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Psychological distress following stroke: a research portfolio

Thesis portfolio

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Research Portfolio Abstract

Introduction: There is a growing literature base focusing on the correlates and predictors of psychological distress following stroke. However, there is still limited understanding regarding the physical, cognitive and psychosocial variables that may increase an individual's vulnerability to experiencing post stroke psychological distress. This thesis had two aims: 1) to review the evidence relating to functional impairment and depression post stroke, in order to identify any differences in this relationship at different stages of recovery, or over time, and 2) to explore whether perceived social support and perceived control moderate the relationship between cognitive impairment and psychological distress following stroke.

Methods: A systematic review of the literature was conducted to investigate any potential differences in the relationship between functional impairment and depression post stroke. Quality criteria were applied to the included studies and the results were discussed in relation to these. A cross-sectional study was conducted to address the second aim of this portfolio. Participants completed three self-report questionnaires and a clinician administered measure. Statistical analysis was utilised to explore the relationships between cognitive impairment, perceived social support, perceived control and psychological distress following stroke.

Results: The results of the systematic review were inconclusive. It was not possible to identify any definitive differences in the relationship between functional impairment and depression post stroke, at different time points or with regard to change over time. With regard to the cross-sectional study, none of the independent variables (cognitive impairment, perceived social support and perceived control) were found to be significantly related to psychological distress following stroke.

Conclusions: The results of the systematic review highlight the need for methodologically robust, longitudinal studies to investigate differences in the relationship between functional

impairment and depression during different stages of recovery and potential change over time in this relationship. Further research into the cognitive and psychosocial correlates and predictors of psychological distress are required in order to identify, and provide timely intervention to, those that are most likely to experience psychological distress following stroke.

Part 1: Systematic Literature Review

The relationship between functional impairment and depression at different stages of recovery post stroke.

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This review has been written in accordance with the author guidelines for Neuropsychological Rehabilitation (Appendix 1).

Total word count: 6198 (excluding references and appendices).

Abstract

The relationship between functional impairment and depression post-stroke is relatively well established. The aim of this study was to identify potential differences in this relationship at different stages of recovery. If possible, this study also sought to identify any evidence for changes in this relationship over time. A systematic review of the literature was conducted. Twelve studies were included in the review. Quality criteria were applied to evaluate the methodological ability of each of the studies to address the review question. The results of the review suggest that, in line with previous research, higher levels of functional impairment are associated with higher levels of depression following stroke (in the acute stage post stroke, at one, three and six months and at one and five years). However, the results did not allow for any firm conclusions regarding differences in this relationship at different stages of recovery, or with regard to change over time, to be made. The results are discussed in the context of the methodological limitations of the included studies and the heterogeneity of the samples. The requirement for methodologically robust, longitudinal studies to further investigate potential differences in this relationship is highlighted.

Introduction

Background

Globally, incidence of stroke ranges from 41 to 316 per 100 000 persons, per year (Thrift et al., 2014) and is estimated to account for 6.6 million deaths per year (WHO, 2015). With the ageing population it is estimated that by 2030 this number will increase to 7.8 million per year (WHO, 2009), undoubtedly placing increasing demand on health services worldwide. In 2010 the number of Disability Adjusted Life Years (DALYs) lost as a result of stroke was 102 million, a 12 % increase from 1990 (Feigin et al., 2014). The severe physical, social and psychological consequences of stroke can be devastating for individuals and their families (Doswell et al., 2000) and can significantly impact on an individual's mental health (Taylor, Todman & Broomfield., 2011). The complex and multidimensional nature of recovery from stroke has been acknowledged (Doswell et al., 2000).

Functional impairment following stroke

Functional impairment or disability following stroke is highly prevalent. Motor impairment, usually affecting movement on one side of the body, is the most common cause of physical disability following stroke (Wade, 1992), with incidence of motor deficit (of any degree) of 83% reported in a community based sample in the acute stages (Bonita & Beaglehole, 1998). Incidence of disability at one month has been reported as 43% in stroke survivors. (Luengo – Fernandez et al., 2013). Longer term, incidence of disability of 36- 39% has been reported at five years post stroke (Hankey, Jamrozik, Broadhurst, Forbes & Anderson, 2002; Luengo – Fernandez et al., 2013). This decrease over time is thought to be largely accounted for by the deaths of the most severely disabled individuals (Luengo – Fernandez et al., 2013). In many Western countries stroke is among the top ten most common causes of long term disability (Pollock et al., 2014). Stroke rehabilitation typically focuses on regaining independence through the reduction of physical impairment (Pollock et al., 2014). Physical rehabilitation

has been found to have a positive effect on the recovery of functional ability and physical independence following stroke (Pollock et al., 2014).

Post stroke depression

Emotional difficulties such as depression following stroke are now increasingly recognised as common sequelae (Kneebone & Lincoln, 2012). However, the true prevalence and course of post stroke depression (PSD) is still somewhat unclear, with a review of its prevalence reporting a wide range of estimates (e.g 11 to 55% at one month post stroke) and conflicting evidence regarding its course (Kouwenhoven, Kirkevold, Engedal & Kim, 2011). A recent review of fifty studies, indicated a pooled prevalence of 29% of individuals experiencing PSD at any one time (Ayerbe, Ayis, Wolfe & Rudd, 2013). The results indicated that the prevalence of depression increases from 28% within one month post stroke, to 31% at 1-6 months and to 33% at 6 months to 1 year. A decrease in the prevalence was noted at more than 1 year (25%) (Ayerbe et al., 2013). An earlier review suggested higher prevalence rates of 41.2% based on pooled data (major depression - 21.7%, minor depression – 19.5%) (Robinson & Spalletta, 2010). Kneebone and Lincoln (2012) identify the difficulty in the assessment and recognition of PSD due to the overlap of symptoms of depression, stroke and cognitive impairment. The discussion regarding the biological or reactive nature of PSD is ongoing with, as of yet, a lack of conclusive evidence to support the suggestion of a biological cause in the acute stages and psychological or reactive cause in the chronic stages (Nys et al., 2005).

Understanding the nature and course of PSD is immensely important due to the lack of well evidenced treatment interventions (Hackett & Anderson, 2005). Despite recognition of the occurrence of PSD, few stroke patients receive effective treatment for their depressive

symptoms (Hackett & Anderson, 2005). PSD is associated with higher risk of mortality (Ellis, Zhao & Egede, 2010; Williams, Ghose & Swindle, 2004) and individuals with PSD have been reported to use rehabilitation services less effectively than those without (Gillen, Tennen, McKee, Gernet-Dott &Affleck, 2001).

The relationship between functional impairment and PSD

The relationship between functional impairment and depression following stroke is relatively well established. In a review of the literature Hackett and Anderson (2005) concluded that physical disability was the only variable which was consistently positively associated with depression (a significant association was identified in nine out of eleven studies exploring this relationship). More recently, fifteen of eighteen studies included in a review, reported a statistically significant relationship between the presence or level of severity of depressive symptoms and impairment in activities of daily living (Robinson & Spalletta, 2010). Furthermore, Ayerbe et al.'s (2013) review concluded that physical disability after stroke was one of two factors most consistently reported as a predictor, with four out of the ten included studies indicating a significant association. However, in all of the above reviews, there is considerable variation across studies with regard to populations, assessment tools and definitions of 'depression' and 'functional impairment'. The three reviews outlined above did not however, explore any potential differences in the relationship between functional impairment and depression at different stages of recovery or time points post stroke. Similarly, although Hadidi, Treat-Jacobson and Lindquist, (2009) acknowledge the potential differences in this relationship at different times post stroke within their review, the literature relating to this is not systematically explored. Hadidi and colleagues (2009) identify the need for further investigation into any differences in the relationship between these variables in the acute and chronic stages following stroke.

Burvill and colleagues (1997) suggest three possible processes accounting for the association between depression and functional impairment: 1) an underlying, most likely biological process which impacts on both depression and functional impairment, 2) adjustment to physical disability impacts on an individual's mood and 3) depression may further impair an individual's functional capacity beyond the effect of their functional impairment alone. However, there is no conclusive evidence to indicate the presence of one process over the other. There is also a suggestion that the reason for the association changes over time: in the acute stages, depression and functional impairment are likely to exacerbate one another, with individuals becoming depressed due to the level of their disability. As time goes on however, it is likely to be the duration of the disability that negatively impacts on mood (Hosking & Marsh, 2013).

Measurement and definition of constructs

The inconsistency in definition and measurement of functional impairment has previously been acknowledged (Hadidi, Treat-Jacobson & Lindquist, 2009). Although many stroke studies use measurement scales sensitive only to physical functioning, for example the Barthel Index (e.g. Johnston, Morrison, Macwalter & Partridge, 1999), others utilise those that also measure other domains such as cognitive and social functioning, for example, Functional Impairment Measure (e.g. Hama et al., 2007) under the construct of functional impairment/outcome/recovery, disability etc. Similarly in stroke literature, PSD is measured by both measures of symptoms of depression (e.g. Thomas & Lincoln, 2006) and diagnosis of a depressive disorder (e.g. Astrom, Adolfsson & Asplund, 1993), the presentation and profile of which may be somewhat different. Furthermore, many rating scales, used as a measure of depression overlap with other constructs such as anxiety, self-esteem and quality of life and as such do not provide an accurate measurement of depression (e.g General Health Questionnaire-60).

Rationale for current study

The current literature base suggests that higher levels of functional impairment are associated with higher levels of PSD. However, to date, no published systematic literature review has been conducted to explore the relationship between functional impairment and depression, post stroke, at different stages of recovery.

Method

Aim

This aim of this review is to rectify the identified gap in the literature by conducting a systematic search and review of relevant literature to identify any differences in the relationship between depression and functional impairment, at different stages of recovery post stroke. If the methodologies of any of the included studies allow, this review also seeks to explore change over time in this relationship.

Search Strategy

A Literature search was conducted on 21st November 2014. The following databases were searched: Ovid Medline (R) (1946- November, 2014), Psychinfo (1806 – November, 2014), and Embase (1974- November, 2014). The following search terms were used in order to identify relevant papers: 'post-stroke' OR 'poststroke' OR 'post stroke' OR 'stroke' OR 'cerebrovascular disease' AND 'depress*' OR 'mood disorder' AND 'functional outcome' OR 'functional impairment' OR 'functional independence' OR 'functional health' OR 'functional recovery' OR 'functional dependen*' OR 'functional ability' OR 'functional disability' OR 'disability' OR 'physical impairment'.

Selection Criteria

Studies published in English language journals only were included. Observational and intervention studies were included where the relationship between depression and functional impairment was explored at the same time, on at least one specified time point, in human adults (≥ 18 years) with a diagnosis of stroke. Other than the exclusion of studies including individuals with Transient Ischaemic Attack (TIA), no restrictions were placed on the type of stroke included. Studies including individuals with TIA were excluded as the effects of a TIA are largely temporary and as such they are typically excluded from research into the psychosocial factors and stroke (e.g Nys et al., 2005). Studies including those with TIA were, however, included if data for different stroke types was presented separately. As the focus of the review was the relationship between depression and functional impairment, studies were included where at least one measure of functional impairment and one measure or diagnostic criteria of depression were included. For the purpose of this review, the following definition of functional impairment was utilised: *level of impairment or dependence on others in activities of daily living (e.g. feeding, mobility, personal care and toileting).* As such, studies were excluded if the Functional Independence Measure (FIM) was used, and only the total score reported, as this measure also includes an assessment of other domains of functioning (communication, psychosocial and cognition). Studies utilising both diagnostic criteria of depression and/or rating scales measuring 'caseness' of depression were included. It is acknowledged that diagnostic criteria have a higher specificity and rating scales a higher sensitivity, however both have clinical utility (e.g. Berg, Psych, Lonnqvist, Palomaki & Kaste, 2009) and as such both are thought appropriate to include.

Quality Assessment

The methodological ability of the included studies to address the review question was evaluated by applying the quality criteria outlined in Appendix 1. As no suitable established quality criteria could be identified, the quality criteria was developed to meet the

requirement of the review question with reference to the STROBE Guidelines (von Elm et al., 2007) and the Sign Guidelines (SIGN 2014). The majority of the included papers (n = seven) were co-rated by a second individual (KP or AL). Following brief discussion of some criteria, a consensus was reached on all of the quality criteria for each study.

Results

Literature search

The search strategy identified 463 articles, after duplicates were removed. Titles and abstracts of the articles were then screened and 346 studies were excluded. The full articles of the remaining 117 studies were screened using the inclusion and exclusion criteria. A further 104 articles were excluded. The reference lists of the twelve remaining articles were screened for potentially suitable articles; no further articles were identified. Twelve articles were included in the review. The process of the systematic literature search is outlined in Figure 1.

Characteristics of included studies

The key characteristics of the included studies are presented in Table 1. The total sample size of the 12 included studies was 2673 participants. The mean age of participants included in studies was 68.1 years (range 21- 95 years). Study samples were drawn from consecutive admissions to hospital in five studies (Brown, Hasson, Thyselius & Almborg, 2012; Hermann, Black, Lawrence, Szekely & Szalai, 1998; Hosking & Marsh, 2013; Nys, van Zandvoort, van der Worp, de Haan, de Kort & Kapelle, 2005; Wong, Lam, Ngai, Wong, Siu, Poon, *et al.*,2013), consecutive admissions to a rehabilitation centre in two studies (Nannetti, Paci, Pasquini, Lombardi & Taiti, 2005; Sit, Wong, Clinton & Li, 2007), all incidence of known stroke in four studies (Appelros & Viitanen, 2004; Burvill, Johnson, Jamrozik,

