Doctorate in Clinical Psychology | Lancaster University

An Exploration of Emotional Distress and Sleep in a Stroke Rehabilitation Setting

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Abstract

This aim of this thesis was to explore experiences of emotional distress and sleep-wake patterns in an acute stroke rehabilitation setting. Both the systematic review and research paper are being prepared for submission to the international Journal of Stroke; the guidelines of which are included in the appendices (Appendix D, paper 1).

Paper one is a systematic review of the literature investigating the potential benefit of third-wave psychological therapies to support individuals experiencing emotional distress resulting from previous stroke. Ten papers were reviewed and included in a narrative synthesis. The quality of the methodology of the studies is evaluated and discussed. Third-wave interventions offer some promising initial results; however, research in this area is in its infancy, and requires further investigation.

The research paper (paper two) explored the relationship between sleep, mood and pain and the possible predictive value these variables have on participation in rehabilitation. Experience sampling methods and actigraphy were utilised in this study. Twenty participants were recruited and took part in the study for an average of seven days. A multi-level model analysis was used to explore the data. Results indicate that sleep efficiency, low mood and pain all offer some predictive value for participation in rehabilitation in this sample.

Paper three is a critical appraisal of the systematic review and research paper. Pertinent issues, relevant to both papers are discussed. Recommendations for future research as well as considerations for clinical implications are discussed within the context of the research findings.

Declaration

No portion of the work referred to in the thesis has been submitted in support of an application for another degree or qualification of this or any other university or other institute of learning.

Name: Leona Rose Signature: Date:

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Contents

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Systematic Literature Review

A Systematic Review Examining the Effects of Third-Wave Psychological Therapies on Emotional Distress Following Stroke.

Target Journal: Stroke.

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Four tables and one figure are included in this paper.

Abstract

Background and Purpose - A clear link between stroke and experiences of emotional distress has been established in extant literature. Recent studies have demonstrated an association between emotional distress and functional recovery of the stroke survivor. Supporting patients to manage distress by equipping them with skills and coping strategies may represent an important intervention for increasing the quality of life experienced by stroke-survivors. Third-wave interventions comprise those that encourage an individual to have compassion for and acceptance of their present moment, or difficulty, rather than attempting to change it. These interventions have become increasingly common in physical health settings, and evidence suggests they can be of significant benefit to patients. However, there has been no systematic examination of the effects of third-wave interventions on emotional distress within a stroke population. This review aims to evaluate the effects and possible benefits of these interventions in a post-stroke context.

Methods - Seven databases were searched using key words. Papers were screened using review specific criteria. Critical appraisal was conducted independently by two reviewers. Data extraction was conducted by the lead author, findings are presented in narrative form.

Results- Ten studies involving 284 participants were reviewed. Five papers reported third-wave interventions on a one-to-one basis and four were group format. The results demonstrate a positive trend in favour of the benefits of third-wave interventions supporting to reduce the level of emotional distress experienced by the individuals after stroke.

Conclusions- Following stroke, individuals experiences of emotional distress may be reduced by engagement with third-wave therapies. However, further methodologically robust research is required to determine the effectiveness of these third-wave interventions.

Key words: ▪third-wave interventions, ▪emotional distress, ▪mood, ▪stroke, ▪rehabilitation.

Emotional distress following stroke is common. Estimates suggest around a quarter of stroke survivors experience anxiety [1] and one third of survivors' experience depression, in the three years following their stroke [2]. Emotional distress can impede rehabilitation activities as well as functional recovery [3]. Yet, currently, evidence remains limited for effective management of emotional distress in the stroke population, with both psychotherapeutic and pharmacological interventions demonstrating limited success [4]. Emerging psychology research has suggested that third-wave psychological interventions can be beneficial and useful to patients experiencing both physical and psychological distress [5]. However, there has been no systematic examination of the effects of third-wave psychological interventions on emotional distress, in the stroke population.

Stroke

Stroke occurs suddenly, often without warning, and can result in significant distress and disability [6]. Medical developments and improved public awareness in the recognition and treatment of stroke have resulted in an increase in survival rates [7], with approximately two-thirds of the estimated 152,000 people who experience stroke each year in the United Kingdom (UK) surviving [8]. Alongside medical advances, much attention has been paid to improving public longer-term support of individuals who experience stroke, and their families [9-11]. Although these initiatives have offered people who experience stroke improved survival rates and care, stroke remains one of the main causes of adult disability in the UK [12]. Physical and communication impairments are among the most recognisable deficits following stroke [13]. However, there are a significant number of stroke survivors who experience a range of less visible impairments such as post stroke fatigue [14], pain [15], cognitive difficulties [16], behavioural problems [17] and issues with mood and emotional distress [18]. As a result, people may experience difficulties caring for themselves or living

independently [19], as well as problems with social activities and relationships [20]. These difficulties can have a significant impact on the lives of stroke survivors and their families.

Epidemiological data suggests there are more than 1.1 million stroke survivors living in the UK alone [21], with more than half of these survivors being dependent on others for support with everyday activities [9]. The incidence rate of stroke is much higher in older adults, with stroke in the over 65-year-old population accounting for three quarters of the total stroke incidence [8]. Given the ageing nature of the population [22], the incidence of stroke is likely to increase, as is the number of people requiring post-stroke support.

Emotional distress following stroke

Depression and anxiety. Stroke can have a considerable impact on psychological wellbeing [23] with 10.6-31.1% of people experiencing post-stroke depression (PSD) and / or post stroke anxiety (PSA) [24]. PSD can be defined as the prolonged (over two weeks) experience of sadness or worry, associated with a lack of energy and changes in sleep. PSA is understood as feelings of anxiety or worry that do not rescind when the stressful situation is over or feeling anxious for no reason [1, 25]. Both PSD and PSA map onto the diagnostic criteria of depression and anxiety respectively as defined by Diagnostic and Statistical Manual DSM-V; [26] and International Classification of Disease ICD-10; [27]. Research posits that both immediately following stroke, as well as in the longer term [28] PSD is linked with: lower functional status [29], poorer rehabilitation outcomes [30], increased rates of mortality [31], and as a reduced quality of life [32]. In addition, longitudinal data suggests that both depression [33] and anxiety[1] can remain a difficulty for survivors of stroke many years after stroke incidence [1].

Emotional/ psychological distress. The experience of stoke can be incredibly distressing for the individual and can contribute to a range of negative emotions that are not

captured by the diagnostic classification of anxiety or depression [34]. Instead, these tend to be captured under the umbrella terms "psychological distress" and/or "emotional distress" [18]. These umbrella terms are often used interchangeably in literature, however, for the purposes of this paper the term emotional distress will be used. The empirical evidence base suggests that these terms are used to describe a range of experiences. These include, but are not limited to: anger, frustration, stress, fear of further stroke, helplessness, apathy, feeling socially isolated, and grief [34-36]. These types of difficulties tend to be overlooked by research in favour of more commonly used diagnostic disorders of mood. One possible explanation for this is that there are fewer validated measures with which to assess general psychological distress. However, many survivors of stroke do not meet diagnostic threshold or classification, but still experience significant psychological impairment which in turn contributes to poor post-stroke adjustment [37] and quality of life [32].

Psychological Interventions

Psychological interventions in health settings are designed to support people who are experiencing distress related to their physical health condition [38]. One way in which they might do this is to support people with their adjustment to living with the effects of their life long and, at times, life limiting conditions.

Cognitive behavioural therapy (CBT) is the most common evidence based psychological treatment option for mood difficulties post-stroke [39, 40]. CBT is a talking therapy that supports individuals to identify unhelpful thoughts and behaviours that may be linked with their experiences of distress, with the primary aim of overall symptom reduction. Despite the popularity of CBT based interventions, therapeutic outcomes for survivors of stroke are varied with studies reporting small effect sizes [41-43]. One suggestion as to why there has been limited success with CBT style interventions is that they require

individuals to monitor and control their thoughts and feelings as a way of reducing symptoms of anxiety and depression. For a stroke survivor with cognitive and/or communication difficulties these internal strategies may be challenging, due to problems with attention, memory, language or executive functioning [44]. In addition, each time they are asked to complete an activity that relies on their cognitive skills, it may act as a reminder of the consequences of their stroke [45]. Struggling with tasks that previously would not have presented as difficult may in itself be distressing for the individual. Furthermore, the thought challenging aspects of CBT can be particularly problematic in the context of actual physical losses. The utility of thought challenging is based on the assumption that the unhelpful thought is a cognitive distortion, which can be resolved and replaced with a more logical thought. However, if the troublesome thoughts are based on facts such as experiences of functional losses following accident or injury, this traditional CBT approach may not be as effective. Consequently, CBT style interventions may not be an effective intervention for everyone [44] and may have limited longer-term success [46].

Third-wave therapies are described as those that encompass aspects of compassion for, and acceptance of, negative internal sensations and thoughts, rather than engaging in a process of trying to change them [47]. Although, there remains differing perspectives on which psychological approaches should be categorised as third-wave interventions [48], it is generally accepted by experts in the field [49] that a number of therapeutic interventions could be classed as third-wave: Acceptance and Commitment Therapy ACT; [50], Compassionate Mind Therapy CMT; [51], Compassion Focused Therapy CFT; [52], Mindfulness Based Cognitive Therapy MBCT; [53], Mindfulness Based Stress Reduction MBSR; [54], Dialectical Behaviour Therapy DBT; [55], and Extended Behavioural Activation [56]. Extended behavioural activation is increasingly regarded as a third-wave approach as it has an explicit focus on shifting attention away from depressive ruminative thoughts [49]. Third-wave approaches

adopt a position in which the aim is to improve quality of life of the individual rather than focusing on a reduction in symptoms of distress. In this sense, these interventions are often trans-diagnostic [57] in nature and more readily adapted to suit different cognitive and communication needs[58]. For a comprehensive discussion of specifics of these third-wave interventions please see Dimidjian and colleague (2016) [59].

Previous reviews have sought to examine the effects of interventions on depression and anxiety post-stroke. In their review, Cole and colleagues (2001) [60] included pharmacological interventions only, whilst recent Cochrane reviews [41, 61] focused on the effects of both pharmacological and non third-wave psychotherapeutic interventions. Although there has been a review of mindfulness interventions in this area, the authors solely included mindfulness interventions and did not evaluate other third-wave approaches [62]. Therefore, to date, there has been no systematic review examining the effects of third-wave intervention on the range of the emotional difficulties experienced by survivors of stroke.

The Present Systematic Review

The primary aim of this review was to (a) assess the effectiveness of available RCT studies based on the Cochrane criteria, and (b) to consolidate the available knowledge and offer recommendations for future clinical practice and future research. In their qualitative study regarding patients' experiences of psychological distress following stroke, Crowe et al, (2016) [34], found that participants spoke of issues of self-compassion and acceptance, which suggests that third-wave psychological therapies could be well placed to address the difficulties experienced by survivors of stroke.

Effectiveness/efficacy will be assessed in those studies which meet the current UK and Cochrane recommendations [63, 64] for conducting intervention reviews, which includes

both randomised controlled trials (RCTs) and non-randomised controlled studies (non-RCT's). Effectiveness will be defined as a statistically significant improvement in emotional distress, compared with a control group as demonstrated under controlled conditions in an RCT. Efficacy will be defined by the same change identified in studies which have lower internal validity but have higher ecological validity, such as case control studies based in hospitals and clinics [63].

Available knowledge will be consolidated and recommendations for future clinical practice and research will be made. This review will have implications for public health and care policies as well as individual stroke survivors and their family/ carers [65].

Method

This systematic review followed guidance from the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement for conducting and reporting systematic reviews [66, 67].

Identification of Studies

All eligible studies were identified by searching seven electronic databases including MEDLINE, EMBASE, psycINFO, CINHAL, Scopus, Academic Search Complete and PsycArticles. All databases were searched on 22nd January 2018. Databases were searched using terms associated with stroke, emotional distress and third-wave psychological interventions, which can be found in Table 1.

In addition, bibliographies of previous reviews and retrieved search articles were hand-searched to identify further relevant articles not included in the search material.

Insert Table 1

Inclusion and Exclusion Criteria

The aim of the search strategy was to locate all published articles in relation to experiences of emotional distress following stroke and any subsequent interventions using third-wave therapies. All studies require publication in a peer reviewed journal to be included in the analysis, allowing for a pre-determined quality control standard. The relevance of each study was assessed using the inclusion criteria which is stated in Table 2.

Studies were excluded from the review if they were: (a) unpublished articles; theses or dissertations; abstracts; posters; (b) qualitative studies; (c) non-third-wave interventions such as traditional CBT. The author screened all titles and abstracts highlighted from the searches for their suitability in the review. Following this, full-text articles considered relevant to the review were retrieved.

