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SCREENING AND INTERVENING: EMOTIONAL WELLBEING FOLLOWING ACQUIRED BRAIN INJURY

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Abstract

Acquired brain injury (ABI) is a leading cause of long term adult disability and many survivors experience chronic difficulties with emotional adjustment. Therefore there is a need for effective assessment tools and intervention programmes with this client group.

The review paper systematically evaluated the emerging empirical literature on mindfulness-based interventions (MBIs) following ABI. The reviewed studies indicated encouraging preliminary evidence for holistic gains in quality of life, mental health, mental fatigue and chronic pain. The studies utilised a range of MBI programmes with many adaptations for ABI participants. As this is a new field, the majority of studies employed uncontrolled designs which limited the conclusions and implications that could be drawn. Future studies using controlled designs with manualised ABI-adapted MBI programmes and active control interventions are warranted.

The empirical paper evaluated a new self-report screening tool for anxiety following ABI. A cross-sectional questionnaire based design was used in this preliminary validation study and 36 stroke survivors (a subset of the ABI population) and carers were recruited. The Anxiety Scale Circles (ASC) demonstrated acceptable convergent and divergent validity, discriminant capacity, and the optimal cut-off score of 0/1 was identified. This represented the first preliminary validation of a simple self-report PSA measure and indicated that the ASC holds potential as a clinical screening tool. Further research will be required to establish test-retest reliability and validate the ASC against a clinical diagnosis of anxiety.

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Paper A

Mindfulness-based group interventions following acquired brain injury: A systematic review

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Mindfulness-based group interventions following acquired brain injury: A systematic review

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Abstract

Acquired Brain Injury (ABI) is a leading cause of long term adult disability and associated with a high rate of residual impairments in physical, cognitive, behavioural and psychosocial functioning. There is an increasing trend towards holistic approaches in ABI rehabilitation which have an emphasis on psychosocial adjustment. Mindfulness-based interventions (MBIs) are one such approach with demonstrated benefits in psychological wellbeing and quality of life in several chronic health conditions. This systematic review aimed to examine the emerging literature on the effectiveness of MBIs with the ABI population. EMBASE, AMED, MEDLINE and PsycINFO databases were searched and 14 studies were identified. The studies utilised a range of MBI programmes with many adaptations for ABI participants. The studies evaluated a wide range of domains and there was encouraging preliminary evidence for gains in quality of life, mental health, mental fatigue and chronic pain. As this is a new field the majority of studies employed uncontrolled designs which limited the conclusions and implications that could be drawn. Limitations of the review and future research directions are discussed.

Keywords: Acquired brain injury; mindfulness; wellbeing; quality of life.

Note: This paper has been prepared for submission to the journal *Neuropsychological Rehabilitation*. Submission guidelines are included in Appendix A.

Introduction

Acquired brain injury

Acquired brain injury (ABI) is a collective term for any injury to the brain sustained since birth. There are a range of causes of ABI including trauma (traumatic brain injury, TBI), stroke (cerebrovascular accident, CVA), anoxia, infection, inflammation and tumours. In the United Kingdom (UK) between 2013 and 2014 there were 348,934 admissions to hospital for ABI, of these 162,544 were for TBI and 130,551 for stroke (Headway, 2015). ABIs are a leading cause of long term adult disability (World Health Organisation, 2010) and the UK incidence rate has increased by 10% over the last decade (Headway, 2015). The UK ABI Foundation (n.d.) estimated the cost of ABI, in terms of health and social care costs and lost earnings, as at least £1 billion per annum. Following ABI, residual impairments are at a high rate, e.g. physical, cognitive, behavioural, and psychosocial difficulties (Royal College of Physicians [RCP]/ British Society of Rehabilitation Medicine [BSRM], 2003). Furthermore, many ABI survivors experience chronic difficulties with emotional adjustment, with a high incidence rate of anxiety and depression (Ponsford, Olver & Curran, 1995).

Towards a holistic approach to neurorehabilitation

Conventional approaches to ABI rehabilitation have tended to focus on ameliorating physical and cognitive impairments, placing less emphasis on psychosocial adjustment. Recently, there has been a growing trend for holistic approaches to neurorehabilitation (Wilson, 2008). Holistic rehabilitation approaches seek to promote awareness, understanding and acceptance in the process of rehabilitation and integrate this with the cognitive, social, emotional and functional aspects of brain injury. In Ben-Yishay and Prigatano's (1990) influential model of holistic rehabilitation, increased awareness,

acceptance and understanding are key principles in the psychosocial adjustment process. Since then holistic rehabilitation programmes have been developed in several countries (e.g. Wilson et al., 2000; Sarajuuri & Koskinen, 2006; Trexler, Eberle, & Zappala, 2000). Holistic interventions facilitate adjustment by supporting ABI survivors and their families to understand and accept the consequences of brain injury through a focus on metacognition (e.g. awareness and self-appraisal), regulation of emotions and interpersonal functioning (Cicerone et al., 2008). The trend for holistic approaches is recognised in the current UK neurorehabilitation guidelines which recommend access to therapeutic interventions that facilitate "long term psychological, family and social adjustment" (RCP/BSRM, 2003, p. 45). Similarly, the Department of Health's (2005) quality indicators for long term neurological conditions stress the importance of a holistic approach to cognitive, behavioural and emotional problems. Notably, in a recent meta-analysis, holistic neurorehabilitation programmes improved quality of life after brain injury (Cicerone et al., 2011).

Mindfulness

The practice of mindfulness has been shown to have positive holistic effects in important life domains of physical and mental health, behavioural regulation and interpersonal relationships (Brown, Ryan & Creswell, 2007). With origins in Buddhist meditation techniques, the practice of mindfulness was first introduced to the West by Jon Kabat Zinn in the 1980s. There is no one accepted operational definition of mindfulness, however there is general agreement that a key component of mindfulness is *sustained attention to the present moment* (Chiesa & Malinowski, 2011). Bishop et al. (2004) proposed that mindfulness is also the adoption of an orientation marked by *curiosity, openness and acceptance*. *Intention,* with regards motivation to engage in mindfulness practice, has also been asserted as a key component (Shapiro, Carlson, Astin & Freedman, 2006). The most widely-used used definition of mindfulness incorporates all of these aspects: "the awareness

that emerges through paying attention on purpose, in the present moment, and non-judgmentally to the unfolding of experience moment to moment." (Kabat-Zinn, 2003, p. 145).

Mindfulness-based interventions

Mindfulness-based interventions (MBIs) are a promising holistic approach (Cullen, 2011) and are increasingly offered as therapeutic interventions to ameliorate distress associated with long-term health conditions. MBIs are structured therapeutic programmes which train people to practice mindfulness using meditation techniques. The literature varies regarding the types of interventions classified as MBI for example Buddhist mindfulness meditations, group-based meditation practices and other mindfulness-informed psychotherapeutic interventions. The first standardised group-based MBI to be developed was Mindfulness-based Stress Reduction (MBSR; Kabat-Zinn, 1992), designed to reduce stress related to medical illnesses. MBSR is the most empirically-validated programme and the most widely-available and has been the foundation for numerous subsequent MBIs developed for specific populations and conditions. For example, Mindfulness-based Cognitive Therapy (MBCT; Segal, Williams & Teasdale, 2002) was developed for depression (see Cullen, 2011 for an overview of the range of MBIs available). *Third wave* behavioural psychotherapies (e.g. dialectical behaviour therapy [DBT; Linehan, 1993] and acceptance commitment therapy [ACT; Hayes, Strosahl & Wilson, 1999]) are sometimes classified as MBIs due to a common emphasis on experiential and contextual change strategies and the incorporation of elements of mindfulness training.

MBIs are commonly delivered as short-term closed groups and have a psycho-educational component. The rationale for delivering MBIs in a group format is threefold: (a) they are more faithful to the traditional monastic meditation practices (Kabat-Zinn, 1982); (b) they are more cost-effective than individual programmes (e.g. Kuyken et al., 2008); and (c)

the social processes within a group are considered an integral part of the intervention (Mental Health Foundation, 2010). A typical MBI group programme comprises eight weekly 2-2.5 hour sessions, each introducing a new meditation technique. MBI programmes also typically include one day-long session, and participants are provided with handouts and guided meditation exercises to facilitate daily home practice. Guided meditation exercises introduce participants to a range of objects of focus to sustain attention such as mindful breathing, mindful walking and body-scanning. For example, in a mindful breathing exercise, participants are encouraged to adopt an upright sitting posture and to sustain attention on the breath. When attention wanders, participants are taught to notice and acknowledge this event, to accept it without judgement, and to redirect attention back to the breath.

Mechanisms of change in mindfulness-based interventions

Several theories have been proposed regarding the mechanisms of change in MBIs, which lead to symptom reduction and behavioural change (for a review see Baer, 2003). The primary goal of mindfulness training is for participants to recognise their thoughts and feelings as mental events rather than as true reflections of reality, a phenomenon described as metacognitive insight (Teasdale, Segal & Williams, 1995). One mechanism of action may be through changes in thought patterns (Kabat-Zinn, 1982); learning to decentre oneself from mental events rather than engage with them may prevent triggering cycles of emotional reactivity (Azulay, Smart, Mott & Cicerone, 2013). A second proposed mechanism is the development of skills in non-judgmental observation during exposure to painful or distressing sensations. Through repeated exposure, the participant develops tolerance and greater acceptance of symptoms (Kabat-Zinn, 1982, 1992). A third proposed mechanism is the development of attentional control, along with an increased moment-to-moment awareness of mental events, which leads to increased self-efficacy in coping with ongoing symptoms. Conceptually, mindfulness training may result in a shift from an external to an internal locus

of control as participants feel more able to self-manage distressing or painful sensations (Azulay et al., 2013). Enhanced attentional control may also improve the ability to encode and retain new information and result in improvements in cognitive functioning (Chiesa, Calati & Serretti, 2011). One additional proposed mechanism of action is modification of brain, neuroendocrine and immune functions (Ludwig & Kabat-Zinn, 2008). There is increasing evidence for experientially-dependent neuroplasticity in the brain following mindfulness training (for a review see Tang, Hölzel, Posner, 2015) in healthy controls (e.g. Lazar et al, 2005) and neurological populations (Pickut et al., 2013; Tang & Tang, 2015). Lastly, meditation often induces relaxation which, whilst not the goal of mindfulness, may nonetheless represent a mechanism (Baer, 2003).

Evidence base for mindfulness-based interventions

MBIs have a growing evidence base for their effectiveness in reducing distress and enhancing quality of life in a range of physical and psychological conditions including chronic pain (Wong et al., 2011), anxiety and depression (Hofmann, Sawyer, Witt & Oh, 2010), coronary heart disease (Parswani, Sharma & Iyengar, 2013) and multiple sclerosis (Simpson et al., 2014). Furthermore, a number of studies using non-clinical samples have demonstrated a positive impact of MBIs on many psychological sequelae common to ABI. These include positive effects on attention (Kozasa et al., 2012), memory and executive function (Zeidan, Johnson, Diamond, David & Goolkasian, 2010), and emotional reactivity (Taylor et al., 2011). Taken together, the evidence base, although small, points to the potential utility of MBIs not just in symptom management but also in reducing common psychological effects of chronic illness (eg. stress, depression, anxiety), promoting coping strategies and adjustment and globally improving quality of life and wellbeing.

MBIs and the ABI population

The empirical evidence demonstrating the effectiveness of MBIs for chronic health conditions as well as psychological sequelae common to ABI, points to the potential utility for the ABI population. Furthermore, the leading theories of mechanisms of change behind mindfulness training (discussed above) were based on Kabat-Zinn's research with stress related to chronic medical conditions and are thus applicable to the ABI population (Azulay et al., 2013). In this context of converging empirical and theoretical strands, MBIs are increasingly investigated as a potentially viable option for use in the ABI population. These aim to improve quality of life, psychological wellbeing and develop skills for coping with long term physical disability and cognitive impairment. In addition, as MBIs are commonly delivered as group interventions they could represent a cost-effective approach within neurorehabilitation. However, mindfulness training places demands on several cognitive skills including attention (e.g. sustained concentration during a meditation exercise), memory (e.g. retention of content between sessions to aid progression), language (e.g. ability to engage in group discussions) and executive skills (e.g. ability to monitor behaviours). It will be important to establish whether MBIs are appropriate and effective for the ABI population and whether adaptations would increase its accessibility for people with cognitive impairment.

Rationale, aims and scope of the current review

A number of studies have been published in the past two decades examining the effectiveness of MBIs following ABI but a review of these has not yet been undertaken. In view of the potential utility of MBIs to this population there is a strong rationale for critically evaluating the existing evidence base and highlighting areas for future research by conducting

a systematic review. This review will seek to evaluate whether mindfulness-based interventions are an effective and appropriate treatment approach following ABI. For the purposes of this review, MBIs were defined as structured group-based therapeutic programmes with the primary focus on training group-members in mindfulness meditation practice. In line with criteria used by Chiesa and Seretti (2010), other *third wave* psychotherapies were not included in the current review because mindfulness training is not the primary focus of these interventions. As this is an emerging field, the literature search will be broad in scope and there will be no restrictions on date of publication. In keeping with the holistic approach of MBIs the current review will encompass studies investigating a broad range of psychosocial outcomes.

Method

Search strategy

In February 2016, the Ovid SP platform was used to perform an electronic literature search of published studies. The following databases were searched: EMBASE, AMED, MEDLINE and PsycINFO. The four databases were searched separately with slightly adjusted strategies reflecting the specific requirements of the operating system. The databases were searched using the keywords “acquired brain injury” and “mindfulness” and their associated synonyms (see Appendix B for search strategies). In addition a hand search of the reference sections of key papers was conducted and leading ABI mindfulness researchers were contacted.

Inclusion and exclusion criteria

Studies were selected for inclusion (table 1) using criteria based on the SPIO (Study Design, Participants, Interventions and Outcomes) framework (as described in Lawrence,

Booth, Mercer & Crawford, 2013). This framework is useful for determining inclusion criteria for systematic reviews incorporating designs other than randomised controlled trials.

Table 1.

SPIO framework to determine inclusion/exclusion criteria

	Inclusion criteria	**Exclusion criteria**
Study Design	Original empirical studies comprising: • Randomised controlled trials (RCTs) • Nonrandomised controlled trials (CTs) • Uncontrolled single group cohort (pre/post) studies • Post hoc effectiveness studies	Case studies and case series Qualitative studies Systematic/literature reviews
Participants	Adults (aged ≥18 years)	<18 years old
	Acquired Brain Injury (ABI): any brain injury occurring after birth from following causes: • Trauma (due to head injury or post-surgical damage) • Cerebrovascular accident (stroke) • Cerebral anoxic injury • Toxic or metabolic insult • Infection or other inflammation • Tumours	Neurological conditions other than ABI (degenerative brain conditions such as Alzheimer's Disease and Parkinson's Disease will be excluded)
	Mixed neurological populations where ABI data can be extracted	
Interventions	Structured group-oriented Mindfulness-based interventions (MBIs) with primary focus on training participants in mindfulness meditation practice	Psychotherapeutic approaches with mindfulness elements MBIs not delivered in a structured group format (ie. Individual therapy delivered face-to-face or on a computer) Yoga interventions with mindfulness as a key but secondary component
Outcomes	Primary focus of interest: Quality of life, psychological wellbeing Additional areas of interest: Psychological outcomes including mood (anxiety, depression, stress), adjustment, cognitive functioning, chronic pain, fatigue	
Additional criteria	Studies must be published in English Studies must use at least one objective validated outcome measure	

As this is a new field of empirical enquiry, this review included original quantitative studies with a range of study designs but excluded case studies and case series on the grounds that these are not group-based. Criteria for participants concerned age (>18 years old) and condition (ABI, as defined in table 1). MBIs were included if they met the criteria of a structured group-based intervention with a primary focus on training participants in mindfulness meditation practice. In terms of outcomes, the primary focus of interest was on quality of life and psychological wellbeing. Additional areas of interest were mood, adjustment, cognitive functioning, chronic pain and fatigue. Studies were excluded if they were not published in English or did not use at least one validated outcome measure.

Methodological quality and risk of bias

The quality of methodology and risk of bias of the included studies was assessed using an adapted version of the Effective Public Health Practice Project (EPHPP) Quality Assessment Tool (Thomas, Ciliska, Dobbins & Micucci, 2004)[1]. The EPHPP tool was appropriate for this review as it provided a standardised way of evaluating the quality of a wide range of study designs. The EPHPP tool was used to examine the following domains of each study: selection bias, study design, confounders, blinding, data collection methods, withdrawals and dropouts, intervention integrity and analysis. Following the EPHPP guidelines, six of the eight domains (excluding intervention integrity and analysis) were then rated as "strong", "moderate" or "weak" and amalgamated to yield a global rating of quality (see Appendix C).

[1] This checklist was judged suitable for use in systematic reviews of effectiveness (Deeks et al., 2003) and has been shown to have acceptable content and construct validity and inter-rater reliability (Thomas et al., 2004).

Data extraction

A data extraction form (see Appendix D) was used to extract information systematically from each article. The form was modelled on the criteria specified in the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement (Moher, Liberati, Tetzlaff & Altman, 2009). Data extracted included: location of study, study design, participant characteristics, measures of outcome, main findings, statistical analyses employed, adverse outcomes and ethical issues.

Results

Results of search

The database and manual searches yielded, after removing duplicates, 327 articles (see Appendix B for database search results). The article abstracts were screened and 305 were excluded for not meeting the inclusion criteria. In total, 22 full text articles were then evaluated and seven were removed in light of not being published in an academic journal or meeting the criteria for group-based MBIs. In total 15 articles, reporting on 14 studies, were identified for inclusion in the review. Figure 1 provides a flow chart showing the process used for identifying relevant studies. Table 2 provides a summary of the included studies in terms of their design, participant details, intervention, outcome measures and key findings. The results are then discussed in terms of the different forms of mindfulness training, the outcomes and a critique of the studies.

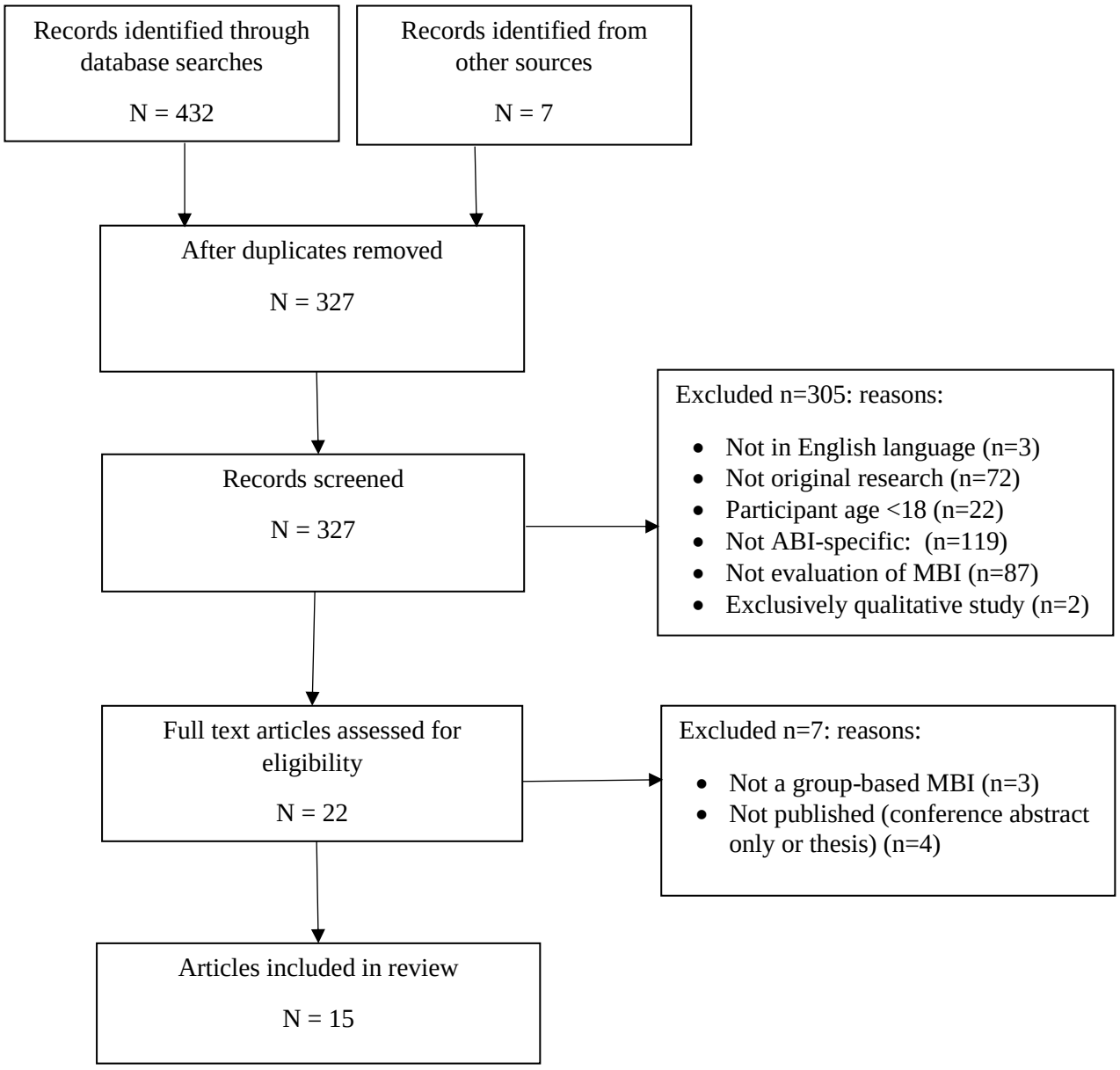


Figure 1. Flow chart showing selection process

Table 2

Summary of design, form of mindfulness training, outcome measures and main findings for the included studies (n = 14)

Authors; Country	***EPHPP Global rating***	***Design***	***Intervention: primary focus of intervention and form of mindfulness training***	***Participant Details***	***Outcome Measures***	***Key findings***
McMillan, Robertson, Brock & Chorlton (2002); United Kingdom (UK)	Strong	RCT	Primary focus: capacity for sustained attention Form of mindfulness: Attentional Control Training (5 sessions) Control condition(s): 1) Physical Exercise 2) No treatment	ABI type: TBI only Time since BI: 3-12 months Participants recruited: n = 145 Drop-outs: n = 15 Treatment group (n=44) Mean age: 34.6(11.4); 80% male Control group 1 (n=38) Mean age: 31.4(13.0); 79% male Control group 2 (n=48) Mean age: 36.2(13.4); 75% male	BI Symptom severity: RPQ Mental health: HADS, GHQ Cognitive functioning: TEA, AMIPB, PASAT, TMT, SMQ, CFQ	• No significant difference on any measure at post-intervention or 12 month follow-up
Bedard et al. (2014); Canada	Moderate	RCT	Primary focus: reduction of depression symptoms Form of mindfulness: combined MBCT/MBSR (10 sessions) Control condition(s): wait-list	ABI type: TBI only Participants recruited: n = 105 Drop-outs: n = 29 Treatment group (n=38) Mean age: 47.1; 50% male Mean time since BI: 4.5(4.1) years Control group (n = 38) Mean age: 45.8; 60% male Mean time since BI: 4.0(3.5) years	Mental health: BDI-II, PHQ, SCL-90R Mindfulness: PHLMS, TMS	• Medium ES on BDI-II (depression), improvements maintained at 3 month follow-up • No change on PHQ/SCL-90R • Non-sig. improvements on PHLMS/TMS (although small ES on PHLMS-acceptance/ TMS-decentering subscales)

Authors; Country	***EPHPP Global rating***	***Design***	***Intervention: primary focus of intervention and form of mindfulness training***	***Participant Details***	***Outcome Measures***	***Key findings***
Johansson, Bjuhr, Rönnbäck (2012); Sweden	Moderate	RCT	Primary focus: mental fatigue reduction Form of mindfulness: MBSR (8 sessions) Control condition(s): wait-list	ABI type: mixed stroke & TBI Participants recruited: n = 29 Drop-outs: 3 Stroke/TBI: 16/10 Treatment group (n = 12) Mean age: 53.7(6.1); 58% male Mean time since BI: 3.3(3.8) years Control group (n = 14) Mean age: 57.1(7.3); 29% male Mean time since BI: 9.8(7.5) years	Mental health: CPRS Cognitive functioning: WAIS-III DS-C; TMT; FAS Physical: MFS (primary outcome measure)	• Sig. improvements on MFS (fatigue) • Sig. reduction in anxiety and depression scores on CPRS • - Sig. improvements on some cognitive tests
Nassif et al.. (2015); USA	Moderate	Pilot RCT	Primary focus: chronic pain reduction Form of mindfulness: Integrative Restoration Yoga Nidra® (iRest) (8 sessions) Control condition(s): no treatment	ABI type: TBI (combat-related) Time since BI: not stated Participants recruited: n = 13 Drop-outs: n=5 (all from treatment group) Treatment group (n=4) Mean age: 45.3(1.5); 100% male Control group 1 (n=5) Mean age: 49.6(8.1); 100% male	Physical: DVPRS, BPI, VAS (pain)	• Clinically meaningful (<20%) reductions in pain intensity/ interference on most outcome measures • At 4 week follow up improvements fully (on DVPRS-I) or partially maintained (on BPI, VAS)

Authors; Country	*EPHPP Global rating*	*Design*	*Intervention: primary focus of intervention and form of mindfulness training*	*Participant Details*	*Outcome Measures*	*Key findings*
Johansson, Bjuhr, Karlsson, Karlsson, Rönnbäck (2015a); Sweden	Weak	CT	Primary focus: mental fatigue reduction Forms of mindfulness: 1) face-to-face MBSR (8 sessions); 2) online MBSR (8 sessions) Control condition(s): walking group	ABI type: mixed stroke/TBI Participants recruited: n = 38 Drop-outs: n = 4 Stroke/TBI: 18/16 Treatment group 1 (n=12) Mean age: 48(9.4); 8% male Time since BI: 120 (152) months Treatment group 2 (n=13) Mean age: 46.3 (12); 15% male Time since BI: 76.2 (75.5) months Control group 1 (n=9) Mean age: 51.2(10.6); 33% male Time since BI: 50.1 (47.3) months	Mental health: CPRS Cognitive functioning: WAIS-III DS-C, AB Physical: MFS (primary outcome measure) Mindfulness: SCS (short form)	• Online MBSR demonstrated as more effective than face-to-face MBSR • Sig. improvements following online MBSR on MFS (fatigue), CPRS (mood) and processing speed coding • No sig. changes on any measure after face-to-face MBSR except on AB task • Sig improvement on SCS (self-compassion)
Bedard et al. (2003)/ Bedard, Felteau, Gibbons & Klein (2005); Canada	Weak	Cohort (one group pre/post) + 1 year follow up	Primary focus: improving quality of life Form of mindfulness: MBSR (12 sessions) Control condition(s): drop-outs used as controls	ABI type: TBI (mild/moderate) Time since BI: not stated Participants recruited: n = 13 Treatment completers (n = 10) Mean age: 43 (23-55); 30% male Drop-outs as controls (n=3) Mean age: 39 (26-46);100% male 1 year FU with treatment completers (n=7) Mean age: 45.6(11.2); 29% male	QoL: SF-36 (primary outcome measure), CIQ Mental health: BDI-II, SCL-90R, PSS Locus of control: MHLC Physical: VAS (pain)	• Statistical and clinical sig. improvements on SF-36 • Medium ES for reduction in depression symptoms (BDI-II), sig. reduction on cognitive-affective not somatic domain • No sig. changes on SCL90R, PSS, MHLC or CIQ • Improvements mostly maintained at 1 year follow up