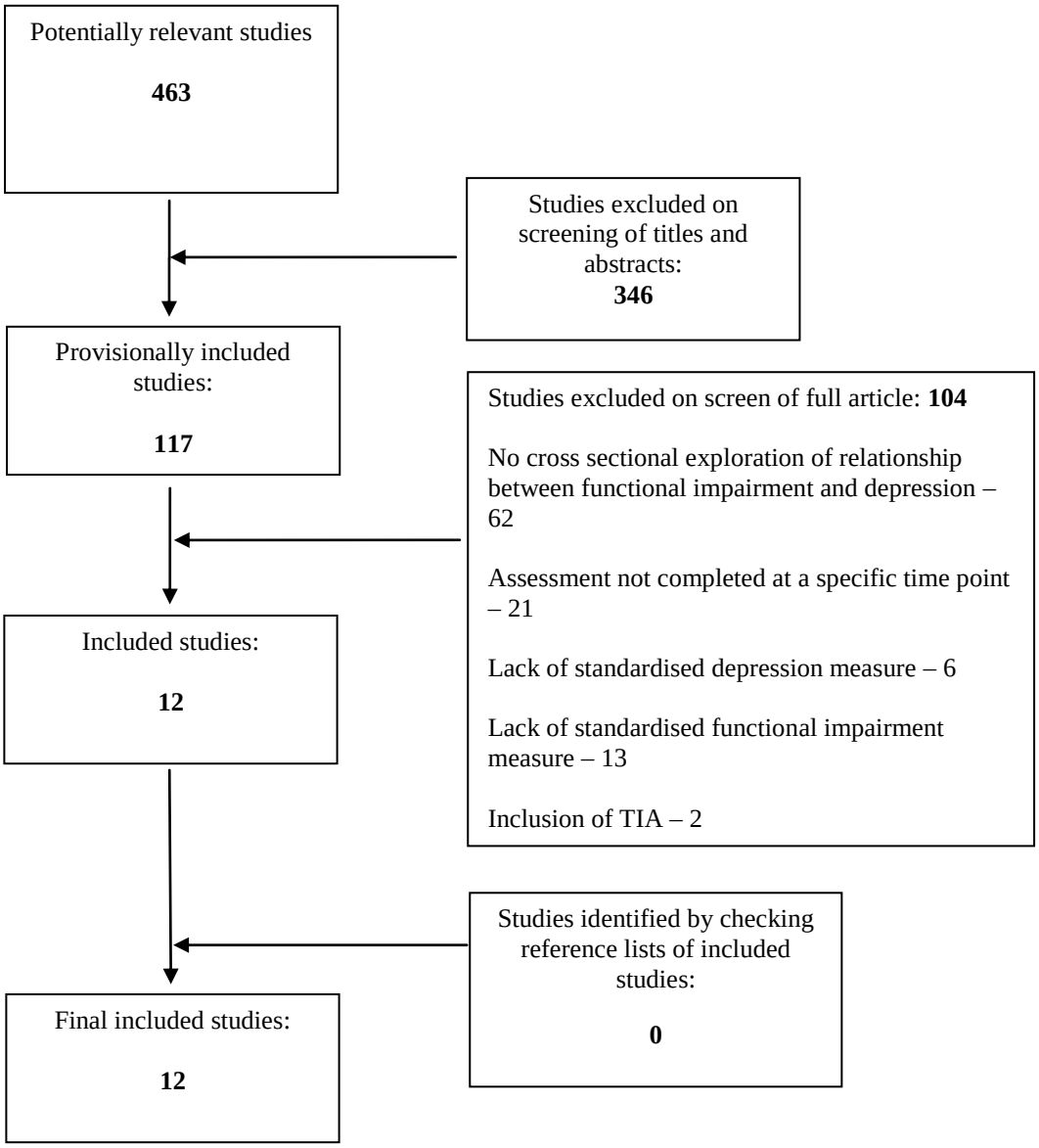

Figure 1. Systematic search of the literature

Anderson & Stewart-Wynne, 1997; Feign, Barker-Collo, Parag, Senior *et al.*, 2010; Ramasubbu, Robinson, Flint, Kosier & Price, 1998), and those registered in a community stroke survey in one study (Wade, Legh-Smith & Hewer, 1987). Of the twelve studies included, two were conducted in Sweden (Appleros & Viitanen, 2004; Brown *et al.*, 2012), two in Hong Kong (Sit *et al.*, 2007; Wong *et al*., 2013), two in New Zealand (Feigin *et*

al.,2010; Hosking & Marsh, 2013), one in Australia (Burvill *et al.*,1997), one in Italy (Nannetti *et al*., 2005), one in the UK (Wade *et al.,* 1987), one in Canada (Hermann *et al*., 1998), one in the USA and Canada (Ramasubbu *et al.*,1998) and one in the Netherlands (Nys *et al*., 2005). With regard to functional impairment measures all studies used either the Modified Rankin Scale (mRS) (n = 3) (Appleros & Viitanen, 2004: Hermann *et al*., 1998; Wong *et al*., 2013), the Barthel Index (BI) (n = 8) (Brown *et al.,* 2012; Burvill *et al.*,1997; Hosking & Marsh, 2013; Nannetti *et al*., 2005; Nys *et al*., 2005; Ramasubbu *et al.*,1998; Sit *et al,* 2007; Wade *et al.,* 1987) or both (n = 1) (Feigin *et al.*,2010). One study used psychiatric interview and diagnostic criteria only to diagnose depression (Diagnostic and Statistical Manual of Mental Disorder – III (DSM – III)) (Burvill *et al.*,1997), two studies used psychiatric interview and diagnostic criteria (Diagnostic and Statistical Manual of Mental Disorder – IV (DSM-IV)) and a depression measure (Geriatric Depression Scale (GDS)) (Appelros & Viitanen, 2004; Nannetti *et al*., 2005), one utilised a clinician rated measure (Montgomery Asberg Depression Rating Scale (MADRS)) and a self-report measure (Zung Self-Rating Depression Scale (SDS)) (Hermann *et al*., 1998), whilst the remaining seven used only a self-report measure of depression, GDS: n = 3 (Hosking & Marsh, 2013; Feigin *et al.*,2010; Wong *et al*., 2013), Centre for Epidemiological Studies Depression Scale (CES-D): n = 3 (Brown *et al.,* 2012; Ramasubbu *et al.*,1998; Sit *et al,* 2007), Wakefield Self-Assessment Depression Inventory (WSADI): n = 1 (Wade *et al*., 1987) or a clinician rated measure, MADRS: n = 1 (Nys *et al*., 2005). Three studies assessed participants within the acute stage (≤ three weeks) (Nys *et al*., 2005; Ramasubbu *et al.*,1998; Wade *et al.,* 1987), three studies assessed participants at three months (Brown *et al.,* 2012; Hermann *et al*., 1998; Nannetti *et al*., 2005) one study at four months (Burvill *et al.*,1997); two studies at six, or six to seven, months post stroke (Sit *et al,* 2007; Wade *et al.,* 1987), six studies assessed at one year (Appelros & Viitanen, 2004; Brown *et al.,* 2012; Hermann *et al*., 1998; Hosking & Marsh, 2013; Wade *et al.,* 1987; Wong *et al*., 2013) and one study assessed individuals at five years post stroke (Feigin *et al.*,2010). Nine of the twelve studies used CT

to diagnosis stroke, usually alongside assessment by a suitable medical practitioner. (Appelros & Viitanen, 2004; Feigin *et al.*,2010; Hermann *et al*., 1998; Hosking & Marsh, 2013; Nannetti *et al*., 2005; Nys *et al*., 2005; Ramasubbu *et al.*,1998; Sit *et al,* 2007; Wong *et al*., 2013). Two studies used the World Health Organisation criteria for diagnosis (Burvill *et al.*,1997; Wade *et al.,* 1987) and one study specified that a 'medical diagnosis of stroke' was provided (Brown *et al.*, 2012). None of the included studies reported whether potential confounding variables had been included in their analysis, or reported either justification of their sample size or statistical power.

Quality of included studies.

The quality ratings for each of the included studies on the six quality criteria are presented in Table 2. The quality criteria ratings indicate the methodological strengths and weaknesses of each of the studies in relation to the review question. There was little variation in relation to the measure of functional impairment with all studies utilising a well validated measure, either the BI or mRS. The main difference was in relation to the assessment of depression with those studies utilising diagnostic criteria, as opposed to rating scales, as they are thought to be methodologically stronger. Diagnostic criteria for depression are widely thought to be more robust, as rating scales are less sensitive to the pervasive aspect of depressive disorders. Individuals may score highly for depressive symptomatology on rating scales on the basis of a transient mood state or situational difficulties (Hermann, Black, Lawrence, Szekely & Szalai, 1998). Moreover, one study used a rating scale which has not been evidenced to be valid or reliable within a stroke population (Wade, Leigh-Smith & Hewer, 1987). The majority of the populations from which samples were drawn appear relatively representative of the stroke population. However, the samples recruited from rehabilitation services only (Nannetti, Paci, Pasquini, Lombardi & Taiti, 2005; Sit, Wong, Clinton & Li, 2007) are likely to include those with higher levels of physical and cognitive

disability and are less likely to be representative of the whole stroke population. The size of included samples were relatively large, other than in the study by Hosking & Marsh (2013) (n = 48). The lack of reporting of potential confounding variables in all of the studies impacted on the methodological quality. However, all of the included studies utilised appropriate statistical analysis to answer the review question.

Main findings

The main findings of the review are presented below and are collated into the following time points, post stroke: acute stage (within three weeks), three months, six to seven months, one year and five years. Furthermore, the results of those studies exploring the relationship at more than one time point are discussed in relation to change over time. The findings will be discussed within the context of the main methodological strengths and weaknesses of the included studies.

Acute Stage

Three studies explored the relationship between PSD and functional impairment within three weeks of a stroke event (n = 1131). One study reported significantly higher levels of physical dependency in those with moderate to severe symptoms of depression (self-report) than those with mild levels (P = 0.003) (Nys et al., 2005). Two studies reported a significant association in the relationship between the two variables (r = 0.25 (p = 0.0001), Ramasubbu, Robinson, Flint, Kosier & Price, 1998) and (r = -0.329 (p < 0.01), Wade et al., 1997). However, Wade et al. (1997) reported that in a path analysis model, path coefficient did not reach a significant level, with social function appearing to mediate the relationship between depression and functional impairment. Although all three studies were methodologically sound, the study by Nys et al. (2005) included a much smaller sample than the others (n =

126). Ramasubbu et al. (1998) excluded patients if they were discharged from hospital before the time of assessment (seven to ten days). This may have resulted in sample bias with more individuals with a higher level of medical need or physical disability, which might account for the stronger relationship identified in this study.

Three to four months

Four studies explored the relationship at either three or four months post stroke (n =585). Two studies reported that participants with depression (based on DSM- III/IV diagnostic criteria) were significantly more functionally impaired that those without depression (Burvill, Johnson, Jamrozik, Stewart-Wynee & Chakera, 1997; Nannetti et al., 2005). Two studies reported a significant association between self-reported symptoms of depression and functional impairment (r = 0.264*;* p = 0.01, Brown, Hasson, Thyselius & Almborg, 2012; r = 0.41, p <.*003,* Hermann et al., 1998) and one study found observer rated symptoms of depression were significantly associated with functional impairment (r = 0.40, p <.*003,* Hermann et al., 1998). The strength of the relationships reported by Hermann and colleagues was very similar between self and observer reports. Three of the studies addressing the relationship at this time point were largely representative of the stroke population (Brown et al., 2012; Burvill et al., 1997; Hermann et al., 1998), although Hermann and colleagues (1998) do acknowledge that their sample is from a largely middle-class demographic. The fourth study is likely to be somewhat less representative however, due to the sample being derived from a rehabilitation setting and the exclusion of those with recurrent stroke, previous diagnosis of depression or use of antidepressant medication.

Six months

Two studies explored the relationship between PSD and functional impairment (n = 472). Both reported a significant correlation between the two factors. Wade et al. (1987) reported a stronger relationship (r = -0.473) than that reported by Sit et al. (2007) (r = -0.219). However, only individuals with a level of functional impairment which restricted their participation in previous activities, were included in the Sit et al. (2007) study, which is likely to have biased the sample somewhat. Furthermore, the depression measure used by Wade et al. (1987) is not well validated in a stroke population.

One year

Six of the included studies considered the relationship between PDS and functional impairment at one year following stroke (n= 1048). Five of these studies reported a significant association between these two variables (OR 1.98 (1.58 – 2.48), Appleros & Viitanen (2004); r = -0.243 (p = 0.01), Brown et al. (2012); r = 0.29, r = 0.36 (p *<.003),* Hermann et al. (1998); r = -0.247 (p *<.01;* Wade et al. (1987); OR 1.24 (1.1-1.3), Wong et al. (2013)). One study indicated that the association, although positively correlated, was not significant (Hosking & Marsh, 2013). It is important to note that this study had a considerably smaller sample size (n = 48) than the five which reported a significant association and as such the results should be interpreted with caution. Participants in the Wong et al. (2013) study included only those with an aneurysmal subarachnoid haemorrhage. Interestingly, despite the low prevalence rate of aneurysmal subarachnoid haemorrhage (only 3% of all strokes) (Chau et al., 2011) and its differential management and prognosis (Hermann et al., 1998), this does not appear to have impacted on the strength of the relationship identified.

Table *1*. Characteristics and main findings of included studies

Reference Country	Sample Characteristics	Time of assessment after stroke	Functional Impairment Measure	Depression Diagnosis/ Measure	Main Findings	Limitations
Appleros & Vittanen, 2004 Sweden	N = 253 Mean age = 74.5 years (35-95)	1 Year	mRS	GDS DSM-IV criteria for major depression	Functional impairment is associated with depression at one year on GDS (OR 1.98 (1.58 – 2.48)) and DSM-IV diagnosis (ORs 2.03 (1.63-2.52))	Diagnosis provide by a geriatrician and neurologist rather than a mental health professional.
Brown et al. 2012 Sweden	N = 123/146 Mean age = 73.9 years (32-92)	3 months 1 year	BI	CES-D	Depression and functional impairment were significantly associated at both 3 months and 1 year post stroke (3 months, r = -0.264, one year, r = -0.243, P = 0.01).	Completers at three months were significantly more functionally impaired than non-completers. Completers at one year were significantly younger than non-completers. Self-report measure of depression used only.
Burvill et al. 1997 Australia	N = 191 Mean age = not reported	4 months	BI	DSM – III Criteria	Depressed participants were significantly more functionally impaired with a BI score of less than 16 (24%) than were non-depressed participants (7%) (χ^2 = 10.29, p <0.01).	Mean age and range of participants not reported.
Feigin et al. 2010 New Zealand	N = 418 Mean age = 66.8 years	5 years	BI mRS	GDS	Functional Impairment at five years (BI score ≤ 19) is associated with depressive symptomatology (GDS ≥ 5) (OR 4.58 (2.48 to 8.46))	Self-report measure of depression used only.

Table 1. Characteristics and main findings of included studies *continued*

Reference Country	Sample Characteristics	Time of assessment after stroke	Functional Impairment Measure	Depression Diagnosis/ Measure	Main Findings	Limitations
Hermann et al. 1998 Canada	N =150/133 Mean age = 74.9 years	3 months 1 year	mRS	MADRS SDS	Functional Impairment was significantly correlated with objective depression at 3 months (*r* =0 .40, *p* = .0001*)* and at 1 year *(r* = 0.29, *p* = .001*)* and with subjective depression at 3 months *(r* = 0.41, *p* = .0001*)* and one year *(r* =0.36, *p* = .0001*).*	Depression based on rating scales rather than psychiatric diagnostic assessment.
Hosking & Marsh, 2013 New Zealand	N = 48 Mean age = 74 years (60-87).	1 year	BI	GDS	At 1 year post stroke, depression (GDS > 9) was not significantly correlated with a measure of basic ADL's (BI) (*r* = .18).	Small sample size. Self-report measure of depression used only.
Nannetti et al. 2005 Italy	N= 121 Mean age = 72 years	3 months	BI	GDS DSM-IV diagnostic criteria	Those in the depression group show significantly lower scores on the BI indicating higher levels of functional impairment (*P* < 0.05). Depression group mean BI score = 61.1 (sd =26.0), no depression group, mean BI score = 71.4 (sd =25.5).	Sample only included those requiring admission to a rehabilitation setting.

Table 1. Characteristics and main findings of included studies *continued*

Reference Country	Sample Characteristics	Time of assessment after stroke	Functional Impairment Measure	Depression Diagnosis/ Measure	Main Findings	Limitations
Nys et al. 2005 The Netherlands	N = 126 Mean age = 62.3 years	Within 3 weeks	BI	MADRS	Those with moderate to severe levels of depression (MADRS > 19) had higher levels of physical dependency than those with mild symptoms (MADRS 8-19) or an absence of symptoms (MADRS <8) (Absent: Median BI = 18, Mild: Median BI = 18, Moderate to Severe: Median BI = 9, *P = 0.003)*	Exclusion of those with pre-existing depression. Mean score for BI in each group not reported.
Ramasubbu et al. 1998 Canada and United States of America	N= 626 Mean age = 63.4	7-10 days	BI	CES-D	Scores on the CES-D were negatively correlated with scores on BI (*r* = 0.25, *P* = 0.0001*)*. Participants with depression (CES-D ≥ 16) were functionally significantly more impaired than those without depression (*t* = 5.10, df = 624, *P*<0.0001*)*.	Those who did not complete the CES-D were older and more impaired.
Sit, et al. 2007 Hong Kong	N = 95 Mean age = 67 years	6 months	BI	CES-D	Depression at 6 months was significantly correlated with functional impairment at 6 months (*r* = -0.473, *p*<.001*)*	Included only individuals who had post stroke functional problems that limit participation in previous activities.