Insert Table 2

Risk of Bias

In accordance with PRISMA guidance, this review evaluated the quality and strength of each included study in order to determine how much confidence could be placed on the overall findings**.** The overall strength of the evidence presented in each study, assessed as strong, moderate or weak, was determined using the Quality Assessment Tool for Quantitative Studies [68] developed by the Effective Public Health Practice Project (EPHPP - See Appendix A). This tool was selected based on its reliability in examining the effectiveness of interventions [69]. In addition, the tool allowed examination of a range of study designs which were reflected in the included papers of this review. The tool adopted a component method of evaluation, considering six domains: selection bias; study design; confounders; blinding; data collection method and; withdrawals and dropouts. Each domain was assigned a strong,

moderate or weak rating and these collected ratings were used to establish the global rating for each study. The tool also allowed space to consider intervention integrity and analyses choice when rating each study.

Data Extraction

Data, including details of the type of third-wave intervention and target population, were extracted from the included studies using a data extraction tool which was designed by the author (see Appendix B). The form was pilot tested for suitability using three randomly selected studies and was amended accordingly. This information is presented in the summary table which includes study, participant, intervention characteristics and outcome measures, as well as outcome and findings (see Table 4).

Data Synthesis

When considering the included studies for data synthesis, a high degree of heterogeneity was observed, with differences noted in study design, length of intervention and outcome measurement. This indicated that pooling the data for a meta-analysis would not be suitable. As such, a narrative synthesis was conducted in line with Cochrane principles [70].

Quality Assessment

Quality assessment was completed using the pre-selected quality assessment tool for quantitative studies (see Table 3). The author's reasons for each quality judgement can be found in Appendix C.

Insert Figure 1

Results

See Figure 1 for a flow diagram of the search results. Following the removal of duplicates a total of 594 articles were identified. Of the 594 articles identified, 561 were excluded based on their titles and abstracts. The remaining 33 articles were read in full and assessed for eligibility. Twenty-three articles were excluded based on the reasons outlined in Figure 1. A total of ten articles were included in this review. Data for stroke participants from two papers were gathered by contacting authors for copies of the study data.

Insert Table 3

Quality Assessment

Study quality is outlined in Table 3. Two of the studies received a rating of 'strong' [71, 72]; a further two were awarded a rating of 'moderate' [73, 74]; the final six studies received a rating of 'weak' [75-80].

Insert Table 4

Study characteristics

Three of the studies were conducted in the UK [71, 76, 77], two studies were conducted in Sweden [73, 74], and one study took place in each of the following: Korea [78], United States of America (USA) [72], Canada [75], New Zealand [79] and Australia [80]. There was an equal mix of group and one-to-one interventions. Studies included were published between 2005 and 2017 and used a range of study designs. Two of the studies were randomised controlled trials [71, 72], a further two studies utilised a controlled clinical trial design, [73, 74], and all of these studies used demographically matched treatment as usual control groups. Three

studies were cohort design [77, 78, 81]. The final three of the included studies were case studies [76, 79, 80].

Participant's characteristics

Participants were adults with an age range of 25-88 years. There was a total of 284 participants across all ten included studies. The ratio of male and female participants was reported in nine of the studies with Johansson et al, (2015) [73] not reporting this information, which related to 16 participants. Across the remaining nine studies, males accounted for 57% of the total participants while female participants made up 43% of the total. Type of stroke was recorded in five of the ten studies [72, 77-79] with ischaemic stroke being the most prevalent. Lateralisation of the deficit was noted in four of the studies [71, 77, 79] with left sided deficit being reported most often. The number of participants taking antidepressant medication was reported in two of the studies [71, 79], and features as an exclusion criterion in one study [78]. All studies reported that participants experienced clinical levels of emotional distress as measured by tools such as the Hospital Anxiety and Depression Scale HADS; [82] and the Beck Depression Inventory BDI; [83].

Intervention characteristics

There were a range of third-wave psychological interventions included in this review. The majority of studies were based on mindfulness principles (n= 6). MBSR accounted for five of these studies [73, 77-79, 84]. The remaining study [81] was an MBCT intervention and specific adaptations were made to physical yoga elements of the intervention to be accessible to the participant population. This study also included a psychoeducation element that was specific to the stroke population. Two [71, 72] of the included studies followed an extended behavioural intervention. One study [72] permitted family members to be present during the intervention session. The final two studies [76, 80]

used an ACT [50] and a CFT [52] based intervention respectively. The number of sessions (range 4-20) and total intervention hours (range 8- 20) varied across all studies.

Outcome characteristics

The aim of this review was to consider the impact of third-wave psychological interventions on emotional distress as a general concept, which would include a range of presentations as mentioned above. However, studies included in this review all used outcome measures that exclusively focused on concepts of depression and anxiety. For the purpose of this section we will refer to anxiety and depression as 'mood'.

Eight studies employed reliable and validated measures of mood, which were normed within a stroke population and measured anxiety and depression either separately or jointly. A range of mood measures were used across the included studies: two studies [73, 74] used the Comprehensive Psychopathological Rating Scale-CPRS [85]; two [78, 81] utilised the Beck Anxiety Inventory as well as the Beck Depression Inventory-BAI; BDI [83]; and two [77, 81] collected information on mood using the Hospital Anxiety and Depression Scale- HADS [82]. A further two studies [76, 80] employed the short form Depression and Anxiety Stress Scale-DASS-21 [86], The Hamilton Rating Scale for Depression-HRSD [87], the Visual Analogue Mood Scale-VAMS [88] 'sad' item, and the Stroke Aphasic Depression Questionnaire SADQ [89] were each used once across the included studies. One further study [79] utilised the BAI [90], which had not been normed for this population. Finally, Joo et al. (2010) [78] choose to measure participants distress using the State Trait Anxiety Inventory-STAI [91], which does not have a demonstrable validity for stroke populations [92]. In addition to the STAI, Joo and colleagues (2010) [78] used the Korean version of the BDI [93]. All but one of the studies reported the measured score means and standard deviations for pre and post intervention assessment. Merriman et al. (2015) [77] reported that there was a demonstrable improvement

in mood as measured by the HADS for three of the four participants, but did not report mean or standard deviation data, nor did they run any statistical analysis. Outcomes other than those considering emotional distress were not the focus of this review and as such were not included in the matrix.

Effectiveness of third-wave psychological interventions

Four controlled studies, two RCTs [71, 72], and two non-RCT [73, 84] were included in this review. Given that information on stroke participants was extracted from the wider studies in the two non-RCT studies, the sample size was small and it was not possible to consider the results of the stroke on participants at a statistical level. Consequently, only two RCT studies were assessed in terms of the effectiveness of third-wave interventions. The RCT samples were classified as experiencing clinical levels of depression as measured by the diagnostically validated scales noted above. Both RCTs reported significant improvement in emotional distress on the intervention arm compared with the control group; however, both studies demonstrated small effect sizes. Both RCTs examined the impact of extended behavioural intervention on depression as measured by validated self-report tools. Both studies reported significant results indicating that behavioural therapy was successful at reducing the rates of depression in the study sample which were maintained at 6 months [71] and 24 months [72] follow up. Both of the interventions were conducted on a one-to-one basis and participants were welcome to bring a family member or carer along to the sessions, although this option was not regularly taken up by participants. In both studies the average number of sessions was nine, although one study offered a maximum of 20 sessions [71]. In both cases, the number of sessions was determined by the therapist who for all participants deemed that 20 sessions were not needed.

Summary of cohort and case studies

While data from cohort and case studies were not included in the appraising of the effectiveness of third-wave interventions, these were examined for findings that were relevant to both future research and clinical practice. All non RCT studies provided evidence that third-wave interventions had a positive and in one case [81], lasting effect on the experience of low mood. Two of the cohort studies that investigated mindfulness-based interventions [78, 81] were able to demonstrate significant results in the comparison of pre and post assessments of mood difficulties, as was a case-study looking at the impact of CFT [80]. This indicates that engaging in the third-wave intervention approaches can have a positive impact in reducing experiences of emotional distress. Two of the case studies indicated a positive impact of third-wave interventions, including a case series with four participants completing a mindfulness intervention [77], and a case-study with one participant engaging in ACT [76]. However, as these studies included no statistical analysis, it was difficult to draw accurate conclusions of the effects of the intervention. One case-study [79], of an individual with mood difficulties following stroke reported a significant reduction in anxiety following a mindfulness intervention, both at completion of intervention and at three months follow up.

Discussion

This literature review demonstrated that experiences of emotional distress following stroke is an active research area. Third-wave interventions showed some promising positive results. The aims of this systematic review were to (a) assess the effectiveness of available RCT studies based on the Cochrane criteria, (b) to consolidate the available knowledge and offer recommendations for future clinical practice and future research.

Effectiveness of Third-Wave Psychological Therapies

The primary aim of third-wave interventions is to support individuals with their adjustment to life as it is now, through methods of acceptance and compassion [94]. A reduction in the experience of mood difficulties is often a by-product of the intervention rather than the primary focus. However, there remains a lack of validated and well-established measures that assess this construct of moving towards acceptance of a new life [95]. Consequently, the studies included in this review have used measures of mood, which are symptom reduction based, as their primary outcome measures. As such these are the measures which this review is required to consider in terms of intervention success.

Both RCTs included in this review used behavioural interventions and reported an overall improvement in depression, which was sustained at 6 months [71] and 24 months [72] follow up. Additionally, both studies reported that participants experienced positive changes in leisure and recreation engagement. A further strength of these studies is that they used validated measures of depression that were appropriate for the stroke population. Both studies included participants with varied severity of low mood, with the mean mood score for both studies being in the mild to moderate range. This is an encouraging finding, as it appears that the interventions were both useful and acceptable to participants across a range of experiences. However, further research may want to consider the impact of these interventions with people with more severe experiences of low mood and anxiety, as it is often these individuals who are in most in need of support.

A further strength is that one of these studies [71] included participants who experienced a range of communication difficulties. Empirical findings postulate that the incidence of emotional distress following stroke is more prevalent in people with aphasia, being around 60% compared with 30% non-aphasic stroke survivors [96]. Additionally,

research has suggested that there is a positive correlation between severity of aphasia and experiences of depression [97]. Despite this, people with aphasia are often excluded from stroke research due to the methodological and practical difficulties associated with their recruitment into studies [98]. The inclusion of this group suggests that third-wave behavioural interventions are practical and beneficial for people experiencing communication difficulties.

When considering these results within the context of the National Institute of Clinical Excellence (NICE) recommended CBT treatment for post-stroke mood difficulties, they represent similar findings. Specifically, significant improvements can be demonstrated but that effect sizes remain small [41]. The limited number of controlled trials reflects the emerging status of third-wave therapies in this area as well as current difficulties conducting RCTs with a post-stroke population.

Effects of Third-Wave Psychological Therapies

All eight non RCT studies indicated a positive impact of third-wave therapies on emotional/psychological distress in the post stroke population. Six of the studies used a validated measure of mood within the stroke population to establish an intervention effect. Although two [73, 74] studies reported significant positive results for the intervention, these were conducted within the context of the wider brain injury participant population. Therefore, inferences based on the included stroke participants alone cannot be made. When interpreting the results of the non-RCTs included, there are a number of methodological issues that need to be taken into consideration. Firstly, three of the studies were case studies [76, 79], and as such, these results need to be interpreted with caution. Although all of these studies indicated positive results for the three participants involved, it is possible that these results may not be replicated on a larger scale. While the findings of these studies are promising, it is important to note that the lack of a control group in six of these studies

means that it cannot be determined whether the change demonstrated is as a direct result of the intervention. Furthermore, in all of the case studies the participant had a pre-existing clinical relationship with the therapist, meaning that there was increased opportunity to develop a therapeutic rapport, which has been shown to be associated with the success of an intervention irrespective of the therapeutic modality [99, 100].

Generalisability of Findings

All of the non-clinical studies included in this review received a rating of 'weak' in terms of controlling for selection bias. It could be argued, however, that the heterogeneous nature of the participants included in the studies reflects a reasonable level of external validity. They included a wide range of participants, including both community and hospital samples that would be representative of the range of individuals who may present to services looking for support with emotional distress following stroke. The high degree of diversity among the participants provides a strong basis for generalising the conclusions drawn on the effects of third-wave therapies. The variety of the locations where the studies were conducted provides further strength to the generalisability of the findings. Furthermore, the collective participant ratio for gender appears to reflect extant literature which has found that males are more likely to experience a stroke [101]. Although the studies in this review represent a good range of countries, the impact of cultural or ethnic influences are not considered in any of the studies. It may be that the effects of these third-wave interventions are impacted by cultural factors as are other psychological therapies [102], and further research in this area is required.

