or image without getting taken over by it.

_____ 20. I pay attention to sounds, such as clocks ticking, birds chirping, or cars passing.

_____ 21. In difficult situations, I can pause without immediately reacting.

_____ 22. When I have a sensation in my body, it's difficult for me to describe it because   I can't find the right words.

_____ 23. It seems I am "running on automatic" without much awareness of what I'm doing.

_____24. When I have distressing thoughts or images, I feel calm soon after.

_____ 25. I tell myself that I shouldn't be thinking the way I'm thinking.

_____ 26. I notice the smells and aromas of things.

_____ 27. Even when I'm feeling terribly upset, I can find a way to put it into words.

_____ 28. I rush through activities without being really attentive to them.

_____ 29. When I have distressing thoughts or images I am able just to notice them without reacting.

_____ 30. I think some of my emotions are bad or inappropriate and I shouldn't feel them.

_____ 31. I notice visual elements in art or nature, such as colors, shapes, textures, or patterns of light and shadow.

_____ 32. My natural tendency is to put my experiences into words.

_____ 33. When I have distressing thoughts or images, I just notice them and let them go. _____ 34. I do jobs or tasks automatically without being aware of what I'm doing.

_____ 35. When I have distressing thoughts or images, I judge myself as good or bad, depending what the thought/image is about.

_____ 36. I pay attention to how my emotions affect my thoughts and behavior.

_____ 37. I can usually describe how I feel at the moment in considerable detail.

_____ 38. I find myself doing things without paying attention.

_____ 39. I disapprove of myself when I have irrational ideas.

Appendix G: Brief COPE Questionnaire

These items deal with ways you've been coping with the stress in your life since you

had your stroke. These items ask what you've been doing to cope with your

stroke. Obviously, different people deal with things in different ways, but I'm interested

in how you have tried to deal with it. Each item says something about a particular way

of coping. I want to know to what extent you've been doing what the item says. How

much or how frequently. Don't answer on the basis of whether it seems to be working

or not—just whether or not you're doing it. Use these response choices. Try to rate

each item separately in your mind from the others.

Make your answers as true FOR YOU as you can.

1	2	3	4
I haven't been doing this at all	I've been doing this a little bit	I've been doing this a medium amount	I've been doing this a lot

1. I've been turning to work or other activities to take my mind off things.

2. I've been concentrating my efforts on doing something about the situation I'm in.

3. I've been saying to myself "this isn't real.".

4. I've been using alcohol or other drugs to make myself feel better.

5. I've been getting emotional support from others.

6. I've been giving up trying to deal with it.

7. I've been taking action to try to make the situation better.

8. I've been refusing to believe that it has happened.

9. I've been saying things to let my unpleasant feelings escape.

10. I've been getting help and advice from other people.

11. I've been using alcohol or other drugs to help me get through it.

12. I've been trying to see it in a different light, to make it seem more positive.

13. I've been criticizing myself.

14. I've been trying to come up with a strategy about what to do.

15. I've been getting comfort and understanding from someone.

16. I've been giving up the attempt to cope.

17. I've been looking for something good in what is happening.

18. I've been making jokes about it.

19. I've been doing something to think about it less, such as going to movies, watching TV, reading, daydreaming, sleeping, or shopping.

20. I've been accepting the reality of the fact that it has happened.

21. I've been expressing my negative feelings.

22. I've been trying to find comfort in my religion or spiritual beliefs.

23. I've been trying to get advice or help from other people about what to do.

24. I've been learning to live with it.

25. I've been thinking hard about what steps to take.

26. I've been blaming myself for things that happened.

27. I've been praying or meditating.

28. I've been making fun of the situation.

Appendix H: Mental Adjustment to Stroke Scale

Please circle the appropriate response for each question based on how you feel at the moment. Thank you for your help.