Table 1. Characteristics and main findings of included studies *continued*

Reference Country	Sample Characteristics	Time of assessment after stroke	Functional Impairment Measure	Depression Diagnosis/ Measure	Main Findings	Limitations
Wade et al. *1987* UK	N= 379/ 377/348 Mean age = 69.6 years	3 weeks 6-7 months 1 year	BI	WSADI	Scores on a depression measure were correlated with functional impairment at 3 weeks, 6 months and one year (r =-0.329, r =-0.219, r =-0.247 respectively, p<0.01).	Wakefield Depression Scale not validated for the stroke population.
Wong et al. 2013 Hong Kong	N = 120 Mean age = 51 years (21-75)	1 year	mRS	GDS	At 1 year, unfavourable outcome on mRS scores were independently associated with higher GDS scores (OR, 1.24; 95% CI 1.1 to 1.3; p<0.001).	Included only those with aneurysmal subarachnoid haemorrhage.

Key: mRS: Modified Rankin Scale, MDRS: Montgomery Asberg Depression Rating Scale, GDS: Geriatric Depression Scale, CES-D: Center forEpidemiological Studies Depression Scale, BI: Barthel Index, SDS: Zung Self-Rating Depression Scale., WSADI: Wakefield Self- Assessment Depression Inventory

Table 2. Quality criteria

Reference	Representative Sample	Functional impairment measure	Depression measure	Statistical Analysis	Sample size	Missing data
Appleros & Vittanen, 2004	Well covered (3)	Well covered (3)	Well covered (3)	Adequately covered (2)	Not reported (0)	Well covered (3)
Brown et al. 2012	Well covered (3)	Well covered (3)	Adequately covered (2)	Adequately covered (2)	Not reported (0)	Poorly addressed (1)
Burvill et al. 1997	Well covered (3)	Well covered (3)	Well covered (3)	Adequately covered (2)	Not reported (0)	Well covered (3)
Feigin et al. 2010	Well covered (3)	Well covered (3)	Well covered (3)	Adequately covered (2)	Not reported (0)	Well covered (3)
Hermann et al. 1998	Well covered (3)	Well covered (3)	Adequately covered (2)	Adequately covered (2)	Not reported (0)	Well covered (3)
Hosking & Marsh, 2013	Well covered (3)	Well covered (3)	Adequately covered (2)	Adequately covered (2)	Not reported (0)	Well covered (3)

Table 2. Quality criteria *continued*

Reference	Representative Sample	Functional impairment measure	Depression measure	Statistical Analysis	Sample size	Missing data
Nannetti et al. 2005	Adequately covered (2)	Well covered (3)	Well covered (3)	Adequately covered (2)	Not reported (0)	Well covered (3)
Nys et al. 2005	Well covered (3)	Well covered (3)	Adequately covered (2)	Adequately covered (2)	Not reported (0)	Not applicable (0)
Ramasubbu et al. 1998	Well covered (3)	Well covered (3)	Adequately covered (2)	Adequately covered (2)	Not reported (0)	Not applicable (0)
Sit, et al. 2007	Adequately covered (2)	Well covered (3)	Adequately covered (2)	Adequately covered (2)	Not reported (0)	Poorly addressed (1)
Wade et al. *1987*	Adequately covered (2)	Well covered (3)	Poorly addressed (1)	Adequately covered (2)	Not reported (0)	Well covered (3)
Wong et al. 2013	Well covered (3)	Well covered (3)	Adequately covered (2)	Adequately covered (2)	Not reported (0)	Well covered (3)

Key: 1)Sample selected were representative of people who have experienced a stroke/ selection bias considered, 2)Functional ability/impairment measure evidenced to be valid, reliable and appropriate for stroke patients, 3)Depression measure evidenced to be valid reliable and appropriate for stroke patients, 4)Appropriate statistical analysis selected for the study design, 5)Sample size is justified/discussion of statistical power, 6)Details of missing data and participants who did not complete are provided.

Five years

Only one study explored the relationship at five years post stroke (Feign et al., 2010) (n = 418). Functional impairment, as measured by a BI score of ≤ 19, was found to be associated with depressive symptomatology (GDS score of ≥5) (OR 4.58 (2.48 to 8.46). Significant cognitive problems were the only factor more strongly associated with functional impairment than depression. This study is generally methodologically very robust, with a large sample and appropriate statistical analysis. However, there is no indication of whether potentially confounding variables were controlled for in their analysis.

Change over time

Although the primary aim of this study was to identify any potential differences in the strength of this relationship at different time points, three studies explored the relationship at more than one time point. As such, it was thought pertinent to review briefly the literature in relation to change over time. Brown and colleagues (2012) and Hermann and colleagues (1998) both assessed participants at three months and one year post stroke. Wade and colleagues (1987) assessed participant at three weeks, six to seven months and one year. The results with regard to changes in this relationship, are somewhat ambiguous. Brown et al. (2012) reported a very similar strength of association at three months (r = -.264, p = 0.01) and at one year (r = -.243, P = 0.01). Hermann et al. (1998) reported a stronger relationship between functional impairment and objective depression at three months, than at one year (r =.40, p =.0001*;* r = .29, p = .001). Similarly, when a subjective measure of depression was used the relationship was stronger at three months than at one year (r = .41, p = .0001*;* r = .36, p = .0001). In contrast to these findings, Wade et al. (1987) reported that the strength of the relationship decreases between three weeks and six/seven months post stroke, before getting stronger again, albeit it only slightly, at one year post stroke (r = .329, r = .219, r= .247, respectively, p <0.01). Each of the studies used rating scales of depression rather than

diagnostic criteria, however, as previously mentioned, the scale used by Wade et al. (1987) the Wakefield Depression Inventory has not been validated within a stroke population. Furthermore the Wade study was based on a community sample (24% of whom had not been admitted to hospital following their stroke). The Hermann et al. (1998) and Brown et al. (2012) samples were identified from inpatient stroke units. This methodological heterogeneity may account for some of the differences in findings.

Discussion

Summary and discussion of main findings

The aims of this review were to identify any differences in the relationship between functional impairment and psychological distress at different stages of recovery and to explore whether this relationship changes over time. Unsurprisingly, the results of the review of the twelve included studies indicate that the presence of depressive symptoms or a diagnosis of depression are associated with higher levels of functional impairment in the acute stage (within three weeks), at three months, six to seven months, one year and five years post stroke, as previously reported in the literature (e.g. Hackett &Anderson, 2005). Secondly, this review aimed to examine possible changes in this relationship over time.

The results of this review do not make it possible to make definitive conclusions regarding the aims of this study with regard to differences in the relationship at different stages of recovery, or over time, which can be applied to the whole stroke population. When data from the included studies was synthesised, there was no evidence of this relationship being of different strengths at different time points following stroke, or of the relationship changing over time. Generally, there was little variation evident in the strength of this relationship at different time points, with similar effect sizes being reported. Although the included studies

are generally of a relatively high methodological quality, the total sample is not a homogenous one. There are a number of methodological differences between the studies which may account for the inconclusive results. The differences in sampling and in the measurement of depression have previously been identified and may well contribute to the inconclusive results. Furthermore, the identification, and controlling of, potentially confounding factors may also have played a significant role in the inconclusive results. For example, pre morbid depression or functional impairment, stroke severity, cognitive impairment, impairment in other activities of daily living and social support may all act us potentially mediating or moderating variables in this relationship. Interestingly, as mentioned previously, one study reported that social function appeared to mediate the relationship between depression and functional impairment (Wade et al., 1987). Similarly, Hosking & Marsh (2013) reported that at one year post stroke, functional impairment as measured by extended Activities of Daily Living (ADL's) (Nottingham Extended ADL) was significantly associated with depression (r = -.32, p = .027), but when measured by basic ADL's (BI), no significant association with depression was found (r = .18).

Treatment provision was another variable which was largely not accounted for within the included studies. Of the twelve included studies, only one provided detailed information regarding the level of intervention provided to individuals. Four studies provided information regarding antidepressant use, but provided no indication of treatment for physical impairment, one study stated that rehabilitation was provided as required and the final four studies did not indicate the presence or level of any intervention. Furthermore, the majority of studies did not provide any information regarding the stroke severity of participants. This impacts further on the heterogeneity of the studies and the conclusions that can be drawn.

Based on rehabilitation studies (Pollock et al., 2014) and theoretical models of adjustment (e.g. Livneh & Antonak, 2007), it may have been expected that the relationship between depression and functional impairment would be weaker in later stages of recovery, either due to individuals regaining their independence and recovering their functional abilities or as a result of individuals adjusting and adapting to their physical impairments. The results of this review with regard to the initial aims did not provide support for this hypothesis. This may well be the result of the methodological heterogeneity and weaknesses outlined above. However, it may also be more suggestive of the model proposed by Taylor et al. (2011), which highlights the importance of viewing adjustment as a fluid and dynamic process rather than a staged one.

Measurement of constructs

The validity of both diagnostic criteria of depression and self-report or observer rated measures have previously been questioned, with the focus on symptom severity and frequency of depressive symptoms in diagnostic criteria being insensitive to qualitative changes in symptomatology and some depression measures being overly sensitive and inflating estimates (Hermann et al., 1998). Within this review, there was little evidence to suggest that the method of identifying depression affected the strength of the reported association between PSD and functional impairment. In fact, a particular strength of this review is the stringency in relation to the measurement of constructs. The inclusion of well validated measures and diagnostic criteria, which measure the constructs defined in the review question, increases the methodological strength of the review. With regard to the diagnosis/measurement of depression, only one study utilised a rating scale which has not been well validated in a stroke population (Wade et al., 1997).

However, the majority of papers dichotomised rating scales and reported only the presence or absence of depression and functional impairment. In relation to the measurement of

functional impairment, it has been proposed that a continuous, interval scale, such as the Academic Medical Center Linear Disability Score (ALDS), would improve measurement of disability/impairment and provide a more meaningful measure than the ordinal scales, such as the Barthel Index or Modified Rankin Scale, typically used in stroke research (Chaisinanunkul et al., 2014). Similarly, despite diagnostic criteria of depression being given more weight with regard to methodological strength, it is possible that total scores of rating scales may be more clinically robust than diagnostic criteria or the dichotomisation of scales which identify only the presence or absence of depressive symptomatology.

Limitations

The limitations of this review, in relation to the methodological weaknesses and differences of the included studies, have been outlined above. The possible role of these limitations in the inconclusive results of the review, and the subsequent impact on the generalisability of the results to the wider stroke population, have been explored.

Due to the cross sectional design of the included studies and the correlational and comparison of means analysis utilised, it is of course also not possible to make assumptions regarding the direction of these relationships, e.g. whether higher levels of functional impairment lead to higher levels of depression or vice versa. A better understanding of the direction of this relationship is pertinent in applying targeted screening and interventions.

A further limitation of this study is the exclusion of unpublished studies and those not published in English. As a result it is possible that studies that may have helped to answer the review question have been excluded.

Clinical implications and future research

Clinically, identifying possible differences in the relationship between functional impairment and depression at different stages of recovery post stroke, is important in the development of screening and intervention for post stroke depression. Anecdotal clinical experience suggests

that individuals are more likely to be involved with support services as a result of their physical impairments rather than psychological distress. The identification of individuals who are more likely to experience depression based on their level of functional impairment at a specific time point, post stroke, would allow for targeted screening of such individuals. Targeted screening would increase the recognition of any psychological difficulties in individuals following stroke and would allow for the implementation of appropriate and timely interventions. Clinically, this may allow for brief psycho-educational interventions to be offered by individuals already involved in a patient's care (e.g. community stroke nurses, physiotherapists or occupational therapists) which may reduce the longer term requirement for specialist psychological support and a subsequent reduction in health care costs.

Increasing the previously recognised low rates of intervention for post stroke depression (Hackett et al., 2005) is pertinent in reducing the long term costs of post stroke care. A well designed study, addressing some of the methodological limitations addressed above, may contribute considerably to our understanding of this relationship. A longitudinal repeated measure designs would be most appropriate in addressing not only the question regarding the differences in this relationship at different stages of recovery, but also the way in which it changes over time. The biopsychosocial model of PSD (Mast & Vedrody, 2006) suggests that neuroanatomical, cognitive and functional deficits should be highlighted in the formulation of the onset, maintenance and course of PSD. Further research into the variables highlighted above would provide further evidence, or otherwise, for the applicability of this model.

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Part 2: Journal Article

The role of cognitive impairment, perceived social support and perceived control in psychological distress following stroke.

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Abstract

Emotional difficulties, such as depression, following stroke are now increasingly recognised as common sequelae. There is evidence within the stroke literature to suggest that higher levels of cognitive impairment are associated with higher levels of psychological distress post stroke. The aim of this study was to further develop the understanding of psychological distress, post stroke, by exploring the possible moderating effects of perceived social support and perceived control on the relationship between cognitive impairment and psychological distress, post stroke. Forty participants were recruited from NHS Tayside's stroke services and took part in the study. Three self-report measures (Recovery Locus of Control Scale, Hospital Anxiety and Depression Scale and The MOS – Social Support Survey) and a demographic questionnaire were completed by individuals, along with a clinician administered brief cognitive assessment (ACE_III). Data was summarised using descriptive statistics. The association of each of the independent variables with the dependent variable, psychological distress, was assessed using Pearson's correlation coefficient. None of the independent variables were significantly related to psychological distress. As such, the planned moderation analysis did not take place. The results of the current study are discussed in relation to those of the existing literature base. Future research should seek to further investigate the cognitive and psychosocial factors associated with post stroke psychological distress.

Introduction

Stroke

Stroke is the leading cause of severe disability in adulthood in Scotland and is the third most common cause of death (SIGN, 2010). It is estimated that there are approximately 12 500 new incidents of stroke per year in Scotland and at any given time approximately 70 000 people are living with the consequences of stroke (SIGN, 2010).

Psychological sequalae of stroke

Mental health difficulties following stroke can act as a significant contributor to difficulties in post stroke adjustment and recovery. Primarily, the research literature around post stroke adjustment has focused on post stroke depression (PSD), however other factors such as quality of life have also been explored (e.g. Teoh, Sims & Milgrom, 2009). A recent systematic review reported that the prevalence of a depressive disorder within one month post-stroke ranged from 11 to 55%, with eight studies included in the review, reporting major or moderate to severe depression in 17 to 27% of their sample (Kouwenhoven, Kirkevold, Engedal & Kim, 2011). Ambiguous findings were reported in this review by Kouwenhoven and colleagues (2011) in relation to patterns of post stroke depression following the acute phase, with some studies suggesting that the prevalence of PSD decreases at 3, 6, 9 and 12 months, others suggesting it remains relatively stable and others concluding that the incidence rate increases from the acute phase to 3 months post stroke. A recent meta-analysis did not report any significant differences in prevalence at different time points post stroke or in studies of different settings (Ayerbe, Ayis, Wolfe & Rudd, 2013). Pre-stroke depression or psychiatric diagnosis have been found to be predictive of post stroke depression (Kouwenhoven et al., 2011; Ayerbe et al., 2013). Associations were also identified between high neuroticism scores and unstable high self-esteem and the development of PSD (Kouwenhoven et al., 2011). However, many of the studies included in both of these reviews, excluded individuals on the basis of past psychiatric history and

cognitive status. Furthermore, assessment methods vary with some prevalence rates based on a diagnosis and others on 'caseness'. As such, the findings may not provide an accurate overview of the prevalence of depression in the stroke population.