Furthermore, there are two studies included in this review [71, 79] that specifically looked at the impact of third-wave therapies on emotional distress in people with aphasia. Both studies demonstrated a positive impact of their respective interventions, ACT [79] and

extended behavioural therapy [71]. This is a positive finding considering that individuals who experience communication difficulties often experience increased emotional distress [103]. However, it is important to note that neither study considered those individuals who experience severe aphasia, and further research is required to establish if third-wave interventions are feasible and acceptable for this group. Furthermore, only one of the studies included in this review specifically recruited a participant who experiences cognitive difficulties following stroke. Research indicates that individuals who experience cognitive difficulties following stroke not only experience greater rates of emotional distress [104], but they are often excluded from research due to methodological and ecological limitations relating to challenges in communication and possible issues with capacity to consent [105].

Interpreting Findings Alongside Previous Research

Taken together the included studies provide an early indication that third-wave therapies can have a positive impact on the experience of emotional difficulties within the post-stroke population. Findings from previous literature indicate that one of the driving factors for the experience of emotional difficulties post-stroke is the difficulty in adjusting to life following the event, where the individual may be experiencing both physical and cognitive deficits [106, 107]. It has been suggested that individuals who experience less emotional distress have a higher level of acceptance of their 'new' life post-stroke [108]. This positive association of acceptance and lower levels of distress post-stroke is one possible reason for the success of the third-wave interventions. It may be that learning to accept emotional experiences within the present moment may allow individuals to more readily adjust to their level of functioning post-stroke. As such, it is possible that the included studies theoretically map onto the concept of successfully adjusting to the new life and living well post-stroke.

The inclusion of some participants who experience communication deficits indicates that third-wave approaches may be more acceptable and accessible to a wider range of individuals who experience stroke, than cognitive based approaches which rely on higher level of cognitive functioning [109].

Strengths and Limitations of Included Studies

One strength of the studies included in this review is that the range of attrition was 0-16%, This is favourable compared with other psychological interventions with this client group, where rates are typically in the region of between 2-22% [110]. One possible reason for this lower attrition could be the inclusion of several case studies and case series designs. Moreover, many interventions in this review contained elements of active outreach where the intervention took place in the participants home, which routinely demonstrates lower attrition rates. Furthermore, one study [72], did not have a predetermined number of sessions for completion. Instead the study had a maximum number of sessions available for participants (up to 20), meaning that there was no clear way to measure the completion rates of the intervention, and as such we are unable to establish what the optimum number of sessions would be, in terms of both adherence to treatment as well as impact of intervention.

A number of studies included participants who self-selected to take part. This may have led to a sample of participants who were especially motivated to participate, or who held positive beliefs about the nature of third-wave interventions. There was also a lack of reporting on participant selection in the case series and case study research included in this review. It is therefore possible that researchers may have selected participants that they believed would engage well with third-wave interventions, or that they may have only reported case studies that reflected a positive result for the intervention.

The risk of bias due to confounding effects was also widespread, which is unsurprising as case series and cohort designs are particularly susceptible to such errors. Confounding variables for this population can include a history of pre-morbid emotional difficulties, aphasia, and cognitive deficits, as well co-morbid physical health difficulties [111]. These variables were not routinely reported, or controlled for, in the included studies. Further to this, none of the included studies differentiated their participants based on location of lesion, which has been shown to have an impact of post stroke mood difficulties and could have a possible impact on an individual's ability to learn and retain new information [112]. In addition, many included studies did not consider of the possible impact of either specific antidepressant medication, or other medication which may either contribute to or alleviate experiences of emotional distress. This makes the mechanism of change more difficult to determine.

Publication bias had limited impact on the included studies as they are predominately case series, case study and cohort design, which engender less possibility of publication bias that RCT research. However, all of the studies reported a positive impact of their respective intervention methods. As publication of non-significant or negatively correlated results are limited [113], it is not possible to attest that publication bias did not play a role in the studies included in this review.

It is also important to note that not all of the studies included in this review used outcome measures that have been validated for a stroke population. As such, it cannot be ascertained that the studies were able to measure the emotional distress that they intended to and so results from these studies must be interpreted with caution. Furthermore, all of the included studies measured emotional distress on the diagnostic constructs of anxiety and depression. Therefore, conclusions cannot be drawn on effects of third-wave intervention across the spectrum of emotional experiences. As noted above, the primary goal of third-

wave interventions is to support individuals to adjust to their 'new' life post-stroke, however none of the studies in this review use this adjustment measure as their primary outcome. There is a need for future researchers to establish the validity and reliability of assessments that successfully measure this construct.

Strengths and Limitations of the Review Process

One strength of this review is that overall it has attempted to follow as closely as possible the PRISMA guidelines [67], which resulted in a transparent, comprehensive and replicable review.

A limitation of this review is that it was conducted by a single author. This could have had an impact at a number of stages, such as database searching, data extraction and quality assessment; however, this draw back was mediated by the process of supervision that occurred throughout the review process. The chosen quality assessment tool relied heavily on a subjective assessment of each component, which has been argued to impact its reliability [114]. In an effort to counter this, the lead author sought consultation from other researchers on the quality assessment of the included studies, and an inter-rater reliability of 80% was reached.

While the inclusion of only peer reviewed literature in this review was necessary to maintain quality standards, it is possible that this has limited the inclusion of some novel research in this area with two unpublished doctoral theses having to be excluded. There is some evidence from medical research that posits that the exclusion of such "grey literature" can result in an overestimation of an interventions effectiveness [115] due to bias towards the publication of positive results. Additionally, the exclusion of articles published in a language other than English can impact on the reliability of evidence as it has been demonstrated that studies with negative or non-significant results often publish in non-

English journals [116]. However, taking the above points into consideration when reflecting on this review process, there is a reasonable level of surety that this review provides a comprehensive overview of the current published peer-reviewed evidence base.

Recommendations for Future Research and Clinical Practice

Despite the recent increase in publications considering the impact of third-wave therapies on emotional and psychological distress following stroke, case studies and cohort studies form a significant proportion of the evidence base. While these studies provide important preliminary insight into the use of third-wave interventions within this population, they carry little weight in terms of developing a robust evidence base for the effectiveness of a therapeutic intervention that might influence national guidelines, such as those published by NICE (2013) and Royal College of Psychiatry (RCP; 2016) [9, 117]. This review highlights the requirement for more focus on the emotional and psychological needs of people post-stroke. Further funding in this area is required as to allow researchers in this field to publish high-quality controlled research. Moreover, conducting more standardised research using reliable and validated measures of distress such as the SADQ [118] and the VAMS [119] as well as interventions that are more consistent in length would allow for an easier comparison against other interventions.

There remains a significant gap in the research into the identification of emotional distress following stroke, whereby currently individual experiences of distress are quantified using the diagnostic categories of anxiety and depression. With measures that divide human experiences into these categorical narratives, there is a risk of missing other problematic experiences of distress such as anger, frustration, and hopelessness. Further development of a clinically valid tool which measures the spectrum of emotional experiences within this

clinical population would facilitate the identification of individuals who may benefit from psychological interventions.

Future research should focus on those individuals who currently do not benefit from or do not complete current recommended interventions [117], to determine if third-wave interventions may be a more suitable therapeutic model. Moreover, given that third-wave therapies focus on improving quality of life rather than aiming to reduce symptoms, future research should consider utilising measures which consider quality of life and psychological functioning, similar to those which have been utilised in one of the included studies [120].

Some of the studies included in this review demonstrate that third-wave therapies can be effective at reducing distress in as little as four sessions. Moreover, there is evidence that third-wave interventions can be effective in a group setting which would provide further cost effectiveness from a health service perspective. Shorter, more cost-effective interventions are beneficial to services, service users and carers as they will positively impact on waiting list times as well as the cost-effective provision of services. Furthermore, as third-wave interventions do not focus specifically on the reduction of symptoms, they can be considered trans-diagnostic in nature, indicating that they have the potential to offer useful interventions across the spectrum of emotional distress.

There is an increasing need for research to include participants from harder to reach groups such as those with communication and/or cognitive difficulties. Third-wave therapies have demonstrated success with these groups within other populations [121, 122]. Further research should consider the feasibility and acceptability of third-wave interventions for people who have additional communication and cognitive needs.

Conclusions

Based on the studies included in this review, the research provides some promising, evidence for the effects of third-wave interventions and their usefulness and feasibility in a post-stroke population. Due to methodological limitations, however there is currently a scarcity of robust evidence to support the utility and effectiveness of third-wave therapies in the context of emotional distress. There is a requirement for further research into this area and consequently, clinicians wishing to adopt third-wave approaches should do so in the context of clinical research, with the aim of contributing to the evidence base.

A potential area for future research could focus on the development of validated and reliable measures of the spectrum of emotional distress. Furthermore, there is scope to develop measures considering issues of adjustment and quality of life for stroke survivors, and not merely symptom reduction. Despite the ongoing need for effective interventions to support people who experience emotional distress following stroke, the lack of RCTs included in this review mean that there is an absence of strong evidence in support of third-wave therapies.

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Table 1

Database Search terms.

Search Domain	Search Terms
Stroke	(cerebral or cerebellar or brain* or vertebrobasilar) AND (infarct* or ischeami* or thrombo* or emboli* or apoplexy) OR (cerebral or intracerebral or intracranial or brain) AND (haemorrhage or haemorrhage or bleed*) OR cerebrovascular disorders OR (stroke* or poststroke* or cva*) OR (cerebrovascular* or cerebral vascular)
Emotional Distress	emotional distress OR psychological distress OR anxiety OR depress* OR posttraumatic stress OR PTSD OR psychological morbidity OR psych* OR adjustment OR emotional adjustment OR mood OR adjustment disorder OR acute stress disorder OR fear of relapse OR Depression* OR involutional* or Depressive disorder* or Dysthymic disorder* OR dysthymi*
Third-Wave Psychological Interventions	"behavio* activation" OR "Compassion focussed therapy" OR "compassionate Mind training" OR "Dialectical behavio* therapy" OR "mindfulness based stress reduction" OR "MBSR" OR "mindfulness based cognitive therapy" OR "MBCT" OR "acceptance and commitment therapy" OR "Metacognitive therapy" OR “MCT”

Note: “ACT” was not used as a search term as it resulted in erroneous studies being retrieved

Table 2.
Inclusion Criteria

	Inclusion Criteria
Population	Individuals over the age of 18 who had experienced a stroke and resulting emotional distress. A broad definition of stroke was adopted to include ischaemic stroke, haemorrhagic stroke, subarachnoid haemorrhage, and transient ischemic attack (TIA) and mixed populations where stroke data could be extracted. The review considered studies which measured levels of emotional distress using either questionnaire-based tools or structured clinical interview assessment.
Intervention	Individuals received an intervention that was classified as a third-wave psychological therapy as detailed above; both individual and group interventions were included
Comparator	Both studies with and without a comparison group or intervention were included
Setting	Community, or hospital.
Study design	All treatment study designs were included to ensure a comprehensive review of existing literature, taking into account the current availability of published literature on third-wave interventions and the lack of RCT's.
Outcomes	At least one quantitative outcome measure was required, either self or other report relating to emotional distress following stroke. Outcome measures were reported pre- or post-intervention or over the course of the intervention
Publication	All studies had to be published in a peer reviewed journal and written or translated into English and were published and available any time prior to and including 22nd January 2018.

Table 3

Quality Assessment Ratings Table of the Included Studies

Study	Selection bias	Study Design	Confounders	Blinding	Data collection Methods	Withdrawals and Dropouts	Global Rating
Moustgaard, Bedard, Felteau (2004) Canada	Moderate	Moderate	Strong	Weak	Strong	Strong	Moderate
Graham, Gillanders, Stuart, Gouick (2015) UK	Moderate	Weak	Strong	Weak	Weak	Strong	Weak
Merriman, Walker-Bircham, Easton, Maddicks (2015) UK	Moderate	Moderate	Strong	Weak	Strong	Strong	Weak
Joo, Lee, Chung, & Shin (2010) Korea	Moderate	moderate	Moderate	Weak	Moderate	Weak	Weak
Dickinson, Friary, McCann (2016) New Zealand	Moderate	Weak	Strong	Weak	Weak	Strong	Weak
Mitchell, Veith, Becker, Buzaitis, Cain, Fruin, Tirschwell, Teri (2009) USA	Strong	Strong	Strong	Strong	Strong	Strong	Strong
Thomas, Walker, Macniven, Haworth, Lincoln (2013) UK	Strong	Strong	Strong	Moderate	Strong	Strong	Strong

Study	Selection bias	Study Design	Confounders	Blinding	Data collection Methods	Withdrawals and Dropouts	Global Rating
Johansson, Bjuhr & Ronnback (2012) Sweden	Moderate	Strong	Strong	Moderate	Moderate	Moderate	Moderate
Johansson, Bjuhr, Karisson, Karlsson, & Ronnback (2015) Sweden	Moderate	Strong	Strong	Moderate	Moderate	Moderate	Moderate
Shield & Ownsworth (2013) Australia	Moderate	Weak	Strong	Weak	Weak	Strong	Weak

Table 4

Results Summary Table showing: Study Characteristics, Outcome Measures, and Results.