Authors; Country	*EPHPP Global rating*	*Design*	*Intervention: primary focus of intervention and form of mindfulness training*	*Participant Details*	*Outcome Measures*	*Key findings*
Moustgaard, Bedard, Felteau (2007)*; Canada	Weak	Cohort (one group pre/post) + 3 month FU	Primary focus: improving health status, mood and quality of life Form of mindfulness: MBSR (9 sessions) Control condition(s): N/A	ABI type: stroke Time since BI: not stated Participants recruited: n = 30 Drop-outs: 7 Treatment completers (n = 23) Mean age: 63(11.8); 74% male	QoL: SS-QOL, SF-36 Mental health: BAI, BDI-II, HADS Cognitive functioning: MMSE	• Sig. improvements (large ES) demonstrated on all mood and QoL measures • Improvements mostly maintained at 3 month follow up • Results on MMSE not reported
Joo, Lee, Chung, Shin (2010); Korea	Weak	Cohort (one group pre/post)	Primary focus: reducing depression/anxiety and HRV Form of mindfulness: MBSR (8 sessions) Control condition(s): N/A	ABI type: stroke (SAH) Time since BI: 6-16 months Participants recruited: n = 28 Drop-outs: 17 Treatment completers (n = 11) Mean age: 52.6(38-65);45% male	Mental health: BDI (Korean version), STAI Physical: heart rate variability, blood pressure	• Sig reduction in depression scores (BDI) • Non-sig. improvement on anxiety (STAI) measure • Improvements demonstrated in a range of HRV parameters • Non-sig. reductions in BP
Bedard et al.. (2012); Canada	Weak	Cohort (one group pre/post)	Primary focus: reducing depression symptoms Form of mindfulness: MBCT (8 sessions) Control condition(s): N/A	ABI type: TBI Time since BI: >1 year Participants recruited: n = 23 Drop-outs: 3 Treatment completers (n = 20) Mean age: 47.1 (15.7); 55% male	QoL: SF-36 Mental health: BDI-II, HADS, PHQ-9, SCL-90R Physical: VAS (pain; energy), medication usage BI Symptom severity: MPAI-4	• Sig. improvements (medium to large ES) on all depression measures • Sig. reductions on SCL-90R and in pain intensity • Sig. increase in energy levels • No sig. changes in QoL, anxiety, pain frequency, adjustment or meds usage

Authors; Country	***EPHPP Global rating***	***Design***	***Intervention: primary focus of intervention and form of mindfulness training***	***Participant Details***	***Outcome Measures***	***Key findings***
Azulay, Smart, Mott, Cicerone (2013); USA	Weak	Cohort (one group pre/post)	Primary focus: improving QoL, self-efficacy, reducing neuro-behavioural symptoms Form of mindfulness: MBSR (10 sessions) Control condition(s): N/A	ABI type: TBI (mild) Time since BI: mostly 7-36 months (1 patient >36 months) Participants recruited: n = 22 (only treatment completers stated) Drop-outs: not stated Treatment completers (n = 22) Mean age: 48.9(8.3); 50% male	QoL: PQOL (primary outcome measure) BI Symptom severity: NSI Self-efficacy: PSES Cognitive functioning: CPT-A, PASAT, CVLT-II, SPSI Mindfulness: MAAS	• Clinically meaningful (moderate ES) improvements on PQoL and PSES measures • Non-sig. reductions (small to mod ES) in symptoms on NSI • Mixed findings on cognitive measures (sig improvements in attention, non-sig changes on other cognitive measures)
Johansson, Bjuhr, Rönnbäck (2015b); Sweden	Weak	Cohort (one group pre/post)	Primary focus: reducing chronic mental fatigue Form of mindfulness: advanced mindfulness program (8 sessions; FU to MBSR study in 2012) Control condition(s): N/A	ABI type: Mixed stroke/TBI Time since BI: not stated Participants recruited: n = 14 Drop-outs: 0 Stroke/TBI: 8/6 Treatment completers (n = 14) Mean age: 58.1 (5.8); 36% male	Cognitive functioning: WAIS-III DS-C; TMT; FAS Physical: MFS (Primary outcome measure)	• No sig. changes on any measure. • However, improvements in fatigue, processing speed and attention observed after previous MBSR group (2012 study) were all maintained after this advanced mindfulness program
Cole et al. (2014); USA	Weak	Cohort (one group pre/post)	Primary focus: reducing psychiatric and neurocognitive symptoms Form of mindfulness: MBSR (8 + 2 sessions) Control condition(s): N/A	ABI type: TBI (mild)/comorbid PTSD Time since BI: <1 year Participants recruited: n = 10 Drop-outs: 1 Treatment completers (n = 9) Mean age: 45.6(11.6);100% male	Mental health: PCL-C Cognitive functioning: Cogstate subtests (D; I)	• Sig. improvements (medium E.S.) in attention, maintained at 3 month follow up • Sig. reduction (large E.S.) in PTSD symptoms and maintained at 3 month follow up

Authors; Country	*EPHPP Global rating*	*Design*	*Intervention: primary focus of intervention and form of mindfulness training*	*Participant Details*	*Outcome Measures*	*Key findings*
Merriman et al. (2015); UK	Weak	Pilot cohort (one group pre/post)	Primary focus: feasibility of MBCT with stroke survivors Form of mindfulness: MBCT (9 sessions) Control condition(s): N/A	ABI type: stroke only Time since BI: 1-4 years Participants recruited: n = 4 Drop-outs: not stated Treatment completers (n = 4) Age range: 47-62; 75% male	QoL: WHOQoL-BREF Mental health: HADS Cognitive functioning: RSAP Mindfulness: FFMQ	• No statistical analysis conducted by authors. • 50% of participants had clinically meaningful improvements on HADS • All participants showed Improvements on an attention measure (RSAP), but significance not stated
Detert & Douglass (2014); UK	N/A	Post-hoc effectiveness	Primary focus: reducing psychiatric symptoms and perceived stress Form of mindfulness: MBSR/MBCT (8 sessions) Control condition(s): N/A	ABI type: Mixed neurological sample (ABI/non-ABI) Time since BI: not stated Participants recruited: n = 182 Drop-outs: 35 (+ 48 did not complete questionnaires) Demographic data for full sample of treatment completers (n = 98): Mean age: 44.0 (12); 28% male ABI* subset of sample (n=14): Demographic info not available TBI/stroke/tumours: 3/5/6	Mental health: BSI, PSS	• Sig. improvement (large ES) on perceived stress measure • Sig. reduction on BSI (full scale). Sig. improvements on depression subscale (large ES) and anxiety subscale (mod. ES)

Note: AB=Attentional Blink task (Dux & Marois, 2009), AMIPB=Adult Memory and Information Processing Battery (Coughlan & Hollows, 1985), BAI=Beck Anxiety Inventory (Beck & Steer, 1993), BDI-Korean=Beck Depression Inventory Korean (Shin et al., 1993), BDI-II=Beck Depression Inventory Revised (Beck et al., 1996), BPI=Brief Pain Inventory (Cleeland & Ryan, 1994), BSI=Brief Symptom Inventory (Derogatis, 1993), Cogstate (D/I)=Cogstate (Detection/Identification subtests) (Maruff et al., 2009), CFQ=Cognitive Failures Questionnaire (Broadbent et al., 1983), CIQ=Community Integration Questionnaire (Sander et al., 1999), CPRS=Comprehensive Psychopathological Rating Scale (Svanborg & Asberg, 1994), CPT-A=Continuous Performance Test of Attention (Cicerone, 1997), CVLT-II=California Verbal Learning Test, Second Edition (Delis et al., 2000), DVPRS=Defense and Veterans Pain Rating Scale (Buckenmaier, 2013), FAS=FAS verbal fluency test (Ellis et al., 2001), FFMQ=Five Facet Mindfulness Questionnaire (Baer, Smith, Hopkins,

Krietemever & Toney, 2006), GHQ=General Health Questionnaire (Goldberg & Williams, 1988), HADS=Hospital Anxiety and Depression Scale (Zigmond & Snaith, 1983), MAAS=Mindful Attention and Awareness Scale (Brown & Ryan, 2003), MFS=Mental Fatigue Scale (Johansson et al., 2010), MHLC=Multidimensional Health Locus of Control scale (Wallston, Wallston & DeVellis, 1978), MMSE=Mini-Mental Status Exam (Folstein, Folstein & McHugh, 1975), MPAI-4=Mayo-Portland Adaptability Inventory (Bohac, Malec & Moessner, 1997), NSI=Neurobehavioral Symptom Inventory (Cicerone & Kalmar, 1995), PASAT=Paced Auditory Serial Addition Test (Gronwall, 1977), PCL-C=PTSD Checklist – civilian version (Weathers, Litz, Herman, Huska & Keane, 1993), PHLMS=Philadelphia Mindfulness Scale (Cardaciotto, Herbert, Forman, Moitra & Farrow, 2008), PHQ=Patient Health Questionnaire-9 (Kroenke & Spitzer, 2002), PSS=Perceived Stress Scale (Cohen, Kamarck & Mermelstein, 1983), PQOL=Perceived Quality of Life scale (Cicerone & Azulay, 2007), PSES=Perceived Self-efficacy Scale (Cicerone & Azulay, 2007), RPQ=Rivermead Post-Concussional Symptoms Questionnaire (King et al., 1995), RSAP=Rating Scale for Attentional Problems (Ponsford & Kinsella, 1991), SCS=Self-compassion Scale (Neff, 2003), SCL90R=Symptom Checklist-90-Revised (Derogatis, 1994), SF-36=36-Item Short-Form General Health Survey (Ware & Sherbourne, 1992), SMQ=Sunderland Memory Questionnaire (Sunderland, Harris & Gleave, 1984), SPSI=Social Problem-solving Inventory-Revised (D'Zurilla, Nezu & Maydeu-Olivares, 2002), SS-QOL=Stroke Specific Quality of Life Scale (Williams, Weinberger, Harris, Clark & Biller, 1999), STAI=State-trait Anxiety Inventory (Spielberger, Gorsuch & Lushene, 1970), TEA=Test of Everyday Attention (Robertson, Ward, Ridgeway & Nimmo-Smith, 1994), TMS=Toronto Mindfulness Scale (Lau et al., 2006), TMT=Trail-making Test (Reitan & Wolfson, 1985), WAIS-III DS-C=Wechsler Adult Intelligence Scale 3rd Edition Digit-Symbol Coding (Wechsler, 1997), WHOQoL-BREF=World Health Organization Quality of Life – BREF (Skevington, Lofty & O'Connell, 2004). See Appendix E for references for all outcome measures.

*supplemented with contact with authors

BI=brain injury, QoL=quality of life, ES=effect size, RCT=randomised controlled trial, CT=controlled trial, SAH=subarachnoid haemorrhage, BP=blood pressure, HRV=heart rate variability, VAS=Visual Analogue Scale

Overview of studies

The 14 studies under review evaluated a range of MBIs which included MBSR, MBCT and a number of modified-MBSR or MBSR-derivative programmes. The duration of MBI programmes ranged from 4 weeks to 12 weeks with the exception of one eight month advanced mindfulness program. The studies were conducted in a number of countries including Canada (4/14), United States of America (3), Sweden (3), United Kingdom (3) and Korea (1).

The study designs included 4 randomised controlled trials (RCT), 1 controlled trial (CT), 1 cohort (one group pre/post) study with drop-outs serving as controls, 7 standard cohort (one group pre/post) studies and one post-hoc effectiveness study. In terms of EPHPP global quality ratings[2], one study was classified as 'strong', three studies as 'moderate' and nine as 'weak'.

The total samples across the 14 studies included 656 participants. Excluding drop-outs[3] and non-ABI participants[4], there were 402 treatment completers (250 completed an MBI; 152 completed control interventions). From the demographic data available, the participants comprised 233 men and 155 women, and the mean ages ranged from 31 to 63 years. Two studies recruited samples of American male combat veterans and the remaining studies recruited civilians. In terms of aetiology, 314 participants had a TBI, 85 had experienced a stroke and 6 had other types of ABI.

[2] Detert and Douglass' (2014) study did not use an experimental design and was therefore not rated using the EPHPP criteria

[3] Several studies reported demographic information only for treatment completers

[4] Detert and Douglass' (2014) study used a mixed neurological sample which included non-ABI participants. ABI-only data were obtained from the authors and included in the review. However, the recruitment and drop-out data specific to ABI participants was not available.

Forms of mindfulness training

The 14 studies under review evaluated a number of MBIs including MBSR, adapted MBSR, MBSR derivatives (Attentional Control Training, Integrative Restoration Yoga Nidra® [iREST], an advanced eight-month mindfulness program), combined MBSR/MBCT and MBCT. It should be noted that iREST (Miller, 2005), was classified as an MBI due the primary focus on learning mindfulness meditation skills. Of note, iREST does not utilise yoga postures. Table 3 provides a summary of the programmes in terms of their format, duration, use of home practice and adaptations for brain injury patients. One study (Joo et al., 2015) reported using a standard MBSR approach with no ABI adaptations. The majority of studies (7/15) employed adapted MBSR programmes which were designed to accommodate the specific needs of ABI patients. The remaining studies utilised MBSR-derivative programmes which included MBCT (a well-established MBI programme) and new MBI programmes developed specifically for this population (Attentional Control Training, iREST). The most common format was to run 8 weekly 150 minute sessions with a day-long silent retreat which is in keeping with the standard MBSR programme format.

Several studies increased the duration of their MBI programmes (up to 12 weeks) and shortened the length of sessions, giving the rationale of accommodating reduced attention and increased fatigue. With one exception (Bedard et al., 2003/Bedard et al., 2005), studies asked participants to conduct regular mindfulness practice (between sessions) at home. To facilitate home practice, participants were commonly issued with an audio CD containing guided meditation exercises. Several authors asked participants to complete a daily log of home practice. Given the potential for home practice to enhance the effectiveness of the group sessions it was surprising that just one study (Johansson et al., 2015a) reported collecting and analysing data relating to home practice.

Table 3

Descriptions of the mindfulness-based group interventions employed in the included studies (n=14)

Study	***Intervention***	***Duration /weeks***	***Format of sessions***	***Daily practice***	***Guidance for daily practice***	***Qualifications of facilitator(s)***	***Adaptations for ABI patients***
McMillan et al. (2002)	Attentional Control Training	4	5 x 45 min	Not stated	Audio tape, daily logs	Not stated	Not stated
Bedard et al. (2014)	MBCT/MBSR	10	10 x 90 min, weekly	20-30 min advised	Handouts, a book, audio CD	Tailored training package for facilitators, personal practice	Shorter sessions, frequent reviews/repetition, simplified language, visual aids
Johansson et al. (2012)	MBSR	8	8 x 150 min, weekly 1 x all-day silent retreat	45 min advised	Guided instructions, audio CD	MBSR trained Clinical Psychologist	Unspecified adaptations for memory/processing difficulties
Johansson et al. (2015a)	MBSR and online MBSR	8	MBSR: 8 x 150 min, weekly 1 x day-long silent retreat Online MBSR: same format but online using microphones/ cameras to interact as a group	Mean of 30 min practice time	Instructional videos, audio CD. Asked to introduce mindfulness into daily living	MBSR trained Clinical Psychologist	Not stated
Nassif et al. (2015)	iRest	8	16 x 60 min, twice-weekly	Not stated	Audio exercises, iRest workbook	Not stated	Not stated
Bedard et al. (2003)/ Bedard et al (2005)	Adapted MBSR	12	12, session duration not stated	Not stated	Not stated	Not stated	Not stated
Moustgaard et al. (2007)	MBCT	9	9 x 105 min, weekly	Not stated	Unspecified at-home task assignments and log books	Trained mindfulness meditation and yoga instructor	Modified physical exercises, stroke-specific psycho-education, pertinent & sensitive language
Joo et al. (2010)	MBSR	8	8 x 150 min, weekly	Not stated	Audio CD	Not stated	Not stated
Bedard et al. (2012)	Combined MBSR/MBCT	8	8 x 90 min, weekly	Not stated	Minor written homework and CD meditation exercises	Experienced MBCT trainer	Shorter sessions, memory aids, repetition, frequent reviews

Study	*Intervention*	*Duration /weeks*	*Format of sessions*	*Daily practice*	*Guidance for daily practice*	*Qualifications of facilitator(s)*	*Adaptations for ABI patients*
Azulay et al. (2013)	Modified MBSR	10	10 x 120 min, weekly	Not stated	Unspecified assignments and log	Experienced MBSR-trained neuropsychologists	More sessions, smaller groups, more modelling, repetition, assignments given verbally and in writing
Johansson et al. (2015b)	Advanced mindfulness	32	8 x 150 min, monthly 1 all-day retreat	Not stated	Unspecified home practice	Clinical Psychologist/MBSR teacher. Followed MBSR group.	Slower pace, repetition, minimal excess talk during exercises. Modified physical exercises
Cole et al. (2014)	MBSR	8	2 hour introductory class. 8 x 150 min. 1 all-day silent retreat	45 min advised	Meditation/yoga using CDs. Asked to bring mindfulness to daily activities.	Experienced MBSR trained Clinical Psychologist	Modified physical exercises
Merriman et al. (2015)	MBCT	9	9 x 120 min, weekly	Not stated	Logs of practice and events	Clinical and Assistant Psychologist	Modified physical exercises. Visual and audio handouts. Reminders
Detert & Douglass (2014)[5]	Combined MBSR/MBCT	8	8 x 150 mins, weekly 1 all-day silent retreat	Not stated	Home practice required but details of guidance not given.	Not stated	Extensive adaptations focused on cognitive function, physical function, fatigue, functional neurological symptoms

Note: iRest=Integrative Restoration Yoga Nidra®, MAP=Mindfulness Attention Program, MBCT=Mindfulness-based cognitive therapy, MBSR=Mindfulness-based stress reduction.

[5] Detert & Douglass (2014) reported results from 13 cycles of mindfulness groups (Cycles 1-11: modified MBSR with elements of MBCT. Cycles 12-13: modified MBCT with elements of MBSR. Only changes were to handouts and order of topics.

The majority (9/14) of studies reported specific adaptations to facilitate ABI patients in learning mindfulness. Aside from shorter sessions, other reported adaptations included smaller group sizes, shorter day retreats, simplified sensitive language (pertinent to ABI) and modified mindful movement exercises (use of sitting/standing yoga positions and shorter walking meditation exercises). In addition, several authors reported adaptations to accommodate memory and processing difficulties such as repetition, frequent reviews, more modelling, guidance, prompts and handouts.

Research findings

The findings from the included studies are discussed in terms of the aims of the intervention. Studies evaluating the impact of MBIs on quality of life were examined first as this was the primary domain of interest for this review. Other key domains of interest were mental health, cognitive functioning, physical health, self-efficacy/health locus of control, brain injury symptom severity and self-reported levels of mindfulness.

Studies with a quality of life focus. In total three studies had health-related quality of life (HRQoL) as their primary intervention focus and a further two studies used HRQoL outcome measures. In Bedard et al.'s (2003/2005) cohort study statistically and clinically significant improvements were demonstrated on the SF-36 Mental Health subscale and maintained at one year follow-up. Moustgaard et al. (2007) demonstrated significant improvements (with a large effect size) on both the SS-QoL and SF-36 QoL measures in their cohort study. Similarly, Azulay et al. (2013) reported clinically meaningful (moderate effect size) improvements on the PQOL measure. Merriman et al. (2015) conducted a pilot cohort study and reported a trend toward improvement (although no statistical analysis was conducted) on the WHOQoL-BREF. However, Bedard et al.'s (2012) cohort study reported no significant changes on the SF-36. In summary, several studies measuring self-reported

quality of life demonstrated encouraging improvements although none of these used controlled designs.

Studies with a mental health focus. Mental health was the most studied outcome; five studies had mental health as their primary focus of interest and a further six used mental health outcome measures. Evidence from the controlled trials was equivocal. Johansson et al. (2012) reported significant reductions on both anxiety and depression scores on the CPRS measure. McMillan et al. (2002) reported no significant changes on both the HADS and GHQ measures. The remaining three controlled trials reported mixed findings. Bedard et al. (2014) demonstrated a significant reduction (medium effect size) of depression symptoms on the BDI-II but found no change on two other depression measures (PHQ, SCL-90R). Lastly, Johansson et al. (2015a) reported significantly improved anxiety and depression scores on the CPRS measure following online MBSR but failed to replicate the improvements (seen in their previous 2012 study) with face-to-face MBSR.

The six cohort studies were more consistent in demonstrating positive improvements in mental health. Cole et al. (2014) reported a significant reduction (large effect size) in post-traumatic stress disorder (PTSD) symptoms which was maintained at 3 month follow-up. Moustgaard et al. (2007) reported significant improvements (large effect sizes) on all mood measures (BAI, BDI-II and HADS) which were mostly maintained at 3 month follow-up. Bedard et al. (2012) demonstrated significant improvements (medium to large effect sizes) on all four depression measures, but no significant improvement on anxiety measures, following an MBCT program. In an earlier study evaluating MBSR, Bedard et al. (2003/Bedard et al., 2005) had demonstrated a significant reduction (medium effect size) on the cognitive affective domain of the BDI-II but no significant improvements on other measures of mood or perceived stress. Joo et al. (2010) demonstrated a significant reduction in depression scores on the BDI-Korean version but no significant improvement on the STAI anxiety

measure. Merriman et al. (2015) demonstrated clinically meaningful improvements for 50% of their participants on the HADS anxiety subscale. Lastly, Detert and Douglass (2014), in their post-hoc effectiveness study, demonstrated significant improvements in both depression and anxiety using the BSI measure, as well as significant improvements (large effect size) on a measure of perceived stress. In summary, there is an emerging evidence base for improvements in mental health but the results remain somewhat equivocal.

Studies with a cognitive functioning focus. Eight studies included measures of cognitive functioning but only one study (McMillan et al., 2002) cited this as their primary focus of interest. The results below have been organised according to the cognitive domain under investigation. Presumably reflecting the focus of mindfulness training, the majority of studies included measures of attention and/or working memory and reported equivocal findings. In an RCT, Johansson et al. (2012) reported significant improvements following both face-to-face and online MBSR in an attentional blink task. In McMillan et al.'s (2002) RCT there were no significant effects reported on two attention test batteries, the TEA and PASAT. Azulay et al. (2013) reported significant improvements (small effect sizes) on two attention measures (CPT-A, PASAT). Cole (2014) demonstrated significant improvements (medium effect sizes) in attention using the Cogstate battery which was maintained at 3 month follow-up. Lastly, Merriman et al. (2015) reported that all participants improved their scores on a clinician-rated measure of attention, although the significance of this is not known as no statistical analysis was conducted.

Only two studies investigated the effectiveness of MBIs on memory and both reported no significant findings. Azulay et al. (2013) demonstrated non-significant improvements on the CVLT-II, and McMillan et al. (2002) demonstrated no significant effects on the SMQ or the AMIPB.

The findings relating to processing speed were more encouraging but were only investigated by Johansson and colleagues using the WAIS-III Digit-Symbol Coding task in a series of three studies. In Johansson et al.'s earlier RCT (2012) a significant improvement was reported on the Coding task following MBSR. This result was found to be maintained but not improved after their follow-up cohort study (2015b). However, in their more recent RCT (2015a), scores on the Coding task significantly improved in the online MBSR and the walking control group but not in the face-to-face MBSR group.

Executive functioning was also investigated by four studies. On the Trail Making Task (TMT), Johansson et al. (2012) reported mixed findings and McMillan et al. (2002) demonstrated no significant changes. Azulay et al. (2013) reported non-significant improvements on the SPSI, a measure of social problem-solving. Lastly, McMillan et al. (2002) reported no significant changes on the CFQ, a measure of cognitive failures.

In summary, both the range of domains under investigation and the variety of neuropsychological measures makes it difficult to draw conclusions about the effectiveness of MBIs on cognitive functioning. Attention has been the most studied domain but yielded equivocal findings, there are currently no studies showing positive effects of MBIs on memory, and at present there is very limited evidence regarding processing speed and executive functioning.

Studies with a physical health focus. One half of the included studies employed measures of physical functioning. For the series of studies conducted by Johansson and colleagues reduction of mental fatigue was the primary objective. Johansson et al., (2012) reported significant improvements on the Mental Fatigue Scale (MFS) and Johansson et al. (2015b) demonstrated that these gains had been maintained. Interestingly, Johansson et al. (2015a) demonstrated significant improvements in the online MBSR group but not the face-

to-face MBSR group. The cohort study conducted by Nassif et al. (2015) focussed on chronic pain reduction and reported clinically meaningful (<20%) reductions in pain intensity/interference on most of their outcome measures, which were largely maintained at 4 week follow-up. Three other studies used supplementary physical measures. Joo et al. (2010), in their cohort study, demonstrated significant improvements in a range of heart rate variability parameters. In a series of cohort studies (Bedard et al., 2003/Bedard et al., 2005; Bedard et al., 2012), visual analogue scales were used to measure pain frequency/intensity and energy levels. Bedard et al., 2003/Bedard et al., 2005 reported significant and maintained improvements on all three scales in their earlier study. In a later study, Bedard et al. (2012) demonstrated significant improvements in pain intensity and energy levels but no change in medication usage. In summary, there is some preliminary evidence that MBIs may be effective for reducing mental fatigue and the experience of pain.

Studies with a self-efficacy or health locus of control focus. Azulay and colleagues (2013) demonstrated clinically and statistically significant improvements (moderate effect size) on a measure of perceived self-efficacy. Bedard et al., 2003/Bedard et al., 2005 reported no significant changes on the MHLC, a measure of health-related locus of control (LoC). Although closely-related, self-efficacy and LoC are separate psychological constructs and the lack of evidence prevents conclusions being drawn with regards the effectiveness of MBIs on these psychological traits.

Studies measuring brain injury symptom severity. Three of the studies under review included global measures of brain injury symptom severity which assess a broad range of sequelae including noise sensitivity, headaches and irritability. McMillan et al. (2002) reported no significant changes on the RPQ in their RCT study. Azulay et al. (2013) demonstrated non-significant improvements (small to moderate effect size) on the Neurobehavioral Symptoms Inventory (NSI). Bedard et al. (2012) demonstrated non-

significant improvements on the MPAI-4. In short, there were no significant positive changes following MBIs on measures of brain injury symptom severity.

Studies measuring self-reported mindfulness levels. Interestingly, only three studies included a measure of self-reported levels of mindfulness and one a measure of self-compassion (a key element of mindfulness). Azulay et al. (2013) reported non-significant improvements on the MAAS measure of mindfulness. Merriman et al. (2015) reported an improved group average score on the FFMQ measure of mindfulness but the significance of this is unknown as no statistical analysis was conducted. Johansson et al. (2015a) found non-significant improvements in both MBSR groups (online and face-to-face) and the walking control group on a self-compassion measure. In Bedard et al.'s (2014) RCT, there were increases in mindfulness levels (small effect sizes) observed on the PHLMS acceptance subscale and the TMS decentering subscale, but not on total scale scores.

Critique of studies

Study design and quality

The hierarchy of the range of study designs reviewed, in terms of strength of experimental evidence (Oxman & GRADE Working Group, 2004), was as follows: RCT (gold standard evidence), non-randomised CT, cohort (one group pre/post) and post hoc effectiveness (weakest evidence). The study design, and the impact of this on blinding and control of confounders, was a key determinant of a study's EPHPP quality rating. However, selection bias, data collection methods, and attrition rate were also important factors (see Appendix C for a summary of quality ratings).