Rates of anxiety following stroke are thought to be at a similar level to those of depression (De Wit et al., 2008), with prevalence rates estimated to be between 22% -25% in a sample of rehabilitation centre patients (De Wit et al., 2008) and, similarly, 28% in a population based sample (Astrom, 1996). Despite anxiety being identified as the second most common emotional disorder following stroke, it has been paid significantly less attention than depression in the research literature (Castillo, Starkstein, Fedoroff, Price & Robinson, 2006). The under-diagnosis of anxiety in general older adult populations is well recognised (Frazier & Waid, 1993).

For some, emotional difficulties may be experienced throughout their recovery and for others they have a more sudden and unexpected onset, often following discharge from services (Tyerman, 2013). The failure to address the emotional needs of individuals throughout their rehabilitation period and thereafter can have a serious impact on an individual's ability to progress in rehabilitation and to adjust to their condition in the longer term (Tyerman, 2013).

There is a small but growing body of stroke literature concerned with predictors of post stroke psychological distress and adjustment. There is some evidence to suggest that stroke severity is associated with post stroke depression in the acute phase (Berg, Palomaki, Lehtihalmes, Lonnqvist & Kaste, 2001) and at 18 month follow-up (Berg, Palomaki, Lehtihalmes, Lonnqvist & Kaste, 2003). There has been some discussion, without

conclusion, around the role of lesion location (right or left hemisphere) in the relationship between stroke severity and post stroke depression with some evidence to suggest that left hemisphere strokes are more predictive of depression (Berg et al., 2001; Bolla-Wilson, Robinson, Starkstein, Boston & Price, 1989)

Cognitive impairment

Estimates of cognitive impairment following stroke vary somewhat, with recent studies reporting rates of 55% (Nys et al., 2007) to 78% (Lesniak, Bak, Czepiel, Seniow & Czlonkowska, 2008) in the very early phase post stroke. One study reported that executive functioning and visuoperception/constructional abilities were the most commonly impaired (Nys et al., 2005), whilst another reported that the domains most frequently impaired were attention, language, short term memory and executive functioning (Lesniak et al., 2008).

Cognitive impairment has been found to be associated with post-stroke depression at three and twelve months post stroke (Kauhanen et al., 1999), with higher levels of cognitive impairment related to higher levels of depression. Cognitive impairment at baseline was found to be predictive of depression at three months and one, three and five years (Ayerbe, Ayis, Rudd, Heuschmann & Wolfe, 2011). Severity of depression and cognitive function were found to be significantly related, with participants with moderate to severe depression experiencing significantly more cognitive impairment than those with mild or no symptoms of depression (Nys et al., 2005). More specifically, those with moderate to severe depression were more impaired on domains of visuoperception, memory and language than those with mild or no symptoms of depression. It should however be noted that individuals within this study were assessed in the acute stage, post stroke (within three weeks), when cognitive impairment may be more pronounced and individuals are trying to accept and adjust to their

condition. At one year post stroke, impairment in attention was still the most common difficulty (Nys et al., 2005). Executive dysfunction has also been found to be associated with PSD (Pohjasvaara et al., 2002). Furthermore, impairment in expressive communication was found to significantly predict emotional distress (measured using The Visual Analogue Self Esteem Scale) at one and six months, post stroke (Thomas & Lincoln, 2008). Distress levels at one month and six months were similar. A significant strength of the Thomas and Lincoln (2008) study was the inclusion of those with Aphasia; this group of individuals are often excluded from PSD research.

Perceived control

Psychosocial predictors, for example, health locus of control and social support, have also gained more attention within the literature. Studies researching the construct of locus of control, generally hypothesise that individuals with an internal locus of control will take more active participation in their health care, will engage in more adaptive behaviours and subsequently experience less psychological distress than those with an external locus of control (Wallhagen, Strawbridge, Kaplan, & Cohen, 1994). Research into the role of health locus of control in post stroke psychological distress is limited. Thomas and Lincoln (2006) found that individuals that remained severely depressed at six month follow-up had an external locus of control as well as impairment in communication. However, the results of their study are likely to be biased as they do not represent a whole stroke cohort due to a diagnosable depressive disorder at recruitment being an inclusion criterion. Similarly, Morrison Johnston and MacWalter (2000) reported that lower levels of internal perceived control was significantly correlated with higher levels of both anxiety and depression. However, within their regression analysis, locus of control was not predictive of anxiety or depression outcome; it was suggested that this may be mediated by the role of satisfaction with treatment and confidence in recovery. Qualitatively, a reduction in mood disturbance

has been linked to an internal health locus of control (White et al., *2012)*. Higher rates of post stroke fatigue have also been associated with those with a locus of control more directed to powerful others (Schepers, Visser-Meilly, Ketelaar & Lindeman, 2006).

Outwith the stroke population, an internal locus of control was strongly associated with lower levels of depression in patients aged 65 years or above, registered with two GP Practices (Harris et al., 2003). Similarly, in a community sample of older adults (aged 60 years or older), an external locus of control was found to contribute to levels of distress, anxiety sensitivity and hypochondriasis (Frazier & Wade, 1999). A review identified external locus of control as a strong prognostic factor of depression in the older adult population, in general practice or the community, based on eight community studies (Licht-Strunk, van der Windt, van Marwijk, de Haan, & Beekman, 2007).

Social support

Levels of emotional support and social ties have been identified as predictors of level of, and change in, cognitive outcome and as playing a vital role in promoting cognitive resilience and protecting against impairments in cognition (Glymour, Weuve, Fay, Glass & Berkman, 2008). Similarly, King, Shade-Zeldow, Carlson, Feldman & Philip, (2002) found lower social support to be a significant predictor of higher levels of depressive symptomatology at acute rehabilitation phase and at two years post discharge. In a sample of hospitalised patients, low perceived social support was found to be associated with depression (Morris, Robinson, Raphael & Bishop., 1991*)*. The inpatient sample and small size of this study are, however, likely to impact on the generalisability of such findings. Lack of family support was associated with twice the prevalence of depression at three months and one, three and five years follow up in a population based study (Ayerbe et al., 2011) and low satisfaction

with social network at baseline predicted distress at six months (Hilari et al., 2010). Lower levels of social contact are also associated with generalised anxiety disorder at three months and one, two and three years post stroke (Astrom, 1996).

Psychological distress

Although there is a growing body of literature exploring predictors of post stroke depression, there is a paucity of research investigating anxiety post stroke (Barker-Collo, 2007) and predictors of it (Campbell Burton et al., 2013), despite, for example, the significant prevalence rates of anxiety in relation to a fear of recurrence of stroke (56%) (Townend, Tinson, Kwan & Sharp, 2006). Clinical experience suggests that depression and anxiety rarely happen in isolation, especially in the adjustment to a health event such as a stroke. Furthermore, there is little evidence in the literature which would allow for the easy identification of individuals who are at the highest risk of developing post stroke psychological distress (Hackett & Anderson, 2005). The term psychological distress will be used, from here on in, to refer to a combination of symptoms of anxiety and depression causing emotional suffering, as proposed by Drapeau, Marchand & Beaulieu-Prévost (2012). Drapeau and colleagues (2012) suggest that psychological distress is "the exposure to a stressful event that threatens the physical or mental health, the ability to cope effectively with this stressor and the emotional turmoil that results from the ineffective coping" (p.105). They suggest that psychological distress, if not addressed may lead to clinically significant levels of depression and/or anxiety. The clinical utility of the construct of psychological distress was identified as a way of increasing our understanding of post stroke adjustment, by capturing those that experience symptoms of anxiety, depression and a combination of both.

Aims of Study

The current literature indicates relationships between higher levels of cognitive impairment, externality of perceived control and lower levels of perceived social support, and higher levels of depression and anxiety. The aim of this study is to explore the possible moderating effects of perceived social support and perceived control on the relationship between cognitive impairment and psychological distress, following stroke. It is hypothesised that 1) higher levels of cognitive impairment will be associated with higher psychological distress, 2) an external locus of control will be associated with higher psychological distress, 3) lower perceived social support will be associated with higher psychological distress, and 4) perceived control and perceived social support will moderate the relationship between cognitive impairment and psychological distress. That is, the strength of the relationship between cognitive impairment and psychological distress will differ at different levels of social support and locus of control; cognitive impairment will be more strongly associated with psychological distress at higher levels of externality of control and at lower levels of perceived social support.

As already noted, the literature suggests that cognitive impairment, locus of control, and perceived social support all independently contribute to higher levels of psychological distress. This study proposes that locus of control and perceived social support may also moderate the relationship between cognitive impairment and psychological distress. Higher levels of perceived social support will likely provide individuals with companionship and access to enjoyable activities, despite levels of cognitive impairment, which are likely to act as buffers to psychological distress. The risk of the co-occurrence of depression and cognitive impairment has been found to be increased in those with higher levels of dissatisfaction of social support (Fuhrer, Antonucci & Dartigues, 1992). It is also proposed that those who believe they have a role to play in their own recovery, and take an active role,

following a stroke are likely to experience less psychological distress, despite higher levels of cognitive impairment.

No study to date has explored the potentially moderating effect of perceived social support and perceived control on the relationship between cognitive impairment and psychological distress. This study aims to rectify this gap in the literature as it is an important area for consideration. Should perceived control and perceived social support be found to moderate the relationship between cognitive impairment and psychological distress, these variables can be screened for in the acute phase and targeted by time limited interventions.

Methods

Study design and participants

A cross-sectional study was conducted. Participants were recruited from NHS Tayside's stroke services (hospital inpatient, rehabilitation inpatient, outpatient and community exercise classes). Potential participants were identified by stroke clinicians by reviewing their case-loads. Individuals, who were identified by clinicians as meeting the inclusion/exclusion criteria, were provided with a brief overview of the research and asked if they would be interested in taking part or in finding out more about the study. Individuals interested in the research were asked for their consent for their contact details to be passed to the Chief Investigator and were provided with a patient information sheet (Appendix 3). They were then contacted by the Chief Investigator by telephone. This allowed interested individuals to ask any questions they had about the research. Individuals who wished to participate provided their verbal consent and an appointment was arranged for the Chief Investigator to meet with them either at home or in clinic. Participants met with the Chief Investigator on one occasion to complete the study. Written consent was gained from each

individual before they participated. Participation typically lasted approximately one hour. The General Practitioner of every participant was informed of their patient's participation in the study.

Sixty three individuals consented to discuss participation. Of these, forty provided informed consent and participated in the study. Eight participants did not complete the study as they had been incorrectly identified as meeting the inclusion criteria, determined by information provided by the referring clinician or by self-report, (three were not within correct time frame since stroke, two had a diagnosis of TIA, two were too cognitively impaired or aphasic to participate, and one was not fluent in English). Four individuals were not contactable, one was deceased, one had a further stroke, one was excluded due to ongoing drug misuse and eight declined to take part.

Ethical approval

Ethical approval was sought from and granted by the University of Edinburgh, School of Health in Social Science and the East of Scotland Research Ethics Service (Appendix 4). Approval was also granted by NHS Tayside's Research and Development department (Appendix 5).

Inclusion/exclusion criteria

The principal inclusion criteria were 1) 18 years or older, 2) ability to give informed consent, 3) diagnosis of stroke in the six to twelve months prior to participation, 4) a diagnosed ischaemic, haemorrhagic or subarachnoid haemorrhagic stroke. Individuals were excluded if they 1) had pre-morbid cognitive deficits, 2) current cognitive impairment, aphasia, hearing or visual impairments to the extent that completion of questionnaires with assistance would

not be possible, 3) diagnosis of a Transient Ischemic Attack, 4) not fluent in English. Stroke diagnosis and date of stroke were ascertained by review of medical notes by referring clinicians. Referring clinicians screened individuals for compliance to the inclusion/exclusion criteria on the basis of their clinical knowledge of the individuals or by reviewing medical notes where appropriate. The Chief Investigator confirmed every participant met the inclusion/exclusion criteria by requesting information from each individual in relation to their age, time and diagnosis of stroke and pre-morbid cognitive deficits. Clinical judgement was utilised in order to ascertain ability to give informed consent, current impairment and English fluency. Taking other studies into consideration, six to twelve months was chosen as the most appropriate time period post stroke. This allowed for the initial stages of recovery and period of adjustment, whilst still remaining close enough to the stroke event and thus reducing potentially confounding variables. It has been suggested that by approximately six months post stroke, an individual's physical and social recovery has largely plateaued and any longer term difficulties are more easily identifiable (Gillham & Clark 2011). Although individuals with subarachnoid haemorrhage have often been excluded from previous research (e.g. Hermann, Black, Lawrence, Szekely & Szalai, 1998) due to the differential management and prognosis, it was thought pertinent to include such individuals in order to provide a representative sample of those accessing stroke services within NHS Tayside. Furthermore, it is hoped that the scientific rigour of this study will provide a representative picture of stroke patients; previous research has often excluded participants on the basis of e.g. language impairment or pre-morbid depression (e.g. Nys et al, 2005) or, for example, included a sample derived from a rehabilitation setting only (e.g. Nannetti, Paci, Pasquini, Lombardi & Taiti, 2005).

Measures

Demographic information regarding participant's age, sex, marital status, education level, pre-morbid psychiatric treatment and pre-morbid cognitive concerns was collected by means

of a questionnaire (Appendix 6). The Addenbrooke's Cognitive Examination III (ACE-III) (Hsieh, Schubert, Hoon, Mioshi & Hodges, 2013) (Appendix 7), measuring five cognitive domains: attention, memory, verbal fluency, language and visuospatial abilities, was used to provide a clinician administered measure of cognitive impairment. The measure has a maximum total score of 100, with lower scores indicating higher levels of cognitive impairment. It replaces the Addenbrooke's Cognitive Examination – Revised (ACE-R) and has been found to be highly correlated to the ACE-R. It has been validated against a number of standardised neuropsychological tests and the domain scores have been found to be highly correlated with the targeted tests (Hsieh et al., 2013). Adequate sensitivity (83%) and specificity (73%) of the measure within the stroke population have been reported (Pendlebury, Mariz, Bull, Mehta & Rothwell, 2012).

The Recovery Locus of Control Scale (Partridge & Johnston, 1989) (Appendix 8) was used to measure perceived control over recovery. This is a nine item self- report measure consisting of five internal items and four external items. Each item is rated on a five point scale (strongly agree, agree, uncertain, disagree, strongly disagree) with each item given a score between one and five. A higher total score indicates higher internality of control. This measure is shown to have good internal consistency and construct validity (Partridge & Johnston, 1989).

A total score on the Hospital Anxiety and Depression Scale (HADS) (Zigmond & Snaith, 1983) (Appendix 9) was used to represent psychological distress. The HADS is a widely used standardised measure comprised of 14 self-report items. Typically the scores of the two subscales are used to measure anxiety and depression as separate constructs. However, the validity of the total score as a measure of psychological distress has been supported

(Crawford et al, 2001), with scores ≥12 used as a cut off. Each item is scored from 0 to 3, with a total maximum score of 46; a higher score indicates higher levels of psychological distress. In a stroke population the measure was found to have acceptable sensitivity (78.1%) and specificity (74.6%) (Aben, verhey, Lousberg, Lodder & Honig,. 2002) and has been recommended for use as a brief mood screening measure with this population by NICE (Gillham et al., 2011). Scores on each of the subscales will also be collated to ensure that any effects on the separate constructs of anxiety and depression are not missed by using a total score only.