Authors (Year & Country)	Design and Comparator	Sample Size/ population characteristics	Intervention delivery and content	Assessment tool of emotional distress	Results
Moustgaard, Bedard, Felteau (2005) Canada	Cohort design - pre and post measure comparison.	30 participants who had experienced a stroke over the age of 30yrs with 23 completers. 23% attrition. A community-based sample. Male =6, female= 17. included both aphasia (n=2) and non-aphasia participants (n=21) Nature of stroke not noted. Lateralisation: Right (n=11), Left (n=12). Antidepressant: not reported.	MBCT - with adaptations to the yoga elements in line with the physical needs of the sample. Psychoeducation specific to stroke was also included. Focus of treatment was to reduce experiences of depression but was extended to include other aspects of emotional and physical coping. Duration and frequency: 9 weekly sessions that were 1.45 hr long. Facilitators: A 3rd year clinical psychology trainee and a certified mindfulness and yoga instructor. Format: Group	Beck anxiety inventory (BAI). Beck depression inventory revised (BDI-II). Hospital anxiety and depression scale (HADS)	Significant reduction of depressive symptoms ($p < .001$) and anxiety (p.001). Measured by both the HADS and BDI/BAI, large effect sizes of between 0.42-0.64 were reported. Reductions were sustained at 3 months follow up.
Graham, Gillanders, Stuart, Gouick (2015) UK	Case Study - pre and post measures	Sample Size: 1 male participant, 40yrs, non-aphasia, who was experiencing anxiety following a stroke. Antidepressant: not reported.	ACT intervention. Duration and frequency: 9 sessions, duration and frequency of sessions is not reported. Format: one to one. Facilitator: 1 trainee clinical psychologist under supervision of a consultant clinical neuropsychologist	Short form depression anxiety stress scale (DASS-21)	Improvements in both depression and anxiety at end of treatment as well as at 2 months follow up as measured by the DASS-21. No details of statistical analysis

Authors (Year & Country)	Design and Comparator	Sample Size/ population characteristics	Intervention delivery and content	Assessment tool of emotional distress	Results
Merriman, Walker-Bircham, Easton, Maddicks (2015) UK	Case series - pre and post measure comparison.	Sample size: Community sample of 4 participants who had experienced a stroke. Age range of 47-62, all participants were between 1-4 years post stoke. Side of deficit: 3 participants right sided ischaemic stroke, 1 participant left sided ischaemic stroke. Gender: Three males and one female. Antidepressant: not reported.	Mindfulness group- MBSR. Duration and frequency: 9 Sessions, lasting for 2 hours each week. Participants were also required to engage with home tasks. Format: group. Facilitor: one clinical psychologist and one assistant psychologist.	Hospital anxiety and depression scale (HADS)	Reductions in the scores for anxiety and depression at end of treatment for three of the four participants, no statistical analysis conducted and no follow up period or score reported.
Joo, Lee, Chung, & Shin (2010) Korea	Cohort design - pre and post measure comparison	Sample size: 28 community-based participants who experienced stroke, and mood difficulties. Age range 38-65 Attrition: 39%. Gender: 5 males and 6 females. All participants experienced a cerebral aneurysm rupture. Antidepressants: Participants using psychiatric drugs were excluded.	MBSR intervention. Duration and frequency: an eight-week programme with a 2.5hr sessions once per week, in addition participants were expected to complete home-based tasks. Format: Group. Facilitator: not reported.	Beck depression inventory - Korean version, The state trait anxiety inventory (STAI)	A significant difference was shown in the depression scores for patients (p=.013). A borderline statistically significant result was demonstrated for the reduction of anxiety both state and trait (p=.091 and p=.056). No follow period reported.

Authors (Year & Country)	Design and Comparator	Sample Size/ population characteristics	Intervention delivery and content	Assessment tool of emotional distress	Results
Dickinson, Friary, McCann (2016) New Zealand	Case Study - pre and post measures	Sample Size: 1 female participant 59 years of age, who was 3 years post stroke and experiencing severe aphasia, MCA infarct. Side of Deficit: right. Antidepressants: not reported	Mindfulness intervention. Duration and frequency: 4-week course of weekly sessions last 90-120mins, the participant was also required to complete a home-based mindfulness exercise 5 times per week between the sessions. Format: one to one. Facilitator: a clinical psychologist who is also a trained MBSR practitioner	Beck Anxiety Inventory (BAI)	Significant reduction in anxiety both immediately following intervention and at 3 weeks follow up (p=.000)
Mitchell, Veith, Becker, Buzaitis, Cain, Fruin, Tirschwell, Teri (2009) USA	RCT	Sample Size: 101 - 53 control and 48 intervention, all participants were recruited within 4 months of experiencing an ischaemic stroke Gender: male 61, female 40, mean age was 57 with a range of 25-88. Attrition: 9% Antidepressants: 60.4% of the intervention, and 64% of control group were taking antidepressants.	Psycho social behavioural intervention. Durations and frequency: 9 sessions over an 8-week period. Format: one to one, participants could opt to have a family member present. Facilitator: nurse led programme.	Hamilton Rating Scale for Depression (HRSD)	Significant reduction in depression: 9 weeks (p<.001, CI= -8.2 - -4.0), 21 weeks (p=0.98, CI= -4.8-0.4), 12 months (p=.023, CI= -5.4—0.4), 24 months (p=.108, CI= -4.9-0.5)

Authors (Year & Country)	Design and Comparator	Sample Size/ population characteristics	Intervention delivery and content	Assessment tool of emotional distress	Results
Thomas, Walker, Macniven, Haworth, Lincoln (2013) UK	RCT	Sample size: 105 - 54 usual care, 51 intervention, participants who had experienced stroke with aphasia and who were identified as experiencing low mood. Gender: 63% male participants. Location: 12 participants were hospital based and 93 were community based. Side of deficit: left (n=72), Right (n=8), Bilateral (3), unknown (n=22). Attrition: 15% Antidepressants: 29 participants were taking antidepressants.	Extended behavioural therapy. Duration and frequency: up to 20 1hour sessions over a 3 months period. Facilitator: delivered by an assistant psychologist supervised by a clinical psychologist. Format: one to one.	Stroke Aphasic Depression Questionnaire, and the VAMS 'sad' item.	Significant reduction in depression. 3months adjusted for baseline communication score: SADQH (p=.20; CI= 7.81-0.01) and at 6 months without the need for adjustment of communication measures (p=.002, CI= -9.95—2.30). VAMS (sad item) 3months (p=.033, CI= -22.30- -0.99). At 6 months (p= .190, CI= -18.34–3.71)
Johansson, Bjuhr & Ronnback (2012) Sweden	Controlled trial	Sample size: 12 Stroke N.B. 22 in sample; 10 traumatic brain injury. Intervention group: Mean age in MBSR1=54.1, Waitlist group: control = 56.9. Gender: there were 12 females and 9 males. Type of stroke and lateralisation not noted, nor	MBSR group programme. Duration and frequency: 8 weekly, 2.5 hour, sessions, one day-long silent retreat between session 6 and 7, as well as home tasks of 45min 6 days per week. Format: Group. Facilitator: profession of delivery clinician not reported	Comprehensive Psychopathological Rating Scale (CPRS) - measures both anxiety and depression.	Depression and anxiety were secondary outcome measures in this study as its primary aim was to look at fatigue. From the extracted data on stroke only participants a downward trend in both anxiety and depression is exhibited for both the active treatment

Authors (Year & Country)	Design and Comparator	Sample Size/ population characteristics	Intervention delivery and content	Assessment tool of emotional distress	Results
		is aphasia. time since stroke is 3-10 years. Antidepressants: Participants using mediation including antidepressants were not excluded from the study, although numbers were not reported. Attrition: 23%			group while mood remains relatively static for the control group.
Johansson, Bjuhr, Karisson, Karlsson, & Ronnback (2015) Sweden	Controlled trial	Sample size: 16 stroke participants, N.B. 34 in total, 18 traumatic brain injury. Stroke participants: f2f = 5, internet =5, walking control = 6. Mean age: f2f=42.6, internet= 47, walking=55.83. Antidepressant: not reported. Attrition: 11% for overall study although it is unclear how many of stroke participants completed the intervention.	MBSR group programme. Duration and frequency: 8-weekly 2.5-hour session MBSR programme. Format: Group. Profession of delivery clinician not reported.	Comprehensive Psychopathological Rating Scale (CPRS) - measures both anxiety and depression.	Reduction in both depression and anxiety scores as measured by the CPRS following the 8-week programme. As this data was extracted from a wider brain injury study it is not possible to comment on the level of significance. Although in the overall study there was a significant reduction in the overall scores of anxiety and depression.

Authors (Year & Country)	Design and Comparator	Sample Size/ population characteristics	Intervention delivery and content	Assessment tool of emotional distress	Results
Shields & Ownsworth (2013) Austrailia	Case Study	One female participant, aged 48, who had experienced a cerebral aneurysm with left sided deficit 18 months previously, and was currently experiencing anxiety. Medication use not reported.	Compassion focussed therapy (CFT) in addition to cognitive rehabilitation. Duration and frequency: ten weekly sessions, length of session not reported. Facilitator: clinical psychologist.	Depression Anxiety Scale (DASS-21).	Reliable change indices (RIC): which measure the efficacy of an intervention based on pre and post measures demonstrated significant positive change ($p< 0.05$). DASS-21 scores were no longer in the clinical range.

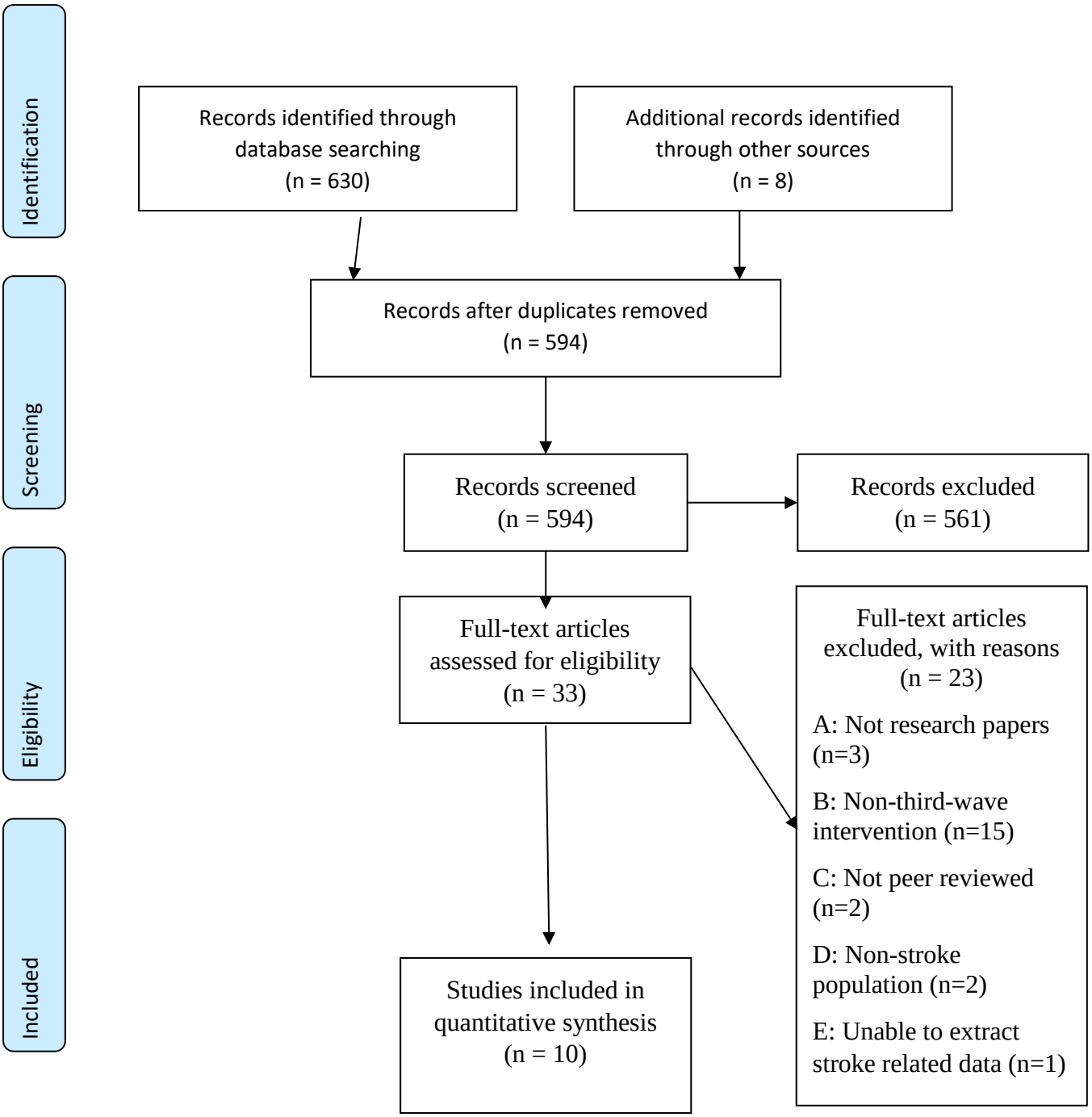

Figure 1. PRISMA flow diagram.