In terms of controlled studies, there were four RCTs (including one pilot RCT) under review and one (partially-randomised) CT. None of the studies published their randomisation procedures which was a reporting weakness. Two studies (Bedard et al., 2014; Johansson et

al., 2015a) did not achieve full randomisation due to recruitment issues. Bedard et al. (2014) placed a small percentage (<5%) of the sample directly in to the treatment arm, however, as allocation was concealed from the site investigator and group facilitators the study was classified as an RCT. By contrast, Johansson et al. (2015a) randomised less than half of their participants with no attempts at allocation concealment so this was classified as a CT. All five controlled trials scored a 'strong' quality rating for their control of confounders.

In terms of blinding, it was not possible to blind participants or group facilitators to the research question but it was possible to blind data assessors. Only McMillan et al. (2002) and Bedard et al. (2014) described taking this measure, leaving the other three controlled trials open to potential detection bias. Most of the controlled trials conducted a follow up which ranged from 4 weeks to 12 months post-intervention. The Johansson et al. (2015b) study was conducted as a maintenance MBI following on from the previous MBSR programme (described in Johansson et al., 2012). Johansson et al. (2015b) reported that the findings from the RCT had been maintained eight months on but cannot say whether this was due to the monthly mindfulness sessions or would have occurred without further active input. Of the five controlled trials, the majority used waitlist control conditions and two employed a physical exercise control condition which meant that key factors such as therapist contact time and group processes were not controlled for.

The most frequently employed design of the studies under review was the cohort one group (pre/post) design. In this design participants are measured before and after the intervention (and in some cases at follow up) and participants serve as their own controls. In view of the lack of control of confounding variables all cohort studies were awarded a 'weak' overall quality rating. However, it should be noted that evaluating MBIs with ABI patients is a new field of inquiry and it was therefore entirely appropriate at this early stage to use uncontrolled designs to demonstrate potential effects and many of these were well-designed

(e.g. Moustgaard et al., 2007). The majority of cohort studies did not conduct follow-up assessments and thus missed the opportunity to evaluate whether outcomes were maintained over time (an important goal of mindfulness training).

Detert and Douglass' (2014) post hoc effectiveness study did not use an experimental design and had no control over patient or situational factors. In addition, the study reported on 13 consecutive cycles of MBI groups and changed the group content for the final two cycles so the intervention was not consistent. From a methodological perspective this study was weak but it was able to demonstrate that an MBI was well-tolerated and attended by a large (n=98) and broad neurological sample in real-life clinical practice.

Participants

There were a number of participant variables including demographics (age, gender, comorbidities, study setting/nationality, employment status) and nature of ABI (subset of ABI, time since brain injury, severity of brain injury). The mean ages ranged from 31 – 63 years so the findings are most relevant to brain injured adults of middle age and less applicable to older adults. The reviewed studies had a higher proportion of men (60%) than women (40%) and ethnicity was only reported in three studies. The presence of comorbidity was often not reported, a potential confound, but the following studies recruited samples of participants with the following specific comorbidities: PTSD (Cole et al., 2014), chronic mental fatigue (Johansson et al., 2012) and chronic pain (Nassif et al., 2013).

The included studies were conducted in a range of countries but with half in North America there may be a strong cultural bias, restricting the generalisability of the results. All studies recruited exclusively community/outpatient samples so the results are not directly applicable to ABI patients in post-acute inpatient units. Studies recruited through rehabilitation centres, outpatient clinics, local support groups and media adverts. Those

studies with systematic referrals from a clinic were judged to have a lower selection bias than studies with convenience or self-selecting samples. No studies scored a 'strong' EPHPP quality rating for eliminating selection bias which would have required selecting participants from a comprehensive list of the target population, an unrealistic gold standard in this research field.

In terms of ABI aetiology, the majority had sustained a TBI (314), a smaller number had experienced a stroke (85) and a very small proportion had other ABIs (6). The findings are therefore of most relevance to TBI patients. Some studies recruited mixed samples of TBI and stroke patients whereas other studies recruited specific subtypes within these brain injury categories: mild TBI, mild/moderate TBI and subarachnoid haemorrhages. There was great variability with regards reporting the time since brain injury (with five studies omitting this information) and there was an extensive range from 3 months post injury to over 10 years post injury. The range of inclusion criteria used by the studies under review makes it difficult to fully synthesise the findings.

In addition, with several studies recruiting from community rehabilitation services, participants were often accessing simultaneous rehabilitation treatments which lowered the integrity of the intervention.

Attrition rate

The study attrition rate can serve as one indicator of the acceptability of the intervention, an important consideration for MBIs with ABI patients. The numbers of dropouts were extracted from all studies but less than half reported the reasons for dropouts, a significant reporting weakness. Eight studies had a participant completion rate of 80-100%, four studies had a rate of 60-79% and one study (Joo et al., 2013) had a high rate (<60% completion rate) of attrition. In general, the low attrition rates suggested that the interventions were well tolerated.

Outcome measurement

The included studies had multiple domains of interest and consequently utilised a range of outcome measures. Across the eight domains (quality of life, mental health, cognitive functioning, physical health, brain injury symptom severity, self-efficacy/health locus of control and mindfulness) a total of 54 different measures were used. Quality of life was the primary focus of interest in this review and measures included three generic health-related QoL scales and two specific ABI QoL scales. The two most frequently employed measures (SF-36; WHOQoL-BREF) have both been validated for use with ABI patients (Findler, Cantor, Gordon & Ashman, 2001; Chiu et al., 2006) and were thus appropriate tools for studies in this review.

Multiple measures were used to assess outcomes across all the domains of interest making direct comparisons between studies difficult. For example, the comparison of the computerised Cogstate battery used by Cole et al. (2014) and the RSAP, a clinician-rated measure of attention used by Merriman et al. (2015). Furthermore, some studies combined physiological readings (e.g. Joo et al., 2010 measured blood pressure) with self-report data, a robust approach but difficult to synthesise across studies.

There were no significant changes reported on global measures of brain injury symptom severity. The two instruments, the RPQ and NSI, assess a range of sequelae including several physical symptoms such as blurred vision, light sensitivity and sleep disturbance. Both measures assess whether the respondent is experiencing symptoms rather than the impact of these or their acceptance in relation to them. Thus, measures of this type may not be sensitive to the changes expected following MBIs.

Statistical analysis and sample size

The reporting of methods used to determine sample size was poor. Of the controlled studies, only Bedard et al. (2013) stated the power analysis used for deriving sample size. None of the uncontrolled studies described how their sample size was derived with many stating simply that a "convenience sample" was used. With no knowledge of whether the sample size was sufficient in most of the studies under review, it remains unclear whether studies had enough statistical power to detect the observed effects or whether a type I error may have been committed.

In terms of statistical analyses, there was a reporting weakness in that only two studies reported residual analyses. Controlled trials compared the means of two or more groups and most used either analysis of variance (ANOVA) or analysis of covariance (ANCOVA). Those studies using ANCOVA were able to control for covariates such as age, time since brain injury and duration of home practice and thus increase the statistical power of the study. Nassif et al. (2015), presumably due to their small sample size (n = 9), used t-tests to compare means but reported no correction for using multiple t-tests increasing the risk of committing a type I error. Uncontrolled studies compared pre- and post-intervention means for a single group. Three studies used repeated measures ANOVAs and four studies used paired t-tests. However, only Azulay and colleagues reported making corrections for multiple t-tests.

Four studies did not report effect sizes which was a reporting weakness as it prevented both appraisal of the magnitude of effects and comparison across studies. In general the statistical analyses were appropriate for the study designs employed but there were widespread reporting weaknesses.

Ethical issues

Few ethical issues were raised in the studies under review. The gathering of informed consent was stated in 11 studies. However, three studies (Bedard et al., 2014; Merriman et al., 2015; Joo et al., 2010) failed to mention the issue of consent which was a significant oversight and potentially poor ethical practice. In the context of recruiting individuals with ABI with potentially reduced capacity to give informed consent (see Johnson-Greene, 2010), only Bedard et al. 2003/Bedard et al., 2005 reported using a measure of awareness of condition (PCRS; Prigatano et al., 1986) to guide selection of participants. There were no adverse outcomes following participation in an MBI reported in any of the studies.

Discussion

Summary of evidence

This review included 14 studies which evaluated group-based MBIs across a number of psychological domains including quality of life, mental health, cognitive functioning, physical health, self-efficacy/locus of control, brain injury symptom severity and levels of mindfulness. The findings were equivocal in several domains, but there was encouraging preliminary evidence for gains in quality of life, mental health, mental fatigue and chronic pain. It was not possible to draw meaningful conclusions with regards the effectiveness of MBIs on cognitive functioning as the evidence was equivocal and based on a wide range of neuropsychological measures used across several cognitive domains. The few studies that used global measures of brain injury symptom severity did not demonstrate significant improvements following MBIs. Most studies did not measure self-reported levels of mindfulness and those that did mostly reported non-significant improvements.

Methodological issues

As this is a new field of enquiry the majority of studies used a single group pre/post cohort designs. There were promising findings but the lack of control groups restricted the conclusions. As befitted the holistic nature of MBIs, there were wide ranging domains of interest and this was reflected in the array of outcome measures used in the included reviews. This demonstration of a wide range of potential improvements was a strength however it made direct comparisons across studies difficult and limited the conclusions. When considered collectively as a group, there were also numerous confounds including small differences in the format of MBIs, participant demographics, and the nature of ABI.

Clinical implications

The conclusions and therefore implications are somewhat limited due to the heterogeneity and uncontrolled designs of the studies under review. However, there is already a large body of robust evidence for MBIs, based on RCTs and meta-analyses, in other clinical populations including multiple sclerosis, chronic pain, cancer and heart disease (Grossman, Niemann, Schmidt & Walach, 2004; Hofmann et al., 2010; Simpson et al., 2014). In common with ABI, these health conditions involve chronic symptoms and long term disability, and there is a similar emphasis placed on acceptance and adjustment. When evaluated in this context, the preliminary positive findings from the studies in this review were very encouraging and suggest that group-based MBIs could represent a clinically valuable and holistic approach for clinicians working with ABI patients.

In the studies under review there were a high proportion of TBI participants which makes the findings less relevant to other types of ABI. The current review chose the inclusive category of ABI as this reflects the composition of patients accessing brain injury services in the UK and is in line with the position taken by the British Society of

Rehabilitation Medicine guidelines (BSRM, 2003). A few studies under review demonstrated that significant clinical gains could be achieved with mixed groups of ABI patients (Johansson et al., 2012; Johansson et al., 2015a) and with mixed neurological conditions (Detert & Douglass, 2014).

With no adverse events reported, high-levels of reported participant satisfaction, and most studies having an acceptable completion rate there were indications that group-based MBIs represent an acceptable treatment for ABI patients. As difficulties with fatigue, reduced concentration and memory impairments are common in this population it seems likely that the adaptations made to the MBIs under review were an important factor in increasing their acceptability. It was not possible to identify what, if any, the key adaptations were but it seemed intuitive that modifications such as fewer participants per group, modified mindful movement exercises, and the use of repetition and memory aids would have made the intervention more accessible. Most studies excluded ABI patients with significant cognitive impairment, recognising that group-based MBIs place demands on specific cognitive skills. Although not explicitly stated in any of the studies, one can deduce the following minimum set of cognitive skills would be required to engage in a group-based MBI. Firstly, sufficient attention skills to enable participants to sustain concentration in a group setting and during guided meditation exercises. Secondly, communication skills sufficient to understand and express key mindfulness concepts and to enable participation in group discussions. Thirdly, sufficient memory to retain the purpose of the group, to follow the thread of discussions and to benefit from progression of treatment. Lastly, sufficient executive skills to enable participants to monitor and regulate their behaviour within social norms, for example turn-taking and inhibiting inappropriate behaviours. In summary, MBIs can be made more accessible to ABI patients through skilled facilitation and adaptations to

format and content, but a significant subgroup of the ABI population would not be able to engage in group-based mindfulness training in view of their cognitive impairment.

The promising set of results in the studies under review suggest that the proposed mechanisms of action (such as developing skills in decentring, greater attentional control, and non-judgemental observation) would still appear to operate even with these adaptations in place. Based on their experiences running 13 cycles of MBIs over a two year period, Detert and Douglass (2014) provided a detailed account of adaptations for neurological patients, a useful resource.

Another important service consideration for delivering MBI groups is having clinicians with the appropriate skillset to facilitate them effectively. Eight studies reported employing facilitators with specialist MBI training and extensive professional and personal experience. It would be helpful to services to establish a minimum set of requirements for facilitators in terms of previous training, experience and personal meditation practice.

Future research implications

The studies under review have generated sufficient evidence to warrant more research into group-based MBIs for ABI. In order to demonstrate effectiveness, more robust study designs are required and should utilise active control interventions, randomisation of participants to groups, blinded data assessors, follow-ups and tighter inclusion criteria with regards participant characteristics and simultaneous treatments. It would also be recommended to utilise recently-developed ABI-specific MBI treatment manuals (e.g. Bedard et al., 2014; Azulay et al., 2013) which detail specific ABI-adaptations and standardise the delivery of the intervention making outcomes directly comparable.

Outcome measures should be carefully chosen on the basis of having acceptable psychometric properties, validated for use with the ABI population and be sensitive to

expected changes following an MBI. Furthermore, to demonstrate effectiveness of MBIs in controlled trials it is necessary to have active control interventions such as the 'healthy-living after TBI group therapy' (HLA-GT; Bay, Ribbens-Grimm and Chan, 2016). The HLA-GT has an emphasis on brain health through stress management and lifestyle change.

There is evidence to show that the amount of MBI home practice mediates increases in wellbeing (Carmody & Baer, 2008), which is understandable given the increased time spent developing mindfulness skills. Future studies could usefully contract an agreed commitment to daily practice, regularly monitor time spent in daily practice through the use of logs, and facilitate the implementation of home practice by time-tabling and problem-solving barriers to practice.

Limitations of the review

There are some limitations with the findings of this review. Due to resource constraints articles were excluded if they were unpublished or not written in English. Given that MBIs are rooted in ancient Buddhist traditions, it is possible that relevant research printed in other languages may have been overlooked. This review adopted a strict definition of MBIs as group-based and having mindfulness training as the primary focus of the intervention. This enabled a greater synthesis of outcomes but came at the expense of excluding other mindfulness-based approaches such as Acceptance Commitment Therapy (Hayes et al.., 1999). The overall low methodological quality of the studies and the heterogeneity of MBIs, participants and outcomes also prevented quantitative meta-analysis.

Conclusion

Although the evidence is limited, this systematic review indicates that MBIs may be an effective holistic approach for people with ABI, particularly with regards improvements in

quality of life, mental health, fatigue and chronic pain. Further research is warranted, particularly randomised controlled trials, paying careful attention to the ABI-specific adaptations and content of the intervention, the control group and measurement of outcomes.

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Paper B

The Anxiety Scale Circles: A first evaluation of a simple assessment tool for anxiety in the context of stroke

David Andrew Stokes

A thesis submitted in partial fulfilment of the requirements of the degree of Doctor of Clinical Psychology, validated by the University of Oxford.

(Trinity Term)

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The Anxiety Scale Circles: a first evaluation of a simple assessment tool for anxiety in the context of stroke

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(Trinity Term, 2016)

Abstract

Stroke is a leading cause of disability worldwide. Anxiety is common following stroke and can impact significantly on recovery. At present there are few effective post-stroke anxiety (PSA) self-report screening tools available. This study aimed to evaluate the psychometric properties of the Anxiety Scale Circles (ASC), a new single item PSA screening tool. 36 stroke-survivor carer dyads, within six months of stroke onset, were recruited from inpatient and community services. Convergent and divergent validity were evaluated by comparing the performance of the ASC with other measures. Test-retest reliability was evaluated by administering the ASC twice to a subgroup of participants. Discriminant capacity was evaluated by comparing the performance of the ASC with the Hospital Anxiety and Depression Scale anxiety (HADS-A) subscale. The ASC demonstrated acceptable levels of convergent and divergent validity, and the capacity to discriminate between anxious and non-anxious participants. The cut-off score of 0/1 offered appropriate levels of sensitivity (90%) and specificity (60%). This study represented the first preliminary validation of a simple self-report PSA screening measure and indicated that the ASC holds potential as a useful clinical screening tool. However, these conclusions were made tentatively as this study was small in scale and test-retest reliability was not established. Further research will be required to evaluate test-retest reliability in a larger sample, to validate the ASC against a clinical diagnosis of anxiety and to extend to the severely aphasic stroke survivor population.

Keywords: Stroke; post-stroke anxiety; screening; validation

Note: This paper has been prepared for submission to the journal *Neuropsychological Rehabilitation*. Submission guidelines are included in Appendix A.

Introduction

Stroke

A stroke or cerebrovascular accident (CVA) is a sudden disruption in the blood supply to the brain causing focal or global cerebral deficit lasting more than 24 hours. There are two main types of stroke: ischaemic stroke (where blood vessels to the brain become blocked) and haemorrhagic stroke (where a blood vessel bursts and leaks into the brain or subarachnoid space). Stroke is a leading cause of death and disability with a worldwide incidence of 17 million first time strokes in 2010 (Feigin et al., 2014). In the United Kingdom, the stroke incidence rate is approximately 152,000 per year with an estimated 1.2 million stroke survivors living in the UK in 2014/15 (Stroke Association, 2016). There is considerable variability in the degree of spontaneous recovery following stroke. Most spontaneous recovery takes place in the first 3 months and some gains, notably in cognitive functioning, have been reported six months or more after stroke onset (Cramer, 2008). Approximately 65% of stroke survivors are able to live independently, whilst the remaining 35% require significant support owing to residual physical and/or cognitive disabilities (King & Dean, 2009). The needs of stroke survivors are complex and wide-ranging and include emotional wellbeing, social, financial, physical health, cognitive and re-enablement needs (French et al., 2009).

Consequences of stroke

Stroke may lead to changes in physical, sensory, communication, cognitive, emotional and behavioural functioning (Lincoln, Kneebone, MacNiven and Morris, 2012). The consequences of stroke arise from the interaction between stroke factors (e.g. severity and location of injury), individual factors (e.g. personality, relationships, and expectations) and the effectiveness of stroke services (Lincoln et al., 2012). Some of the most notable post-stroke difficulties are sensory and motor deficits (such as muscle weakness, paralysis or changes in

sensation) and visual field problems (Bogousslavsky and Caplan, 2001). Common neuropsychological sequelae include aphasia, apraxia and visual inattention, however impairments can occur in virtually any cognitive domain (Lincoln et al., 2012).

Psychological adjustment following stroke

Psychological adjustment following a stroke can be a challenging process. Difficulties such as emotional lability, apathy, disinhibition and aggression can arise directly from the brain injury (Division of Clinical Psychology/Division of Neuropsychology, 2010). Furthermore, Lincoln et al. (2012) suggest that stroke survivors commonly experience a range of emotional reactions in the months following a stroke such as frustration, embarrassment, distress, fear, confusion, anger, despair, sadness and boredom. These may be considered normal and understandable reactions to a potentially life-threatening traumatic event (Campbell Burton et al., 2013) and are integrated within models of adjustment following stroke. For example, Holbrook's (1982) influential four-phase model of post-stroke adjustment proposed an initial crisis stage (shock, confusion, high anxiety and numbness), a treatment stage (high expectations of recovery and denial of disability), a realisation of disability stage (anger, despair, depression and grief) and a final adjustment stage. Whilst consistent patterns have been identified in post-stroke emotional changes, some stroke survivors may develop 'clinically significant emotional problems' (Division of Clinical Psychology/Division of Neuropsychology, 2010). The most common disorders following stroke are post-stroke depression (PSD) and post-stroke anxiety (PSA). PSD is the most researched and approximately one third of stroke survivors experience it (Hackett, Yapa, Parag & Anderson, 2005). This thesis focuses on PSA, however for a recent review of the PSD literature see Robinson and Jorge (2016).

Prevalence and clinical correlates of PSA

PSA is used to collectively refer to several anxiety conditions including generalised anxiety disorder, agoraphobia, panic disorder, obsessive-compulsive disorder and post-traumatic stress disorder (PTSD). Although each anxiety condition has unique clinical features there are similarities in the experience of excessive and irrational fear, apprehension, tension and distress in managing daily tasks. One of the most widely-used models of anxiety is the cognitive model which proposes that all anxiety conditions arise from an overestimation of danger and an underestimation of personal ability to cope (Beck, Emery & Greenberg, 1985). Anxiety can be readily understood in the context of stroke, whereby survivors have a very real sense of danger and find their physical and psychosocial resources reduced.

A recent systematic review reported a PSA population prevalence of 25%, based on self-report screening tools (Campbell Burton et al., 2013). The prevalence rate was reported as fairly stable over the first six months (Campbell Burton et al., 2013). Based on their comprehensive review of 44 studies, Campbell Burton et al. (2013) reported a strong association between PSA and PSD, but no reliable association between other clinical and demographic variables including age, gender or lesion location. Most studies have reported no correlation between PSA and cognitive functioning (e.g. Shimoda & Robinson, 1998) although Barker-Collo et al. (2007) did report a significant association.

Post-stroke anxiety and the recovery process

It is important to formulate the potential role of PSA in disrupting the recovery process, through maintaining difficulties and impacting negatively on treatment programmes. For example, in Evans' (2006) biopsychosocial formulation model (developed for neurorehabilitation services), PSA is integrated with psychosocial and premorbid factors and functional consequences. PSA may be linked to a fear of a repeat stroke, social anxiety

regarding residual disabilities, loss of confidence following repeated failures in familiar activities and perceived threats to the future. Examples of PSA manifestations are avoidance of the location where the stroke occurred and non-adherence with physiotherapy recommendations such as not practising walking due to fear of falling.

Although in its infancy, PSA research points toward a significant negative impact of anxiety on engagement with treatment and rate of recovery. PSA is associated with a reduced social network, reduced functional recovery and decreased quality of life (Åström, 1996; Donnellan, Hickey, Hevey & O'Neill, 2010; Raju, Sarma & Pandian, 2010). Post-stroke affective disorders are associated with poorer functional outcomes and higher utilisation of outpatient services (House et al., 1991). Thus earlier identification and intervention for PSA could reduce the expense of care and rehabilitation (Gillham, Carpenter & Leathley, 2012).

Assessment of post-stroke anxiety

Given the prevalence of stroke and PSA, there is a clear need for effective assessment methods. This need has been highlighted in national stroke guidelines (National Institute of Clinical Excellence [NICE], 2010; Intercollegiate Stroke Working Party, 2012). The NHS Stroke Improvement Programme (Gillham & Clark, 2011) recommends that stroke survivors should be routinely assessed for PSA on at least three occasions after a stroke: at one month, three months and six months and then kept under review. However, the assessment of PSA is problematic for several reasons: (a) deficits in executive functioning and memory can interfere with a person's ability to report symptoms; (b) language and visuo-spatial difficulties can cause interference on assessment measures using verbal or visual items; and (c) symptoms arising directly from the stroke, such as headaches and dizziness, can mimic anxiety symptoms. In addition, it is not straightforward to define a clinical threshold for PSA given that some degree of anxiety would be expected after a potentially traumatic life event.

Clinical interview, observation and screening questionnaires are the three main methods of assessing PSA and should be used in conjunction whenever possible (Gillham & Clark, 2011). For stroke patients with preserved communication skills, interviews can yield important information about the possible presence of panic attacks, physical symptoms of anxiety, avoidance behaviours and other clinical markers of anxiety. However, clinical interviews are not the most practical option for initial screening purposes as they take time and require skilled interview techniques. Consequently, PSA screening is often performed using questionnaires. Ideally, screening measures have robust psychometric properties and are quick and easy to administer and interpret so that a multi-disciplinary staff can use them. These tools can identify when further assessment is required.

Screening measures for post-stroke anxiety

There are several generic mood screening questionnaires available, although few have been found to be reliable or valid screening tools in the stroke population (Bennett & Lincoln, 2006). To accurately screen for PSA, clinicians require sensitive and specific assessment measures and to know the optimum cut-off scores for stroke survivors. The Royal College of Physicians (RCP) have published national clinical guidelines for stroke (Intercollegiate Stroke Working Party, 2012). For stroke patients with no aphasia or only minor expressive or receptive aphasia, the RCP recommend adapting generic assessment measures. The anxiety subscale of the Hospital Anxiety and Depression Scale (HADS-A; Zigmund & Snaith, 1983) has been recommended for this purpose by NHS Improvement (Gillham & Clark, 2011) and by two recent reviews (Campbell Burton et al., 2013; Bennett & Lincoln, 2006).

For screening mood in stroke patients with significant aphasia, the RCP (Intercollegiate Stroke Working Party, 2012) and NHS Improvement (Gillham & Clark, 2011) recommended using specifically designed tools. At present, only measures for PSD have been recommended by the RCP such as the Depression Intensity Scale Circles (DISCS; Turner-Stokes, Kalmus,

Hirani & Clegg, 2005). Since the RCP guidelines were published, the Behavioural Outcomes of Anxiety scale (BOA; Kneebone, Neffgen & Pettyfer, 2012), a carer-report PSA measure, has been validated (Linley-Adams, Morris and Kneebone, 2014). In addition, the Visual Analog Mood Scales (VAMS) has been proposed as a simple self-report mood screening tool appropriate for aphasic stroke survivors (Arruda, Stern & Somerville, 1999). However, Bennett et al. (2006) demonstrated that the VAMS failed to show acceptable cut-offs for PSA screening and was therefore not recommended in the subsequent RCP guidelines.

Anxiety Scale Circles

Recently, the Anxiety Scale Circles (ASC; as described by North Central London Cardiac and Stroke Network, 2012) has been developed as a screening measure for anxiety following acquired brain injury. The ASC is a simple self-report questionnaire (an equivalent measure to the DISCs) which consists of a vertical visual scale depicting six circles with increasing proportion of shading enabling a graded evaluation of anxiety (see Appendix F). The design of the ASC has features designed to make it suitable for assessing PSA in stroke survivors, including those with significant aphasia. Firstly, the scale relies mainly on visual rather than verbal processing which is appropriate for patients with aphasia. Furthermore, the scale is vertical rather than horizontal to accommodate patients with hemispatial neglect who have difficulties perceiving the full range of a horizontal scale. To date, the ASC has not been validated as a measure of PSA in the stroke population so there are no indications of sensitivity, specificity or clinical cut-off scores. Some neuropsychology services in the UK have already adopted the ASC into their standard post-stroke assessment battery and would value this information to enable more accurate screening for PSA. There is also potential for the ASC to be used widely by other neurorehabilitation services if found to be a useful and valid measure.

Aims of this study

This study aimed to evaluate the psychometric properties of the ASC in terms of its convergent validity, divergent validity and test-retest reliability. In addition, this study aimed to evaluate the discriminant capacity of the ASC as a PSA screening measure and determine the optimal clinical cut-off score.

Research Questions

1. Does the ASC have acceptable convergent validity as a screening tool for PSA?
2. Does the ASC have acceptable divergent validity as a screening tool for PSA?
3. Does the ASC have acceptable test-retest reliability?
4. Does the ASC have acceptable discriminant capacity to distinguish between anxious and non-anxious 'cases'[6]?
5. What is the best cut-off score on the ASC to identify 'cases' of PSA?

Hypotheses

1. The ASC will demonstrate acceptable convergent validity as a screening tool for PSA.
2. The ASC will demonstrate acceptable divergent validity as a screening tool for PSA.
3. The ASC will demonstrate acceptable test-retest reliability as a screening tool for PSA.
4. The ASC will have acceptable discriminant capacity to distinguish between anxious and non-anxious 'cases'.
5. The use of receiver operating characteristic (ROC)[7] analysis will enable appropriate cut-off scores to be identified.