1	2	3	4
Definitely does not apply to me	Does not apply to me	Applies to me	Definitely applies to me

	1	2	3	4
1. 1. I have been doing things that I believe will improve my health (e.g. changed my diet)				
2. 2. I feel I can't do anything to cheer myself up				
3. I feel that problems with my health prevent me from planning ahead				
4. I feel that my positive attitude will benefit my health				
5. I don't dwell on my illness				
6. I firmly believe that I will get better				
7. I feel that nothing I can do will make any difference				
8. I've left it all to my doctors				
9. I feel that life is hopeless				
10. I have been doing things that I believe will improve my health (i.e. exercise)				
11. Since my stroke I now realise how precious life is, and I'm making the most of it				
12. I've put myself in the hands of God				
13. I have plans for the future (e.g. holidays, jobs, housing)				
14. I worry about the stroke returning or getting worse				
15. I've had a good life, what's left is a bonus				
16. I think my state of mind can make a lot of difference to my health				
17. I feel that there is nothing I can do to help myself				
18. I try to carry on life as I've always done				

19. I would like to make contact with others in the same boat				
20. I am determined to put it all behind me				
21. I have great difficulty in believing that this happened to me				
22. I suffer great anxiety about it				
23. I am not very hopeful about the future				
24. At the moment I take one day at a time				
25. I feel like giving up				
26. I try to keep a sense of humor about it				
27. Other people worry about me more than I do				
28. I think of other people who are worse off				
29. I am trying to get as much information as I can about strokes				
30. I feel I can't control what is happening				
31. I try to have a very positive attitude				
32. I keep quite busy, so I don't have time to think about it				
33. I avoid finding out more about it				
34. I see my illness as a challenge				
35. I feel fatalistic about it				
36. I feel completely at a loss about what to do				
37. I feel very angry about what has happened				
38. I don't really believe I had a stroke				
39. I try to count my blessings				
40. I try to fight the illness				

Appendix I: Patient Health Questionnaire

Over the <u>last 2 weeks</u>, how often have you been bothered by any of the following problems?	Not at all	Several days	More than half the days	Nearly every day
1 Little interest or pleasure in doing things	0	1	2	3
2 Feeling down, depressed, or hopeless	0	1	2	3
3 Trouble falling or staying asleep, or sleeping too much	0	1	2	3
4 Feeling tired or having little energy	0	1	2	3
5 Poor appetite or overeating	0	1	2	3
6 Feeling bad about yourself — or that you are a failure or have let yourself or your family down	0	1	2	3
7 Trouble concentrating on things, such as reading the newspaper or watching television	0	1	2	3
8 Moving or speaking so slowly that other people could have noticed? Or the opposite — being so fidgety or restless that you have been moving around a lot more than usual	0	1	2	3
9 Thoughts that you would be better off dead or of hurting yourself in some way	0	1	2	3

A11 – PHQ9 total score

Appendix J: Generalised Anxiety Disorder Questionnaire

Over the <u>last 2 weeks</u>, how often have you been bothered by any of the following problems?	Not at all	Several days	More than half the days	Nearly every day
1 Feeling nervous, anxious or on edge	0	1	2	3
2 Not being able to stop or control worrying	0	1	2	3
3 Worrying too much about different things	0	1	2	3
4 Trouble relaxing	0	1	2	3
5 Being so restless that it is hard to sit still	0	1	2	3
6 Becoming easily annoyed or irritable	0	1	2	3
7 Feeling afraid as if something awful might happen	0	1	2	3

A12 – GAD7 total score

Appendix K: Demographic Questionnaire

Demographic variables – *collected from participants*

1. Age: _____

2. Sex: Male   Female

3. Marital Status_____

4. Age left full time education _____

5. Employment status:_____

6. Current or last known occupation: _____

7. Ethnic origin:

   White British Irish   Black British Afro-Caribbean   Asian

    Other: _____

Stroke and medical history – *collected from clinical records.*

1. When was the stroke? _____

2. What type of stroke? _____

3. Previous number of strokes, if any? _____

4. Level of post-stroke disability? _____