Note: PRISMA= Preferred Reporting for Systematic Reviews and Meta-Analyses.
A = [123-125], B = [126-140], C = [141, 142], D = [143, 144], E = [145].

Appendix A

QUALITY ASSESSMENT TOOL FOR QUANTITATIVE STUDIES

COMPONENT RATINGS

A) SELECTION BIAS

(Q1) Are the individuals selected to participate in the study likely to be representative of the target population?

Very likely
Somewhat likely
Not likely
Can't tell

(Q2) What percentage of selected individuals agreed to participate?

80 - 100% agreement
60 – 79% agreement
less than 60% agreement
Not applicable
Can't tell

RATE THIS SECTION	STRONG	MODERATE	WEAK
See dictionary	1	2	3

B) STUDY DESIGN

Indicate the study design

Randomized controlled trial
Controlled clinical trial
Cohort analytic (two group pre + post)
Case-control
Cohort (one group pre + post (before and after))
Interrupted time series
Other specify _____
Can't tell

Was the study described as randomized? If NO, go to Component C.

No Yes

If Yes, was the method of randomization described? (See dictionary)

No Yes

If Yes, was the method appropriate? (See dictionary)

No Yes **RATE THIS SECTION**	STRONG	MODERATE	WEAK
See dictionary	1	2	3

C) CONFOUNDERS

(Q1) Were there important differences between groups prior to the intervention?

Yes
No
Can't tell

The following are examples of confounders:

Race
Sex
Marital status/family
Age
SES (income or class)
Education
Health status
Pre-intervention score on outcome measure

(Q2) If yes, indicate the percentage of relevant confounders that were controlled (either in the design (e.g. stratification, matching) or analysis)?

80 – 100% (most)
60 – 79% (some)
Less than 60% (few or none)
Can't Tell

RATE THIS SECTION	STRONG	MODERATE	WEAK
See dictionary	1	2	3

D) BLINDING

(Q1) Was (were) the outcome assessor(s) aware of the intervention or exposure status of participants?

Yes
No
Can't tell

(Q2) Were the study participants aware of the research question?

Yes
No
Can't tell

RATE THIS SECTION	STRONG	MODERATE	WEAK
See dictionary	1	2	3

E) DATA COLLECTION METHODS

(Q1) Were data collection tools shown to be valid?

Yes
No
Can't tell

(Q2) Were data collection tools shown to be reliable?

Yes
No
Can't tell

RATE THIS SECTION	STRONG	MODERATE	WEAK
See dictionary	1	2	3

F) WITHDRAWALS AND DROP-OUTS

(Q1) Were withdrawals and drop-outs reported in terms of numbers and/or reasons per group?

Yes
No
Can't tell
Not Applicable (i.e. one time surveys or interviews)

(Q2) Indicate the percentage of participants completing the study. (If the percentage differs by groups, record the lowest).

80 -100%
60 - 79%
less than 60%
Can't tell
Not Applicable (i.e. Retrospective case-control)

RATE THIS SECTION	STRONG		MODERATE	WEAK
See dictionary	1	2	3	Not Applicable

G) INTERVENTION INTEGRITY

(Q1) What percentage of participants received the allocated intervention or exposure of interest?

80 -100%
60 - 79%
less than 60%
Can't tell

(Q2) Was the consistency of the intervention measured?

Yes
No
Can't tell

(Q3) Is it likely that subjects received an unintended intervention (contamination or co-intervention) that may influence the results?

Yes
No
Can't tell

H) ANALYSES

(Q1) Indicate the unit of allocation (circle one)

community organization/institution practice/office individual

(Q2) Indicate the unit of analysis (circle one)

community organization/institution practice/office individual

(Q3) Are the statistical methods appropriate for the study design?

Yes
No
Can't tell

(Q4) Is the analysis performed by intervention allocation status (i.e. intention to treat) rather than the actual intervention received?

Yes
No
Can't tell

GLOBAL RATING

COMPONENT RATINGS

Please transcribe the information from the gray boxes on pages 1-4 onto this page. See dictionary on how to rate this section. **A**	**SELECTION BIAS**	**STRONG**	**MODERATE**	**WEAK**
1		2		3
B	**STUDY DESIGN**	**STRONG**	**MODERATE**	**WEAK**
1		2		3
C	**CONFOUNDERS**	**STRONG**	**MODERATE**	**WEAK**
1		2		3
D	**BLINDING**	**STRONG**	**MODERATE**	**WEAK**
1		2		3
E	**DATA COLLECTION METHOD**	**STRONG**	**MODERATE**	**WEAK**
1		2		3
F	**WITHDRAWALS AND DROPOUTS**	**STRONG**	**MODERATE**	**WEAK**
1	2		3	Not Applicable

GLOBAL RATING FOR THIS PAPER (circle one):

1 STRONG (no WEAK ratings)

2 MODERATE (one WEAK rating)

3 WEAK (two or more WEAK ratings)

With both reviewers discussing the ratings:

Is there a discrepancy between the two reviewers with respect to the component (A-F) ratings?

No Yes

If yes, indicate the reason for the discrepancy

1 Oversight

2 Differences in interpretation of criteria

3 Differences in interpretation of study

Final decision of both reviewers (circle one): 1 STRONG

2 MODERATE

3 WEAK

Appendix B Data Extraction Tool.

Study	When intervention conducted	Country	Setting	Commercial research supported	Study design

	Intervention	Comparison	N total	N third-wave intervention	N control	N competed intervention	N completed control	# of therapists	# of weeks	# of sessions	# of hours	Follow-up months	Therapist adherence / competence

Mean Age	Gender	Ethnicity	Type of Stroke	Medication	Side of Deficit	Inclusion / Exclusion	Intervention credibility
Outcomes							Conclusions

Appendix C

Judgements of Quality Assessment.

Quality Assessment for Moustgaard et al. (2005) [75].

Component	Judgement	Rating
Selection Bias	The individuals taking part in the research are likely to be representative of the population – however participants were self-selected from poster advertisements – so results should be viewed with caution.	Moderate
Study Design	This was not a randomised design – however it was experimental in that participants mood was measured pre and post intervention.	Moderate
Confounders	This study included participants who were representative of the target population – however they did exclude participants who experienced severe cognitive impairment.	Strong
Blinding	This was not an RCT – both the researchers and the participants were clear about the aims of the study.	Weak
Data Collection Methods	Used reliable and validated measures of emotional distress for a stroke population.	Strong
Withdrawals and dropouts	A 23% attrition rate was reported, as well as reasons for drop out. Completers did not differ from drop outs.	Strong

Judgement of Quality for Graham et al. (2015) [76].

Component	Judgement	Rating
Selection Bias	The participant involved in this study is likely to be representative of the target population, however this participant had been referred to psychotherapy – and was undergoing treatment as part of usual care. The participant may have been more open to the support of psychology than the target population as a whole.	Moderate
Study Design	Case study	Weak
Confounders	The participant was not being compared with another individual, only with their own outcomes, pre and post intervention.	Strong
Blinding	Both the participant and the researcher were aware of the research questions as well as the hypothesis for the intervention.	Weak
Data Collection Methods	This study did not use a valid or reliable measure for a stroke population, so the outcomes can not be assessed in comparison to others in the literature.	Weak
Withdrawals and dropouts	As this was a case study there were no drop outs.	Strong

Judgement of Quality for Merriman et al. (2015) [77].

Component	Judgement	Rating
Selection Bias	The participants are likely to be representative of the target population, however they were all recruited from a support group of people who were already accessing support for stoke related difficulties. It is also unclear if participants knew one another, and if so this may have impacted on the group dynamics of the intervention. In addition, no inclusion or exclusion criteria were reported.	Moderate
Study Design	This study opted for a cohort design and measured participants mood pre and post intervention.	Moderate
Confounders	These participants are likely to be representative of the target population. Details of type of stroke, location and ongoing difficulties reported.	Strong
Blinding	Both the participants and the researchers were aware of the research questions.	Weak
Data Collection Methods	This study used a validated and reliable tool for the stroke population to measure participant emotional distress.	Strong
Withdrawals and dropouts	There were no drop outs in this study.	Strong

Judgement of Quality for Joo et al. (2010) [78].

Component	Judgement	Rating
Selection Bias	The participants in this study were recruited from a hospital sample and were likely to be representative of the target population in terms of stroke related difficulties. However, the study considered patients who had experienced an aneurysmal subarachnoid haemorrhage which account for only 5% of all strokes.	Moderate
Study Design	This was cohort design with per and post measures of mood.	Moderate
Confounders	This study although did not report inclusion and exclusion criteria, and only considered participants who experienced a specific type of stroke. However, this may represent to some extent the target population.	Moderate
Blinding	Both the researchers and the participants were aware of the research question.	Weak
Data Collection Methods	This study used a combination of measures to look at experiences of emotional distress, the measure of depression was a validated tool for the stroke population, however the measure of anxiety was not.	Moderate
Withdrawals and dropouts	There was a very high attrition rate for this study 61%, no details are provided for the group differences between drop outs and completers.	Weak

Judgement of Quality for Dickinson et al. (2016) [79].

Component	Judgement	Rating
Selection Bias	The participant in this study is typical of the target population in terms of experiences of distress following stroke. It is important to note that the participant was self-selected and as such may be more open to psychological intervention that the typical population.	Moderate
Study Design	The is a case study	Weak
Confounders	The participant in the study, was typical of the target population and was not excluded from the research due to difficulties with communication, which is unusual in stoke research.	Strong
Blinding	Both the researcher and the participant were aware of the research aims.	Weak
Data Collection Methods	This study is not utilise a validated and reliable measure of mood for a stroke population.	Weak
Withdrawals and dropouts	There were no drop outs – case study design.	Strong

Judgement of Quality for Mitchell et al. (2009) [72].

Component	Judgement	Rating
Selection Bias	The participants were reprehensive of this population, all having experienced a stroke and being identified by clinical interview as having difficulties with mood post-stroke.	Strong
Study Design	RCT – computer generated randomisation, groups matched by severity of stroke and severity of depression.	Strong
Confounders	Participants were not excluded due to cognitive or physical difficulties, and Barthel index was reported.	Strong
Blinding	All outcome assessors were blinded to the group allocation of the participants at each assessment stage.	Strong
Data Collection Methods	This study used a validated and reliable measure of mood for the stroke population.	Strong
Withdrawals and dropouts	The study reported an attrition rate of 9%, dropouts did not differ from completers.	Strong

Judgement of Quality for Thomas et al. (2013) [71].

Component	Judgement	Rating
Selection Bias	Participants are reprehensive of the target population, recruitment took place in hospital and community setting as well as community groups.	Strong
Study Design	RCT	Strong
Confounders	Study controlled well for confounding effects – individuals who were currently undergoing treatment for depression were excluded from the study.	Strong
Blinding	Participants were not aware of group allocation, although it is unclear if researchers who were collecting outcome measures were aware.	Moderate
Data Collection Methods	This study used reliable and validated measures of mood for a stroke population.	Strong
Withdrawals and dropouts	There was a 19% attrition rate for this study, drop outs did not differ from the completers.	Strong

Judgement of Quality for Johansson et al. (2012) [74].