[6] In this context 'cases' of PSA means a score of $\geq$6 on the HADS-A subscale, the criterion screening measure for anxiety, and not a clinical diagnosis of anxiety

[7] A Receiver Operating Characteristic (ROC) curve is a graphical plot illustrating the performance of a binary classifier system, in this case "anxious" or "non-anxious", as its discrimination threshold is varied. The ROC curve plots the true positive rate (sensitivity) against the false positive rate (100 – specificity) at various

Method

Design

This study used a cross-sectional questionnaire-based design and recruited stroke survivor – carer dyads. In the absence of a 'gold standard' measure for the severely aphasic stroke population, it was first necessary to demonstrate that the ASC performs adequately in comparison with a well-established standardised test in a group of non-aphasic stroke patients capable of being assessed with both types of measures. Adopting a similar procedure to Linley-Adams et al. (2014) and Bennett et al. (2006), the HADS-A scale was chosen as the criterion measure for assessing PSA and used in ROC analysis to evaluate the discriminant capacity and cut-offs of the ASC. Convergent validity was evaluated by comparing the ASC with the HADS-A and BOA-carer scales. Divergent validity was evaluated by comparing the ASC against a number of variables shown to have no reliable association with PSA including cognitive functioning, age, gender and hemisphere of stroke. A repeated measures design was used to assess test-retest reliability in a subset of participants (all those recruited from the inpatient neurorehabilitation centres).

Sample size

Sample size was determined by power calculations performed using Medcalc® for Windows, version 16.4.3 (Medcalc Software, Ostend, Belgium), a statistical software package. The sample size requirements were different for the three types of analysis:

1. For correlation analysis (used to evaluate validity), the effect size is the same as the *r* correlation coefficient. With power set at 0.8 and alpha set at 0.05, 22 participants were

threshold settings. This enables the optimal clinical cut-off score to be identified. Please see Analysis section below for further details.

required to detect a large effect ($r \geq 0.5$) and 68 participants were required to detect a medium effect ($r = 0.3 – 0.49$) (Cohen, 1992).

2. For kappa analysis (used to evaluate strength of agreement between test and retest scores), with power set at 0.8, 18 participants were required to detect a kappa coefficient of 0.6 (classified as "substantial" by Landis & Koch, 1977).
3. For ROC analysis (used to evaluate discriminant capacity), the effect size is the same as the area under the curve. In order to detect a typical area under the curve of 0.8 (a large effect), with power set at 0.8 and alpha set at 0.05, a sample of 36 participants was required.

Taking all forms of analysis into account, and the resources available for this preliminary study, the minimum sample size was set at 36 in order to detect large effect sizes across all analyses. Within this target of 36, a minimum subsample of 18 participants was required for test-retest reliability. However, although the minimum sample size was set at n = 36, an ideal sample size of n = 68 was set to give the study sufficient statistical power to detect medium effects in the correlation analyses.

Participants

Stroke survivor – carer dyads were recruited from four neurorehabilitation services comprising two inpatient units and two community services. To be considered eligible for inclusion, stroke survivor participants had to be:

- Fluent English speakers
- Over 18 years of age
- To have experienced an ischaemic or haemorrhagic stroke more than 1 week but less than 6 months prior to the assessment.

Stroke survivor participants were excluded from the study for the following reasons:

- Lacked of capacity to provide written consent
- Communication or other cognitive difficulties which restricted their ability to complete questionnaires
- Severe sight or hearing impairment
- Acute medical or psychological distress
- Provisional diagnosis of dementia.

The only criterion for carer participants was the requirement to have spent at least three hours with the stroke survivor participant in the past week. Consequently, family members, friends and healthcare professionals were eligible to be recruited as carer participants. This criterion was in line with the inclusion criteria used by the BOA validation study using stroke survivor-carer dyads (Linley-Adams et al., 2014).

Measures

This study used four self-report measures, one carer-report measure and one questionnaire capturing background information. These measures were reproduced and collated in an assessment booklet with large-print versions to aid the assessment process (see Appendix F). Brief descriptions of these measures are provided below and more details regarding psychometric properties can be found in Appendix G.

Background information questionnaire. This was created by the author and used to capture demographic information, stroke information, and key details about the stroke survivor – carer relationship.

Anxiety Scale Circles (ASC). The ASC is a six point vertical visual scale depicting six grey circles with increasing proportion of shading. The bottom circle is accompanied by the verbal description "No anxiety/fear" and a line drawing of a relaxed smiling face. The top circle is accompanied by the verbal description "Most severe anxiety/fear" and a line

drawing of an anxious face. To administer the ASC, the assessor explains the task and asks "Which of these circles shows best how anxious or fearful you feel today?". The six circles are converted to numerical values for data analysis with 0 as "No anxiety/fear" and 5 as "Most severe anxiety/fear". To the author's knowledge, the ASC has not yet been formally evaluated.

Depression Intensity Scale Circles (DISCs). The DISCs is a six point vertical visual scale depicting six grey circles with increasing proportion of shading. The bottom circle is accompanied by the verbal description "No depression" and a line drawing of a smiling face. The top circle is accompanied by the verbal description "Most severe depression" and a line drawing of a sad face. To administer the DISCs, the assessor explains the task and asks "Which of these circles shows how depressed you feel today?". The six circles are converted to numerical values for data analysis with 0 as "No depression" and 5 as "Most severe depression". The DISCs was validated against clinical diagnoses of depression and demonstrated acceptable psychometric properties as a PSD screening tool.

Hospital Anxiety and Depression Scale (HADS). The HADS is a brief self-report measure for screening anxiety and depression amongst hospital patients aged 16-65. The questionnaire consists of two subscales: the HADS-A (anxiety subscale) which comprises 7 items, and the HADS-D (depression subscale) which comprises 7 items. Respondents indicate how they currently feel by rating their response on a 4-point Likert scale ranging from 0 to 3. The total score for both HADS-A and HADS-D scales ranges from 0 to 21, with higher scores indicating higher distress.

The HADS-A is the only anxiety scale validated for use with stroke survivors with reported sensitivity and specificity data (Lincoln et al., 2012) and was therefore chosen as the criterion measure of PSA. The following HADS-A cut-off scores have been proposed for

PSA, based on validation studies with stroke samples: 4/5 (Sagen et al., 2009), 5/6 (Johnson et al., 1995) and 6/7 (O'Rourke, MacHale, Signorini & Dennis, 1998). There is no consensus on the optimal PSA cut-off (Lincoln et al., 2012), so the 5/6 cut-off was chosen because the sample characteristics in Johnson et al. (1995) were most similar to the inclusion criteria used in the current study.

Montreal Cognitive Assessment (MoCA). The Montreal Cognitive Assessment (MoCA; Nasreddine et al., 2005) is a brief global cognitive screening tool. The MoCA consists of 30 items with seven cognitive subtests: visuospatial/executive, naming, attention, language, abstraction, delayed recall, and orientation. The NHS Improvement for Stroke project (Gillham & Clark, 2011) recommended using the MoCA as a post-stroke cognitive screening tool following validation in both acute and rehabilitation settings. The MoCA is free to use and has two validated alternate versions. This study will use version 7.3 to avoid practice effects because the majority of participants in the local stroke services pathway are assessed with MoCA versions 7.1 and 7.2 during their inpatient admission.

Behavioural Outcomes of Anxiety scale (BOA) - carer. The BOA-carer is a PSA carer-report screening tool consisting of 10 items rated according to how the stroke survivor felt over the past week. The items are rated on a 4 point Likert scale ranging from 0 points "never" (0 points) to "often" (3 points) with a maximum of 30 points indicating high anxiety. Linley-Adams et al. (2014) demonstrated acceptable psychometric properties and discriminant capacity. This will serve as an additional measure of PSA to demonstrate convergent validity.

Procedure

The general procedure used to recruit participants across the four services was very similar and is detailed below (see Appendix I for service specific adaptations).

Multidisciplinary teams utilised the study inclusion/exclusion criteria to identify eligible patients. Those identified were approached by a clinician and given a brief description of the study and copies of the participant information sheets (Appendix J). A minimum of 24-hours later, the patient and carer were approached by the Chief Investigator (CI) or the Research Assistant (RA) and asked if they wished to participate. If they both assented to participate then an assessment appointment was arranged. In a few circumstances when it was impracticable for the carer to attend in person, a telephone assessment appointment was made. All participants were made aware that if they declined to participate or withdrew part-way through the study this would have no impact on their care.

Assessment

Assessments began with a discussion about the participant information sheets. Participants were asked for written consent (appendix K) provided they were able to recall the study aims, procedure, option to withdraw and potential risks and benefits of participating (see Appendix L). The researcher then administered the four patient measures to the stroke survivor participant. All mood measures were laminated and presented in large print to aid administration. The researcher read all of the instructions aloud and recorded the answers on response sheets. The carer completed the carer measures at the appointment or by telephone within one week. The background information questionnaire was also completed. Current inpatients were asked for their consent to return approximately five hours later to re-administer the ASC (to obtain test-retest scores). It was necessary to retest on the same day due to the ASC asking respondents to rate their anxiety "today" and five hours was chosen as the interval as this was practicable given the resources available to the study.

Stroke-related information was obtained from the patient's medical records. Clinically significant information was shared with the referring service. Response forms were labelled with the participant ID code. Consent forms and anonymised response forms were stored

separately in locked filing cabinets. A letter was sent to participants' General Practitioners informing them of their participation in their study (see appendix M). The assessment data were manually entered into a password-protected IBM Statistical Package for the Social Sciences (SPSS) version 23.0 database.

Statistical Analysis

Statistical software. All statistical analyses were performed using SPSS except for ROC analysis which was performed using Medcalc®.

Data Characteristics. The ASC, HADS and BOA produce data at an ordinal level so non-parametric statistics were applied throughout and residual analysis plots were not necessary. SPSS was used to obtain descriptive statistics of the dataset.

Analysis of convergent validity. To establish whether the ASC has acceptable convergent validity the relationship with the HADS-A and BOA-carer scales was examined using correlation analysis. The *r* correlation coefficient is also a measure of the size of observed effect. The effect sizes were evaluated using Cohen's (1992) widely-used classification system of small effect (r = .10 - .29), medium effect (r = .30 - .49) and large effect (r = ≥.50).

Analysis of divergent validity. To establish whether the ASC has acceptable divergent validity the relationship with MoCA score, age, gender and hemisphere of stroke was examined. For continuous variables (MoCA score and age) correlation analysis was performed and the effect sizes were interpreted using Cohen's (1992) classifications. For categorical variables (gender and hemisphere of stroke) Fisher's exact tests of independence were performed. Fisher's exact test was chosen for several reasons: the relatively small sample size, the use of a 2x2 crosstabs table, the low expected cell counts, and to obtain exact p-values. For the purposes of conducting Fisher's Exact tests, the scores on the ASC were classified into non-

anxious and anxious groups and the cut-off was chosen based on the optimal cut-off identified through ROC analysis.

Analysis of test-retest reliability. To evaluate test-retest reliability the agreement between repeat scores on the ASC would have been examined using the quadratic weighted kappa (κ) statistic (Cohen, 1960), to accommodate the ordinal level data provided by the ASC (Sim & Wright, 2005). The following classification system specified by Landis and Koch (1977) would have been used to interpret the kappa values: "almost perfect" (κ=.81 – 1.0), "substantial" (κ=.61-.90), "moderate" (κ=.41-.60), "fair" (κ=.21-.40), "slight" (κ=.01-.20), and "poor" (κ≤0).

ROC Analysis. In order to perform ROC analysis, the sample was classified as "anxious" and "non-anxious" using the stroke-specific 5/6 HADS-A cut-off. Sensitivity, specificity, positive predictive values and negative predictive values were calculated for all possible cut-off values on the ASC and used to plot a ROC curve. The area under the curve (AUC) was calculated to provide an indicator of discriminant capacity (DeLong, DeLong & Clarke-Pearson, 1988). The AUC equals 0.5 when the ROC curve corresponds to random chance and 1.0 for perfect accuracy. The following criteria were used to interpret the results of the ROC analysis. The Hosmer and Lemeshow (2000) classification system was used to interpret the AUC value, which define 0.7-0.8 as "acceptable", 0.8-0.9 as "excellent" and >0.9 as "outstanding". Bennett et al. (2006) defined acceptable levels of sensitivity as ≥80% and specificity as ≥60%.

Ethical Review

The study was approved by the NHS Health Research Authority (South Central – Oxford B Research Ethics Committee reference number: 15/SC/0708). The study was also approved by local research committees Oxford Health NHS Foundation Trust (project

sponsor) and Buckinghamshire Healthcare NHS Trust (project host). Please see Appendix N for copies of approval letters.

Results

Data characteristics

The study was conducted between February and July 2016 and recruited 36 stroke survivor–carer dyads. One stroke-survivor participant did not complete the MoCA due to fatigue, therefore for correlation analysis between the MoCA and ASC this missing data point was dealt with through pairwise deletion of data, leaving 35 pairs of data. Although 12 inpatient stroke survivor participants were recruited, it was only possible to complete retests with 10 participants in this subsample due to practical issues on the ward.

Two carers did not return completed questionnaires so the sample consisted of 34 carers. For correlation analysis of the self-report measures with the carer-report measure, the missing data was dealt with through pairwise deletion leaving, 34 pairs of data.

Participant characteristics

Table 1 summarises the stroke survivor participants' demographic and clinical characteristics. The stroke survivor sample (19 males, 17 females) had an average age of 71.3 years and 35 participants described their ethnicity as White British. The majority (66.7%) of stroke survivors were community outpatients. The carer sample, who returned completed questionnaires (n=34), was comprised of 12 males and 22 females and were predominantly family members (family members: n=30; friends: n=2; professionals: n=2). The range of time spent with stroke survivor in the last week was from 3.5 hours up to living

together full time (this applied to 21 dyads). The descriptive statistics of the clinical measures are displayed in table 2.

Table 1

Demographic and clinical characteristics of stroke survivor participants (n=36)

		Mean	**SD**	**range**
Age		71.3	9.74	51 - 86
Education (years)		13.6	3.59	6 – 23
Time since stroke (days)		68.89	39.06	9 – 157
			N	**%**
Gender	Male		19	52.8
	Female		17	47.2
Ethnicity	White British		35	97.2
	Other		1	2.8
Occupation before stroke	Working		11	30.6
	Retired		25	69.4
Living circumstances	Living with carer		21	58.3
	Living with non-carer		1	2.8
	Living alone		2	5.6
	Inpatient		12	33.3
Hemisphere of stroke	Left		20	55.6
	Right		16	44.4
Stroke type	Ischaemic		31	86.1
	Intracerebral haemorrhage		4	11.1
	Subarachnoid haemorrhage		1	2.8
Previous strokes	0		34	94.4
	1		2	5.6

Table 2

Descriptive statistics of scores on clinical measures (n=36)

Measure (range)	Mean	SD	Response range
ASC (0 - 5)	1.33	1.12	0 – 4
DISCs (0 - 5)	0.64	0.90	0 – 4
HADS-A (0 - 21)	6.22	3.42	0 – 14
HADS-D (0 - 21)	5.39	3.47	0 – 12
HADS-total (0 - 42)	11.61	5.53	0 – 22
MoCA (0 – 30) [a]	23.91	3.95	15 – 30

Note. [a] n = 35

Research question 1: Does the ASC have acceptable convergent validity as a screening tool for post-stroke anxiety?

The results of the correlation analysis (table 3) indicated that the ASC was significantly correlated with the HADS-A (r_s = .553, n=36, p<.001), and constituted a large effect size. The ASC also correlated significantly with the BOA-carer (r_s = .309, n=34, p=.038). This may constitute a medium effect size but was interpreted with caution due to the limited power of this study to detect medium effect sizes. Taken together, these results suggest that the ASC has acceptable convergent validity. Analysis of the association between the BOA and HADS-A demonstrated a significant correlation which was cautiously interpreted as a medium effect size (r_s = .387, n=34, p=.012).

Table 3

Correlations between ASC, HADS-A and BOA-carer scores

	Rated by stroke-survivor: HADS-A (n=36)		Rated by carer: BOA-carer (n=34)	
	r_s	p	r_s	p
ASC	.553	<.001**	.309	.038*

Note. r_s = Spearman rank correlation coefficient; * = correlation significant at the 5% level (1-tailed); ** = correlation significant at the 1% level (1-tailed)

Research question 2: Does the ASC have acceptable divergent validity as a screening tool for post-stroke anxiety?

Divergent Validity. The ASC was compared against clinical and demographic variables shown by previous studies to have no reliable association with post-stroke anxiety including cognitive functioning, age, gender and hemisphere of stroke.

For continuous variables (MoCA and age), correlation analysis (table 4) indicated no significant correlations between the ASC and the MoCA (r_s = -.014, n=35, p=.469), or with age (r_s = -.045, n=36, p=.396).

Table 4 - *Correlations for ASC with age and MoCA*

	MoCA		**Age**	
	r_s	**p**	**r_s**	**p**
ASC	-.014	.469	-.045	.396

Note. r_s = Spearman rank correlation coefficient; p = probability; * = correlation significant at the 5% level (1-tailed)

For categorical variables (gender, hemisphere of stroke) Fisher's exact tests of independence were performed. For the purposes of this analysis, the scores on the ASC were classified into a non-anxious (score = 0) and anxious group (score $\geq$ 1). This cut-off was chosen based on the ROC analysis detailed below (see page 81). The Fisher's Exact test was non-significant for both gender (p=.309) and hemisphere of stroke (p=.636) indicating no significant association between the ASC and these two variables.

In summary, in line with all hypotheses, there were no significant associations between the ASC score and MoCA, age, gender and hemisphere of stroke.

Co-morbidity with PSD. The ASC was compared with two measures of depression (DISCs and HADS-D) which were expected to demonstrate some correlation due to comorbidity of PSA and PSD. The ASC did not correlate significantly with the HADS-D (r_s = .122, n=36, p=.240) but did correlate significantly with the DISCs (r_s = .366, n=36, p=.014). This appeared to be a medium effect size but this was again interpreted with caution due to the limited power of this study. The association between the ASC and DISCs was stronger than between the ASC and HADS-D.

Research question 3: Does the ASC have acceptable test-retest reliability?

Due to the number of participants recruited from inpatient units, in which retests were conducted, there were insufficient data (n=10) to evaluate the test-retest reliability of the ASC (the minimum target was set at n = 18). However, there was a high degree of concordance within this sub-sample with 80% of retest ratings matching the initial scores and the remaining 20% were different by just one score.

Research question 4: Does the ASC have acceptable discriminant capacity to distinguish between anxious and non-anxious cases?

The HADS-A was used as the criterion measure to define anxiety 'caseness' in the sample using the 5/6 cut-off. This resulted in 21 (58%) participants classified as "anxious" and 15 (42%) classified as "non-anxious". The paired sensitivity and 100- specificity values for each possible ASC cut-off score were plotted to produce a Receiver Operating Characteristic (ROC) curve (Figure 1). The ASC had an AUC of 0.80 (95% CI, 0.63-0.91; z = 3.52, p=.0004). This indicated that the ASC was significantly better than chance at predicting anxiety 'caseness' in this sample of stroke survivors and was on the threshold between "acceptable" and "excellent" in terms of discriminant capacity.

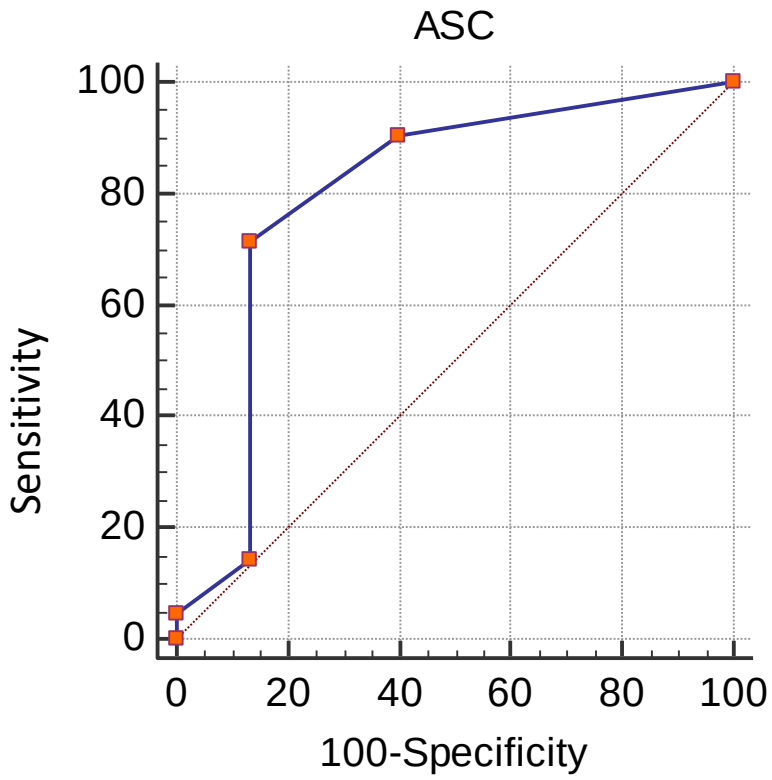


Figure 1. Receiver Operating Characteristic (ROC) curve for the ASC

Research question 5: What is the best ASC cut-off score to identify 'cases' of PSA?

In order to identify the optimum ASC cut-off score, sensitivity and specificity were calculated for all possible criterion values on the ASC (table 5). Applying the Bennett et al. (2006) recommendations for PSA cut-off scores (see Method section), the optimum cut-off score on the ASC was identified as 0/1 as this produced a sensitivity of 90% (95% CI, 70%-99%) and a specificity of 60% (95% CI, 32%-84%). An alternative cut-off score of 1/2 was considered due to a better balance of sensitivity and specificity than the 0/1 cut-off score, but was rejected because the 71% sensitivity would be too compromised for the ASC to be useful as a screening instrument.

In selecting the optimal cut-off score for the ASC, greater weighting was placed on sensitivity compared with specificity. For a brief screening tool it is preferable to overestimate potential 'caseness' (which can be confirmed or subsequently ruled out with

further assessment) than underestimate it (which would increase the chance of PSA remaining undetected). The 0/1 ASC cut-off detected 90% of anxiety 'cases' which is excellent for a screening tool. The high level of sensitivity came at the cost of relatively lower specificity (60%). The ASC therefore detected 40% false positives, which highlighted that further assessment would be essential for people scoring above the 0/1 cut-off in order to confirm or rule out 'caseness'. In summary, ROC analysis suggested that the ASC with a 0/1 cut-off has an acceptable level of discriminant capacity for PSA.

Table 5

Sensitivity and specificity values for the ASC

Cut-off	Sensitivity (%)	Specificity (%)
0	100	0
0/1	90	60
1/2	71	87
2/3	14	87
3/4	5	100
4/5	0	100

Discussion

Overview of results

Based on this relatively small study, the results suggested that the ASC has acceptable convergent and divergent validity. This study also demonstrated that the ASC had acceptable discriminant capacity as a PSA screening tool in this sample and identified 0/1 as the optimal cut-off score. Although there were preliminary indications of test-retest reliability, the retest sample was insufficient for statistical analysis. Consequently, all conclusions in this study were made tentatively.

A preliminary psychometric evaluation of the ASC

The ASC correlated strongly with the HADS-A, and appeared to correlate significantly with the BOA-carer. This suggested a fairly robust finding as there were correlations with two sources of information. In line with hypothesis 1, this study provided preliminary evidence of acceptable convergent validity which suggested that the ASC is measuring the construct of PSA. It was not unexpected that the ASC correlated more strongly with another self-report measure than a carer measure. Although carers provide valuable information about a patient's mood, they can only offer their perspective, which may be based on limited contact or specific contexts, especially in inpatient units.

PSA is assessed in the context of several other patient variables including age, gender, level of cognitive functioning and hemisphere of stroke, which have been shown to have no reliable association with PSA (Campbell Burton et al., 2013; Shimoda & Robinson, 1998). In line with hypothesis 2, the results provided preliminary evidence that the ASC was not associated with these variables, which suggested that the ASC may be a valid measure of PSA, should its test-retest reliability be established. The relationship between the ASC and depression measures was more complex given that PSA/PSD co-morbidity is common (Castillo, Schultz & Robinson, 1995). An ideal measure of PSA would be expected to show some association with measures of PSD but a much stronger association with other measures of PSA. Broadly speaking this was observed in the results reported here. The results suggested a small non-significant correlation with the HADS-D and a medium significant correlation with the DISCs. The strength of these associations was stronger than those observed between the ASC and unrelated variables (such as age and hemisphere of stroke), but weaker than that observed between the ASC and the HADS-A. In summary, the results of this analysis added further weight to the validity of the ASC as a PSA measure.

This study also provided preliminary evidence that the ASC had an acceptable level of discriminant capacity to identify 'cases' of PSA, which was in line with hypothesis 4. The area under the curve (AUC) of 0.8 was on the threshold between "acceptable" and "excellent" as a PSA screening tool. To put this in context, a recent study validated the HADS-A against clinical diagnoses of anxiety disorders and reported an AUC of 0.85 (Sagen et al., 2009). The 0/1 cut-off score gave the ASC sensitivity and specificity values above the recommended standard for PSA screening (Bennett et al, 2006). The identification of an appropriate clinical cut-off (in line with hypothesis 5), above which would indicate 'cases' of PSA, suggested that the ASC has potential as a useful tool for clinicians in screening for PSA. Furthermore, this result indicated that the ASC is superior to the Visual Analog Mood Scale, which failed to show appropriate cut-offs in relation to anxiety cases identified by the HADS-A (Bennett et al, 2006).

As the ASC is a single item self-report measure internal consistency and inter-rater reliability were not applicable. However, test-retest reliability is required to establish that when no change in PSA levels has occurred the outcome is the same, or if there has been change this is detected. In line with hypothesis 3, the preliminary data showed a high rate of concordance, but the subsample of participants who completed a retest was not large enough to be subjected to statistical analysis. Reliability is an essential property of a screening tool so in the absence of this data the conclusions regarding the other psychometric properties (detailed above) were made tentatively. It will be very important to establish that the ASC has acceptable test-retest reliability in future research.

Clinical implications

At present there is a clear need for brief aphasia-friendly PSA screening tools as there is only one tool available and this is carer-report rather than self-report. The ASC appears to fulfil many of the criteria of a clinically useful post-stroke mood screening measure (Lincoln

et al., 2012) as it: (a) has demonstrated acceptable psychometric properties; (b) has a stroke-specific clinical cut-off score; (c) has been specifically designed to make it accessible for patients with an ABI, including stroke; and (d) is a practical and intuitive instrument with a short administration time and an unambiguous scoring method.

NICE (2010) recommended that "all stroke patients should be screened within 6 weeks of diagnosis using a validated screening tool to identify mood disturbance" (p. 47). Gillham & Clark (2011) recommended screening for PSA three times in the first six months, and a recent review demonstrated a relatively stable prevalence of anxiety across this time period (Campbell Burton et al., 2013). Thus, this preliminary validation study recruited participants within the first six months following their stroke. Furthermore, the short and simple administration procedure of the ASC gives it practical value for multidisciplinary stroke teams. This is in line with the NHS Stroke Improvement Programme (Gillham & Clark, 2011) which recommends a stepped-care approach whereby the MDT provides low-intensity psychological assessment and care, often supervised by a psychologist. The ASC represents a method of regular, efficient and effective screening for PSA which would help teams to identify stroke survivors in need of further support. If a patient scores above the clinical cut-off this would indicate the need for further assessment.

As with the DISCs, the ASC was carefully designed to facilitate screening anxiety in a population which commonly has impairments in cognitive functioning and aphasia. The ASC relies on visual rather than verbal processing which is designed for patients with aphasia, and has a vertical rather than horizontal to accommodate stroke survivors with hemispatial neglect. These features of the ASC address some of the limitations of the HADS-A which takes longer to administer, makes greater demands on cognitive abilities, and requires respondents to rate their mood over the past week (which can change quickly following a stroke, particularly in inpatient units). In addition there is a lack of consensus

over the optimal cut-off score to use on the HADS-A (Lincoln et al., 2012) which creates a challenge for stroke services in developing the stepped care model. The ASC therefore represents a useful alternative to the HADS-A as a brief initial screening tool for PSA.