Perceived social support was assessed using The Medical Outcomes Study (MOS) Social Support Survey (Sherbourne & Stewart, 1991) (Appendix 10). The nineteen item measure assesses four dimensions of social support: emotional/informational, tangible, affectionate and positive social interaction. Respondents are asked to indicate how often a certain type of social support is available to them on a five point scale (none of the time, a little of the time, some of the time, most of the time, all of the time) scoring from 1 to 5. Total scores range from 19 – 95, with a higher score indicating a higher level of perceived social support. The internal reliability of the MOS Social Support Survey has been demonstrated (Cronbach's alpha - 0.97) (Sherbourne & Stewart, 1991).

Statistical analysis

A formal sample size calculation was completed using GPOWER* (version 3.1). Based on a medium effect size (ρ = .3) at an alpha level of .05 and power of .80, a suggested required sample size of 64 for correlational analysis was provided.

The data was analysed using the statistical computer package IBM SPSS Statistics Version 19. Data was summarised using descriptive statistics. The association of each of the control and independent variables with the dependent variable, psychological distress, was assessed using Pearson's correlation coefficient or Spearman's Rho where appropriate. Potentially confounding variables such as age, gender and time since stroke, were controlled for in the analysis. In order to explore any moderating effects of perceived social support and perceived control on the relationship between cognitive impairment and psychological distress, cross sectional moderation analysis, using the PROCESS custom dialog box in SPSS, was planned. Unfortunately however, the sample size and the results of the correlation analysis did not allow for the moderation analysis to be conducted. The differences in scores on measures of cognitive impairment, perceived social support and perceived control, between individuals who did and did not report psychological distress, anxiety and depression were also compared using independent samples t-tests or Mann Whitney U where appropriate. The relationship between cognitive impairment and psychological distress was further explored by exploring those with 'low' and 'high' score on the measures of perceived social support and perceived control separately.

To test for normality, outliers and any input/coding errors, histograms and Q-Q plots were visually explored. Variance within the main variables was as expected; there was no evidence of floor or ceiling effects. A Kolmogorov – Smirnov test was subsequently run. The scores on the HADS, $D(40) = 0.119$, $p = .165$, RLOC, $D(40) = 0.121$, $p = .143$ and ACE-III, $D(40) = .115$, $p = .200$, did not deviate significantly from a normal distribution. However, scores on the MOS-Social Support Survey, $D(40) = 0.166$, $p = .007$, were significantly non - normally distributed with skewness of -.703 ($SE = .374$) and kurtosis of -.008 ($SE = .733$). The relationship between this variable and the dependent variable was analysed using non-parametric tests. Prior to conducting correlational analysis, scatterplots

of the variables were examined. Pearson's correlation was used to analyse the relationship between the normally distributed variables. Spearman Rho Correlation Coefficient, the non-parametric equivalent, was used to analyse the data that was not normally distributed. Each of the measures used within the study had high reliability: HADS, Cronbach's α = .875, RLOC, Cronbach's α = .767, ACE-III, Cronbach's α = .892 and MOS-Social Support Survey, Cronbach's α = .958.

Results

Participant characteristics and descriptive statistics

The key demographic information of participants are detailed in Table 3. The mean age of participants was 67.3 years (± 12.43). Participants completed the study at a mean of 32.2 weeks (± 9.0) post stroke. Sixty per cent of the sample were male (*n = 24)*. Twenty five per-cent (*n* = 10) indicated that they had received treatment/support for a mental health difficulty prior to their stroke. Two participants (5%) reported expressing concerns to their GP about their memory prior to their stroke. The marital status of participants was 50 % married/living with partner, 22.5% single, 17.5 % divorced and 10% widowed. Forty seven and a half per cent of the sample lived alone. The majority of participants (75%) completed between nine and twelve years of education; 22.5 % completed thirteen years or more and 2.5%, completed eight years or less. The majority of participants were living in their own homes (97.5 %); only one participant resided in an inpatient rehabilitation service at the point of assessment.

Table 3. Participant Characteristics

Variable	Total N = 40	
	N or Mean	*% or SD*
Age (years)	67.3	±12.4
Time since stroke (weeks)	32.2	±9.0
Sex		
Female	16	40
Male	24	60
Marital Status		
Married/Living with Partner	20	50
Single	9	22.5
Divorced	7	17.5
Widowed	4	10
Living Alone	19	47.5
Years of Education		
< 8 years	1	2.5
9-12 years	30	75
≥ 13 years	9	22.5
Pre morbid mental health difficulties	10	25
Pre morbid memory concerns	2	5
Living Arrangement		
Own home	39	97.5
Rehabilitation ward	1	2.5

Descriptive statistics of the main variables are detailed in Table 4. Based on the total score cut off suggested by Crawford *et al* (2001) of twelve, scores on the HADS indicated that 50 % (n = 20) of the sample reported clinically significant levels of psychological distress. The more widely used cut off scores of ≥ 8 on the sub scales of anxiety and depression (Zigmond & Snaith, 1983), indicated a 35% incidence rate of anxiety and a 30% incidence of depression in the sample. Individuals who reported receiving support or treatment for a mental health difficulty prior to their stroke, reported higher levels of psychological distress (M = 19, SE = 1.81) than those who did not (M =10.83, SE = 1.33). This difference, 8.17, BCa 95% CI [4.01, 12.44] was significant, t (38) = 3.22, p = *.003.*

The main variables, along with each of the control variables, were entered into the correlation matrix. The results of the correlational analysis of the main variables are detailed

in Table 5. With regard to the control variables, age was significantly related to psychological distress, r = -.338, 95% BCa [-.605, -.021], p = .033, with higher levels of psychological distress being negatively correlated with age. Age was also significantly related to level of perceived social support with a moderate effect size, r_s = .373, 95% BCa [.116, .574], p = .018, with higher age positively correlated with higher levels of perceived social support. Time since stroke was significantly negatively correlated with the memory subscale of the ACE-III used to measure cognitive impairment, r = -.342, 95% BCa [-.609, -.033], p = .031, indicating that increased time since stroke was related to lower levels of memory difficulties. As would be expected, the anxiety and depression subscales of the HADS were significantly related, r = .615, 95% BCa [.290, .810], p <.001.

Table 2. Mean scores and standard deviations of main variables

Variable	*Mean*	*(SD)*
Psychological Distress[a]	12.88	(7.73)
Anxiety	6.70	(4.47)
Depression	6.40	(3.84)
Perceived social support[b]	73.72	(17.42)
Perceived control[c]	36.25	(4.74)
Cognitive Impairment[d]	79.97	(13.29)
Attention	15.85	(2.77)
Memory	19.15	(5.12)
Fluency	8.07	(3.14)
Language	23.20	(3.02)
Visuospatial	13.70	(2.86)

[a]Hospital Anxiety and Depression Scale [b]MOS- Social Support Scale [c]Recovery Locus of Control Scale [d]ACE-III.

Hypothesis driven results

Firstly, it was hypothesised that higher level of cognitive impairment would be associated with higher levels of psychological distress. Cognitive impairment was not significantly related to psychological distress, r = -.099, 95% BCa [-.390, .142], p = .542. Secondly, it was

hypothesised that externality of perceived control would be associated with higher levels of psychological distress. Perceived control was not significantly related to psychological distress, r = -.232, 95% BCa [-.492, .108], p = .149. The two variables are however correlated in the hypothesised direction despite not being significantly correlated. Thirdly, it was hypothesised that lower levels of perceived social support would be associated with higher levels of psychological distress. Perceived social support was not significantly related to psychological distress, r_s = -.222, 95% BCa [-.560, .144], p = .169. Although not significantly related, the variables are correlated in the hypothesised direction. Partial correlation was also conducted to control for any effect of the demographic variables of age, gender, time since stroke, previous treatment for a mental health difficulty, previous memory concerns and education level. No significant relationships between any of the three independent variables and psychological distress were identified. This analysis did however indicate a significant correlation between the fluency subscale of the ACE-III and the depression subscale of the HADS, r = -.399, 95% BCa [-.738, .003], p = .019.

Table 3. Results of correlation analysis of main variables

	Perceived Control	**Cognitive Impairment**	**Perceived Social Support**
Psychological distress	- .232	-.099	#-.222
Perceived Control	-	.096	#.206
Cognitive Impairment		-	# .078

Non-parametric test – Spearman's rho

The fourth hypothesis of this study was that perceived social support and perceived control would moderate the relationship between cognitive impairment and psychological distress. Unfortunately, due to a combination of the small sample size and the absence of any

significant relationships between the proposed independent variables and the dependent variable, it was not possible to enter the variables into the planned moderation analysis.

Despite the planned moderation analysis not being possible to complete, it was thought pertinent to further explore whether the relationship between cognitive impairment and psychological distress was different at different levels of perceived control and perceived social support. As such, participants were divided into two groups based on their scores on each of the measures of the proposed moderating variables (perceived control and perceived social support) using a median split.

When the relationship between cognitive impairment and psychological distress was explored using only those with a 'low' score (below the median score of 35.5) on the measure of perceived control (indicating a higher internality of control) no significant relationship was identified (r = .108, 95% BCa [-.270, .439], p = .650). Similarly, when only participants with 'high' scores (above the median score of 35.5) on the measure of perceived control (indicating a higher externality of control) where included in the analysis, no significant association between the two variables was identified (r = -.247, 95% BCa [-.646, .193], p = .294).

When the relationship was explored using only those with 'low' scores (below the median split of 80, indicating lower levels of perceived social support) on the measure of perceived social support, again no significant relationship between cognitive impairment and psychological distress was identified (r = .191, 95% BCa [-.215, .546], p = .433). However, a significant association was identified between cognitive impairment and psychological distress when only those individuals reporting 'high' levels of perceived social support were included in the analysis (r = -.488, 95% BCa [-.721, -.227], p = .025). This indicates that

higher levels of cognitive impairment are significantly associated with higher levels of psychological distress in those reporting 'high' levels of perceived social support.

Discussion

Summary of main findings

The rationales for the hypotheses proposed in this study were well supported by the current literature (e.g. Kauhanen et al., 1999; King et al., 2002; Thomas & Lincoln, 2006). However, the anticipated relationships between the independent variables (perceived social support, perceived control and cognitive impairment) and psychological distress were not supported by the results of the current study, even when potentially confounding variables were controlled for. As a result, the final hypothesis that perceived social support and perceived control would act as moderators in the relationship between cognitive impairment and psychological distress, was not possible to explore.

A significant relationship was identified between cognitive impairment and psychological distress in those reporting 'high' levels of perceived social support but not in those reporting 'low' levels of perceived social support. This suggests that the relationship between cognitive impairment and psychological distress does differ at different levels of perceived social support within this sample. However, this result is somewhat surprising as it was hypothesised that the association between higher levels of cognitive impairment and higher levels of psychological distress would be stronger in those reporting lower levels of perceived social support. There was no indication of insufficient variance on any of the variables in either the 'low' or 'high' groups which may account for this unexpected result. One possible, but tentative, explanation for this finding is that more cognitive demands are placed upon those with higher levels of social support in maintaining relationships, attending

sociable activities etc. This may have the effect of highlighting the impact of higher levels of cognitive impairment with the subsequent result of higher levels of psychological distress. Of course, this result should be interpreted with caution due to this analysis being conducted on a sample of only twenty one individuals. This is an interesting finding and would warrant further investigation in an adequately powered future study.

The finding that age was negatively correlated with psychological distress, indicating that younger individuals experience higher levels of distress, has previously been reported (Barker-Collo, 2007; Robinson, Starr, Kubos & Price, 1983; Paradiso & Robinson, 1998), but is inconsistent with other reports that they are unrelated (e.g. Morrison et al., 2000; Thomas & Lincoln, 2008). Studies reporting this relationship tended to have a younger sample (e.g. mean = 51.7 ± 10.19 years. Barker-Collo, 2007); other studies may not have found this relationship due to the age range of their participants (e.g. mean = 69.4 ± 9.15 years, Morrison et al., 2000). This finding may be accounted for by the increased unexpectedness of stroke within a younger age and the higher levels of disruption caused e.g. ability to continue with employment. Significantly higher levels of psychological distress were reported in individuals who had experienced a mental health difficulty prior to their stroke; this is consistent with previous findings (e.g. Caeiro, Ferro, Santos & Figueira, 2006).

Exploration of the main findings

There are several reasons why the results of this study, which suggest that there are no significant relationships between the three independent variables (cognitive impairment, perceived social support and perceived control) and psychological distress, may differ from previous research which has provided evidence for these relationships (e.g. Kauhanen et al., 1999; King et al., 2002; Thomas & Lincoln, 2006). The populations from which samples

have been derived may be one possible explanation. The majority of studies in which relationships between cognitive impairment, perceived social support, perceived control and psychological distress have been identified, included samples of consecutive admissions to stroke units. Other samples have been derived from population based stroke registers (e.g. Ayerbe et al., 2011; Thomas & Lincoln 2006). The population from which the current sample was selected does differ slightly from previous studies. To establish a sample representative of the stroke population in Tayside, participants were those who had contact with any of the stroke services provided by NHS Tayside (inpatient, outpatient, inpatient rehabilitation and exercise classes) and who met inclusion/exclusion criteria. In this study, although all individuals were admitted to hospital post stroke, this was not always to a specialist stroke unit and this data was not specifically collected. A minority of the sample was identified during inpatient admission, with the majority being recruited to the study through outpatient services.

Previous studies were largely based within the UK or in Europe and as such, it is not expected that the sample in this study would deviate significantly from previous populations or health care systems. Tayside is a socioeconomically diverse area and it is therefore unlikely that the population from which the sample is drawn will have skewed the results with regard to socioeconomic status. The sample is, however, somewhat smaller, than the majority of previous studies in this area.

Time since stroke is another variable which is important to consider. The time point of assessment (six months to one year) is unlikely to have impacted on the different outcome concluded by this research. Previous studies have assessed individuals at various time points, post stroke, from the acute stage (Nys et al., 2005) to five years (Ayerbe et al., 2011) and

concluded that cognitive impairment, perceived social support, perceived control and PSD continue to be associated at various stages of recovery. The time point of assessment is a particular strength of this study due to its clinical relevance. Assessment of mood disorders at six months post stroke has been recommended by NICE; by this stage "physical and social recovery has stabilised" (Gillham & Clark, 2011, p9) and the longer term outcome can be assessed.

Previous research has often only included individuals with first ever stroke (e.g. Ayerbe et al., 2011; Nys et al., 2005). Recurrent stroke was not an exclusion criteria in this study, in order to increase the representativeness of the sample, and information regarding this was not collected, which is a limitation of this study. It is possible that this may be particularly important with regard to cognitive impairment; individuals who have experienced recurrent stroke may experience higher levels of cognitive impairment, and this may also impact on an individual's perceived control. However, no significant difference in frequency of anxiety was found between those with first- ever stroke (21%) and those with recurrent stroke (25%), in a recent review (Campbell Burton et al., 2012). There was however, significant heterogeneity with regard to samples and methodologies in the studies included in this review.