Component	Judgement	Rating
Selection Bias	This study included participants who are representative of the population, however participants were self-selected from a newspaper advertisement. The study also excluded participants who have any cognitive deficits, although participants who were taking medication were permitted to take part.	Moderate
Study Design	This was a controlled trial, it states that the participants were randomised to groups, however does not give details of the procedure for this. It also adopted a design, whereby the control group are then after a waiting time offered the intervention and this is then analysis as intervention group 2.	Strong
Confounders	The groups in this study were matched for age and disability, they are representative of a stroke population.	Strong
Blinding	It is not clear how the participants were randomised to the study, it is also not clear from the study if the investigators knew which group the participants belonged to when they administered the assessments.	Moderate
Data Collection Methods	This study used a measure of mood that has received some evidence for the stroke population, however the validation study had a small sample size as was conducted a number of years ago.	Moderate
Withdrawals and dropouts	The attrition rate for this study was 24%, reasons for drop out were reported. Participants dropped out the study namely due to issues of ill health and cognitive impairment, as such they represent a difference from the completer group.	Moderate

Judgement of Quality for Johansson et al. (2015) [73].

Component	Judgement	Rating
Selection Bias	This study included participants who are representative of the population, however participants were self-selected from a newspaper advertisement. The study also excluded participants who have any cognitive deficits, although participants who were taking medication were permitted to take part.	Mod
Study Design	This study was a controlled trial, with a waitlist control group, participants were able to select to be part of either the face to face or the internet group for the MBSR delivery.	Strong
Confounders	Groups were matched in terms of time since injury, age and gender, and type of injury, stroke or TBI.	Strong
Blinding	It is not clear if the researchers were aware of which group the participants belonged to when they were administering the follow up assessments.	Moderate
Data Collection Methods	This study used a measure of mood that has received some evidence for the stroke population, however the validation study had a small sample size as was conducted a number of years ago.	Moderate
Withdrawals and dropouts	Attrition rates are not reported in this study, however it is not possible to establish how many of the participants who experienced stroke may have completed the intervention.	Moderate

Judgement of Quality for Shield & Ownsworth (2013) [80].

Component	Judgement	Rating
Selection Bias	The participant involved in this study is likely to be representative of the target population, however this participant was referred initially for neuropsychology testing and anxiety was identify as an issue. As such following the neuro assessment and support the participant may have been more open to the support of psychology than the target population as a whole.	Moderate
Study Design	Case study	Weak
Confounders	The participant was not being compared with another individual, only with their own outcomes, pre and post intervention.	Strong
Blinding	Both the participant and the researcher were aware of the research questions as well as the hypothesis for the intervention.	Weak
Data Collection Methods	The study used the DASS-21 validated for measuring anxiety in post-stroke population	Strong
Withdrawals and dropouts	As this was a case study there were no drop outs.	Strong

Appendix D

Submission Guidelines (notes for authors) - Stroke.

New Submissions

To submit your manuscript online, please visit the journal's online manuscript submission site (http://stroke-submit.aha-journals.org), and follow the instructions for creating an author account and submitting a manuscript. Access can also be gained by visiting *Stroke* online at http://stroke.ahajournals.org and selecting the Online Submissions button. If you have any questions about the online submission process, contact the Editorial Office by e-mail at stroke@strokeahajournal.org.

Initial Review Process

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References

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Example References:

Print journal reference: Mistry EA, Mistry AM, Nakawah MO, Chitale RV, James RF, Volpi JJ, et al. Mechanical Thrombectomy Outcomes With and Without Intravenous Thrombolysis in Stroke Patients: A Meta-Analysis. *Stroke.* 2017;48:2450-2456.

Online journal references: Chamberlain AM, Brown RD, Alonso A, Gersh BJ, Killian JM, Weston SA, et al. No Decline in the Risk of Stroke Following Incident Atrial Fibrillation Since 2000 in the Community: A Concerning Trend. *J Am Heart Assoc.* 2016;5:e003408.

Li J, Liu J, Liu M, Zhang S, Hao Z, Zhang J, et al. Closure versus medical therapy for preventing recurrent stroke in patients with patent foramen ovale and a history of cryptogenic stroke or transient ischemic attack. *Cochrane Database Syst Rev.* 2015; 9: CD009938.

Publish-Ahead-of-Print reference: Sanossian N, Rosenberg L, Liebeskind DS, Starkman S, Eckstein M, Stratton S, et al. A Dedicated Spanish Language Line Increases Enrollment of Hispanics Into Prehospital Clinical Research. [published online ahead of print April 7, 2017]. *Stroke.* 2017. http://stroke.ahajournals.org/content/early/2017/04/07/STROKEAHA.117.014745. Accessed April 12, 2017.

Book reference: Caplan L. Caplan's Stroke: A Clinical Approach. 4rd Ed. Philadelphia, PA: Saunders; 2009.

Website reference: Stroke Death Rates, Total Population Age 65+. National Heart Disease and Stroke Maps. National Center for Chronic Disease Prevention and Health Promotion, Division for Heart Disease and Stroke Prevention. http://www.cdc.gov/dhdsp/maps/national_maps/stroke65_all.htm. Accessed September 6, 2016.

Web sites generally follow this format: Author names (if any). Title of information or page. Name of website. URL. Publication date (if any). Access date.

Software manual reference: StataCorp. Stata statistical software: Release 12. College Station, TX: StataCorp LP; 2011.

Government bulletin: Author. Title of bulletin. Place of publication: Name of issuing department or agency; publication date. Page numbers (if any). Publication number (if any). Series number (if any).

Database reference: CANCERNET-PDQ [database online]. Bethesda, MD: National Cancer Institute; 1996. Updated March 29, 1996.

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An Examination of Sleep and Mood in Predicting Rehabilitation Participation in an Inpatient Stroke Sample.

Target Journal: Stroke.

Lancaster University

Doctorate in Clinical Psychology

Leona Rose

2015 Intake

Word count: 6,855 words, excluding title page, tables, figures and references.

There are nine tables and four figures included in this paper.

Abstract

Background and Purpose- Stroke is one of the leading causes of disability worldwide, with lower rates of recovery linked with patients' participation in rehabilitation. The purpose of this study was to conduct a prospective examination of the relationship between night time sleep, and participation in rehabilitation in an acute hospital setting. The study also considered the temporal relationship between mood and participation in rehabilitation, as well as the possible interplay between sleep and mood.

Methods- Experience sampling methodology was integrated with actigraphy, across a range of between 3-15 days (mean-7.5, SD=4.4) in 20 participants (53% female, mean age= 74, SD= 11.8) who had experienced a recent stroke and were undergoing inpatient rehabilitation Daily measures of sleep, mood, pain and participation were recorded for each participant for the duration of the study. Multilevel modelling was employed for data analysis.

Results- Results indicate that sleep efficiency was a predictor of participation in rehabilitation, however, this significance was not sustained in a more stringent model that accounted for other predictor variables. Experiences of low mood predicted lower levels of participation in activities of rehabilitation, while a small increase in pain experience predicted increased levels of participation. All findings are at a within-person level.

Conclusions- For the first time we show that sleep efficiency is linked with participation in rehabilitation. We also show that there is a temporal relationship between experiences of mood and pain and participation in rehabilitation in a post-stroke population. Results indicate that sleep, mood and pain are linked with a person's ability to participate in activities in rehabilitation. Interventions targeting these experiences may improve participation in rehabilitation and consequently may have an impact on a person's recovery from stroke.

Key words: ▪Stroke, ▪rehabilitation, ▪sleep, ▪mood, ▪actigraphy, ▪experience sampling

Stroke is the second leading cause of death worldwide [1] and has been described as the most debilitating of conditions [2]; likely due to its wide-reaching impact across several life domains. Stroke occurs suddenly and often without warning [3], affecting approximately 2-3 individuals per 100 per year. Despite recent advances in treatment, it remains the most common neurological cause of hospitalisation and disability in adulthood worldwide [4]. Advances in the recognition and treatment of stroke have led to improved survival rates, with mortality rates falling by 35% [5]. Thus, there is an increased need for longer term and specialist care for stroke survivors and their families, as increasingly more people are living with the consequences of stroke and the resulting cognitive, physical, and emotional difficulties [6, 7].

Stroke is associated with a range of sleep and mood related difficulties [8-10]. Poor sleep efficiency (SE), lower total sleep time (TST), and experiences of low mood and depression [11-13] are commonly reported difficulties following stroke. Over the past 20 years, research into the aetiology of stroke has suggested that optimising functional recovery is contingent upon engagement with an intense programme of rehabilitation [14]. Front line rehabilitation efforts focus on motor and cognitive re-learning of functional skills. This process of re-learning can be both demanding and challenging for participants and can be impacted by a number of factors for example cognitive function [15]. However, the potential impact of sleep and mood disturbances on participation in rehabilitation following stroke remains unclear.

Existing research examining the relationship between stroke and sleep has found that various types of sleep disturbance, such as insomnia, sleep disordered breathing (SDB), and restless leg syndrome (RLS) are common in people who have experienced stroke, impacting as many as 50% of stroke survivors [16, 17]. Furthermore, there is emerging evidence that

patients experience significant difficulties with sleep whilst in hospital [18, 19], possibly due to the effect of light and noise pollution on medical wards [20]. This is particularly relevant to the stroke population given that the length of inpatient stays for stroke rehabilitation range between 13-162 days [21, 22]. Therefore, hospital settings may further impair both sleep quality and efficiency at a time when its importance is paramount. It has been well documented that sleep disturbances have a negative impact on physical health recovery [16] and are strongly correlated with experiences of depression and anxiety in both post stroke and healthy populations [23, 24]. Poor sleep is also correlated with poorer life satisfaction, as well as lower functional recovery following stroke [16, 25]. One possible reason for this link is that sleep promotes neuroplasticity which is essential for the neural processes of memory and learning [26, 27]. These processes are fundamental to a person's ability to learn and retain new skills acquired during rehabilitation activities. Evidence of this link can be found in literature which suggests that sleep promotion can facilitate recovery in a stroke population [24, 28].

In addition to difficulties with sleep, around one third of all stroke survivors experience difficulties with mood and approximately 10% receive a diagnosis of major depression with co-morbid anxiety [29]. Mood difficulties can be further exacerbated and compounded by prolonged stays in hospital [30, 31]. Moreover, it is common for people to experience a range of other emotional and psychological difficulties such as anger, frustration, helplessness, low self-esteem, and apathy [32, 33]. The experience of emotional difficulties has been linked with reduced independence [34], lower quality of life, increased mortality and participation in rehabilitation [35, 36]. Research in other health populations [37, 38] has also indicated that mood has a significant impact on recovery and that functional improvements can be better achieved when both psychological and physical health needs are addressed [39, 40].

Although some research has been conducted into the possible impact of mood on a person's participation with rehabilitation [41], this area remains relatively unexplored.

There is a dynamic and reciprocal relationship between mood and sleep [42, 43]. Clear links have been found between the experiences of low mood and/or anxiety and sleep disturbances in general populations [44]. Furthermore, it has been suggested that individuals who have a lower average SE (a percentage of amount of time asleep compared with the time spend in bed) or sleep difficulties are often less able to cope with the emotional and psychological consequences of difficult situations. This in turn may lead to more experiences of anxiety and depression [45]. Difficult experiences with mood and sleep can have a negative impact on wellbeing, however the bi-directional relationship between mood and sleep is yet to be examined in this population.

With the main aim of stroke rehabilitation activities being to support functional recovery and a return to a meaningful life for the survivor [46], it is unsurprising that improved participation in rehabilitation activities can have a positive impact on overall recovery rates [47]. The link between recovery and participation warrants further investigation in the stroke population; however, research in cancer populations has demonstrated that both mood and sleep deficits can have a negative impact on a person's ability to engage in their rehabilitation activities [48]. Although sleep and mood have been implicated in rehabilitation literature as factors which influence participation, pain has also been noted as an important factor in a person's ability to participate [49]. Empirical findings suggest that experiences of pain as well as a fear of inducing pain during rehabilitation often impede a patient's ability and/or motivation to engage [50]. Pain is an important variable to measure, as research posits that it has impact on both mood and social engagement within a stroke population [51].

The research outlined above indicates that sleep and mood difficulties following stroke are common and linked with poorer outcomes. Furthermore, current evidence suggests that participation in rehabilitation activities is linked with improved levels of functional recovery. There is some evidence to suggest that experiences of poor sleep, low mood and pain can have a negative impact on a person's ability to engage with rehabilitation [52, 53], however, the temporal mechanisms of this association remain unclear. Understanding how sleep and mood may impact a person's ability to engage with rehabilitation is imperative in terms of supporting patients to access rehabilitation to the best of their ability. Increasing participation in rehabilitation may result in improved rates of recovery as well as reducing the length of stay in a rehabilitation unit, reducing the global economic burden of stroke.