It is important to highlight that the ASC is not a comprehensive psychological assessment of PSA. Campbell Burton et al. (2013) demonstrated that the prevalence of PSA is higher when assessed with screening tools (which measure anxiety symptoms) than by clinical diagnostic interviews (which diagnose anxiety conditions). This suggests that screening measures, such as the ASC, may overestimate 'caseness'. However, this befits a brief screening tool as it is preferable to overestimate potential 'caseness' (which can be confirmed or subsequently ruled out with further assessment) than underestimate it (which would increase the chance of PSA remaining undetected). Further assessment is necessary to clarify the nature, focus and severity of the anxiety and would usefully include some combination of clinical interview, observations from the team, and multiple anxiety measures.

There is a clear need for a robust brief PSA self-report screening measure suitable for those with communication difficulties, the purpose for which the ASC was designed. Firstly, national stroke guidelines provide recommendations for aphasia-friendly PSD screening tools but not for PSA. Secondly, this gap was highlighted in recent reviews (Lincoln et al., 2012; Campbell Burton et al., 2013) which highlight the dearth of PSA screening tools and critique the HADS-A for its relative complexity. Thirdly, the ASC is already being used as a brief screening tool in some UK neurorehabilitation services, indicating the appetite for such a measure. Indeed the North Central London Cardiac and Stroke Network (2012) have recommended the use of the (as yet unvalidated) ASC to its members, on the basis of clinical experience. Fourthly, the DISCs, which has an equivalent format to the ASC, is used widely

and effectively as an initial screening measure for PSD. Lastly, untreated PSA has a significant impact on recovery and screening is the first step in identifying an issue.

PSA can have a wide-ranging impact in terms of reduced social network, reduced functional recovery, and decreased quality of life (Åström, 1996; Donnellan et al., 2010; Raju et al., 2010). The ASC could increase the likelihood of stroke survivors with PSA receiving appropriate and timely psychological care. There are a number of effective psychological packages for targeting specific anxiety presentations but these can only be delivered if the presence of PSA is detected first.

This study recruited stroke survivors without significant aphasia in order that participants were capable of completing established post-stroke measures to determine validity. Consequently, the ASC cannot yet be recommended, on the basis of empirical validation, as a tool for stroke survivors with significant aphasia. The next step will be validating the ASC with an aphasic stroke survivor sample against clinical observations and carer report. However, at this time, as there are currently no tools that are recommended for this subsection of the stroke population, the ASC (which was designed to be aphasia friendly, although not yet validated as such) represents a potentially useful self-report screening tool for stroke services.

Future Directions

This relatively small-scale validation study was the necessary first stage in demonstrating the utility and effectiveness of the ASC as a PSA screening tool. The promising results in this fairly homogenous stroke sample can be used as justification for larger scale studies. These could usefully include the following:

- Evaluation of the test-retest reliability is a key aim for any future evaluation.
- Evaluation of the responsiveness to change following physical and psychological interventions. If the ASC can be demonstrated to be responsive to change, it can be

used as a monitoring tool and an outcome measure, in addition to its use as an initial screening tool.

- Comparison of the ASC against a clinical diagnosis of anxiety (a true gold standard of comparison) which is the optimal way of validating an instrument. The results here strongly indicate that the resources needed for this type of study would be well invested.
- Exploration of the utility of the ASC with aphasic stroke survivors.
- Exploration of the utility of the ASC in screening for anxiety following other types of ABI. Given that many neurorehabilitation services have mixed ABI patients, the ASC, like the DISCs, would be most useful if shown to be sensitive to all post-ABI anxiety.

Limitations and strengths of study

The main limitation of the current study was that it was not possible to formally evaluate test-retest reliability. The key measures had to be administered face-to-face for consistency of administration, and the retest period of five hours meant that only inpatients could be recruited for retests. With the resources available to the study, it was often a challenge to gain access to patients on busy hospital wards, many of whom had acute medical needs. This issue could be addressed in a future study through cohort analysis of consecutive patients admitted to an inpatient unit in which the ASC is integrated in the standard care pathway. Repeat administration of the ASC would be easier to arrange for clinicians working with patients in their own unit.

A second limitation of this study was the relatively small sample size. This study met the minimum target for participants and was sufficiently powered to detect large effects only.

A total of 68 participants would have been needed to detect medium effects and was not achievable given the delays in the approval process and recruitment. Consequently, this placed restrictions on the conclusions that could be drawn from some of the correlation analyses. However, this study was similarly powered to another validation study of visual post-stroke mood scales (Arruda et al., 1999) and succeeded in its preliminary validation of the ASC's psychometric properties and in making a case for further larger scale studies.

This study recruited stroke survivors from four NHS services which spanned different stages of the rehabilitation process. In view of the need for a suitable screening tool for the first six months following stroke, this sample was appropriate in its inclusion and exclusion criteria. This time period also increased the likelihood that the anxiety was related to the stroke rather than other life events; this was an advantage over many other validation studies (e.g. Linley-Adams et al., 2014) which have recruited survivors several years after their stroke.

The greatest strength of this study was that it represented the first preliminary empirical validation of a simple self-report measure of PSA. In time the ASC will hopefully prove to be of great value in facilitating a vulnerable population with communication difficulties to express their emotional needs and receive appropriate care.

Conclusions

In conclusion, this validation study provided preliminary evidence that the ASC may have acceptable validity and discriminant capacity as a screening measure of PSA, should its test-retest reliability be established. There is a clear need for a measure of this kind, particularly for stroke survivors with significant aphasia. In line with national stroke guidelines, the results of this study suggested that the ASC holds potential as a brief PSA screening tool in the first six months following a stroke. If a stroke survivor scores above the identified clinical cut-off of 0/1 they should be followed up with further assessment. Further

research can usefully build on these findings by establishing test-retest reliability, validating against a clinical diagnosis and extending to the aphasic stroke survivor population.

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Appendix A: Neuropsychological Rehabilitation Instructions for Authors

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Appendix B: Search Results

In February 2016, the Ovid SP platform was used to perform an electronic literature search of published studies. The following databases were searched: EMBASE (1974 – 19th February 2016), AMED (1985 – February 2016), MEDLINE (1946 – February Week 2, 2016) and PsycINFO (1967 – February Week 2, 2016). The four databases were searched separately with the strategy slightly adjusted to the specific requirements of the operating system (see below for search strategies). The databases were searched using the following keywords and their associated synonyms: acquired brain injury, traumatic brain injury, head injury, brain damage, stroke, cerebrovascular accident, cerebrovascular disorder, hypoxic brain injury, cerebral anoxic injury, transient ischaemic attack, mindfulness, meditation, relaxation training, attention training, mindfulness-based intervention, mindfulness based cognitive therapy (MBCT) and mindfulness based stress reduction (MBSR). Where possible, search limiters were applied for age (all adult >18 years), subject type (human only), language (studies published in English only) and publication type (journal articles and reports). In addition a hand search of the reference sections of key papers was conducted and leading ABI mindfulness researchers were contacted.

The following searches were performed on the 21st February 2016. The numbers in brackets show the number of articles obtained from each search.

EMBASE (Ovid) 1974-19/February, 2016

1. stroke.mp. or exp cerebrovascular accident/ (342598)
2. ABI.mp. or exp acquired brain injury/ (10778)
3. exp traumatic brain injury/ or TBI.mp. (39857)
4. exp brain injury/ or "brain injur*".mp. (152208)
5. exp head injury/ or "head injur*".mp. (243862)
6. cerebrovascular accident.mp. or exp cerebrovascular accident/ (122345)

7. CVA.mp. or exp cerebrovascular accident/ (121647)
8. cerebrovascular disorder.mp. or exp. cerebrovascular disease/ (450813)
9. cerebral hypoxia.mp. or exp brain hypoxia/ (11006)
10. “cerebral anoxic injur*”.ti,ab,kw (5)
11. brain damage.mp. or exp brain damage/ (39438)
12. transient isch?emic attack.mp. or exp transient isch?emic attack/ (30461)
13. 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 (833735)
14. mindfulness.mp. or exp mindfulness/ (4518)
15. meditation.mp. or exp transcendental meditation/ or exp meditation/ (6446)
16. relaxation training.mp. or exp relaxation training/ (9860)
17. attention training.mp. (303)
18. ("mindfulness-based intervention" or "mindfulness based intervention").ti,ab,kw. (115)
19. ("mindfulness based cognitive therapy" or MBCT).ti,ab,kw. (446)
20. ("mindfulness based stress reduction" or MBSR).ti,ab,kw. (747)
21. 14 or 15 or 16 or 17 or 18 or 19 or 20 (18619)
22. 13 and 21 (434)
23. limit 22 to (human and (article or report)) (176)

AMED (Ovid) 1985-February, 2016

1. exp stroke/ or stroke.mp. (7719)
2. ("acquired brain injury" or ABI).ti,hw,ab. (434)
3. Brain injuries/ or acquired brain injury.mp. (4148)
4. ("traumatic brain injury" or TBI).ti,hw,ab. (2539)
5. head injury.mp. or Head injuries/ (1043)
6. exp Brain injuries/ or brain injury.mp. (4597)
7. exp Cerebrovascular accident/ or cerebrovascular accident.mp. (1688)
8. exp Cerebrovascular disorders/ or CVA.mp. (7874)
9. cerebrovascular disease.mp. (76)
10. cerebral hypoxia.mp. (4)
11. "cerebral anoxic injur*".ti,hw,ab. (0)
12. Brain disease/ or brain damage.mp. (976)
13. transient isch?emic attack.mp. or Cerebral ischemia/ (224)
14. 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12 or 13 (15013)
15. mindfulness.mp. (223)
16. exp Meditation/ or meditation.mp. (579)
17. exp Relaxation/ or relaxation training.mp. (1052)
18. attention training.mp. (22)
19. ("mindfulness-based intervention" or "mindfulness based intervention").mp. [mp=abstract, heading words, title] (4)
20. ("mindfulness based cognitive therapy" or MBCT).mp. [mp=abstract, heading words, title] (8)
21. ("mindfulness based stress reduction" or MBSR).mp. [mp=abstract, heading words, title] (56)
22. 15 or 16 or 17 or 18 or 19 or 20 or 21 (1742)
23. 14 and 22 (35)
24. Limit 23 to (brief report or brief research report or journal article or report) (32)

MEDLINE (Ovid) 1946-February Week 2, 2016

1. Exp Stroke, Lacunar/ or exp Stroke/ or stroke.mp. (206843)
2. (acquired brain injury or ABI).ab,kf,ti. (5070)
3. (traumatic brain injury or TBI).ab,kf,ti. (22765)
4. brain injury.mp. or exp Brain Injuries/ (67476)
5. head injury.mp. or exp Craniocerebral Trauma/ (135737)
6. (cerebrovascular accident or CVA).ab,kf,ti. (4509)
7. cerebrovascular disorder.mp. or exp Cerebrovascular Disorders/ (300707)
8. cerebral hypoxia.mp. or exp Hypoxia, Brain/ (11326)
9. "cerebral anoxic injur*".ab,kf,ti. (2)
10. transient isch?emic attack.mp. or exp Ischemic Attack, Transient/ (21680)
11. exp Brain Ischemia/ or brain damage.mp. (109671)
12. 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 (532077)
13. exp Mindfulness/ (680)
14. meditation.mp. or exp Meditation/ (3153)
15. exp Relaxation Therapy/ or relaxation training.mp. (7994)
16. attention training.mp. (142)
17. ("mindfulness-based intervention" or "mindfulness based intervention").ab,kf,ti. (52)
18. ("mindfulness based cognitive therapy" or MBCT).ab,kf,ti. (217)
19. ("mindfulness based stress reduction" or MBSR).ab,kf,ti. (351)
20. 13 or 14 or 15 or 16 or 17 or 18 or 19 (9644)
21. 12 and 20 (118)
22. limit 21 to (humans and (case reports or classical article or clinical study or clinical trial, all or comparative study or controlled clinical trial or introductory journal article or journal article or multicenter study or observational study or randomized controlled trial or validation studies)) (112)

PsycINFO (Ovid) 1967 to February week 2, 2016

1. exp Cerebrovascular Accidents/ or stroke.mp. (26628)
2. (acquired brain injury or ABI).ab,hw,ti. (1559)
3. traumatic brain injury.mp. or exp Traumatic Brain Injury/ (16004)
4. brain injury.mp. (19785)
5. head injury.mp. or exp Head Injuries/ (6950)
6. (cerebrovascular accident or CVA).ab,hw,ti. (731)
7. cerebrovascular disorder.mp. or exp Cerebrovascular Disorders/ (21720)
8. cerebral hypoxia (144)
9. "cerebral anoxic injur*".ab,hw,ti. (0)
10. brain damage.mp. or exp Brain Damage/ (33178)
11. exp Cerebral Ischemia/ or transient isch?emic attack.mp. (4271)
12. 1 or 2 or 3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 (67859)
13. mindfulness.mp. or exp Mindfulness/ (7234)
14. meditation.mp. or exp Meditation/ (6034)
15. exp Relaxation/ or exp Relaxation Therapy/ or exp Stress Management/ or relaxation training.mp. (10280)
16. attention training.mp. (312)

17. ("mindfulness-based intervention" or "mindfulness based intervention").ab,hw,ti. (127)
18. ("mindfulness based cognitive therapy" or MBCT).ab,hw,ti. (534)
19. ("mindfulness based stress reduction" or MBSR).ab,hw,ti. (581)
20. 13 or 14 or 15 or 16 or 17 or 18 or 19 (21130)
21. 12 and 20 (159)
22. limit 21 to (human and ("0100 journal" or "0110 peer-reviewed journal" or "0120 non-peer-reviewed journal" or "0130 peer-reviewed status unknown" or "0500 electronic collection")) (112)

Appendix C: EPHPP quality ratings for experimental studies under review

EPHPP quality ratings for the included studies with an experimental design (n = 13)

Study	*Selection bias*	*Study Design*	*Confounders*	*Blinding*	*Data Collection methods*	*Withdrawals and drop-outs*	*Global Rating*
McMillan et al. (2002)	moderate	strong	strong	moderate	strong	strong	STRONG
Bedard et al. (2013)	weak	strong	strong	moderate	strong	moderate	MODERATE
Johansson et al. (2012)	weak	strong	strong	moderate	strong	strong	MODERATE
Nassif et al. (2015)	moderate	strong	strong	weak	strong	moderate	MODERATE
Johansson et al. (2015a)	weak	strong	strong	weak	strong	strong	WEAK
Bedard et al. (2003/Bedard et al., 2005)	weak	moderate	weak	weak	strong	moderate	WEAK
Moustgaard et al. (2007)	weak	moderate	weak	weak	strong	moderate	WEAK
Joo et al. (2010)	moderate	moderate	weak	weak	strong	weak	WEAK
Bedard et al. (2012)	moderate	moderate	weak	weak	strong	strong	WEAK
Azulay et al. (2013)	moderate	moderate	weak	weak	strong	weak	WEAK
Cole et al. (2014)	moderate	moderate	weak	weak	strong	weak	WEAK
Merriman et al. (2015)	weak	moderate	weak	weak	strong	strong	WEAK
Johansson et al. (2015b)	weak	moderate	weak	weak	strong	strong	WEAK

Note. Global quality ratings are determined by the following system (described by Thomas et al., 2004): A 'STRONG' global rating is awarded for studies with no 'weak' ratings in any of the six domains. A 'MODERATE' global rating is awarded for studies with one 'weak' rating in any of the six domains. A 'WEAK' global rating is awarded for studies with two or more 'weak' ratings in any of the six domains.

Appendix D: Data Extraction Form

Citation	
Location of study & setting (research trial, clinic)	
Theoretical models/useful definitions	
Aims	
METHODS	
Design (RCT, quasi-randomised, case control, single case, case series)	
No. participants (& key demographics)	
Participant details – Inclusion or exclusion criteria, selection/Recruitment	
Outcome measures	
Procedure: Type of Intervention, Description, Selection and Allocation	
Frequency of intervention	
Duration of intervention	
Intervention Delivered by	
Data Analysis (including drop out, follow up)	
Key results	
Ethical Issues/Adverse outcomes	
Key implications / conclusions / relationship with other studies	
Study strengths	
Study weaknesses	
Other	

Appendix E: References for Outcome Measures used in included studies

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Appendix F: Measures

1. Assessment booklet (for completion by researcher)
    a. Background Information questionnaire
    b. Anxiety Scale Circles administration instructions
    c. Depression Intensity Scale Circles administration instructions
    d. Hospital Anxiety and Depression Scale
    e. Montreal Cognitive Assessment, version 7.3

2. Participant stimulus materials (all presented in laminated form to participants)
    f. Anxiety Scale Circles
    g. Depression Intensity Scale Circles
    h. Hospital Anxiety and Depression Scale – large print version
    i. Behavioural Outcomes of Anxiety – carer version

Assessing Anxiety following stroke
Background Information

Participant ID: _____

Stroke Survivor Demographic Details					
Age (years)			Gender		
Ethnic Background	White	Mixed/Multiple ethnic groups	Asian/Asian British	Black/ African/ Caribbean/ Black British	Other
	1. English/ Welsh/ Scottish/ Northern Irish/ British 2. Irish 3. Gypsy or Irish Traveller 4. Any other White background	5. White and Black Caribbean 6. White and Black African 7. White and Asian 8. Any other Mixed/Multiple ethnic background	9. Indian 10. Pakistani 11. Bangladeshi 12. Chinese 13. Any other Asian background	14. African 15. Caribbean 16. Any other Black/African/ Caribbean background	14. African 15. Caribbean 16. Any other Black/African/ Caribbean background
Occupation before stroke	*Working*		*Retired*		
Living Circumstances	*Live with carer*		*Live with non-carer*	*Live alone*	
No. years in education	*[NB. If ≤12 yrs. edu. add 1 point to MOCA score]*				

Stroke Details				
Time since stroke (days)		Hemisphere of stroke	*Left*	*Right*
Type of stroke	*Ischaemic*	*Intracerebral haemorrhage*	*Subarachnoid haemorrhage*	
Previous stroke(s)	*0*	*1*	*2*	*3*

Cognitive Assessment		
MoCA already completed?	*Yes*	*No*
Previous MoCA score(s) and date of testing:		
Cognitive impairments identified in previous assessments		

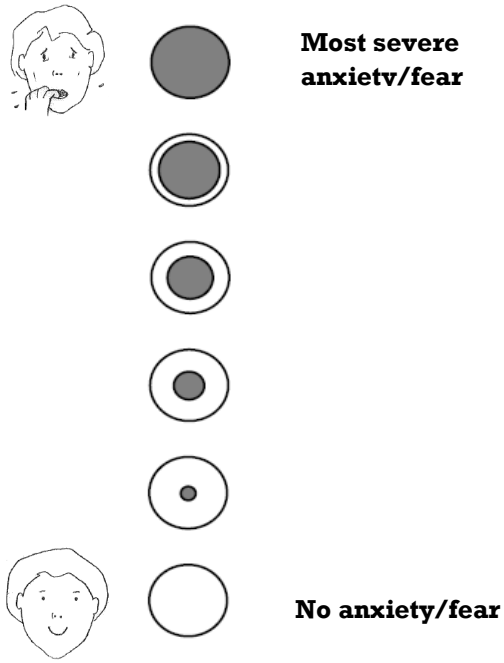
Recent history of Anxiety/Depression		
History of clinical anxiety in 2 years before the stroke	*Yes*	*No*
History of clinical depression in 2 years before the stroke	*Yes*	*No*

Carer Details			
Relationship to survivor	*Family member*	*Friend*	*Professional*
Time spent with him/her in last week (hours)			

Impact of Stroke		
	Survivor rating of Stroke Impact	**Carer rating of Stroke Impact**
Ability to remember things	Not at all A little A lot	Not at all A little A lot
Ability to do things	Not at all A little A lot	Not at all A little A lot
Ability to walk	Not at all A little A lot	Not at all A little A lot
Ability to communicate	Not at all A little A lot	Not at all A little A lot

Version 1, 15th December 2015

The Anxiety Scale Circles (ASC) – pictorial version



Instructions for administration:

[Say to the participant:]

- "This is a scale to measure anxiety or fear."
  "Please point to each of the circles in turn to make sure that you can see them all."

[Continue only if satisfactorily accomplished]

[Say to the participant:]

- "The grey circles show how anxious or fearful you feel."

[Indicate the clear circle at the bottom]

- "The bottom circle shows no anxiety or fear."

[Indicate the fully shaded circle at the top]

- "The top circle shows anxiety or fear as bad as it can be."

[Pointing at each circle in ascending order]

- "As you go from the bottom circle to the top, you can see that anxiety or fear is becoming more and more severe."

[CHECK UNDERSTANDING:]

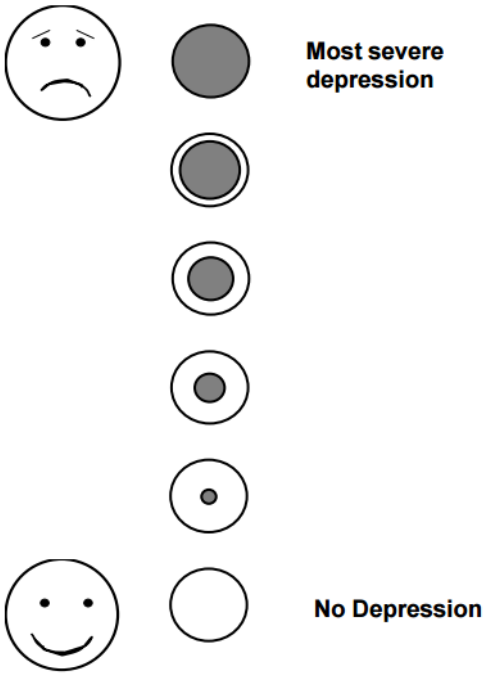
Ask participant to point to the circle that shows "no anxiety/fear"
Ask participant to point to the circle that shows "most severe anxiety/fear"

[Say to the participant:]

- "Which of these circles shows best how anxious or fearful you feel today?"

[Scoring: 0, 1, 2, 3, 4, 5]

The Depression Intensity Scale Circles (DISCs) – pictorial version



Instructions for administration:

[Say to the participant:]

- "This is a scale to measure depression."
  "Please point to each of the circles in turn to make sure that you can see them all."

[Continue only if satisfactorily accomplished]

[Say to the participant:]

- "The grey circles show how depressed you feel."

[Indicate the clear circle at the bottom]

- "The bottom circle shows no depression."

[Indicate the fully shaded circle at the top]

- "The top circle shows depression as bad as it can be."

[Pointing at each circle in ascending order]

- "As you go from the bottom circle to the top, you can see that depression is becoming more and more severe."

[CHECK UNDERSTANDING:]

Ask participant to point to the circle that shows "no depression"
Ask participant to point to the circle that shows "most severe depression"

[Say to the participant:]

- "Which of these circles shows how depressed you feel today?"

[Scoring: 0, 1, 2, 3, 4, 5]

Hospital Anxiety and Depression Scale (HADS)

Tick the box beside the reply that is closest to how you have been feeling in the past week.
Don't take too long over you replies: your immediate is best.

D	A		D	A	
		I feel tense or 'wound up':			**I feel as if I am slowed down:**
	3	Most of the time	3		Nearly all the time
	2	A lot of the time	2		Very often
	1	From time to time, occasionally	1		Sometimes
	0	Not at all	0		Not at all
		I still enjoy the things I used to enjoy:			**I get a sort of frightened feeling like 'butterflies' in the stomach:**
0		Definitely as much		0	Not at all
1		Not quite so much		1	Occasionally
2		Only a little		2	Quite Often
3		Hardly at all		3	Very Often
		I get a sort of frightened feeling as if something awful is about to happen:			**I have lost interest in my appearance:**
	3	Very definitely and quite badly	3		Definitely
	2	Yes, but not too badly	2		I don't take as much care as I should
	1	A little, but it doesn't worry me	1		I may not take quite as much care
	0	Not at all	0		I take just as much care as ever
		I can laugh and see the funny side of things:			**I feel restless as I have to be on the move:**
0		As much as I always could		3	Very much indeed
1		Not quite so much now		2	Quite a lot
2		Definitely not so much now		1	Not very much
3		Not at all		0	Not at all
		Worrying thoughts go through my mind:			**I look forward with enjoyment to things:**
	3	A great deal of the time	0		As much as I ever did
	2	A lot of the time	1		Rather less than I used to
	1	From time to time, but not too often	2		Definitely less than I used to
	0	Only occasionally	3		Hardly at all
		I feel cheerful:			**I get sudden feelings of panic:**
3		Not at all		3	Very often indeed
2		Not often		2	Quite often
1		Sometimes		1	Not very often
0		Most of the time		0	Not at all
		I can sit at ease and feel relaxed:			**I can enjoy a good book or radio or TV program:**
	0	Definitely	0		Often
	1	Usually	1		Sometimes
	2	Not Often	2		Not often
	3	Not at all	3		Very seldom

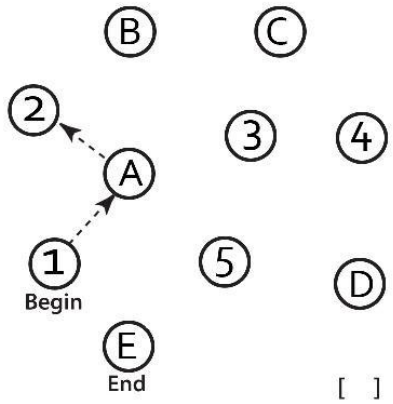
Please check you have answered all the questions

MONTREAL COGNITIVE ASSESSMENT (MOCA)

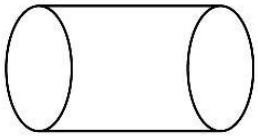
Version 7.3 Alternative Version

NAME :
Education : Date of birth :
Sex : DATE :

VISUOSPATIAL / EXECUTIVE



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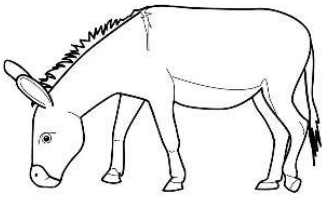
[ ] [ ]

Draw CLOCK (Ten past nine)
(3 points)

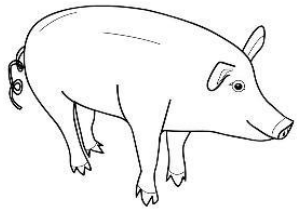
[ ] Contour [ ] Numbers [ ] Hands

POINTS __/5

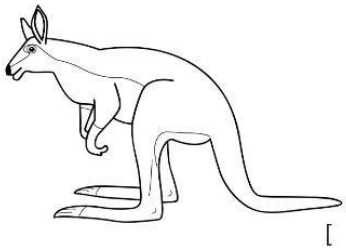
NAMING



[ ]



[ ]



[ ]

__/3

MEMORY

Read list of words, subject must repeat them. Do 2 trials, even if 1st trial is successful. Do a recall after 5 minutes.

	TRAIN	EGG	HAT	CHAIR	BLUE
1st trial					
2nd trial					

No points

ATTENTION

Read list of digits (1 digit/ sec.).