The measurement of variables is another methodological area which may account for some of the difference in findings, for example, the assessment of cognitive impairment by the ACE-III. Previous research exploring this relationship has more commonly utilised, for example, the Mini Mental State Examination (MMSE) (Ayerbe et al., 2011), the modified MMSE (Fatoye, , 2009) or a detailed neuropsychological test battery (Kauhanen et al., 1999; Nys et al., 2005).

Previous studies within this area have utilised both diagnostic criteria and rating scales in the identification of anxiety and depression. It may be argued that applying diagnostic criteria of anxiety and depression would improve the methodological rigor of this study. However, the author believes that a particular strength of the current study is the acknowledgment of the cumulative effect of anxiety and depression and its recognition as psychological distress, for which there is not a diagnostic criteria. Furthermore, prevalence rates of anxiety and depression are often under identified by diagnostic criteria, such as the DSM-IV, due to individuals reporting symptoms but not meeting criteria (Campbell Burton et al., 2013). The HADS is a recommended screening tool for mood disorders after stroke (Gillham & Clark, 2011), particularly due to its measurement of both anxiety and depression (Campbell Burton et al., 2013).

The points discussed above indicate that there are methodological strengths and weaknesses, in both the current study and the existing literature base, which are important to acknowledge in the exploration of the different findings of the current study, when compared to previous evidence. However, it is not possible to conclude from this exploration that the findings of this study are more robust, and therefore representative, than those of previous studies or vice versa.

Prevalence of psychological distress, anxiety and depression

As might be expected, higher rates of psychological distress, than anxiety and depression were reported within this sample. However, higher rates of anxiety (35%) than depression (30%) were also reported within this sample. Similarly, higher levels of anxiety than depression have been reported in the acute stage post stroke and at four months (26.4% vs.

14%; 23% vs. 19%: Fure, Wylier, Engedal & Thommessen, 2006; Sagen et al., 2009, respectively). The frequency of anxiety in this study is somewhat higher than the pooled estimate of 24% (in individuals assessed at six months or more post stroke) reported in a recent meta-analysis (Campbell Burton et al., 2013). The pooled sample does however differ from the current sample due to the inclusion of a number of participants in rehabilitation settings, individuals with TIA and individuals assessed up to five years post stroke. The reported frequency is similar to that reported by Barker-Collo (2007) of 38.6%, although this was a sample of patients in a rehabilitation setting at only three months post stroke. Interestingly, the frequency of both anxiety and depression in this study may well be underestimated; a cut off score of four or five on the subscales of the HADS has been recommended (Sagen at al., 2009), rather than the score of ≥8 utilised within this study.

Limitations

The small sample size is a particularly significant limitation of the current study. The power calculation completed for this study indicated that 64 participants would be required to achieve a medium effect size (ρ = .3) at an alpha level of .05 and power of .80. The final sample of forty participants means this study is underpowered to reliably detect a significant relationship should there be one present in the population. It is possible that the reason that the relationships were not found to be significant, despite small effect sizes being identified, was the small sample size. A larger sample is required in order to ascertain whether the proposed relationships between the independent variables and psychological distress genuinely do not exist within this population, or whether the small sample size has limited the power of this study to detect this relationship.

Furthermore, it may well be that there are pre-morbid or other factors that play a significant role in the relationship between the independent variables and psychological distress that are

not accounted for within the current study. Although there are an infinite number of variables which may impact on this relationship, this study did not collect information from participants regarding some commonly explored variables e.g. psychotropic medication, stroke severity, stroke type or level of functional impairment. Previous research has indicated significant relationships between e.g. functional impairment and psychological distress (Ayerbe *et al., 2013).* The current study does not account for the possible moderating/mediating role of such variables.

The measurement of cognitive impairment is another limitation of this study. It has been suggested that a previous version of the ACE-III, the ACE_R, was unable to adequately detect cognitive impairment when compared with a detailed neuropsychological battery (Morris, Hacker & Lincoln, 2012). It is therefore a possibility that the results of this study have been affected by the sensitivity and specificity of the ACE-III. However, it should be noted that the same was concluded with regard to the validity of the more widely used MMSE in assessing post stroke cognitive impairment (Lees, Fenton, Harrison, Broomfield & Quinn, 2012; Morris et al., 2012). Furthermore, in their study Morris and colleagues (2012) administered the cognitive screening measures (ACE-III and MMSE) up to seven days before the neuropsychological battery. As assessment was completed within the acute stages, when recovery can be rapid, this may well account for the number of 'false positives' and low specificity reported on the ACE-R. Due to the time limitations of this study, the measurement of cognitive impairment with a detailed neuropsychological battery was not possible. However, future research should utilise this in order to increase the specificity and sensitivity of the measurement of cognitive impairment.

Finally, there is of course the possibility of publication bias; previous studies that have also not found significant relationships between the three independent variables and either psychological distress, anxiety or depression, may well not have been published and are therefore not accessible.

Clinical implications and future research

There are methodological differences that may account for the differential findings of this study, when compared to previous research, in relation to the main variables. However, as explored above, despite the acknowledged limitations, this study raises some important considerations for clinical practice and future research. With regard to the proposed role of perceived control and perceived social support on the relationship between cognitive impairment and psychological distress, the results of this study do not lend themselves to making recommendations for clinical practice with regard to the importance of screening for these variables. However, the results of the study highlight the importance of screening for psychological distress as opposed to solely depression or anxiety symptomatology.

A recent review reported that the Hamilton Rating Depression Scale is the most frequently used mood assessment in stroke research (Lees et al., 2012). It is not clear whether this is reflective of clinical practice; however, it does highlight the possibility of psychological distress not being appropriately identified. NICE guidance (Gillham & Clark, 2011) suggests the use of, amongst others, the Patient Health Questionnaire (PHQ-9) as a mood screening measure; it is likely that those experiencing psychological distress may well be undetected when this is utilised. The reported development of a post stroke, adjustment-related distress, psychometric scale (Taylor et al., 2011) is of particular interest.

As previously mentioned, it has been suggested that those experiencing psychological distress may have an increased risk of experiencing clinically significant anxiety or depression (Drapeau *et al*. 2012). Early screening may be key in supporting such individuals. The HADS is a recommended screening tool after stroke particularly due to its measurement of both anxiety and depression (NICE, 2011). The utilisation of the HADS in clinical practice would allow for the identification of psychological distress by using the total score cut-off utilised in this study. This would allow for the identification of individuals who may benefit from, for example, a watchful waiting approach or the provision of psycho-educational materials. The screening and early identification of individuals experiencing psychological distress can be completed by a number of professionals involved in an individual's care (e.g. nurses, allied health professionals). The provision of early intervention by such professionals, may lead to a reduction in psychological distress and a reduction in the likelihood that such individuals will go on to experience clinically significant levels of anxiety or depression. In turn, this is likely to reduce the demand on specialist services (e.g. clinical neuropsychology) and subsequently the cost of long term care of individuals following a stroke.

Further research into this area is required to ascertain more conclusive evidence regarding the nature of the relationship between cognitive impairment and psychological distress, whilst addressing some of the methodological limitations detailed above. A model of post stroke adjustment has been proposed by Taylor and colleagues (2011) which highlights the importance of the variables explored within this study. They suggests that "post-stroke cognitive, emotional and behavioural and coping responses are dynamically and reciprocally linked. Moreover, these responses occur within a particular social context, which will influence coping strategies and subsequent adjustment" (Taylor et al., 2011, p. 815). Further research into the cognitive and psychosocial factors affecting post stroke psychological

distress is pertinent in identify appropriate screening and interventions and reducing the associated financial implications to the National Health Service.

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Appendices

Appendix 1. Journal Guidelines for Submission – Neuropsychological Rehabilitation

This journal uses ScholarOne Manuscripts (previously Manuscript Central) to peer review manuscript submissions. Please read the guide for ScholarOne authors before making a submission. Complete guidelines for preparing and submitting your manuscript to this journal are provided below.

Use these instructions if you are preparing a manuscript to submit to *Neuropsychological Rehabilitation*. To explore our journals portfolio, visit http://www.tandfonline.com/, and for more author resources, visit ourAuthor Services website.

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This journal accepts original (regular) articles, scholarly reviews, and book reviews.
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There is no word limit for manuscripts submitted to this journal. Authors should include a word count with their manuscript.

2. General guidelines

- Manuscripts are accepted in English. Oxford English Dictionary spelling and punctuation are preferred. Please use double quotation marks, except where “a quotation is ‘within’ a quotation”. Long quotations of words or more should be indented without quotation marks.
- Manuscripts should be compiled in the following order: title page; abstract; keywords; main text; acknowledgements; references; appendices (as appropriate); table(s) with caption(s) (on individual pages); figure caption(s) (as a list).
- Abstracts of 150-200 words are required for all manuscripts submitted.
- Each manuscript should have up to 5 keywords.
- Search engine optimization (SEO) is a means of making your article more visible to anyone who might be looking for it. Please consult our guidance here.
- Section headings should be concise.
- All authors of a manuscript should include their full names, affiliations, postal addresses, telephone numbers and email addresses on the cover page of the manuscript. One author should be identified as the corresponding author. Please give the affiliation where the research was conducted. If any of the named co-authors moves affiliation during the peer review process, the new affiliation can be given as a footnote. Please note that no changes to affiliation can be made after the manuscript is accepted. Please note that the email address of the corresponding author will normally be displayed in the article PDF (depending on the journal style) and the online article.
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Information about supplemental online material

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site, submissions should be made via the Author Centre. Online user guides and access to a helpdesk are available on this website.
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Last updated 11/03/2014

Appendix 2: Quality Criteria

1. Sample selected were representative of people who have experienced a stroke/selection bias considered	Participants were recruited from a representative healthcare setting and were reasonable representative of the clinical population being studied with very little potential for selection bias	Well covered (3)
	Participants were recruited from a healthcare setting, however there is likely to be bias in those that were approached and/or agreed to participate	Adequately covered (2)
	Participants were recruited from a healthcare setting but there is clear and substantial bias in those that were approached and/or agreed to participate.	Poorly addressed (1)
	No details provided	Not addressed (0)
2. Functional ability/impairment measure evidenced to be valid, reliable and appropriate for stroke patients.	Robust measurement tool used with evidenced reliability and validity. Considered to be appropriate for a stroke population.	Well covered (3)
	Robust measurement tool used but not evidenced to be valid or reliable in a stroke population.	Adequately covered (2)
	Level of functional impairment measured but tool used is not evidenced to be valid or reliable.	Poorly addressed (1)
	Measure of functional ability/ impairment not used.	Not addressed/reported (0)
3. Depression measure evidenced to be valid, reliable and appropriate for stroke patients.	Robust diagnostic tool used with evidenced reliability and validity. Considered to be appropriate for a stroke population.	Well covered (3)
	A reliable and valid screening tool used. Considered to be appropriate for a stoke population.	Adequately covered (2)
	Depressive symptoms measured but tool used is not valid or reliable for a stroke population.	Poorly addressed (1)
		Not addressed/reported/applicable (0)
4. Appropriate statistical analysis	Appropriate analyses used to allow exploration of relationship	Well covered (3)

selected for the study design	between depressive symptoms and level of functional impairment. Statistical analyses controlled for any potentially confounding factors such as age, gender or stroke severity.	
	Appropriate analyses used to allow exploration of relationship between depressive symptoms and level of functional impairment. Statistical analyses did not report controlling for any potentially confounding factors such as age, gender or stroke severity.	Adequately covered (2)
	Appropriate analyses were not conducted and the relationship between depressive symptoms and level of functional impairment was not explored.	Poorly addressed (1)
		Not addressed/reported/applicable (0)
5. The sample size is justified/ discussion of statistical power	The sample size was sufficient to enable power of at least 0.8, where effect size was anticipated to be medium and alpha was 0.5	Well covered (3)
	The sample size was sufficient to enable power of at least 0.7, where effect size was anticipated to be medium and alpha was 0.5.	Adequately covered (2)
	The sample size was only sufficient to enable power of less than 0.7, where effect size was anticipated to be medium and alpha was 0.05.	Poorly addressed (1)
		Not addressed/reported/applicable (0)
6. Details of missing data and participants who did not complete are provided	The number of participants who did not complete all times points was reported and the reasons for this were given.	Well covered (3)
		Adequately covered (2)
	The number of participants who did not complete all times point was reported, however no information was given regarding the reason for this.	Poorly addressed (1)
		Not addressed/reported/applicable (0)

Appendix 3: Patient Information and Consent Form

The role of sense of control over recovery and social support in post stroke emotional function

Dear Mr/Mrs

My name is Kate Campbell and I am training to be a Clinical Psychologist at the University of Edinburgh and I work for NHS Tayside. As part of my training I am carrying out a study looking at different factors that may make people more likely to experience anxiety and depression following a stroke. I would like to invite you to participate in my study.

Before you say "yes" or "no", I would like to tell you why I am carrying out this study and what you will be asked to do.

Please take your time and read the information sheet carefully before deciding whether you would like to take part. You do not have to decide right away. You might wish to talk to friends or family about it first.

Please also feel free to ask me any questions about this study.

Thank you for taking time to read this.

Yours sincerely

Kate Campbell

Trainee Clinical Psychologist

University of Edinburgh/NHS Tayside

katecampbell1@nhs.net

Tel: 01382 740406

Participant Information Sheet and Consent Form

The role of sense of control over recovery and social support in post stroke emotional function

You are being invited to take part in a research study. Before you decide whether or not to take part, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully. Talk to others about the study if you wish. Contact us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

What is the purpose of the study?
The purpose of this study is to identify psychological factors that might make people more likely to experience difficulties with anxiety and depression following a stroke.

Why have I been asked to take part?
You have been asked to take part as you have been diagnosed with a stroke in the past six months.

Do I have to take part?
No, it is up to you to decide whether or not to take part. If you do decide to take part you will be asked to sign a consent form. If you decide to take part you are still free to withdraw at any time and without giving a reason. Deciding not to take part or withdrawing from the study will not affect the healthcare that you receive, or your legal rights.

What will I be asked to do?
If you have given your consent to your stroke clinician to pass on your contact details to the me then you can expect to be contacted within the next two weeks (If you have not given consent for this then you will not be contacted again in relation to this study).

During this telephone conversation I will give you the opportunity to ask any questions you may have regarding the study. At this point you might decide that you do not wish to take part.

If you wish to take part I will arrange a time and place to meet you that is suitable for you to complete the study. This meeting will take approximately 45 minutes. If you wish, you can also complete the study in two shorter sessions instead.

During this session you will be asked to complete three questionnaires. These ask you questions about:

1. how you are feeling
2. the support you receive from friends and family
3. whether you think that you have control over your recovery and health.

I will be available to assist you in completing these if required.

I will also ask you to do some tasks that involve:

1. naming tasks
2. memory tasks

3. copying and drawing tasks

You will be able to take a break or stop the session at any point. You can also change your mind at any point if you decide you no longer want to take part. If you decide this when you have already completed the study then your details will be destroyed and will not be included in the study. The Chief Investigator will also ask for your consent to gather information from your stroke clinician regarding the severity of your stroke when you were first seen in hospital.

What are the possible benefits of taking part?
You may not get a direct benefit from taking part in this study, however it is hoped that the results of this study might inform the future healthcare of other patients who have experienced a stroke.

What are the possible disadvantages and risks of taking part?
It is not thought that there are many disadvantages; however, it is possible that you may become upset by some of the material included in the assessment. If this were to happen, the Chief Investigator would be able to discuss your concerns with you and identify further sources of support if required. If the Chief Investigator has any concerns about your safety during the assessment process they may be required to share this information with your GP. This study will require you to meet with the Chief Investigator for approximately 45 minutes.