The purpose of this study was to evaluate the reciprocal and dynamic relationship between sleep and mood on participation in rehabilitation over time, while controlling for the possible impact of pain using an experience sampling approach (ES). The study aimed to address the following questions:

1. Does sleep predict participation in rehabilitation?
2. Does sleep predict mood, and in turn does mood predict sleep?
3. Does mood predict participation in rehabilitation across time?
4. Does sleep and/or mood predict participation in rehabilitation after controlling for pain.

It was hypothesised that; (i) improved rates of Sleep (SE and TST) would predict increased participation in rehabilitation; (ii) that sleep and mood would demonstrate a reciprocal relationship; (iii) low mood would be negatively related to participation in rehabilitation; (iv) that after controlling for the possible confounding impact of pain, that

improved sleep (SE and TST) and mood would be significantly positively associated with participation in rehabilitation.

Method

An experience sampling (ES) method [54] was employed to evaluate the relationship between sleep, mood, pain and participation in rehabilitation. By collecting daily measures of the variables, the 'real time' relationship between them was determined. This study was reviewed and approved by the National Health Service (NHS) Research and Ethics Committee (REC ref: 17/SC/0421), and by local research and development offices.

Participants

A convenience sample of participants was recruited from one local NHS trust in the Northwest of England. All participants had experienced a stroke (ischaemic or haemorrhagic) as established by medical clinical assessment and either a Computerized Tomography (CT) scan or Magnetic Resonance Imaging (MRI) scan. Participants had been admitted onto an acute stroke ward and resided there for a minimum of 48 hours prior to being invited to participate in this study. All participants were expected to remain as an inpatient for the duration of data collection (between 3-15 days). Participants were required to have a command of the English language sufficient to complete assessments, be fully conscious (or able to awaken to full consciousness during evaluations) and provide informed consent for participation. Participants were required to be orientated to time (year) and place and were all over the age of 18.

Participants were excluded from the study if they: (a) had a current or previous diagnosis of sleep apnoea, (b) had a significant cognitive impairment which impaired their ability to provide informed consent, or (c) had significant impairments to mobility, which inhibited the use of an actigraph.

Measures

All participants completed measures of mood and pain (baseline and daily) as well as an assessment of their current cognitive function at baseline. As this study included participants with aphasia, three of the measures detailed below were selected due to their suitability for use with potential participants who were experiencing significant communication difficulties.

Hospital Anxiety and Depression Scale (HADS). The HADS is a validated, widely-used, self-report scale, in which participants are asked to rate their agreement with seven anxiety and seven depressive items over the previous week on a four-point scale (0 to 3) to give a maximum score of 42 [55]. The HADS excludes most somatic symptoms, therefore avoiding potential confounders in a hospital-based, physically unwell population. The scale has been normed and validated for use within the stroke population [56] and demonstrates acceptable internal consistency (Cronbach's $\alpha = 0.79$) [57].

Depression Intensity Scale Circles (DISCS). The DISCS is a visual measure of low mood and was used to determine current levels of depression with participants who were experiencing aphasia. The DISCS was developed within the context of a brain injury population and has been validated within an aphasia population demonstrating a strong reliability (Cronbach's $\alpha = 0.83$) compared with the Beck Depression Inventory (BDI) [58].

Behavioural Outcome of Anxiety Scale (BOA) - carer. This is a ten-item measure of anxiety where carers of the participants were asked to rate the frequency of participants experiences of anxiety on a four-point scale between 0-3, with maximum possible score of 30 [59]. The BOA-carer has been validated within the stroke population and has demonstrated strong reliability (Cronbach's $\alpha = 0.81$) in identifying experiences of anxiety, [60].

Numerical pain rating scale supplemented with the Faces pain scale - NPRS-FPS. The NPRS-FPS is a visual measure of pain [61] which consists of a 100mm line with 0 (no pain) and 10 (worst possible pain) at the other, the numbers were supplemented with faces indicating a neutral face at 0 and a tearful face at 10. This measure has been validated within a stroke population, with good internal reliability (intra-class correlation coefficient (ICC) = 0.82). This measure was used with both participants with and without aphasia.

Montreal Cognitive Assessment (MoCA). The MoCA [62] is a 30-point global cognitive screening tool used to assess stroke-relevant domains. It has been shown to have good sensitivity in detecting post-stroke cognitive impairment as well as global impairment and has strong internal consistency (Cronbach $\alpha = 0.83$) [63]. Experiences of cognitive impairment has been linked with limited participation with rehabilitation [64]

Oxford Cognitive Scale (OCS). The OCS is a short cognitive screen which provides a profile of the participants' cognitive abilities. This scale has been validated within a population of people experiencing aphasia [65] and has demonstrated fair internal reliability (ICC= .55). This measure was used to assess cognition for participants who have been identified as aphasic.

Visual Analogue Mood Scale -Revised (VAMS-R). The VAMS-R [66] was administered to participants once per day for the length of time they were active in the study. The VAMS has demonstrated validity and reliability in a stroke population, (Cronbach's $\alpha = 0.71$). It measures eight specific mood states (afraid, confused, sad, angry, energetic, tired, happy and tense). Participants in this study were asked only to rate themselves using the 'sad' mood construct, due to this study investigating the relationship between the experience of low mood on participation in rehabilitation [67]. The measure is a simple cartoon face with verbal descriptors of "sad" at one end of the 10-centimetre line and

"neutral" at the other. Results range from 0-100, with higher scores indicating increased experience of sadness. This visual measure was chosen as it places minimal cognitive and linguistic demands on the respondent and is appropriate for neurologically impaired individuals [68]. This measure was used with both aphasic and non-aphasic participants.

Sleep. Objective measurement of sleep-wake patterns was obtained via wrist actigraphy (GENEActive, Activeinsights, Cambs, UK). Actigraphy provides a recording of continuous motor activity and has been used before within the stroke population [69]. All participants were instructed to wear the actigraph on their most mobile wrist for a maximum of 15 days or until discharge. The raw actigraph data was analysed using GGIR [70] which is an open source R package, whose algorithms are designed to characterise sleep and have shown high sensitivity and specificity when characterising sleep patterns. GGIR algorithms use estimated arm angles which are averaged every 5 second epoch and used to assess the change in arm angle between sequential epochs. Periods of time during which there is no change in the arm angle >5◦ over at least five minutes are classified as bouts of sustained inactivity, or potential sleep periods. Total sleep time (TST) and sleep efficiency (SE) were the constructs considered for this study as they have been identified by previous research to be the most impaired functions following stroke [17].

The Pittsburgh Rehabilitation Participation Scale (PRPS). The PRPS has been validated and normed against a stroke population and has been shown to correlate with functional outcomes for patients experiencing neurological and orthopaedic conditions (ICC= 0.91) [71]. The PRPS is a clinician-rated, 6-point Likert-type item measuring patient participation in inpatient rehabilitation sessions. The PRPS was completed by the relevant clinician after each structured session of rehabilitation therapy that the participant was offered, including physiotherapy, speech and language therapy and occupational therapy.

Where participants were involved in more than one session of rehabilitation per day, the mean value of all the scores was used as the daily score.

Procedure

Participants who met the inclusion criteria and gave their informed consent to take part in the study were invited to complete the baseline measures of mood and pain, which were conducted by the lead author (LR). If not already available from routine clinical records, a cognitive screen was conducted by (LR). All verbal measures were read to the participants, who were provided with written response choices in large-point font. Following baseline measures, the participants were provided with an actigraph and were advised that they did not need to take it off for the duration of the study. Each actigraph was set to begin recording at midnight on the night of enrolment into the study. The daily measures of mood, pain and participation commenced the following day and were conducted by members of the research team. Once the participants had completed the study (at a maximum of 15 days or upon discharge from the acute ward), they were debriefed and the actigraph was collected. The daily measures of participation were then retrieved from the clinical team. A copy of all the measures used in the study can be found in section four of this thesis.

Data Analysis

All analyses were conducted using R program [72]. Descriptive/exploratory analyses were computed to evaluate the characteristics of baseline and experience sampling (ES) data. All participant level and day level data were assessed via graphical inspection. To answer the main research questions, a series of hierarchical linear models or multi-level models (MLM) were built. This analysis strategy was able to take into account the nested nature of the data. An initial unconditional means model was used to evaluate levels of

between and within- person variance on participation in rehabilitation and other time variant predictors such as sleep, mood and pain. As a complement to time variant predictors ("state variables"), new "trait average" time invariant predictors were generated and included in final models. Linear growth models using Lag 1 auto-regression with random intercepts and slopes were used to answer the five main questions. This type of model is useful to remove time-dependencies in the data and demonstrated a better fit than those that did not take into account this dependency. Considering the exploratory nature of this study we did not conduct corrections for multiple tests.

Results

Demographics and clinical characteristics

Twenty-five participants were approached to take part in this study. Four participants were excluded due to difficulties with orientation to time and place and one participant due to a pre-existing clinical diagnosis of sleep apnoea. Of the final 20 participants recruited, one withdrew following baseline data collection, resulting in a final sample of 19 with ES data.

The average length of participation in the study was 7.5 days (SD=4.4). Participant age ranged from 56-94 with a mean age of 74 (SD=11.8). The ratio of male to female was relatively equal (53% females). Seventeen participants had an ischemic stroke and left sided deficit was the most common experience (n=12). In terms of baseline evaluations, mean scores for depression and anxiety were 7.5 (SD=5.3) and 8.9 (SD=5.1) respectively. As the clinical cut off score for the HADS is >8, it could be argued that experiences of anxiety and depression for this sample would meet the clinical threshold for mood difficulties within the moderate range [73]. The mean baseline pain score for the sample was 2.3 (SD=2.8), therefore given that the maximum possible score is 10, this is suggestive of lower levels of pain across

the sample [61]. Finally, cognitive functioning scores indicate that on average participates in this sample were experiencing mild cognitive impairment (Mean= 18.9, SD= 6.9). (Table 1).

Insert Table 1

Compliance with the actigraph was good. The mean number of nights of data collected was 7.5 (SD = 4.4), representing a total of 202 measures of sleep across the sample. Daily measures of mood and pain had a 98% collection rate across the sample, which is a result of four missing data points. This equated to one missing day across four participants. Participation in rehabilitation scores were recorded 170 times across the data set, out of a possible 172 sessions of rehabilitation provided. This represented a 99% completion rate. Measures of sleep, mood and pain were collected seven days per week, whereas measures of participation in rehabilitation were collected Monday-Friday as clinical rehabilitation activities were not conducted at the weekends.

Descriptive details of the ES data are also shown in table 1. Mean SE was 63% (SD= 18%), and TST was 396 minutes in a 24-hour period (SD= 136 minutes). In terms of mood, the mean was 25.5 (SD= 33), and the mean of pain was 2.4 (SD= 2.4). Finally, the mean of our main outcome; participation in rehabilitation, was 4.3 (SD = 1.2) out of a possible score of 6, reflecting a high average level of participation across the sample. Figure's 1 to 4 show the state (time variant) and trait (time invariant) predictor variables (sleep, mood, pain). These plots demonstrate the variability across the sample for all predictor variables, specifically how they vary within and between persons. There was significant variability between and within participant's score on daily measures. For example, the between ICC (between person variance) for participation was 34% and the within ICC (within-person variance) was 66%.

Insert Figure 1 to 4

Relationship Between, Sleep, and Mood on Participation in Rehabilitation Following Stroke.

To explore the first research question 'does sleep predict participation in rehabilitation?', two MLM's were conducted which explored the relationship between participation in rehabilitation and both the state and trait versions of the sleep variables, SE and TST. Table 2 shows that SE variables are predictors of participation in rehabilitation. SE state (a time variant predictor) showed a significant association with participation rehabilitation after controlling for SE trait-average (a time invariant predictor) (b=1.58, p=.04). This result indicates the expected difference in participation on a day with one unit increase in SE for a prototypical participant. In other words, on days with higher state sleep efficiency the prototypical participant had higher levels of participation across the following day. Comparatively, neither state nor trait total sleep time was associated with the level of participation in rehabilitation ($p.>.05$) (Table 3).

Insert Tables 2 and 3

To explore the second research question 'does sleep predict mood, and in turn does mood predict sleep?', two MLM's were performed. Analysis revealed that there was no significant reciprocal relationship between either of the sleep constructs and mood. Neither sleep efficiency nor total sleep time (state or trait-average) were associated with mood ($p.>.05$) (Tables 4 and 5). Furthermore, daily mood (state or trait-average) was not a significant prospective predictor of either sleep efficiency or total sleep time ($p. >.05$) (Tables 6 and 7).