Subject has to repeat them in the forward order [ ] 5 4 1 8 7

Subject has to repeat them in the backward order [ ] 1 7 4

__/2

Read list of letters. The subject must tap with his hand at each letter A. No points if ≥ 2 errors

[ ] F B A C M N A A J K L B A F A K D E A A A J A M O F A A B

__/1

Serial 7 subtraction starting at 80 [ ] 73 [ ] 66 [ ] 59 [ ] 52 [ ] 45

4 or 5 correct subtractions: **3 pts**, 2 or 3 correct: **2 pts**, 1 correct: **1 pt**, 0 correct: **0 pt**

__/3

LANGUAGE

Repeat : She heard his lawyer was the one to sue after the accident. [ ]

The little girls who were given too much candy got stomach aches. [ ]

__/2

Fluency / Name maximum number of words in one minute that begin with the letter B [ ] _____ (N ≥ 11 words)

__/1

ABSTRACTION

Similarity between e.g. banana - orange = fruit [ ] eye – ear [ ] trumpet – piano

__/2

DELAYED RECALL

	Has to recall words WITH NO CUE	TRAIN	EGG	HAT	CHAIR	BLUE	Points for UNCUED recall only
		[ ]	[ ]	[ ]	[ ]	[ ]	
Optional	Category cue						
	Multiple choice cue						

__/5

ORIENTATION

[ ] Date [ ] Month [ ] Year [ ] Day [ ] Place [ ] City

__/6

Adapted by : Z. Nasreddine MD, N. Phillips PhD, H. Chertkow MD

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Normal ≥ 26 / 30

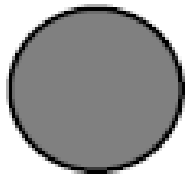
TOTAL __/30

Add 1 point if ≤ 12 yr edu

Administered by: _____

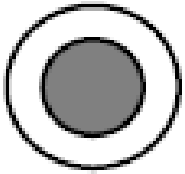
The Anxiety Scale Circles

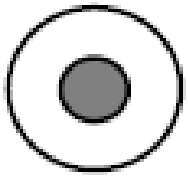


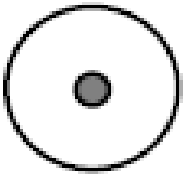


Most severe anxiety/fear

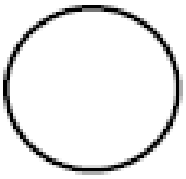






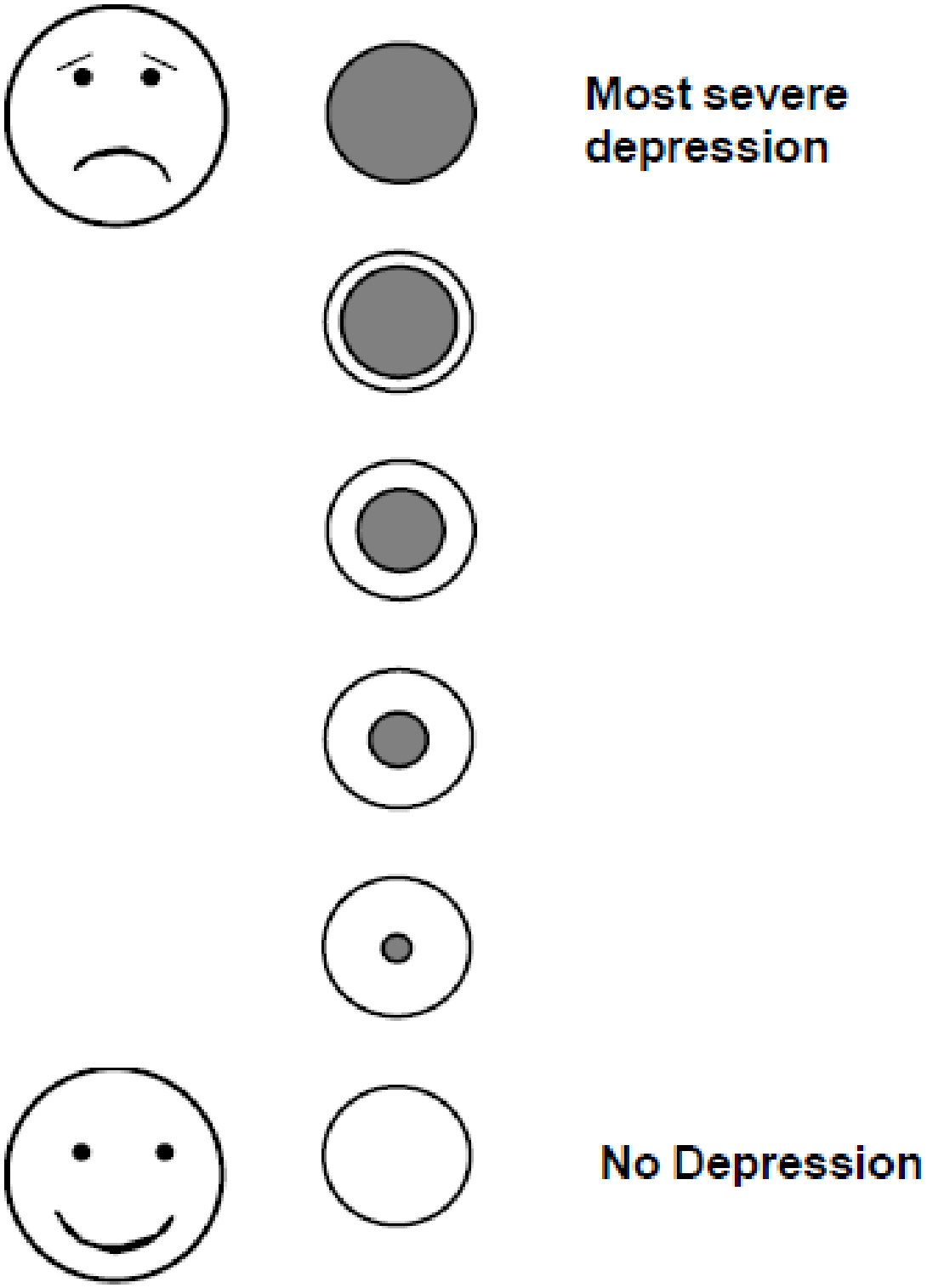






No anxiety/fear

The Depression Intensity Scale Circles



Hospital Anxiety and Depression Scale
Large print version

1. **I feel tense or wound up:**
   Most of the time
   A lot of the time
   From time to time, occasionally
   Not at all

2. **I still enjoy the things I used to**
   Definitely as much
   Not quite so much
   Only a little
   Hardly at all

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

4. **I can laugh and see the funny side of things:**
   As much as I always could
   Not quite so much now
   Definitely not so much now
   Not at all

5. **Worrying thoughts go through my mind:**
   A great deal of the time
   A lot of the time
   From time to time, but not too often
   Only occasionally

6. **I feel cheerful:**
   Not at all
   Not often
   Sometimes
   Most of the time

7. **I can sit at ease and feel relaxed:**
   Definitely
   Usually
   Not Often
   Not at all

8. **I feel as if I am slowed down:**
   Nearly all the time
   Very often
   Sometimes
   Not at all

9. **I get a sort of frightened feeling like butterflies in the stomach:**
   Not at all
   Occasionally
   Quite Often
   Very Often

10. **I have lost interest in my appearance:**
    Definitely
    I don't take as much care as I should
    I may not take quite as much care
    I take just as much care as ever

11. **I feel restless as if I have to be on the move**:
    Very much indeed
    Quite a lot
    Not very much
    Not at all

12. **I look forward with enjoyment to things:**
    As much as I ever did
    Rather less than I used to
    Definitely less than I used to
    Hardly at all

13. **I get sudden feelings of panic:**
    Very often indeed
    Quite often
    Not very often
    Not at all

14. **I can enjoy a good book or radio or TV programme:**
    Often
    Sometimes
    Not often
    Very seldom

Assessing anxiety following stroke - Carer Questionnaires

Impact of stroke – from a carer's perspective

Please rate the impact of the stroke by circling one of the following options.

1) His/her ability to remember things	Not at all	A little	A lot
2) His/her ability to do things	Not at all	A little	A lot
3) His/her ability to walk	Not at all	A little	A lot
4) His/her ability to communicate	Not at all	A little	A lot

Behavioural Outcomes of Anxiety scale - Carer version

Please read each item and place a tick in the box which comes closest to how he/she has been feeling in the PAST WEEK.

Try not to take too much time over it, as your immediate reaction should be accurate.

	Often	**Sometimes**	**Rarely**	**Never**
Has he/she appeared particularly tense or on edge?				
Has he/she had a strained face?				
Has he/she had trouble falling asleep?				
Has he/she been getting tired easily?				
Has he/she been restless or constantly on the move (e.g. do they pace)?				
Has he/she appeared anxious?				
Has he/she appeared to suddenly panic?				
Has he/she appeared fearful of falling?				
Has he/she avoided activities or social engagements?				
Has he/she been jumpy or easily startled?				

Appendix G: Psychometric properties of measures used in this study

Depression Intensity Scale Circles

Turner-Stokes et al. (2005) demonstrated that the DISCs had acceptable concurrent validity (Spearman r= .66 correlation with the Beck Depression Inventory-II; Beck, Steer & Brown, 1996) and identified cases of depression (according to the Diagnostic and Statistical Manual of Mental Disorders 4th edition criteria [American Psychiatric Association, 1994]) with 60% sensitivity and 87% specificity, and using a cut-off score of $\geq$2. Turner-Stokes (2005) also demonstrated that the DISCs had "excellent" test-retest reliability (κ= .84). The DISCs will be administered in this study as the primary screening tool for PSD. This measure takes seconds to administer and offers important contextual data given the high rate of co-morbidity between PSA and PSD.

Hospital Anxiety and Depression Scale

In a large review of the HADS (Bjelland, Dahl, Haug & Neckelmann, 2002), the mean Cronbach's alpha coefficient for internal consistency was reported as .83 for the HADS-A and .82 for the HADS-D. Aben, Verhey, Lousberg, Lodder & Honig (2002) reported excellent internal consistency (Cronbach's alpha = 0.85) in an acute stroke sample. Bjelland et al. (2002) classified the HADS as having "good to very good" concurrent validity (correlations ranging between .60 and .80) to other commonly used scales for depression and anxiety. Based on a meta-analysis of HADS studies, Hermann (1997) reported excellent test-retest reliability (r = 0.84 – 0.85) within two weeks of first administration.

The original HADS validation study (Zigmond & Snaith, 1983) recommended an 8/9 HADS-A cut-off for 'possible' cases of anxiety and 10/11 for 'probable' cases. However, Campbell Burton et al (2013) highlighted that the 8/9 and 10/11 cut-offs give the HADS-A

low sensitivity and thus likely underestimate the prevalence of anxiety 'caseness' in the stroke population. Campbell Burton et al. (2013) and Lincoln et al. (2012) suggest using a lower HADS-A cut-off validated with stroke survivor samples. The following HADS-A cut-off scores have been proposed for PSA, based on validation studies with stroke samples: 4/5 (Sagen et al., 2009), 5/6 (Johnson et al., 1995) and 6/7 (O'Rourke, MacHale, Signorini & Dennis, 1998). When compared with clinical diagnoses of anxiety, the three proposed cut-offs (4/5, 5/6, 6/7) gave the HADS-A sensitivity values ranging between 80% and 83% and the specificity values ranging between 46% and 68%. There is no consensus on the optimal PSA cut-off on the HADS-A (Lincoln et al., 2012), so the 5/6 HADS-A cut-off was chosen based on the Johnson et al (1995) validation sample being the closest match to the inclusion criteria used in the current study.

Montreal Cognitive Assessment

The MoCA has recently been shown to have acceptable levels of sensitivity and specificity in detecting post-stroke cognitive impairment in both acute (Dong et al., 2010; Chen et al., 2011) and rehabilitation (Pendlebury, Cuthbertson, Welch, Mehta & Rothwell, 2010) settings. Nasreddine et al. (2005) reported acceptable internal consistency (Cronbach's alpha = 0.83) and test-retest reliability (r = 0.92) and a high level of concurrent validity (r = 0.87) with the well-established Mini Mental State Examination (MMSE; Folstein, Folstein & McHugh, 1975).

Behavioural Outcomes of Anxiety - carer

Linley-Adams, Morris and Kneebone (2014) demonstrated that the BOA-carer has acceptable psychometric properties in a preliminary validation study with a sample of 89 stroke survivor-carer dyads. Linley-Adams et al. (2014) reported that the BOA-carer demonstrated acceptable levels of concurrent validity (a correlation of r=0.55 with the

HADS-A), internal consistency (Cronbach's alpha = 0.81) and test-retest reliability (r = 0.83). Linley-Adams et al. identified 13/14 as the optimal cut-off score giving a sensitivity of 0.77 and specificity of 0.58 (in respect of identifying positive 'cases' of anxiety on the HADS-A).

Appendix H: Prevalence of anxiety caseness

One of the most important decisions made in this project was selecting the most appropriate HADS-A cut-off score as this was used to define anxiety 'caseness' in the current sample. There was a clear and strong rationale for the selection of the stroke-specific 5/6 HADS-A cut-off (see Method). Of note, this produced a much higher level of caseness (58%) in the current sample than the reported mean population prevalence of 25% (Campbell Burton et al., 2013). This was expected given that the 25% population prevalence estimate is based on studies using the standard (not stroke-specific) HADS-A cut-offs of 8/9 ('possible anxiety') and 10/11 ('probable anxiety') as defined by Zigmund and Snaith (1983). Had the current sample been classified using the 8/9 HADS-A cut-off, the level of caseness would have been 31% which is more in line with the reported population prevalence of 25%. This suggested that the current sample was broadly representative of the stroke population which was important for the generalisability of the results.

As ROC analysis is not directly influenced by known population prevalence, the discrepancy between the prevalence of anxiety caseness in the current sample and in the population was not an issue. However, the discrepancy between sample and population prevalence did have one disadvantage in that positive predictive values (PPV) and negative predictive values (NPV) could not be reported. The definitions for PPV and NPV are as follows:

- PPV = the probability that anxiety is present when the respondent scores above clinical cut-off score on the ASC.
- NPV = the probability that anxiety is not present when the respondent scores below the clinical cut-off score on the ASC.

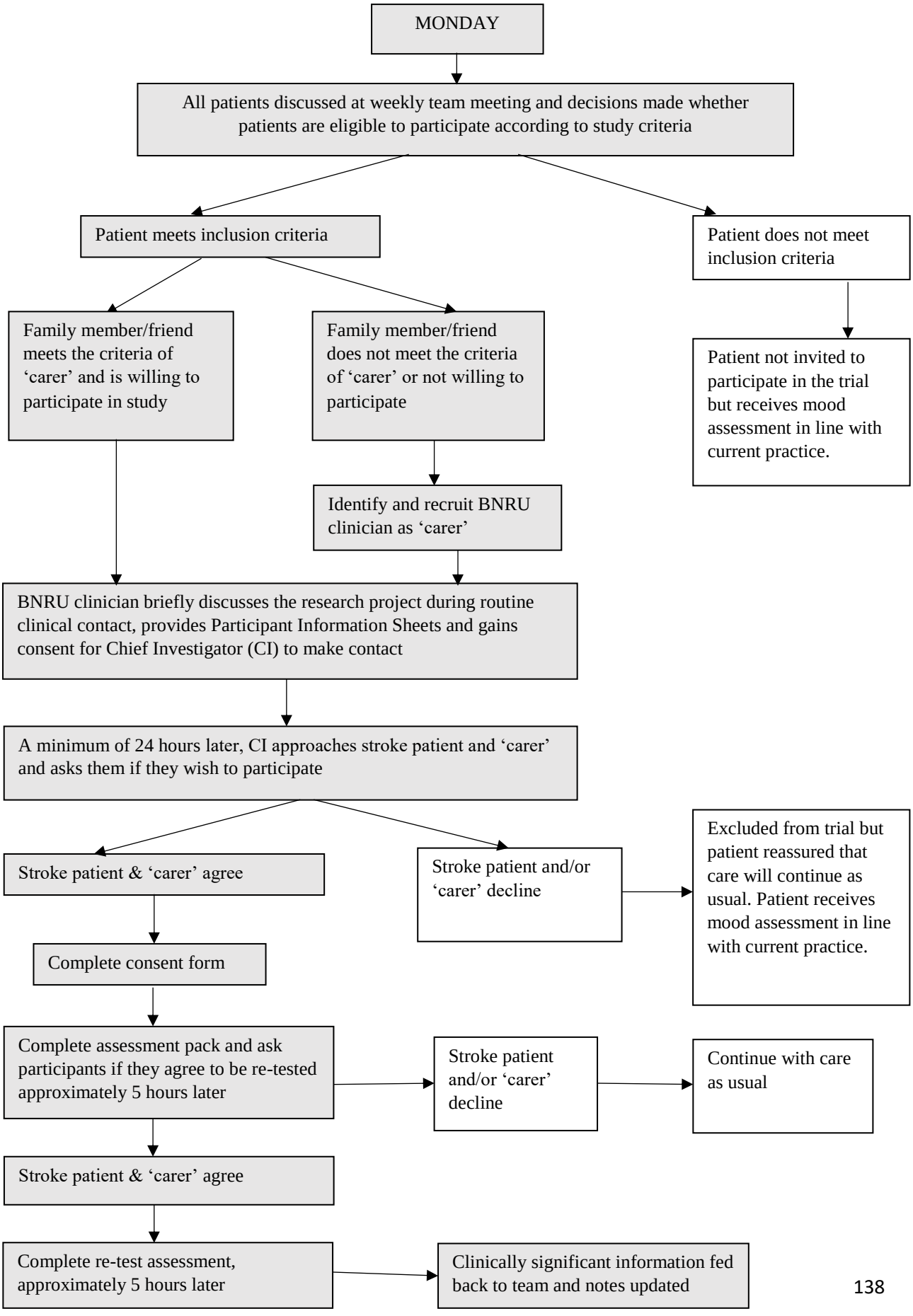
Although less fundamental than sensitivity and specificity, the PPV and NPV data help the reader to evaluate a screening measure's ability to detect caseness in the population. The PPV and NPV values are strongly influenced by 'known' population prevalence which necessarily reflects the most recent evidence-based prevalence estimate, which in this case is 25%. Linking back to the discussion above, the 'known' population prevalence of 25% is likely an underestimate of the true PSA prevalence rate as it is not based on stroke-specific cut-off scores (Campbell Burton et al., 2013). Taking all of this in to account, the notable discrepancy between sample and population prevalence would have meant the results of PPV and NPV analysis were not meaningful for the current sample.

Appendix I: Site-specific recruitment procedures and flowcharts

Neurorehabilitation ward (1 of 2): Buckinghamshire Neurorehabilitation Unit (BNRU)

All patients admitted to BNRU were routinely discussed in a weekly multidisciplinary team meeting. During this meeting the team considered whether patients were eligible for the study using the inclusion and exclusion criteria. Those patients identified as eligible were then approached by a member of the team and provided with a brief description of the study and copies of the stroke survivor and carer participant information sheets. A minimum of 24 hours later, the patient and carer were approached by the Chief Investigator (CI) or the Research Assistant (RA; an Assistant Psychologist) and asked if they wished to participate. If they both assented to participate then an assessment appointment was arranged in a private side room off the ward.

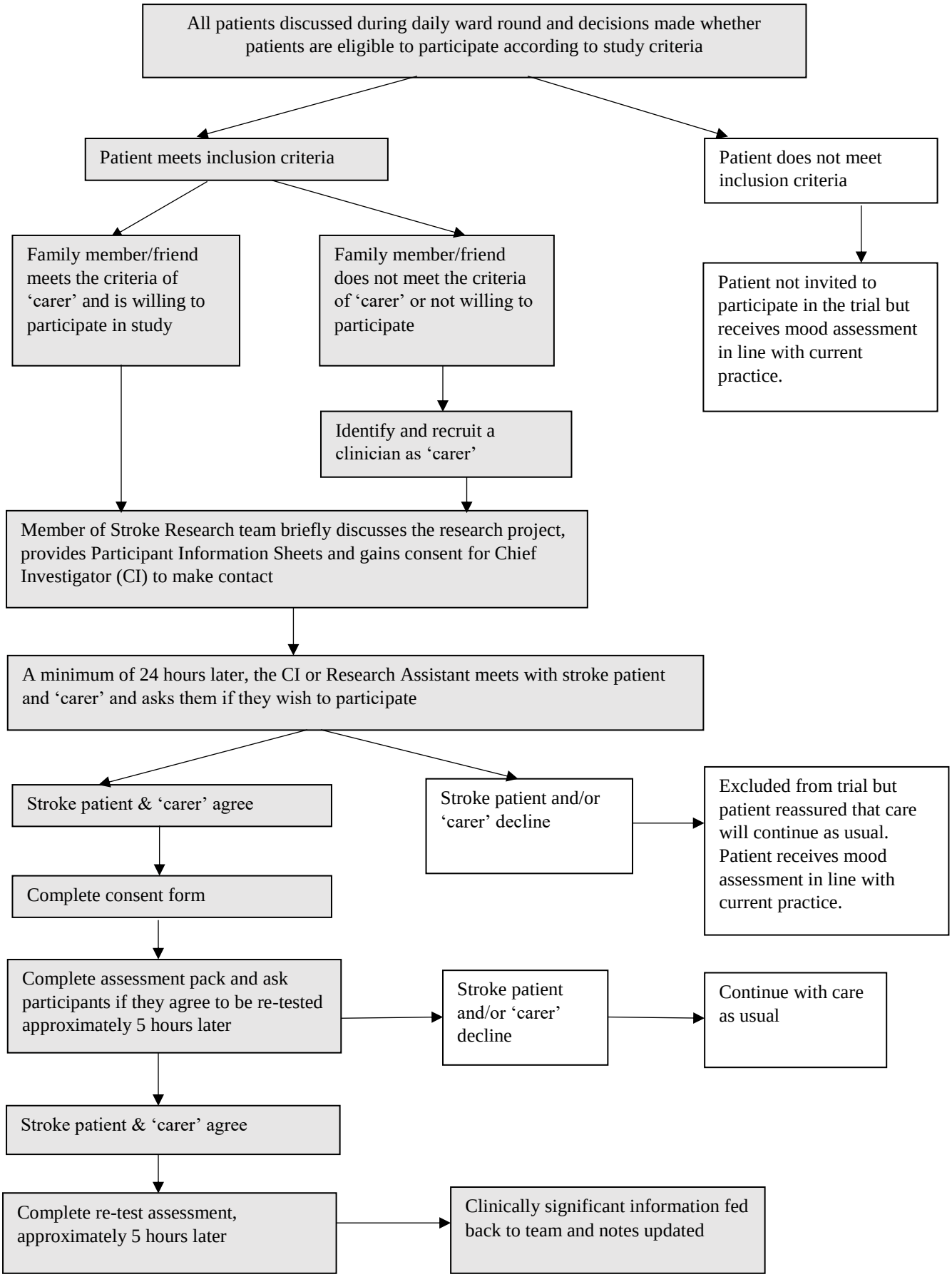
Recruitment flowchart: Bucks Neurorehabilitation Unit (BNRU)



Neurorehabilitation ward (2 of 2): Wycombe General Hospital (WGH) Stroke Unit

All patients admitted to the WGH Stroke Unit reviewed on a daily basis by a Consultant Physician and a Stoke Research Nurse. Those patients meeting the study criteria were identified during this ward round and provided with a brief description of the study and participant information sheets. A minimum of 24 hours later the Stroke Research Nurse approached the patient and asked them if they wished to participate. If the patient and carer agreed to be contacted, the Stroke Research Nurse passed on the contact details to the CI. If the patient was due to remain on the ward then the CI arranged an assessment appointment in a private side room. If the patient was due to be imminently discharged from the unit, an assessment appointment was arranged with them in their own home.

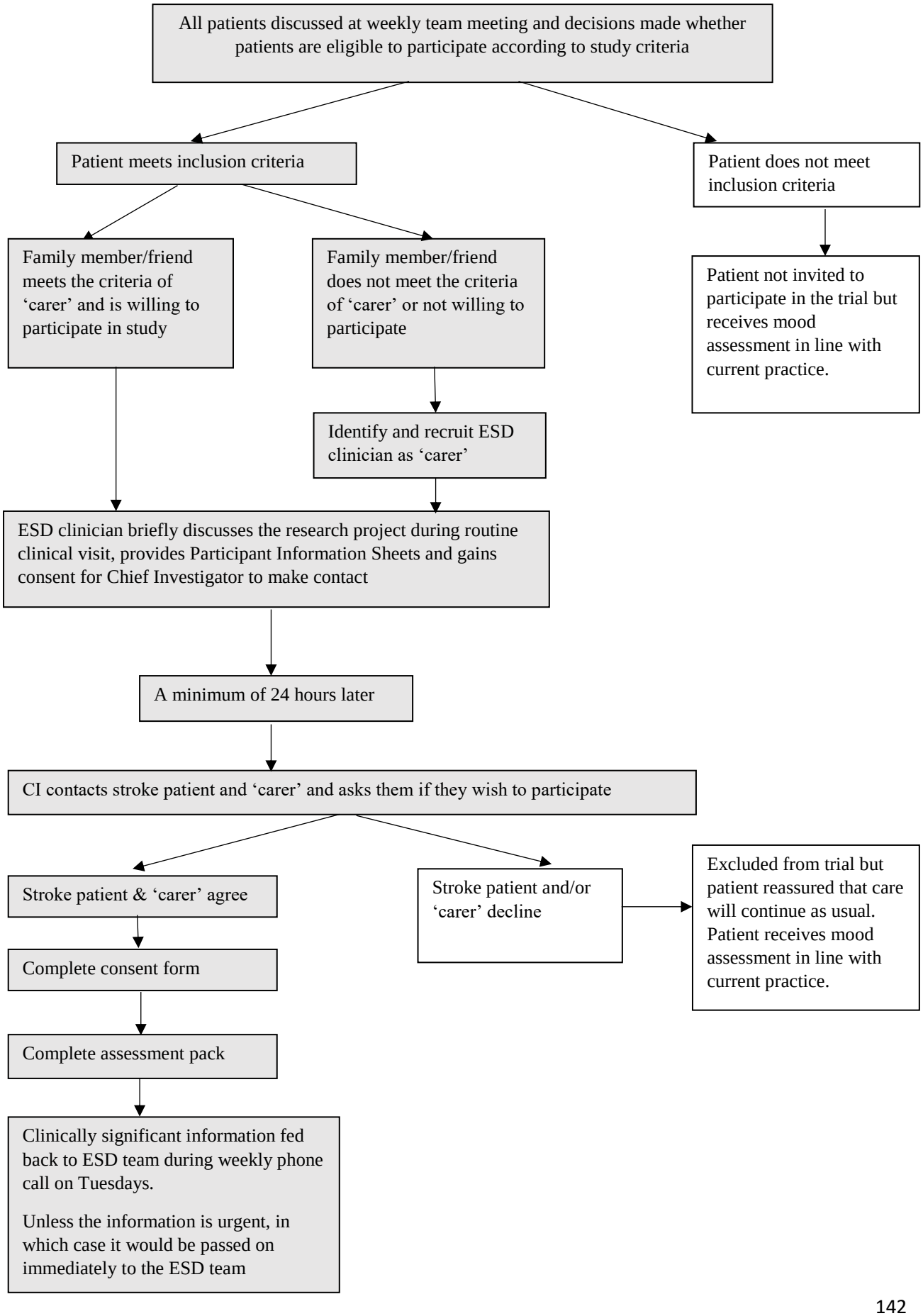
Recruitment flowchart: Wycombe General Hospital stroke unit



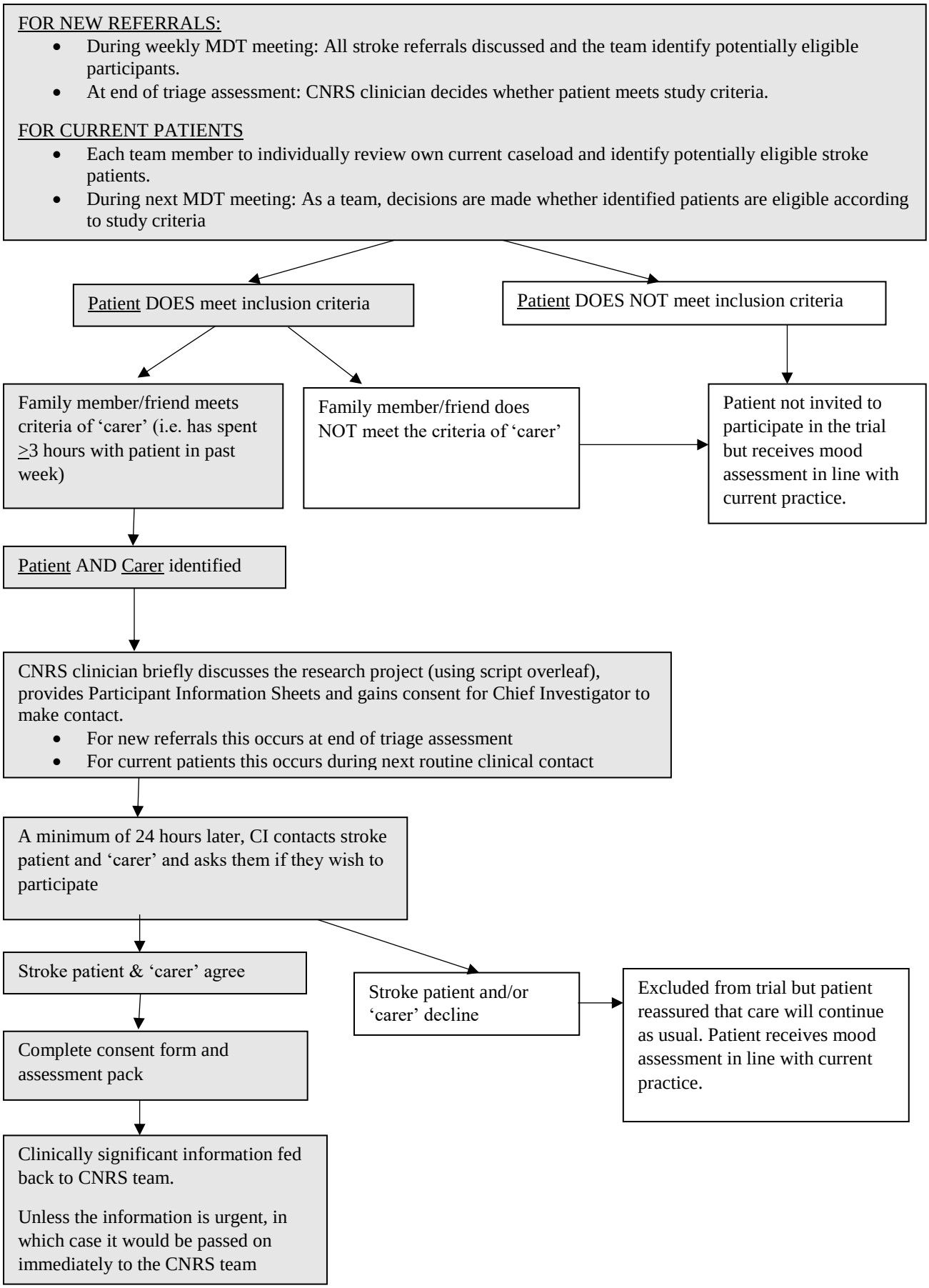
Community services: Buckinghamshire Stroke Early Supported Discharge service and Buckinghamshire Community Neurological Rehabilitation Service

All newly-referred patients were discussed in weekly multidisciplinary team meetings. During this meeting the team considered whether patients were eligible for the study using the inclusion and exclusion criteria. During the next routine clinical visit, the patient's keyworker provided the patient and carer with a brief description of the study and participant information sheets. A minimum of 24 hours later the CI or RA made contact with the patient and carer by telephone and asked them if they wished to participate. Whenever possible, assessment appointments were arranged to take place at home with the patient and carer both present. In a few circumstances when it was impracticable for the carer to attend in person, a telephone assessment appointment was made with the carer participant.