Will my taking part in the study be kept confidential?
My supervisors (Professor Kevin Power, Dr Alison Livingstone and Dr Paul Morris) and I (Kate Campbell) will be allowed to see the information that I collect from you. Once you have completed all of the tasks, your name and all other identifiable information will be removed. This means that no one will be able to tell it is you. With your consent we will inform your GP that you are taking part.

In line with the NHS Research Ethics' Guidelines, all the information gathered during this study will be kept securely for 5 years after the study is completed.

If, during the study, you tell me anything that makes me think that you or others around you are at risk of harm, I will have to tell someone. This is to make sure that you and other people are safe. I will either tell the person who told you about the study in the first place or a Clinical Psychologist working for NHS Tayside. I may also have to inform your GP. If this were to happen, I would talk to you about it first and discuss what to do next with you.

What will happen to the results of the study?
The study will be written up as part of the Chief Investigator's Doctorate in Clinical Psychology qualification and for publication in a scientific journal. You will not be identifiable in any published results. I can also provide you with a written copy of the results if you wish to see them.

Who is organising the research and why?
This study is being organised by the University of Edinburgh and NHS Tayside. The study is funded by the University of Edinburgh and NHS Tayside

Who has reviewed the study?
The East of Scotland Research Ethics Committee REC 2, which has responsibility for scrutinising all proposals for medical research on humans in Tayside, has examined the

proposal and has raised no objections from the point of view of medical ethics. It is a requirement that your records in this research, together with any relevant records, be made available for scrutiny by monitors from The University of Edinburgh and NHS Tayside. Their role is to check that research is being carried out properly and that anyone taking part is protected.

If you have any further questions about the study please contact:

Kate Campbell (Chief Investigator) on: 01382 740406 or email: katecampbell1@nhs.net

Or

Dr Alison Livingstone (supervisor) on: 01382 740406 or email: alison.livingstone@nhs.net

If you would like to discuss this study with someone independent, please contact: Linda Graham

Deputy Head of Service

NHS Tayside Psychological Therapies Service

7 Dudhope Terrace

Dundee

DD3 6HG

Tel: 01382 306150

If you wish to make a complaint about the study please contact NHS Tayside:

Complaints and Feedback Team Lead
Complaints and Advice Team
Level 9
Ninewells Hospital
Dundee
DD1 9SY Freephone: 0800 027 5507 Email: complaints.tayside@nhs.net

Thank you for taking the time to read this information sheet.

Consent Form

The role of sense of control over recovery and social support in post stroke emotional dysfunction

Participant ID:

Person taking consent:

Please initial box

1. I confirm that I have read and understand the information sheet for the above study and have had the opportunity to consider the information and ask questions. ☐

2. 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. ☐

3. I understand that data collected during the study may be looked at by individuals from the The University of Edinburgh and from NHS Tayside where it is relevant to my taking part in this research. I give permission for these individuals to have access to this data. ☐

4. I agree to my General Practitioner being informed of my participation in this study ☐

6. I agree to take part in the above study ☐

_____	_____	_____
Name of Participant	Date	Signature
_____	_____	_____
Name of Person taking consent	Date	Signature

Appendix 4. Research Ethics Approval

EoSRES

NHS SCOTLAND
Research Ethics Service

East of Scotland Research Ethics Service (EoSRES) REC 2
Tayside Medical Sciences Centre (TASC)
Residency Block C, Level 3
Ninewells Hospital & Medical School
George Pirie Way
Dundee DD1 9SY

Miss Kate Parker
Trainee Clinical Psychologist
NHS Tayside
7 Dudhope Terrace
Dundee
DD3 6HG

Date: 01 May 2014
Your Ref:
Our Ref: LR/**14/ES/0044**
Enquiries to: Mrs Lorraine Reilly
Direct Line: 01382 383878
Email: eosres.tayside@nhs.net

Dear Miss Parker

Study Title:	**A cross sectional study examining the relationships between stroke severity, cognitive impairment, health locus of control, social support and emotional dysfunction in adults who have experienced a stroke.**
REC reference:	**14/ES/0044**
Protocol number:	**N/A**
IRAS project ID:	**138915**

Thank you for your letter of 30 April 2014, 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, unless you expressly withhold permission to do so. Publication will be no earlier than three months from the date of this favourable opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to withhold permission to publish, please contact the REC Manager Mrs Lorraine Reilly, lorraine.reilly@nhs.net.

Confirmation of ethical opinion

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

Ethical review of research sites

NHS sites

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

Non-NHS sites

Conditions of the favourable opinion

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

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

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

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

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

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

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

Registration of Clinical Trials

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

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

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

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

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

Approved documents

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

Document	Version	Date
Evidence of insurance or indemnity		25 June 2013
GP/Consultant Information Sheets		
Investigator CV		
Investigator CV		
Letter from Sponsor		11 March 2014
Letter of invitation to participant	5	17 April 2014

Other: CV - Dr Stuart Johnston		
Other: CV - Dr Alison Livingstone		
Other: CV - Dr Paul Morris		
Other: Dr Priya Nair		
Other: Recruitment Flowchart.		
Other: covering email		30 April 2014
Participant Consent Form	5	17 April 2014
Participant Information Sheet: Highlighted changes	5	17 April 2014
Protocol	3	30 January 2014
Questionnaire: Demographic		
Questionnaire: MOS Social Support Survey		
Questionnaire: NIHS Scale		
Questionnaire: Adenbrookes ACE-III		
Questionnaire: HADS		
Questionnaire: Recovery Health Locus of Control		
REC application	138915/580121/1/273	12 March 2014
Response to Request for Further Information		30 April 2014

Statement of compliance

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

After ethical review

Reporting requirements

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

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

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

Feedback

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

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

14/ES/0044:	***Please quote this number on all correspondence***

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

Yours sincerely

L Reilly

Ms Tara Graham
Chair

eosres.tayside@nhs.net

Enclosures:	"After ethical review – guidance for researchers"
Copy to:	Charlotte Clark, University of Edinburgh NHS Tayside R&D office

Appendix 5. Research and Development Approval

NHS Tayside

12 May 2014

Miss Kate Parker
Trainee Clinical Psychologist
NHS Tayside
7 Dudhope Terrace
Dundee
DD3 6HG

Dear Miss Parker,

R & D MANAGEMENT APPROVAL - TAYSIDE

Title: A cross sectional study examining the relationships between stroke severity, cognitive impairment, health locus of control, social support and emotional dysfunction in adults who have experienced a stroke.

Chief Investigator: Kate Parker

Principal Investigator: Kate Parker

Tayside Ref: 2014PZ05 **NRS Ref: N/A**

REC Ref: 14/ES/0044

EudraCT Ref: N/A **CTA Ref: N/A**

Sponsor(s): University of Edinburgh

Funder(s): Unfunded

Many thanks for your application to carry out the above project here in NHS Tayside. I am pleased to confirm that the project documentation (as outlined below) has been reviewed, registered and Management Approval has been granted for the study to proceed locally in Tayside.

Approval is granted on the following conditions:-

- ALL Research must be carried out in compliance with the Research Governance Framework for Health & Community Care, Health & Safety Regulations, data protection principles, statutory legislation and in accordance with Good Clinical Practice (GCP).
- All amendments to be notified to TASC R & D Office.
- All local researchers must hold either a Substantive Contract, Honorary Research Contract, Honorary Clinical Contract or Letter of Access with NHS Tayside where required (http://www.nihr.ac.uk/systems/Pages/systems_research_passports.aspx).
- TASC R & D Office to be informed of change in Principal Investigator, Chief Investigator or any additional research personnel locally.

- Notification to TASC R & D Office of any change in funding.

- As custodian of the information collated during this research project you are responsible for ensuring the security of all personal information collected in line with NHS Scotland IT Security Policies, until destruction of this data.

- All eligible studies will be added to the UKCRN Portfolio http://public.ukcrn.org.uk/. Recruitment figures for eligible studies must be recorded onto the Portfolio every month: This is the responsibility of the lead UK site. If you are the lead, or only, UK site, we can provide help or advice with this. For information, contact Sarah Auld – (01382) 383822 – sarah.auld@nhs.net or Liz Livingstone – (01382) 383872 – elivingstone@nhs.net.

- Annual reports are required to be submitted to TASC R & D Office with the first report due 12 months from date of issue of this management approval letter and at yearly intervals until completion of the study.

- Notification of early termination within 15 days or End of Trial within 90 days followed by End of Trial Report within 1 year to TASC R & D Office.

- You may be required to assist with and provide information in regard to audit and monitoring of study.

Please note you are required to adhere to the conditions, if not, NHS management approval may be withdrawn for the study.

Approved Documents

Document	Version	Date
Protocol	**3**	**30/01/14**
IRAS R & D Form		
SSI Form		
PIS	**5**	**17/04/14**
Consent Form	**5**	**17/04/14**
Insurance		**25/06/13**
Letter of invitation to participants		
GP/Consultant Information sheet		
CV – Kate Parker		
CV – Kevin Power		
CV – Alison Livingstone		
CV – Paul Morris		
CV – Stuart Johnston		
CV – Priya Nair		
Recruitment flowchart		
Demographic questionnaire		
MOS Social Support Survey		
NIHS Scale		
Addenbrookes ACE-III		
HADS		
Recovery Health Locus of Control		
REC favourable opinion		**01/05/14**

May I take this opportunity to wish you every success with your project.

Please do not hesitate to contact TASC R & D Office should you require further assistance.

Yours sincerely,

Elizabeth Coote
R&D Manager

TAyside medical Science **C**entre (TASC)
Ninewells Hospital & Medical School
TASC Research & Development Office
Residency Block, Level 3
George Pirie Way
Dundee DD1 9SY
Email: liz.coote@nhs.net
Tel: 01382 383876 Fax: 01382 740122

c.c.

Paul Morris
Liz Livingstone
Jennifer Flach

Appendix 6. Demographic Questionnaire

1. Gender:
2. Age:
3. Marital status:
4. How many years of formal education have you completed?
5. What is your current/previous occupation?
6. Have you ever received any treatment for a mental health difficulty e.g depression or anxiety?

   Yes ☐

   No ☐

   If yes, please give details:

7. Prior to your stroke did you ever raise any concerns about your memory with your GP?

   Yes ☐

   No ☐

   If Yes, please give details:

Appendix 7. Addenbrooke's Cognitive Examination - III

ADDENBROOKE'S COGNITIVE EXAMINATION – ACE-III
English Version A (2012)

Name: Date of Birth: Hospital No. or Address:	Date of testing: ___/___/___ Tester's name:_____ Age at leaving full-time education:_____ Occupation: _____ Handedness: _____

ATTENTION

➢ Ask: What is the	Day _____	Date _____	Month _____	Year _____	Season _____	**Attention** [Score 0-5] ☐
➢ Ask: Which	No./Floor _____	Street/Hospital _____	Town _____	County _____	Country _____	**Attention** [Score 0-5] ☐

ATTENTION

➢ Tell: "I'm going to give you three words and I'd like you to repeat them after me: lemon, key and ball." After subject repeats, say "Try to remember them because I'm going to ask you later". ➢ Score *only* the first trial (repeat 3 times if necessary). ➢ Register number of trials: _____	**Attention** [Score 0-3] ☐

ATTENTION

➢ Ask the subject: "Could you take 7 away from 100? I'd like you to keep taking 7 away from each new number until I tell you to stop." ➢ If subject makes a mistake, do not stop them. Let the subject carry on and check subsequent answers (e.g., 93, 84, 77, 70, 63 – score 4). ➢ Stop after five subtractions (93, 86, 79, 72, 65): ___ ___ ___ ___ ___	**Attention** [Score 0-5] ☐

MEMORY

➢ Ask: 'Which 3 words did I ask you to repeat and remember?' _____ _____ _____	**Memory** [Score 0-3] ☐

FLUENCY

➢ **Letters** Say: "I'm going to give you a letter of the alphabet and I'd like you to generate as many words as you can beginning with that letter, but not names of people or places. For example, if I give you the letter "C", you could give me words like "cat, cry, clock" and so on. But, you can't give me words like Catherine or Canada. Do you understand? Are you ready? You have one minute. The letter I want you to use is the letter "P".	**Fluency** [Score 0 – 7] ☐

				≥ 18	7
				14-17	6
				11-13	5
				8-10	4
				6-7	3
				4-5	2
				2-3	1
				0-1	0
				total	correct

➢ **Animals** Say: "Now can you name as many animals as possible. It can begin with any letter."	**Fluency** [Score 0 – 7] ☐

				≥ 22	7
				17-21	6
				14-16	5
				11-13	4
				9-10	3
				7-8	2
				5-6	1
				<5	0
				total	correct

MEMORY

➢ Tell: "I'm going to give you a name and address and I'd like you to repeat the name and address after me. So you have a chance to learn, we'll be doing that 3 times. I'll ask you the name and address later."

Score only the third trial.

Memory
[Score 0 – 7]

	1st Trial	*2nd Trial*	*3rd Trial*
Harry Barnes 73 Orchard Close Kingsbridge Devon	_____ _____ ____ _____ _____ _____ _____	_____ _____ ____ _____ _____ _____ _____	_____ _____ ____ _____ _____ _____ _____

MEMORY

➢ Name of the current Prime Minister.....
➢ Name of the woman who was Prime Minister .....
➢ Name of the USA president.....
➢ Name of the USA president who was assassinated in the 1960s.....

Memory
[Score 0 – 4]

LANGUAGE

➢ Place a pencil and a piece of paper in front of the subject. As a practice trial, ask the subject to "**Pick up the pencil and then the paper**." If incorrect, score 0 and do not continue further.

➢ If the subject is correct on the practice trial, continue with the following three commands below.
- Ask the subject to "**Place the paper on top of the pencil**"
- Ask the subject to "**Pick up the pencil but not the paper**"
- Ask the subject to "**Pass me the pencil after touching the paper**"

Note: Place the pencil and paper in front of the subject before each command.

Language
[Score 0-3]

LANGUAGE

➢ Ask the subject to write two (or more) complete sentences about his/her last holiday/weekend/Christmas. Write in complete sentences and do not use abbreviations.
Give 1 point if there are two (or more) complete sentences about the one topic; and give another 1 point if grammar and spelling are correct.

Language
[Score 0-2]

LANGUAGE

➢ Ask the subject to repeat: **'caterpillar'; 'eccentricity; 'unintelligible'; 'statistician'**
Score 2 if all are correct; score 1 if 3 are correct; and score 0 if 2 or less are correct.

Language
[Score 0-2]

Updated 20/11/2012

LANGUAGE

➢ Ask the subject to repeat: **'All that glitters is not gold'**

Language [Score 0-1] ☐

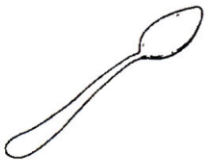
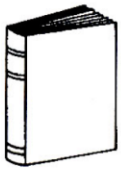
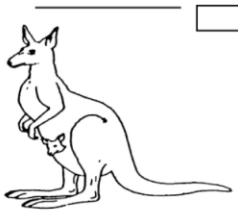
➢ Ask the subject to repeat: **'A stitch in time saves nine'**

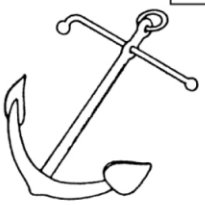
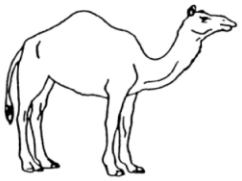
Language [Score 0-1] ☐

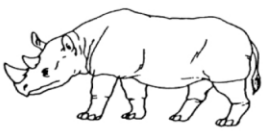
LANGUAGE

➢ Ask the subject to name the following pictures:

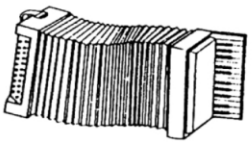
Language [Score 0-12] ☐







LANGUAGE

➢ Using the pictures above, ask the subject to:

- Point to the one which is associated with the monarchy .....
- Point to the one which is a marsupial .....
- Point to the one which is found in the Antarctic .....
- Point to the one which has a nautical connection .....