Recruitment flowchart: Bucks Stroke Early Supported Discharge service



Recruitment flowchart: Bucks Community Neurological Rehabilitation Service



Appendix J: Participant information sheets

1. Participant information sheets (PIS) for Bucks Neurorehabilitation Unit
    a. Stroke survivor PIS
    b. Carer PIS

2. PIS for Wycombe General Hospital stroke unit
    a. Stroke survivor PIS
    b. Carer PIS

3. PIS for Bucks Stroke Early Supported Discharge service
    a. Stroke survivor PIS
    b. Carer PIS

4. PIS for Bucks Community Neurological Rehabilitation Service
    a. Stroke survivor PIS
    b. Carer PIS

REC Ref. No: 15/SC/0708

Assessing anxiety following stroke

Stroke survivor participants from the Buckinghamshire Neurorehabilitation Unit (BNRU)

Information Sheet: Part 1

We would like to invite you to take part in our research study. Before you decide we would like you to understand why the research is being done and what it would involve for you. Please take the time to read the following information carefully and discuss it with others if you wish.

What is the purpose of the study?

The study you have been asked to take part in is concerned with assessing anxiety in people who have had a stroke. The study is being carried out as part of the Chief Investigator's Doctorate in Clinical Psychology.

Why have I been asked to take part in the study?

This study is recruiting stroke survivors and their carers. You have been asked to participate because you have recently had a stroke.

Do I have to take part in the study?

No. Agreeing to take part with this study is optional. This means that you are under no obligation to participate. If you decide not to take part, this will not affect the care you receive in any way. If you decide not to take part your care will continue as usual.

As this study requires pairs of stroke survivors and carers, a family member or friend will also be invited to participate as your carer in this study. However, there is no pressure for your family member or friend to participate if they do not wish to. If they choose not to participate then a member of your care team will be asked if they would like to participate in this study as your carer instead.

If it is not possible to find a carer then unfortunately it will not be possible for you to participate in the study. This will not affect the care you receive in any way.

Can I withdraw from the study once I have agreed?

Yes. If you agree to take part but later change your mind, you can withdraw at any time until two weeks after you have completed the assessment. After this time, the information you have provided will be anonymised and it will not be possible to remove it.

What will happen if I agree to take part?

You will be given at least one day to decide if you want to take part. If you agree a researcher will ask you to complete a written consent form to confirm your agreement to take part. The consent form will ask if you have read this information sheet and if you agree to participate in this study.

The researcher will then complete a number of questionnaires with you.

You will be asked to complete four short questionnaires asking about your mood and thinking skills. This will take about 45 minutes and will normally take place in a private side room. You will be offered the chance to take a break during the assessment. Approximately five hours later the researcher will return to repeat one of the questionnaires with you. This will take around 5 minutes.

Please be informed that the researcher will also complete one short questionnaire with your carer and ask a few questions to gather background information. This is expected to take approximately 10 minutes.

What are the possible benefits of taking part in the study?

Taking part in the study may help with the development of a new anxiety assessment tool, which if shown to be effective, may contribute to improving the care of people who have had a stroke. The questionnaires may give you a chance to think about how you are feeling since the stroke.

In addition, for some people a stroke can affect their thinking skills so these will also be briefly assessed. If the assessment picks up mood or thinking difficulties, these will be shared with your care team to help improve your care and recovery from your stroke.

What are the possible disadvantages and risks of taking part in the study?

The questionnaires will ask you about your feelings which may be upsetting. If you wish, the researcher can stop the assessment at any time during the process and give you time to talk about any issues that may be upsetting.

Thank you for reading so far – if you are still interested please go to part 2:

Part 2

Confidentiality and Information Sharing

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Data Protection and Anonymity

The assessment pack will not record your name. You will be allocated a unique reference number, which can only be linked to you through the consent form that you will have completed. The consent forms will be stored separately from the assessment pack. Once you have completed the assessment, the information you have provided will be entered anonymously into a secure database. This anonymous research data will be held in a secure store for five years, after which it will be destroyed.

What if there is a problem?

In the event that something does go wrong and you are harmed during the research and this is due to negligence then you may have grounds for legal action for compensation against Oxford Health NHS Foundation Trust who are the sponsors of the study, however you may have to pay your legal costs. NHS indemnity does not offer no-fault compensation and cannot agree to pay compensation for non-negligent harm.

Who has reviewed this study?

Before any research goes ahead it has to be checked by a Research Ethics Committee. They make sure that the research is fair. This project has been reviewed and approved by the Oxford B NHS Research Ethics Committee (Project ID 15/SC/0708).

Publication of Results

This study will be submitted for publication in a peer reviewed journal when it has been completed. Individual participants will not be identifiable in any report or publication. If you wish to receive a summary of the completed report, please inform the researcher and they will make a note of your contact details.

More Information

If you would like more information concerning the study, or would like to discuss taking part in more detail, please let a member of the BNRU team know, and they will contact the researcher, David Stokes or the researcher's supervisor, Dr David Dean, who will arrange to meet with you.

Complaints and Concerns

If you have any complaints regarding this study, please speak to a member of the study team who may be able to address your concern. Otherwise you may contact the Patient Advice and Liaison Service (PALS) who offer confidential advice, support and information on health-related matters.

Thank you for reading this – please ask any questions if you need to.

David Stokes
Trainee Clinical Psychologist

Dr David Dean
Consultant Clinical Neuropsychologist

Chief Investigator:

David Stokes
Trainee Clinical Psychologist

Oxford Institute of Clinical Psychology Training
The Isis Education Centre
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Research Supervisor:

Dr David Dean
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Version 5, 15th December 2015

REC Ref. No: 15/SC/0708

Assessing anxiety following stroke

Carer participants from the Buckinghamshire Neurorehabilitation Unit (BNRU)

Information Sheet: Part 1

We would like to invite you to take part in our research study. Before you decide we would like you to understand why the research is being done and what it would involve for you. Please take the time to read the following information carefully and discuss it with others if you wish.

What is the purpose of the study?

The study you have been asked to take part in is concerned with assessing anxiety in people who have had a stroke. The study is being carried out as part of the Chief Investigator's Doctorate in Clinical Psychology.

Why have I been asked to take part in the study?

This study is recruiting stroke survivors and their carers. You have been asked to participate because you are a carer for someone who has had a stroke. A carer can be a family member, friend or a professional.

Do I have to take part in the study?

No. Agreeing to take part in this study is optional. This means that you are under no obligation to participate. If you decide not to take part, this will not affect the care received by the stroke survivor in any way. If the stroke survivor is willing to take part in the study there is no pressure or expectation for you to participate in the study as their carer.

Please note that as the study requires pairs of stroke survivors and carers, if you decide not to participate in the study then a member of the care team will be asked if they would like to participate in this study. If it is not possible to find a carer then the stroke survivor will be withdrawn from the study but this will not affect the care they receive in any way.

Can I withdraw from the study once I have agreed?

Yes. If you agree to take part but later change your mind, you can withdraw at any time until two weeks after you have completed the assessment. After this time, the information you have provided will be anonymised and it will not be possible to remove it.

What will happen if I agree to take part?

You will be given at least one day to decide if you want to take part. A researcher will approach you to ask if you wish to take part. If you agree you will be asked to complete a written consent form to confirm your agreement to take part. The consent form will ask if you have read this information sheet and if you agree to participate in this study.

The researcher will then complete one short questionnaire with you and ask you a few questions to gather background information. This will take place in a private side room and is expected to take approximately 10 minutes.

Please be informed that the stroke survivor will also be asked to complete four short questionnaires asking about their mood which will take approximately 45 minutes. Approximately five hours later the stroke survivor will be asked to repeat one of the questionnaires and this is expected to take approximately 5 minutes.

What are the possible benefits of taking part in the study?

Taking part in the study may help with the development of a new anxiety assessment tool, which if shown to be effective, may contribute to improving the care of people who have had a stroke. The questionnaires may give you a chance to think about how the stroke survivor you are caring for has been feeling since the stroke.

What are the possible disadvantages and risks of taking part in the study?

The questionnaires will ask you about the stroke survivor's feelings which may be upsetting. If you wish, the researcher can stop the assessment at any time during the process and give you time to talk about any issues that may be upsetting.

Thank you for reading so far – if you are still interested please go to part 2:

Part 2

Confidentiality and Information Sharing

During the study, some of the information that you provide during the assessment will be part of the stroke survivor's confidential medical record that is maintained by the hospital. As such, information you provide in the assessment concerning the stroke survivor's mood and issues of concern will only be shared with the professionals directly involved in your care. The information will not be passed on to your GP or any other health services that you are involved with, unless you or someone else is at risk of harm. The term 'risk of harm' when applied to carers refers to the possibility of carers experiencing high levels of stress or depression and would benefit from accessing support quickly. If this is the case, the researcher will discuss this with you at the end of the assessment and make contact with your GP.

Data Protection and Anonymity

The assessment pack will not record your name. You and the stroke survivor will be allocated a unique reference number, which can only be linked to you through the consent form that you will have completed. The consent forms will be stored separately from the assessment pack. Once you have completed the assessment, the information you have provided will be entered anonymously into a secure database. This anonymous research data will be held in a secure store for five years, after which it will be destroyed.

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Version 5, 15th December 2015

REC Ref. No: 15/SC/0708

Assessing anxiety following stroke

Stroke survivor participants from the Wycombe General Hospital Stroke Unit

Information Sheet: Part 1

We would like to invite you to take part in our research study. Before you decide we would like you to understand why the research is being done and what it would involve for you. Please take the time to read the following information carefully and discuss it with others if you wish.

What is the purpose of the study?

The study you have been asked to take part in is concerned with assessing anxiety in people who have had a stroke. The study is being carried out as part of the Chief Investigator's Doctorate in Clinical Psychology.

Why have I been asked to take part in the study?

This study is recruiting stroke survivors and their carers. You have been asked to participate because you have recently had a stroke.

Do I have to take part in the study?

No. Agreeing to take part with this study is optional. This means that you are under no obligation to participate. If you decide not to take part, this will not affect the care you receive in any way. If you decide not to take part your care will continue as usual.

As this study requires pairs of stroke survivors and carers, a family member or friend will also be invited to participate as your carer in this study. However, there is no pressure for your family member or friend to participate if they do not wish to. If they choose not to participate then a member of your care team will be asked if they would like to participate in this study as your carer instead.

If it is not possible to find a carer then unfortunately it will not be possible for you to participate in the study. This will not affect the care you receive in any way.

Can I withdraw from the study once I have agreed?

Yes. If you agree to take part but later change your mind, you can withdraw at any time until two weeks after you have completed the assessment. After this time, the information you have provided will be anonymised and it will not be possible to remove it.

What will happen if I agree to take part?

You will be given at least one day to decide if you want to take part. If you agree a researcher will ask you to complete a written consent form to confirm your agreement to take part. The consent form will ask if you have read this information sheet and if you agree to participate in this study.

The researcher will then complete a number of questionnaires with you.

You will be asked to complete four short questionnaires asking about your mood and thinking skills. This will take about 45 minutes and will normally take place in a private side room. You will be offered the chance to take a break during the assessment. Approximately five hours later the researcher will return to repeat one of the questionnaires with you. This will take around 5 minutes.

Please be informed that the researcher will also complete one short questionnaire with your carer and ask a few questions to gather background information. This is expected to take approximately 10 minutes.

What are the possible benefits of taking part in the study?

Taking part in the study may help with the development of a new anxiety assessment tool, which if shown to be effective, may contribute to improving the care of people who have had a stroke. The questionnaires may give you a chance to think about how you are feeling since the stroke.

In addition, for some people a stroke can affect their thinking skills so these will also be briefly assessed. If the assessment picks up mood or thinking difficulties, these will be shared with your care team to help improve your care and recovery from your stroke.

What are the possible disadvantages and risks of taking part in the study?

The questionnaires will ask you about your feelings which may be upsetting. If you wish, the researcher can stop the assessment at any time during the process and give you time to talk about any issues that may be upsetting.

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Version 5, 15th December 2015

REC Ref. No: 15/SC/0708

Assessing anxiety following stroke

Stroke survivor participants from the Bucks Stroke Early Supported Discharge (ESD) service

Information Sheet: Part 1

We would like to invite you to take part in our research study. Before you decide we would like you to understand why the research is being done and what it would involve for you. Please take the time to read the following information carefully and discuss it with others if you wish.

What is the purpose of the study?

The study you have been asked to take part in is concerned with assessing anxiety in people who have had a stroke. The study is being carried out as part of the Chief Investigator's Doctorate in Clinical Psychology.

Why have I been asked to take part in the study?

This study is recruiting stroke survivors and their carers. You have been asked to participate because you have recently had a stroke.

Do I have to take part in the study?

No. Agreeing to take part with this study is optional. This means that you are under no obligation to participate. If you decide not to take part, this will not affect the care you receive in any way. If you decide not to take part your care will continue as usual.

As this study requires pairs of stroke survivors and carers, a family member or friend will also be invited to participate as your carer in this study. However, there is no pressure for your family member or friend to participate if they do not wish to. If they choose not to participate then a member of your care team will be asked if they would like to participate in this study as your carer instead.

If it is not possible to find a carer then unfortunately it will not be possible for you to participate in the study. This will not affect the care you receive in any way.

Can I withdraw from the study once I have agreed?

Yes. If you agree to take part but later change your mind, you can withdraw at any time until two weeks after you have completed the assessment. After this time, the information you have provided will be anonymised and it will not be possible to remove it.

What will happen if I agree to take part?

You will be given at least one day to decide if you want to take part. If you agree to take part a clinician from the Early Supported Discharge service will ask you for a contact number. A researcher will then contact you by telephone and arrange a convenient time, date and location to visit (usually at home).

At this meeting you will be asked to complete a written consent form to confirm your agreement to take part. The consent form will ask if you have read this information sheet and if you agree to participate in this study.

The researcher will then complete a number of questionnaires with you.

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More Information

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At this meeting you will be asked to complete a written consent form to confirm your agreement to take part. The consent form will ask if you have read this information sheet and if you agree to participate in this study.

The researcher will then complete one short questionnaire with you and ask you a few questions to gather background information. This is expected to take approximately 10 minutes.

Please be informed that the stroke survivor will also be asked to complete four short questionnaires asking about their mood which will take approximately 45 minutes.

What are the possible benefits of taking part in the study?

Taking part in the study may help with the development of a new anxiety assessment tool, which if shown to be effective, may contribute to improving the care of people who have had a stroke. The questionnaires may give you a chance to think about how the stroke survivor you are caring for has been feeling since the stroke.

What are the possible disadvantages and risks of taking part in the study?

The questionnaires will ask you about the stroke survivor's feelings which may be upsetting. If you wish, the researcher can stop the assessment at any time during the process and give you time to talk about any issues that may be upsetting.

Thank you for reading so far – if you are still interested please go to part 2:

Part 2

Confidentiality and Information Sharing

During the study, some of the information that you provide during the assessment will be part of the stroke survivor's confidential medical record that is maintained by the hospital. As such, information you provide in the assessment concerning the stroke survivor's mood and issues of concern will only be shared with the professionals directly involved in your care. The information will not be passed on to your GP or any other health services that you are involved with, unless you or someone else is at risk of harm. The term 'risk of harm' when applied to carers refers to the possibility of carers experiencing high levels of stress or depression and would benefit from accessing support quickly. If this is the case, the researcher will discuss this with you at the end of the assessment and make contact with your GP.

Data Protection and Anonymity

The assessment pack will not record your name. You will be allocated a unique reference number, which can only be linked to you through the consent form that you will have completed. The consent forms will be stored separately from the assessment pack. Once you have completed the assessment, the information you have provided will be entered anonymously into a secure database. This anonymous research data will be held in a secure store for five years, after which it will be destroyed.

What if there is a problem?

In the event that something does go wrong and you are harmed during the research and this is due to negligence then you may have grounds for legal action for compensation against Oxford Health NHS Foundation Trust who are the sponsors of the study, however you may have to pay your legal costs. NHS indemnity does not offer no-fault compensation and cannot agree to pay compensation for non-negligent harm.

Who has reviewed this study?

Before any research goes ahead it has to be checked by a Research Ethics Committee. They make sure that the research is fair. This project has been reviewed and approved by the Oxford B NHS Research Ethics Committee (Project ID 15/SC/0708).

Publication of Results

This study will be submitted for publication in a peer reviewed journal when it has been completed. Individual participants will not be identifiable in any report or publication. If you wish to receive a summary of the completed report, please inform the researcher and they will make a note of your contact details.

More Information

If you would like more information concerning the study, or would like to discuss taking part in more detail, please let your Stroke Specialist Nurse know, and they will contact the researcher, David Stokes or the researcher's supervisor, Dr David Dean, who will arrange to meet with you.

Complaints and Concerns

If you have any complaints regarding this study, please speak to a member of the study team who may be able to address your concern. Otherwise you may contact the Patient Advice and Liaison Service (PALS) who offer confidential advice, support and information on health-related matters.

Thank you for reading this – please ask any questions if you need to.

David Stokes
Trainee Clinical Psychologist

Dr David Dean
Consultant Clinical Neuropsychologist

Chief Investigator:

David Stokes
Trainee Clinical Psychologist

Oxford Institute of Clinical Psychology Training
The Isis Education Centre
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Research Supervisor:

Dr David Dean
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Buckinghamshire Neurorehabilitation Unit
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Whielden Street
Amersham
Bucks
HP7 0JD

Telephone: 01494 734102
Email: david.dean@buckshealthcare.nhs.uk

Version 5, 15th December 2015

REC Ref. No: 15/SC/0708

Assessing anxiety following stroke

Stroke survivor participants from the Community Neurological Rehabilitation Service

Information Sheet: Part 1

We would like to invite you to take part in our research study. Before you decide we would like you to understand why the research is being done and what it would involve for you. Please take the time to read the following information carefully and discuss it with others if you wish.

What is the purpose of the study?

The study you have been asked to take part in is concerned with assessing anxiety in people who have had a stroke. The study is being carried out as part of the Chief Investigator's Doctorate in Clinical Psychology.

Why have I been asked to take part in the study?

This study is recruiting stroke survivors and their carers. You have been asked to participate because you have recently had a stroke.

Do I have to take part in the study?

No. Agreeing to take part with this study is optional. This means that you are under no obligation to participate. If you decide not to take part, this will not affect the care you receive in any way. If you decide not to take part your care will continue as usual.

As this study requires pairs of stroke survivors and carers, a family member or friend will also be invited to participate as your carer in this study. However, there is no pressure for your family member or friend to participate if they do not wish to. If they choose not to participate then a member of your care team will be asked if they would like to participate in this study as your carer instead.

If it is not possible to find a carer then unfortunately it will not be possible for you to participate in the study. This will not affect the care you receive in any way.

Can I withdraw from the study once I have agreed?

Yes. If you agree to take part but later change your mind, you can withdraw at any time until two weeks after you have completed the assessment. After this time, the information you have provided will be anonymised and it will not be possible to remove it.

What will happen if I agree to take part?

You will be given at least one day to decide if you want to take part. If you agree to take part a clinician from the Community Neurological Rehabilitation Service will ask you for a contact number. A researcher will then contact you by telephone and arrange a convenient time, date and location to visit (usually at home).

At this meeting you will be asked to complete a written consent form to confirm your agreement to take part. The consent form will ask if you have read this information sheet and if you agree to participate in this study.

The researcher will then complete a number of questionnaires with you.

You will be asked to complete four short questionnaires asking about your mood and thinking skills. This will take about 45 minutes and will normally take place in a private side room. You will be offered the chance to take a break during the assessment.

Please be informed that the researcher will also complete one short questionnaire with your carer and ask a few questions to gather background information. This is expected to take approximately 10 minutes.

What are the possible benefits of taking part in the study?

Taking part in the study may help with the development of a new anxiety assessment tool, which if shown to be effective, may contribute to improving the care of people who have had a stroke. The questionnaires may give you a chance to think about how you are feeling since the stroke.

In addition, for some people a stroke can affect their thinking skills so these will also be briefly assessed. If the assessment picks up mood or thinking difficulties these will be shared with your care team to help improve your care and recovery from your stroke.

What are the possible disadvantages and risks of taking part in the study?

The questionnaires will ask you about your feelings which may be upsetting. If you wish, the researcher can stop the assessment at any time during the process and give you time to talk about any issues that may be upsetting.

Thank you for reading so far – if you are still interested please go to part 2:

Part 2

Confidentiality and Information Sharing

During the study, the information that you provide during the assessment will be part of your confidential medical record that is maintained by the hospital. As such, information you provide in the assessment concerning your mood and issues of concern to you will only be shared with the professionals directly involved in your care. The information will not be passed on to your GP or any other health services that you are involved with, unless you or someone else is at risk of harm. You would only be considered at 'risk of harm' if you are currently feeling very low in mood and experiencing thoughts of wanting to hurt yourself or to end your life. In this case, the researcher will discuss this with you at the end of the assessment.

Data Protection and Anonymity

The assessment pack will not record your name. You will be allocated a unique reference number, which can only be linked to you through the consent form that you will have completed. The consent forms will be stored separately from the assessment pack. Once you have completed the assessment, the information you have provided will be entered anonymously into a secure database. This anonymous research data will be held in a secure store for five years, after which it will be destroyed.

What if there is a problem?

In the event that something does go wrong and you are harmed during the research and this is due to negligence then you may have grounds for legal action for compensation against Oxford Health NHS Foundation Trust who are the sponsors of the study, however you may have to pay your legal costs. NHS indemnity does not offer no-fault compensation and cannot agree to pay compensation for non-negligent harm.

Who has reviewed this study?

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Publication of Results

This study will be submitted for publication in a peer reviewed journal when it has been completed. Individual participants will not be identifiable in any report or publication. If you wish to receive a summary of the completed report, please inform the researcher and they will make a note of your contact details.

More Information

If you would like more information concerning the study, or would like to discuss taking part in more detail, please let your keyworker know, and they will contact the researcher, David Stokes or the researcher's supervisor, Dr David Dean, who will arrange to meet with you.

Complaints and Concerns

If you have any complaints regarding this study, please speak to a member of the study team who may be able to address your concern. Otherwise you may contact the Patient Advice and Liaison Service (PALS) who offer confidential advice, support and information on health-related matters.

Thank you for reading this – please ask any questions if you need to.

David Stokes
Trainee Clinical Psychologist

Dr David Dean
Consultant Clinical Neuropsychologist

Chief Investigator:

David Stokes
Trainee Clinical Psychologist

Oxford Institute of Clinical Psychology Training
The Isis Education Centre
Roosevelt Drive
Warneford Hospital
Oxford
OX3 7JX

Telephone: 01865 226431
Email: david.stokes@hmc.ox.ac.uk

Research Supervisor:

Dr David Dean
Consultant Clinical Neuropsychologist

Buckinghamshire Neurorehabilitation Unit
Amersham Hospital
Whielden Street
Amersham
Bucks
HP7 0JD

Telephone: 01494 734102
Email: david.dean@buckshealthcare.nhs.uk

Version 5, 15th December 2015

REC Ref. No: 15/SC/0708

Assessing anxiety following stroke

Carer participants from the Community Neurological Rehabilitation Service

Information Sheet: Part 1

We would like to invite you to take part in our research study. Before you decide we would like you to understand why the research is being done and what it would involve for you. Please take the time to read the following information carefully and discuss it with others if you wish.

What is the purpose of the study?

The study you have been asked to take part in is concerned with assessing anxiety in people who have had a stroke. The study is being carried out as part of the Chief Investigator's Doctorate in Clinical Psychology.

Why have I been asked to take part in the study?

This study is recruiting stroke survivors and their carers. You have been asked to participate because you are a carer for someone who has had a stroke. A carer can be a family member, friend or a professional.

Do I have to take part in the study?

No. Agreeing to take part in this study is optional. This means that you are under no obligation to participate. If you decide not to take part, this will not affect the care received by the stroke survivor in any way. If the stroke survivor is willing to take part in the study there is no pressure or expectation for you to participate in the study as their carer.

Please note that as the study requires pairs of stroke survivors and carers, if you decide not to participate in the study then a member of the care team will be asked if they would like to participate in this study. If it is not possible to find a carer then the stroke survivor will be withdrawn from the study but this will not affect the care they receive in any way.

Can I withdraw from the study once I have agreed?

Yes. If you agree to take part but later change your mind, you can withdraw at any time until two weeks after you have completed the assessment. After this time, the information you have provided will be anonymised and it will not be possible to remove it.

What will happen if I agree to take part?

You will be given at least one day to decide if you want to take part. If you agree to take part a clinician from the Community Neurological Rehabilitation Service will ask you for a contact number. A researcher will then contact you by telephone and arrange a convenient time, date and location to visit (usually at home).

At this meeting you will be asked to complete a written consent form to confirm your agreement to take part. The consent form will ask if you have read this information sheet and if you agree to participate in this study.

The researcher will then complete one short questionnaire with you and ask you a few questions to gather background information. This is expected to take approximately 10 minutes.

Please be informed that the stroke survivor will also be asked to complete four short questionnaires asking about their mood which will take approximately 45 minutes.

What are the possible benefits of taking part in the study?

Taking part in the study may help with the development of a new anxiety assessment tool, which if shown to be effective, may contribute to improving the care of people who have had a stroke. The questionnaires may give you a chance to think about how the stroke survivor you are caring for has been feeling since the stroke.

What are the possible disadvantages and risks of taking part in the study?

The questionnaires will ask you about the stroke survivor's feelings which may be upsetting. If you wish, the researcher can stop the assessment at any time during the process and give you time to talk about any issues that may be upsetting.

Thank you for reading so far – if you are still interested please go to part 2:

Part 2

Confidentiality and Information Sharing

During the study, some of the information that you provide during the assessment will be part of the stroke survivor's confidential medical record that is maintained by the hospital. As such, information you provide in the assessment concerning the stroke survivor's mood and issues of concern will only be shared with the professionals directly involved in your care. The information will not be passed on to your GP or any other health services that you are involved with, unless you or someone else is at risk of harm. The term 'risk of harm' when applied to carers refers to the possibility of carers experiencing high levels of stress or depression and would benefit from accessing support quickly. If this is the case, the researcher will discuss this with you at the end of the assessment and make contact with your GP.

Data Protection and Anonymity

The assessment pack will not record your name. You will be allocated a unique reference number, which can only be linked to you through the consent form that you will have completed. The consent forms will be stored separately from the assessment pack. Once you have completed the assessment, the information you have provided will be entered anonymously into a secure database. This anonymous research data will be held in a secure store for five years, after which it will be destroyed.

What if there is a problem?

In the event that something does go wrong and you are harmed during the research and this is due to negligence then you may have grounds for legal action for compensation against Oxford Health NHS Foundation Trust who are the sponsors of the study, however you may have to pay your legal costs. NHS indemnity does not offer no-fault compensation and cannot agree to pay compensation for non-negligent harm.

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This study will be submitted for publication in a peer reviewed journal when it has been completed. Individual participants will not be identifiable in any report or publication. If you wish to receive a summary of the completed report, please inform the researcher and they will make a note of your contact details.

More Information

If you would like more information concerning the study, or would like to discuss taking part in more detail, please let your keyworker know, and they will contact the researcher, David Stokes or the researcher's supervisor, Dr David Dean, who will arrange to meet with you.

Complaints and Concerns

If you have any complaints regarding this study, please speak to a member of the study team who may be able to address your concern. Otherwise you may contact the Patient Advice and Liaison Service (PALS) who offer confidential advice, support and information on health-related matters.

Thank you for reading this – please ask any questions if you need to.

David Stokes
Trainee Clinical Psychologist

Dr David Dean
Consultant Clinical Neuropsychologist

Chief Investigator:

David Stokes
Trainee Clinical Psychologist

Oxford Institute of Clinical Psychology Training
The Isis Education Centre
Roosevelt Drive
Warneford Hospital
Oxford
OX3 7JX

Telephone: 01865 226431
Email: david.stokes@hmc.ox.ac.uk

Research Supervisor:

Dr David Dean
Consultant Clinical Neuropsychologist

Buckinghamshire Neurorehabilitation Unit
Amersham Hospital
Whielden Street
Amersham
Bucks
HP7 0JD

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Email: david.dean@buckshealthcare.nhs.uk

Version 5, 15th December 2015

Appendix K: Consent Forms

1) Consent Forms (CF) for Bucks Neurorehabilitation Unit

    c. Stroke survivor CF

    d. Carer CF

2) CF for Wycombe General Hospital stroke unit

    a. Stroke survivor CF

    b. Carer CF

3) CF for Bucks Stroke Early Supported Discharge service

    a. Stroke survivor CF

    b. Carer CF

4) CF for Bucks Community Neurological Rehabilitation Service

    a. Stroke survivor CF

    b. Carer CF

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Buckinghamshire Healthcare NHS
NHS Trust

REC Ref No: 15/SC/0708

Participant ID:

Name of Researcher:

CONSENT FORM

Assessing anxiety following stroke

Stroke survivor participants from the Bucks Neurorehabilitation Unit (BNRU)

Please read the statements below and initial each statement that is applicable:

Please initial box

1. I confirm that I have read the Information sheet (dated 15th December 2015, version 5) and had the opportunity to discuss taking part, including having any questions answered satisfactorily. ☐
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 being affected. ☐
3. I give permission for my GP to be informed as part of my participation in this study. ☐
4. I agree to complete one of the questionnaires later the same day ☐
5. I give permission for the researcher to access my medical records to obtain information about my stroke. ☐
6. I agree for information to be passed on to my GP if the researcher believes that I or someone else is at risk of harm. ☐
7. I understand that relevant sections of the data collected during the study may be looked at by authorised individuals from the Sponsor organisation, Oxford Health NHS Foundation Trust, from regulatory authorities, or from the NHS Trust where it is relevant to my taking part in this research. I give permission for these individuals to have access to the data that I have provided ☐
8. I agree to take part in the above named study ☐

Name of Participant	Date	Signature
Name of person taking consent	Date	Signature

When signed & completed: 1 copy for participant, 1 for researcher 1 (original copy) to be kept in the medical records.

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Buckinghamshire Healthcare NHS
NHS Trust

REC Ref No: 15/SC/0708

Participant ID:

Name of Researcher:

CONSENT FORM

Assessing anxiety following stroke

Carer participants from the Buckinghamshire Neurorehabilitation Unit (BNRU)

Please read the statements below and initial each statement that is applicable:

Please initial box

1. I confirm that I have read the Information sheet (dated 15th December 2015, version 5) and had the opportunity to discuss taking part, including having any questions answered satisfactorily ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason ☐
3. I agree for information to be passed on to my GP if the researcher believes that I or someone else is at risk of harm. ☐
4. I understand that relevant sections of the data collected during the study may be looked at by authorised individuals from the Sponsor organisation, Oxford Health NHS Foundation Trust, from regulatory authorities, or from the NHS Trust where it is relevant to my taking part in this research. I give permission for these individuals to have access to the data that I have provided ☐
5. I agree to take part in the above named study ☐

Name of Participant	Date	Signature
Name of person taking consent	Date	Signature

When signed and completed: 1 copy for the participant and original for the researcher.

Version 5, 15th December 2015

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NHS Trust

REC Ref No: 15/SC/0708

Participant ID:

Name of Researcher:

CONSENT FORM

Assessing anxiety following stroke

Stroke survivor participants from the Wycombe General Hospital Stroke Unit

Please read the statements below and initial each statement that is applicable:

Please initial box

1. I confirm that I have read the Information sheet (dated 15th December 2015, version 5) and had the opportunity to discuss taking part, including having any questions answered satisfactorily. ☐
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 being affected. ☐
3. I give permission for my GP to be informed as part of my participation in this study. ☐
4. I agree to complete one of the questionnaires later the same day ☐
5. I give permission for the researcher to access my medical records to obtain information about my stroke. ☐
6. I agree for information to be passed on to my GP if the researcher believes that I or someone else is at risk of harm. ☐
7. I understand that relevant sections of the data collected during the study may be looked at by authorised individuals from the Sponsor organisation, Oxford Health NHS Foundation Trust, from regulatory authorities, or from the NHS Trust where it is relevant to my taking part in this research. I give permission for these individuals to have access to the data that I have provided ☐
8. I agree to take part in the above named study ☐

Name of Participant	Date	Signature
Name of person taking consent	Date	Signature

When signed & completed: 1 copy for participant, 1 for researcher 1 (original copy) to be kept in the medical records.

Version 5, 15th December 2015

UNIVERSITY OF OXFORD

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NHS Foundation Trust

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NHS Trust

REC Ref No: 15/SC/0708

Participant ID:

Name of Researcher:

CONSENT FORM

Assessing anxiety following stroke

Carer participants from the Wycombe General Hospital Stroke Unit

Please read the statements below and initial each statement that is applicable:

Please initial box

1. I confirm that I have read the Information sheet (dated 15th December 2015, version 5) and had the opportunity to discuss taking part, including having any questions answered satisfactorily ☐
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3. I agree for information to be passed on to my GP if the researcher believes that I or someone else is at risk of harm. ☐
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5. I agree to take part in the above named study ☐

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Safe & compassionate care, every time

Buckinghamshire Healthcare NHS
NHS Trust

REC Ref No: 15/SC/0708

Participant ID:

Name of Researcher:

CONSENT FORM

Assessing anxiety following stroke

Stroke survivor participants from the Bucks Early Supported Discharge (ESD) Service

Please read the statements below and initial each statement that is applicable:

Please initial box

1. I confirm that I have read the Information sheet (dated 15th December 2015, version 5) and had the opportunity to discuss taking part, including having any questions answered satisfactorily. ☐
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 being affected. ☐
3. I give permission for my GP to be informed as part of my participation in this study. ☐
4. I give permission for the researcher to access my medical records to obtain information about my stroke. ☐
5. I agree for information to be passed on to my GP if the researcher believes that I or someone else is at risk of harm. ☐
6. I understand that relevant sections of the data collected during the study may be looked at by authorised individuals from the Sponsor organisation, Oxford Health NHS Foundation Trust, from regulatory authorities, or from the NHS Trust where it is relevant to my taking part in this research. I give permission for these individuals to have access to the data that I have provided ☐
7. I agree to take part in the above named study ☐

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NHS Trust

REC Ref No: 15/SC/0708

Participant ID:

Name of Researcher:

CONSENT FORM

Assessing anxiety following stroke

Carer participants from the Bucks Early Supported Discharge (ESD) Service

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1. I confirm that I have read the Information sheet (dated 15th December 2015, version 5) and had the opportunity to discuss taking part, including having any questions answered satisfactorily ☐
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason ☐
3. I agree for information to be passed on to my GP if the researcher believes that I or someone else is at risk of harm. ☐
4. I understand that relevant sections of the data collected during the study may be looked at by authorised individuals from the Sponsor organisation, Oxford Health NHS Foundation Trust, from regulatory authorities, or from the NHS Trust where it is relevant to my taking part in this research. I give permission for these individuals to have access to the data that I have provided ☐
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REC Ref No: 15/SC/0708

Participant ID:

Name of Researcher:

CONSENT FORM

Assessing anxiety following stroke

Stroke survivor participants from the Community Neurological Rehabilitation Service

Please read the statements below and initial each statement that is applicable:

Please initial box

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3. I give permission for my GP to be informed as part of my participation in this study. ☐
4. I give permission for the researcher to access my medical records to obtain information about my stroke. ☐
5. I agree for information to be passed on to my GP if the researcher believes that I or someone else is at risk of harm. ☐
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Participant ID:

Name of Researcher:

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Assessing anxiety following stroke

Carer participants from the Community Neurological Rehabilitation Service

Please read the statements below and initial each statement that is applicable:

Please initial box

1. I confirm that I have read the Information sheet (dated 15th December 2015, version 5) and had the opportunity to discuss taking part, including having any questions answered satisfactorily ☐
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3. I agree for information to be passed on to my GP if the researcher believes that I or someone else is at risk of harm. ☐
4. I understand that relevant sections of the data collected during the study may be looked at by authorised individuals from the Sponsor organisation, Oxford Health NHS Foundation Trust, from regulatory authorities, or from the NHS Trust where it is relevant to my taking part in this research. I give permission for these individuals to have access to the data that I have provided ☐
5. I agree to take part in the above named study ☐

Name of Participant	Date	Signature
Name of person taking consent	Date	Signature

When signed and completed: 1 copy for the participant and original for the researcher.

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NHS Foundation Trust

Appendix L: Ethical Issues

Participant Wellbeing

Informed by models of adjustment following stroke (e.g. Holbrook, 1982), and the often traumatic nature of a stroke, it was expected that many participants would be experiencing current distress. I was therefore very mindful that I was recruiting and interviewing stroke survivors and their families at a potentially vulnerable time and it was essential to both minimise the possibility of causing distress and to appropriately manage distress arising from participation in the study. Following consultation with stroke services, discussions with a panel of service users and carers and with the research ethics committee, and drawing on my own clinical experience, the following measures were employed:

- Decisions on when to approach inpatient participants were made following discussions with ward staff. This helped to prevent testing during inappropriate times, for example after distressing events occurring on the ward or participants receiving significant news (e.g. being told discharge is imminent).
- The testing procedure time was kept to a minimum (maximum 45 minutes for initial testing and 10 minutes for re-testing) to avoid over-loading participants who may have a shortened attention span (Wade, Wood & Hewer, 1988).
- The chosen measures were short and not cognitively demanding to minimise the possibility of participants becoming confused by the tasks or fatigued by the effort of completing them.
- Assessments were conducted either at home or in a side consultation room for privacy, confidentiality and to ensure fewer distractions.

- If participants had experienced distress during the assessment, the plan was as follows: the Chief Investigator or Research Assistant managed this distress by remaining with the participant to talk through the issues raised, alerted a senior clinician in the recruiting service (agreed in advance of the appointment) and referred on as appropriate. Both researchers had clinical experience, in hospital and community settings, of working with, and managing distress in, stroke survivors.
- Feedback was continually sought regarding the participants' wellbeing throughout the duration of the study.

These measures worked well and very few participants became upset during their interview, indicating that this was a largely acceptable procedure. In the few instances when participants became upset, the assessment was immediately paused and the researcher was able to help contain their distress. In all cases participants chose to continue with the study and complete all measures. Comments from participants indicated that these experiences had helped them continue to process their thoughts and feelings about their stroke. The participant's keyworker in the referring service was also informed when this occurred which was useful clinical information that helped to inform their ongoing care. These experiences highlighted the value of being a clinician as well as a researcher, as I was able to draw on my clinical experience of managing distress to facilitate this research.

Cognitive capacity

With the majority of stroke survivors having some form of cognitive and physical impairment (Lincoln et al., 2012), this can significantly impact on the ability to give informed consent to take part in a research study. It was therefore essential that appropriate and ethically robust procedures were in place to ensure that only participants with cognitive capacity were recruited. Again the procedure was developed following consultation with stroke services, discussion with the research ethics committee, and by drawing on my own

clinical experience. Firstly, stroke survivors were screened by a team of senior stroke clinicians enabling a range of professionals to comment on different aspects of cognitive functioning, as well as the other inclusion and exclusion criteria. This process helped to avoid stroke survivors being approached about the study who were not eligible or when the timing would have been insensitive. Stroke survivors were given at least 24 hours to consider participating in the study before being contacted by a researcher, allowing time to talk about this decision with family or close friends. At the beginning of each interview, researchers would discuss the procedure and establish that participants were able to recall the following: (a) the purpose of the study; (b) what they would be asked to do; (c) what they would do if they wished to withdraw; and (d) the potential risks and benefits of participating. In practice only one participant at time of assessment was judged as unable to give informed consent due to difficulties understanding and retaining the nature and purpose of the study. This potential participant was excluded from the study but continued to receive care as usual. This experience again highlighted the value of holding clinical and research skills which helped me to make an important decision and communicate this sensitively to the patient.

Appendix M: Sample letter to GP

Oxford Health NHS
NHS Foundation Trust

David Stokes
The Oxford Institute of Clinical Psychology Training
Isis Education Centre
Warneford Hospital
Headington
Oxford
OX3 8SE
Tel: 01865 226431
Email: david.stokes@hmc.ox.ac.uk

GP address

Date

Dear Dr ___,

RE: The Anxiety Scale Circles (ASC): a first evaluation of a simple assessment tool for anxiety in the context of stroke.

REC Ref: 15/SC/0708

Patient's name and DOB

I am writing to inform you that your patient has agreed to participate in the above research study. He/she has been recruited from the [INSERT NAME OF SERVICE] and the study will take place [INSERT LOCATION]

Summary of the study

It is common for people to experience anxiety following a stroke and this can have a big impact on a person's recovery from stroke and their quality of life. Post-stroke anxiety (PSA) often goes undetected due to a lack of appropriate screening tools, particularly when people have significant communication problems. The Anxiety Scale Circles (ASC) is a new measure which may be appropriate for screening for PSA in people with significant communication problems. The ASC is already being used by some stroke services but has not yet been shown to an effective measure. This study aims to evaluate whether the ASC has sufficient validity and reliability as a screening measure and to identify the best clinical cut-off score. Stroke patients and their carers will be recruited for this study and will be asked to complete brief mood and cognitive screening questionnaires.

Ethical Review

This research has been reviewed and approved by the Oxford B NHS Research Ethics Committee (Project ID 15/SC/0708).

Possible risks to participating in the study

There are no medical risks to participating in this study. As the questionnaires will ask your patient about their mood following the stroke this may potentially be upsetting. The assessment will be conducted by either a Trainee Clinical Psychologist or an Assistant Psychologist, both of whom have clinical experience working with stroke patients. Usually a carer will be present during the assessment and there will be time to discuss any issues raised at the end.

I have enclosed a copy of the Participant Information Sheet for your reference, however if you have any queries or require further information please contact David Stokes (Chief Investigator) on 01865 226431.

Yours sincerely,

David Stokes
Chief Investigator
Trainee Clinical Psychologist
The Oxford Institute of Clinical Psychology Training

Dr David Dean
Research Supervisor
Consultant Clinical Neuropsychologist
Buckinghamshire Neurorehabilitation Unit

Version 4, 15th December 2015

Appendix N: Training course, ethical and trust approval

1. Training course approval letter
2. Research Ethics Committee approval letter
3. Buckinghamshire Healthcare NHS Trust approval letter

Oxford Health NHS
NHS Foundation Trust

The Oxford Institute of Clinical Psychology Training

UNIVERSITY OF OXFORD

Oxford Doctoral Course in Clinical Psychology
An NHS Course validated by the University of Oxford

Isis Education Centre, Warneford Hospital, Oxford OX3 7JX
Tel: +44(0)1865 226431
Website: www.oxicpt.co.uk

9th July, 2015

David Stokes
Trainee Clinical Psychologist
Oxford Doctoral Course in Clinical Psychology
Isis Education Centre
Warneford Hospital

Dear David,

Thank you for a very thorough reply to the issues raised by the Research Sub-Committee. I am pleased to say that you now have full approval for your research dissertation.

We wish you all the very best with your study.

Yours sincerely,

Myra

Dr Myra Cooper
Chair, Research Sub-Committee

c.c. David Dean
Ian Barkataki

NHS
Health Research Authority

South Central - Oxford B Research Ethics Committee
Whitefriars
Level 3, Block B
Lewin's Mead
Bristol
BS1 2NT

Telephone: 0117 342 1387

30 December 2015

Mr David Stokes
Trainee Clinical Psychologist
Oxford Health NHS Foundation Trust
Oxford Institute of Clinical Psychology Training
The Isis Education Centre. Roosevelt Drive
Warneford Hospital, Oxford
OX3 7JX

Dear Mr Stokes

Study title:	**The Anxiety Scale Circles (ASC): a first evaluation of a simple assessment tool for anxiety in the context of stroke.**
REC reference:	**15/SC/0708**
IRAS project ID:	**179073**

Thank you for your letter of 22 December 2015, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to make a request to postpone publication, please contact the REC Manager, Mr Stephan Ramey, nrescommittee.southcentral-oxfordb@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.

Conditions of the favourable opinion

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

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

Management permission should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Guidance on applying for NHS permission for research is available in the Integrated Research Application System, www.hra.nhs.uk 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 management permissions 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).

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

Approved documents

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

Document	*Version*	*Date*
Covering letter on headed paper [covering letter]	1	03 November 2015
GP/consultant information sheets or letters [Letter informing GP for BNRU participants]	4	15 December 2015
GP/consultant information sheets or letters [Letter informing GP for ESD participants]	4	15 December 2015
IRAS Checklist XML [Checklist_17122015]		17 December 2015
Non-validated questionnaire [Anxiety Scale Circles]	1	03 November 2015
Other [Background Information form (demographics)]	1	15 December 2015
Other [Responses to REC provisional opinion]	1	17 December 2015
Participant consent form [Consent form - BNRU stroke survivor participants]	4	30 October 2015
Participant consent form [Consent form - BNRU carer participants]	4	30 October 2015
Participant consent form [Consent form - BNRU stroke survivor participants]	5	15 December 2015
Participant consent form [Consent form - BNRU carer participants]	5	15 December 2015
Participant consent form [Consent form - ESD stroke survivor participants]	5	15 December 2015
Participant consent form [Consent form - ESD carer participants]	5	15 December 2015
Participant information sheet (PIS) [PIS - BNRU carer participants]	5	15 December 2015
Participant information sheet (PIS) [PIS - ESD carer participants]	5	15 December 2015
Participant information sheet (PIS) [PIS BNRU stroke survivor participants]	5	15 December 2015
Participant information sheet (PIS) [PIS - ESD stroke survivor participants]	5	15 December 2015
REC Application Form [REC_Form_03112015]		03 November 2015
Referee's report or other scientific critique report [Referee's report - full approval for project]	1	09 July 2015
Research protocol or project proposal [Research protocol]	3	15 December 2015
Summary CV for Chief Investigator (CI) [Summary CV for CI]	1	15 September 2015
Summary CV for supervisor (student research) [Summary CV for supervisor]	1	15 September 2015
Summary, synopsis or diagram (flowchart) of protocol in non	2	30 October 2015

technical language [Recruitment flowchart - BNRU participants]		
Summary, synopsis or diagram (flowchart) of protocol in non technical language [Recruitment flowchart - ESD participants]	2	30 October 2015
Validated questionnaire [Hospital Anxiety and Depression Scale]	1	03 November 2015
Validated questionnaire [Behavioural Outcomes of Anxiety scale - carer version]	1	03 November 2015
Validated questionnaire [Depression Intensity Scale Circles]	1	03 November 2015
Validated questionnaire [Montreal Cognitive Assessment Version 7.3]	1	15 September 2015

Statement of compliance

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

After ethical review

Reporting requirements

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

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

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

User Feedback

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

HRA Training

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

15/SC/0708	**Please quote this number on all correspondence**

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

Yours sincerely



PP Mr Chris Foy
Chair

Email:nrescommittee.southcentral-oxfordb@nhs.net

Enclosures: "After ethical review – guidance for researchers"
Copy to: *Ms Victoria Rush, Oxford Health NHS Foundation Trust*

Safe & compassionate care, every time

Buckinghamshire Healthcare NHS
NHS Trust

Research & Innovation Office
Direct dial: 01296 316200
Email: Sharon.lambert@buckshealthcare.nhs.uk

Stoke Mandeville Hospital
Mandeville Road
Aylesbury
Buckinghamshire
HP21 8AL
Tel: 01296 315000
www.buckshealthcare.nhs.uk

14th January 2016

Mr David Stokes
Trainee Clinical Psychologist
Oxford Institute of Clinical Psychology Training
Isis Education Centre
Warneford Hospital
Headington
Oxford OX3 7JX

Dear David

RE: RXQ/673 Assessing anxiety following stroke

We are pleased to tell you that all governance checks have been completed and are happy to issue trust approval.

Your target of patients to recruit to the study is 68.

Could you please confirm the start and end dates of the study.

The lists of documents below are the documents that approval is issued on.
We have enclosed a version control form that you should update should you need to submit an amendment for this study, (i.e. if any changes are made to the protocol during the study you should work to the new protocol version when we issue approval to continue and enter the new version on the version control form).
All details of any amendment required should be forwarded to us so we can process for you.

Documents reviewed and agreed:

Protocol	Current version: V3 dated 15/12/2015
Patient information sheet	Current version: V5 dated 15/12/2015 (x4) (BNRU stroke survivor, BNRU carer participants ESD stroke survivor, ESD carer participants)
Patients consent form	Current version: V5 dated 15/12/2015 (x4) (BNRU stroke survivor, BNRU carer participants ESD stroke survivor, ESD carer participants)
Contract	Current version: N/A
Costing	Current version: N/A

We have also enclosed a copy of an auditing form used by the trust when auditing a study, this gives good guidance on the expectations of your study file and recording patient data, if you have any queries relating to this then please contact Jacqui Carr (07825 281910).

If any changes are made to the research team then please let us know so we can amend our records. You will be contacted on a monthly basis to provide recruitment numbers.

We wish you well with your study, if you have any queries then please do not hesitate in contacting me.

Yours faithfully

Sharon Lambert
Research Facilitator

Appendix O: Reflections

Challenges

The successful completion of this study involved overcoming a number of challenges arising from the approval process and recruitment. Considerable delays were encountered in obtaining approval from both the sponsoring and host NHS trusts for this project which delayed the start date of the project and reduced the period of time for data collection. This was not due to any ethical or procedural concerns raised by the two research departments. Instead the delays arose from a back-log of other research projects under review, and numerous administrative procedures involved in conducting research as a visiting student researcher in an external NHS trust.

In addition, the pace of recruitment was slower than expected and necessitated the expansion of the study to two additional stroke services partway through the project. In my final year of clinical training, there were heavy restrictions on time that could be devoted to data collection and it was a considerable challenge to recruit from four different stroke services. It was very apparent that referrals to the study noticeably increased following opportunities to attend a service in person. I reflected that having personal relationships with teams was hugely helpful for recruitment and that it helped to keep the study high on the agenda by attending in person as often as possible.

However, whilst certainly frustrating at times, I was able to keep in mind that many of my experiences arose from this being a doctoral project (namely the time-pressure and the need to involve more than one NHS trust research department), and will not dissuade me from conducting future research.

Dual Role

Ethical issues were discussed at length in appendix L but one other issue is worth highlighting here. I recruited from two services where I was also based for my specialist clinical placement. This meant having a dual role of clinician and researcher within these two services and at times it was difficult to keep these two roles distinct. I was careful not to recruit patients that I was working with as a clinician to avoid patients feeling coerced into participating and to reduce the chance of interviewer bias. Keeping the roles distinct was fairly straightforward in the community service where participants were assessed at home. This meant that participants were meeting me for the first time at assessment in my capacity as a researcher, and were less likely to feel obligated to participate. It was more of a challenge in the inpatient unit where participants may have observed me working as a clinician in the unit and possibly felt that declining to participate would impact, albeit subtly, on their care. Being mindful of this, the following measures were taken: (a) potential participants were identified as quickly as possible following their admission to the inpatient unit; (b) the research team did not make the initial approach to invite potential participants to take part in the study; and (c) participants were regularly reminded throughout the process that participation was entirely voluntary. However, having a dual role also conferred benefits, namely that I had a thorough understanding of how the two services worked, I had already developed relationships with key personnel whose ongoing support with recruitment was vital, and access to resources (e.g. clinic rooms) was more straightforward.

Appendix P: References for Paper B appendices

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