Language [Score 0-4] ☐

Updated 20/11/2012

LANGUAGE

- Ask the subject to read the following words: (Score 1 only if all correct)

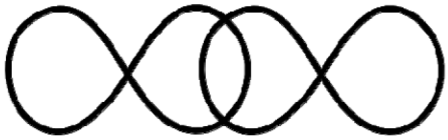
Language
[Score 0-1] ☐

sew
pint
soot
dough
height

VISUOSPATIAL ABILITIES

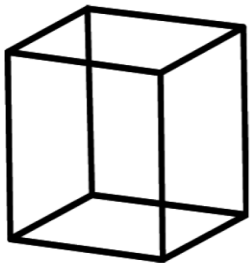
- Infinity Diagram: Ask the subject to copy this diagram

Visuospatial
[Score 0-1] ☐



- Wire cube: Ask the subject to copy this drawing (for scoring, see instructions guide).

Visuospatial
[Score 0-2] ☐



- Clock: Ask the subject to draw a clock face with numbers and the hands at ten past five. (For scoring see instruction guide: circle = 1, numbers = 2, hands = 2 if all correct).

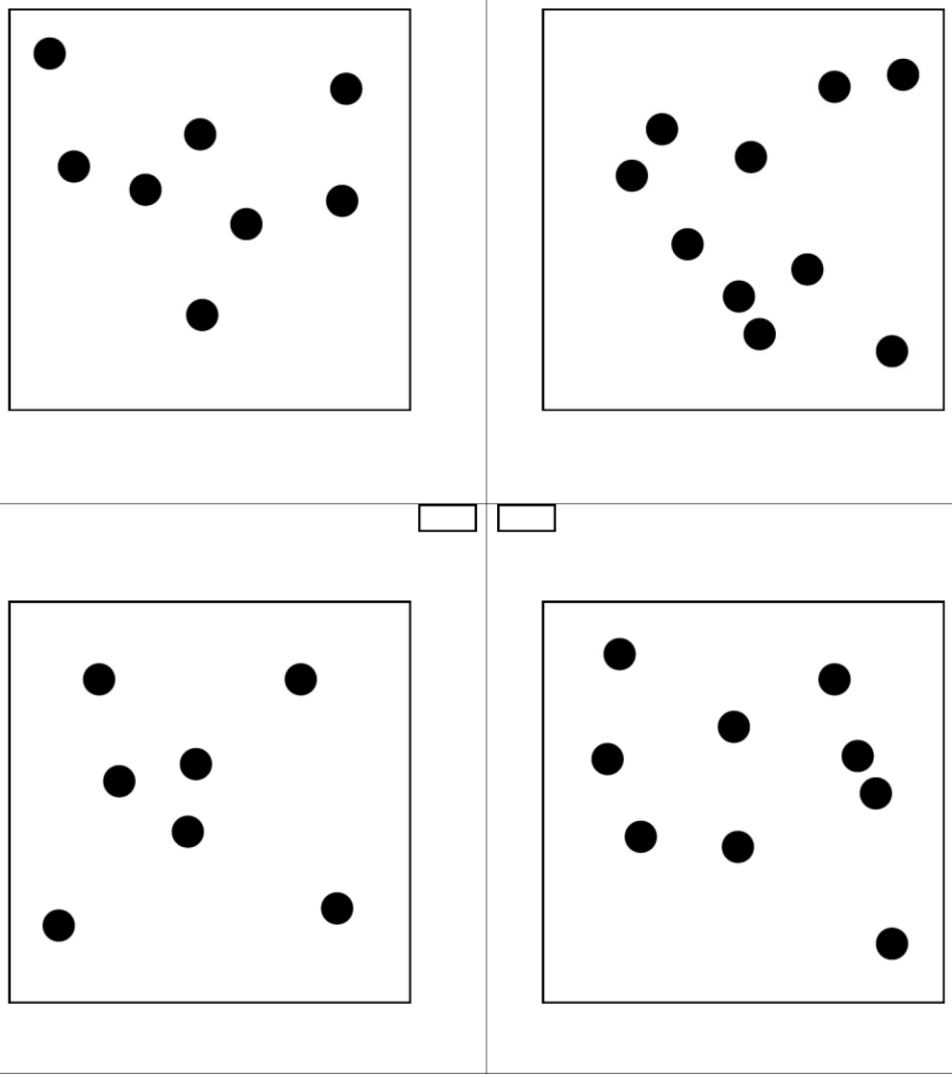
Visuospatial
[Score 0-5] ☐

Updated 20/11/2012

VISUOSPATIAL ABILITIES

- Ask the subject to count the dots without pointing to them

Visuospatial
[Score 0-4]

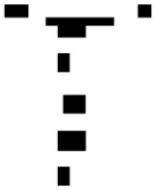


Updated 20/11/2012

VISUOSPATIAL ABILITIES

➢ Ask the subject to identify the letters

Visuospatial
[Score 0-4] ☐



MEMORY

➢ Ask "Now tell me what you remember about that name and address we were repeating at the beginning"

Harry Barnes 73 Orchard Close Kingsbridge Devon	....	**Memory** [Score 0-7] ☐

MEMORY

➢ This test should be done if the subject failed to recall one or more items above. It all items were recalled, skip the test and score 5. If only part was recalled start by ticking items recalled in the shadowed column on the right hand side; and then test not recalled items by telling the subject "ok, I'll give you some hints: was the name X, Y or Z?" and so on. Each recognised item scores one point, which is added to the point gained by recalling.

Memory
[Score 0-5] ☐

Jerry Barnes	☐	Harry Barnes	☐	Harry Bradford	☐	recalled	☐
37	☐	73	☐	76	☐	recalled	☐
Orchard Place	☐	Oak Close	☐	Orchard Close	☐	recalled	☐
Oakhampton	☐	Kingsbridge	☐	Dartington	☐	recalled	☐
Devon	☐	Dorset	☐	Somerset	☐	recalled	☐

SCORES

TOTAL ACE-III SCORE	/100
Attention	/18
Memory	/26
Fluency	/14
Language	/26
Visuospatial	/16

Updated 20/11/2012

Appendix 8. Recovery Locus of Control Measure

RECOVERY LOCUS OF CONTROL SCALE

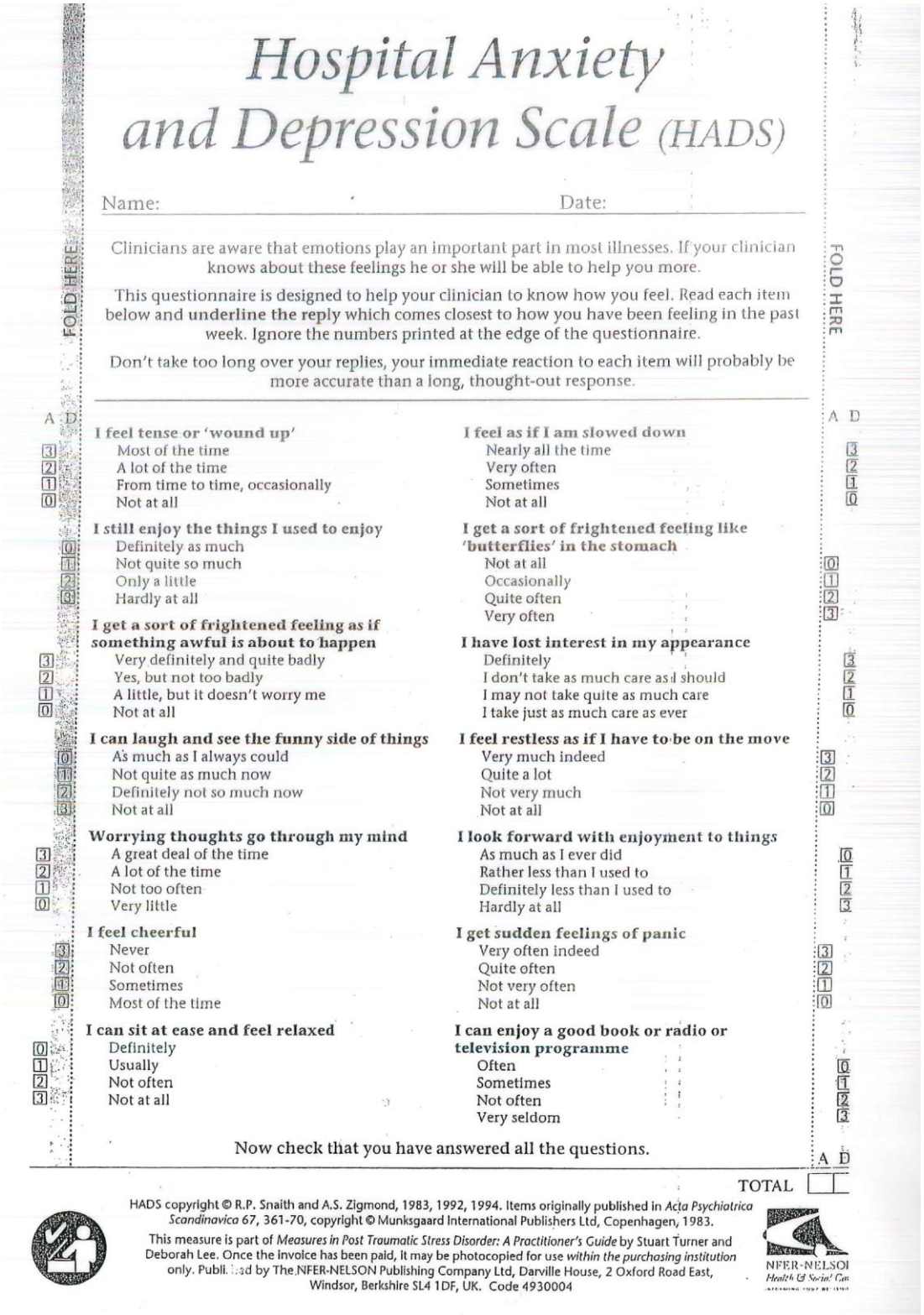
Name: .....

Date: ..... Record Number: .....

These are statements other people have made about their recovery. Please will you indicate the extent to which you agree or disagree with them in the right-hand columns.

	Strongly agree	Agree	Uncertain	Disagree	Strongly disagree
1. How I manage in the future depends on me, not on what other people can do for me.					
2. It's often best just to wait and see what happens.					
3. It's what I do to help myself that's really going to make all the difference.					
4. My own efforts are not very important, my recovery really depends on others.					
5. It's up to me to make sure that I make the best recovery possible under the circumstances.					
6. My own contribution to my recovery doesn't amount to much.					
7. Getting better now is a matter of my own determination rather than anything else.					
8. I have little or no control over my progress from now on.					
9. It doesn't matter how much help you get, in the end it's your own efforts that count.					

Appendix 9. Hospital Anxiety and Depression Scale



Hospital Anxiety and Depression Scale (HADS)

Name: Date:

Clinicians are aware that emotions play an important part in most illnesses. If your clinician knows about these feelings he or she will be able to help you more.

This questionnaire is designed to help your clinician to know how you feel. Read each item below and **underline the reply** which comes closest to how you have been feeling in the past week. Ignore the numbers printed at the edge of the questionnaire.

Don't take too long over your replies, your immediate reaction to each item will probably be more accurate than a long, thought-out response.

FOLD HERE

A D

I feel tense or 'wound up'
- 3 Most of the time
- 2 A lot of the time
- 1 From time to time, occasionally
- 0 Not at all

I still enjoy the things I used to enjoy
- 0 Definitely as much
- 1 Not quite so much
- 2 Only a little
- 3 Hardly at all

I get a sort of frightened feeling as if something awful is about to happen
- 3 Very definitely and quite badly
- 2 Yes, but not too badly
- 1 A little, but it doesn't worry me
- 0 Not at all

I can laugh and see the funny side of things
- 0 As much as I always could
- 1 Not quite as much now
- 2 Definitely not so much now
- 3 Not at all

Worrying thoughts go through my mind
- 3 A great deal of the time
- 2 A lot of the time
- 1 Not too often
- 0 Very little

I feel cheerful
- 3 Never
- 2 Not often
- 1 Sometimes
- 0 Most of the time

I can sit at ease and feel relaxed
- 0 Definitely
- 1 Usually
- 2 Not often
- 3 Not at all

I feel as if I am slowed down
- 3 Nearly all the time
- 2 Very often
- 1 Sometimes
- 0 Not at all

I get a sort of frightened feeling like 'butterflies' in the stomach
- 0 Not at all
- 1 Occasionally
- 2 Quite often
- 3 Very often

I have lost interest in my appearance
- 3 Definitely
- 2 I don't take as much care as I should
- 1 I may not take quite as much care
- 0 I take just as much care as ever

I feel restless as if I have to be on the move
- 3 Very much indeed
- 2 Quite a lot
- 1 Not very much
- 0 Not at all

I look forward with enjoyment to things
- 0 As much as I ever did
- 1 Rather less than I used to
- 2 Definitely less than I used to
- 3 Hardly at all

I get sudden feelings of panic
- 3 Very often indeed
- 2 Quite often
- 1 Not very often
- 0 Not at all

I can enjoy a good book or radio or television programme
- 0 Often
- 1 Sometimes
- 2 Not often
- 3 Very seldom

Now check that you have answered all the questions.

A D

TOTAL

Appendix 10. MOS – Social Support Survey

MOS Social Support Survey

People sometimes look to others for companionship, assistance, or other types of support. How often is each of the following kinds of support available to you if you need it? Circle one number on each line

	None of the time	A little of the time	Some of the time	Most of the time	All of the time
Emotional/informational support					
Someone you can count on to listen to you when you need to talk	1	2	3	4	5
Someone to give you information to help you understand a situation	1	2	3	4	5
Someone to give you good advice about a crisis	1	2	3	4	5
Someone to confide in or talk to about yourself or your problems	1	2	3	4	5
Some whose advice you really want	1	2	3	4	5
Someone to share your most private worries and fears with	1	2	3	4	5
Someone to turn to for suggestions about how to deal with a personal problem	1	2	3	4	5
Someone who understands your problems	1	2	3	4	5
Tangible support					
Someone to help you if you were confined to bed	1	2	3	4	5
Someone to take you to the doctor if you needed it	1	2	3	4	5
Someone to prepare your meals if you were unable to do it yourself	1	2	3	4	5
Someone to help with daily chores if you were sick	1	2	3	4	5
Affectionate support					
Someone who shows you love and affection	1	2	3	4	5
Someone to love and make you feel wanted	1	2	3	4	5
Someone who hugs you	1	2	3	4	5

	None of the time	A little of the time	Some of the time	Most of the time	All of the time
Positive social interaction					
Someone to have a good time with	1	2	3	4	5
Someone to get together with for relaxation	1	2	3	4	5
Someone to do something enjoyable with	1	2	3	4	5
Additional item					
Someone to do things with to help you get your mind off things	1	2	3	4	5