Insert Tables 4 to 7

A further MLM was completed to determine the effect of mood on participation in rehabilitation (question three). In line with our hypothesis, the results indicated that mood was a significant predictor of participation in rehabilitation. Table 8 shows that the mood variable (trait average) demonstrated a significant negative association with participation in rehabilitation (*b=-.02, p=.02)* after controlling for mood state. Given that a higher score in the mood variable indicates poorer mood, average lower mood was significantly associated with lower levels of participation.

Finally, to explore the fourth research question 'does sleep and/or mood predict participation in rehabilitation after controlling for pain?', a more stringent MLM, with all predictor variables together was conducted. Daily mood (state) scores (*b*= -.01 *p*=.02) and daily pain (state) (*b*=.12, *p*=.01) both significantly predicted participation levels. (Table 9). These results indicated that low mood was negatively associated with participation in rehabilitation and an increase in pain was positively associated with participation in rehabilitation at a within subject level. Therefore, if a participant was feeling lower in mood today they would have lower levels of participation in rehabilitation tomorrow. Moreover, if a participant had a higher level of pain today, they would have increased levels of participation tomorrow.

Insert Table 9

Discussion

This is one of the first studies to consider the temporal effects of sleep and mood on participation in rehabilitation following stroke in an acute clinical setting. Understanding these effects could allow for the development of guidelines to support better participation in activities of rehabilitation, which may promote improved rates of recovery. The integration of actigraphy and ES enabled the longitudinal assessment of sleep-wake patterns, as well as

the assessment of mood, pain and participation in rehabilitation across various days and nights. Findings from this study indicate that sleep efficiency, mood and pain predict levels of participation and rehabilitation within a sample of stroke participants.

Average sleep efficiency (SE) for the stroke survivors in this sample was 62.7%, which is in line with extant literature [17]. It is widely accepted that SE is an important factor for both mental and physical health [74], with the recommended rate of SE for general populations being more than 80% [75]. Analysis revealed that SE had a significant relationship with participation, which is in line with the first hypothesis. However, this predictive ability did not remain significant when a more stringent model, which included all predictor variables was conducted. SE does not account for as much of the variance in participation in rehabilitation scores as other variables. However, it appears that it may still have a role in participation in rehabilitation as increases in scores of participation can, in some part, be explained by the role of SE, as demonstrated by the first model.

Previous literature has found that a reduction in TST has a negative impact on a person's overall functional recovery from stroke [76]. However, the current study did not find that TST was a significant predictor of participation in rehabilitation. One possible explanation for this is that the participants included in this study were achieving a good amount of sleep when compared with previous literature. Participants were achieving on average 76 minutes more sleep per night, when compared with other stroke populations [17]. High TST could be accounted for by the nature of the sample. Participants on average had experienced their stroke 15.5 days prior to commencing the study and they were all in the early stages of recovery and the body's natural sleep requirement may have been higher than for patients who are further along their recovery journey. This is in line with research by Sommerauer and colleagues (2013) [77] who suggest that increased need for sleep following brain injury may be due to the bodies recovery mechanisms. This increased sleep need is

also supported by literature on the role of sleep in an acute hospital setting [78]. However, increased TST may extend beyond its own helpfulness. A recent study investigated the impact of increased TST in a stroke population and found that patients with higher TST (>8 hours) were at greater risk of experiencing a further stroke [79]. Ezeugwu et al, (2017) [79] posit that this increased risk of further stroke may be due to decreased physical activity which is highly correlated with increased TST.

When interpreting the findings from this study it is useful to consider the mechanism of poor sleep following stroke that has been suggested by Baglioni and colleagues (2016) [17]. They propose that sleep difficulties post-stroke are as a result of the cyclical relationship between poor sleep in the initial stage of stroke recovery and decreased psychological mood and motivation. Experiences of poor sleep leads to a reduction in motivation which impacts on a person's desire and ability to engage in rehabilitation. As such, people may experience a further decrease in mood and sleep. It may be that had this study continued to monitor the participation, sleep and mood of participants following their discharge from hospital, that it would have identified this pattern. This potential relationship is worthy of further investigation in future research.

In line with our third hypothesis, low mood had a significant negative impact on participation. This supports previous findings which have identified that mood difficulties are prevalent in the post-stroke population and may impact on a person's ability to participate in their activities of rehabilitation [80]. These findings have important clinical implications, given that participation in rehabilitation activities results in improved rates of recovery. This study represents further evidence to support the development of both assessment and treatment options for mood following stroke.

Research into the reciprocal relationship between mood and sleep has been well documented in both general and mental health populations [81-83]. Specifically, sleep disturbances have been linked with experiences of both low mood and anxiety in the stroke population [84], as well as low mood being linked with experiences of sleep disruption in both adult [85] and older adult populations [86]. The third research question hoped to explore this relationship further, by investigating the possible predictive ability of each variable on one another. Findings from this study did not demonstrate a predictive relationship between sleep and mood. It is possible that there are a number of reasons for this, such as sample size, and the possible confounding impact of pain. These findings will be discussed below.

The final MLM in this study examined the predictive impact of all variables (sleep, mood and pain) in terms of their possible relationship with participation. It was found that when all variables were included in the model and baseline mood scores were controlled for that daily (state – time variant) mood and pain remained significant predictors of participation in rehabilitation. This finding that daily fluctuations in mood and pain can predict participation in rehabilitation, may mean that there is clinical value in taking into account this day-level interaction. This would allow clinicians to respond to patients' needs as and when they present rather than engaging with experiences of low mood and pain as chronic conditions, that require a diagnostically driven treatment plan.

A further finding of this study is that an increase in pain demonstrates a positive impact on participation in rehabilitation. This finding does not converge with wider health rehabilitation research, which posits that pain is an inhibitory factor for participation in rehabilitation [87]. Indeed, the hypothesis for looking at the relationship between pain and participation in this study was to control for its probable negative relationship. One possible reason for this finding may be the level of pain experienced by participants in this sample was relatively low (mean = 2.4, SD=2.4). Meaning that a 1-unit increase in pain would

range between 3.4-5.8, (on a pain scale of 0-10 where 0 is no pain and 10 is the worst possible pain), suggesting that pain may still have been at a manageable level for the participants.

Clinical and Research Implications

Sleep. This study represents a significant addition to research considering sleep in an acute hospital setting. In line with previous literature, this study investigated sleep across two separate constructs in order to facilitate a more nuanced understanding of the impact of sleep on participation in rehabilitation following stroke. Measuring 'sleep' as one variable does not offer a meaningful understanding of an individual's sleep-wake pattern. This is demonstrated by measurements of SE and TST being different in terms of their ability to predict participation in rehabilitation.

The low SE across the sample reflects that a patient's experience of sleep in an acute stroke rehabilitation setting is challenging and signifies an area for improvement. Research has demonstrated that frequent and prolonged disturbances in sleep can result in protracted and chronic difficulties with ongoing sleep disturbances post-discharge from hospital [88]. Following release from hospital, patients may continue to experience disruption in sleep with significant deficits in SE as they attempt to re-establish a functional sleep schedule [89]. Given that patients who experience low SE routinely report higher levels of psychological and physical difficulty [88], as well as lower overall quality of life [79, 90], addressing hospital sleep environments should be a priority for care providers. Emerging evidence suggests that hospital settings may be able to improve the sleep environments for patients by considering the impact of light [91] and noise pollution [20, 92] during night time hours, as well as finding less invasive methods of continued physical health observation throughout the night. Dubose and Colleagues (2016) [93], posit that small practical changes, such as providing patients with

ear plugs and eye masks, may improve sleep quality. However, in order to make significant and sustained improvements for patient sleep, the sound and light environments need to be addressed at a wider level. Further research is required in this area so as to ensure that all potential improvements to sleep quality can be made.

Robinson et al (2005) posit that the body's healing processes are at their peak during sleep; an important finding when considering the possible clinical impact of this study. However, given that TST has been associated with an increased risk of stroke and this study did not demonstrate any significant relationship with participation in rehabilitation, previous literature espousing the protective or recovery related properties of increased TST should be interpreted with caution. It may be beneficial for overall patient functional recovery for TST to be monitored within the acute recovery setting. In the event of a patient oversleeping (TST >8hrs), increased physical and social activity should be encouraged so as to mediate the impact of any associated functional loss.

Mood. Findings from this study are in line with previous literature that suggests that mood can have a significant impact on a person's ability to engage with activities of rehabilitation following illness or injury [94-96]. Feelings of sadness or worry are very understandable experiences for patients recovering from stroke, given the potential and often inevitable life altering consequences of stroke. Although these feelings are common in a post-stroke population, the underlying causes for this emotional distress are yet to be explored. In order to successfully address patient's experiences of emotional distress, clinicians need to know more about the sources of these difficulties. One possible suggestion would be that during screening, clinicians could use measures that assess the person's actual experience of distress. One such tool could be the Distress Thermometer [97] and the accompanying problem checklist, which asks patients to rate their current level of distress and identify which life domains this distress is generated from. This tool has been

successfully used within cancer services and participants have found it both acceptable and beneficial in terms of facilitating their access to appropriate care [98, 99]. Clinical psychologists working in stroke rehabilitation settings are well placed to support staff and patients to understand more about the genesis of any distress and to use this knowledge to inform any subsequent interventions.

In acute medical settings, it is possible that expressions of emotional distress are viewed by staff teams as clinical experiences that require treatment or intervention. However, often these experiences are normal emotional responses to distressing life events, such as a stroke. It is important for clinical psychologists to work collaboratively with staff teams, supporting them to engage with patients about their experiences of distress and to be alongside the patient, rather than attempting to alleviate a normal human reaction to a traumatic life event.

Pain. Our findings suggest that a small increase in pain is a predictor of increased participation in rehabilitation. This finding was significant even when the impact of mood had been controlled for, suggesting that the predictive value of pain in participation in rehabilitation is independent of its relationship with mood. When we consider this impact of lower levels of pain on participation in rehabilitation, it may be useful to draw on the theoretical concept of pain being a motivator for action [100]. Consequently, participants in this sample who were experiencing lower level average pain, may have found that a small increase in their pain experience acted as a driver for increased participation in rehabilitation. This represents a novel finding and future research is required to understand more about this relationship between pain and participation in rehabilitation.

Methodological Strengths and Limitations

Strengths of the study include a well characterised sample, with multiple measures of sleep, mood, pain, and participation across the sample. In contrast to experimental studies, the current study was an observational study which utilised ES methods. ES is concerned with understanding the association between different variables across time within an individual, rather than a scientific association between variables across groups of people. This is a novel approach, given that current research in this area is dominated by cross-sectional design. Moreover, this study's unique ability to consider both the state and trait versions of predictor variables means that both within and between group associations were able to be tested. Therefore, it may be possible to say that the current study sought to ask/answer questions that were most relevant to those of a clinician, for whom it would be important to know whether a person's participation in rehabilitation post-stroke was impacted by their experiences of mood, sleep, or pain. Although the associations detected do not imply causation between variables, the model's ability to take into account the potential lagged nature of the data helped to establish a temporal precedence between key variables within the acute clinical setting.

The use of actigraphy in this study provided an indirect estimate of sleep, based on physical activity data. Although it does not provide information on participants sleep architecture, like polysomnography, it remains a cost effective, non-invasive method of collecting information about a person's sleep within the environment of interest.

There are some limitations in the study that are inherent in its design. Several supporters of experience sampling studies have cautioned that between-persons and within-person associations can differ in both magnitude and direction [101]. This may in part explain this study's finding that there are differences in the predictive ability of the state and trait versions of the variables.

It has been argued that the process of ES may in fact interfere with the process being observed. This interference has been labelled 'reactivity' and refers to the process of repetitive measurement having an impact on the concept being measured. For example, asking a participant about their mood everyday may have the effect of influencing their mood without the addition of other factors [102, 103]. This issue of reactivity was minimised in this sample as participants had no retrospective access to their data, which has been shown to mitigate the reactivity response [104].

Another possible limitation of this study is that there is no clear guidance on power calculations for multilevel data [105], therefore it is difficult to evaluate the current approach, and as such it was difficult to estimate a recruitment threshold during study design. Future studies should aim to recruit a larger sample and perhaps consider the exploration of variations in the sleep disturbance of patients accessing rehabilitation in hospital, compared with those in a community setting.

The decision to measure sleep using actigraphy alone precluded the measurement of subjective estimations of sleep. However, subjective measures of sleep are susceptible to reporting biases [106] and may have increased the cognitive load of participation on individuals who were already experiencing both physical and emotional stress. A further important factor to consider with the use of actigraphy is that it has a tendency to overestimate sleep and under report wakefulness [102], which has possible implications for this study sample due to the low activity levels of some of the participants. However, attempts were made to mitigate this complication by using the GGIR algorithm of arm angle discussed above. This could be another possible reason for the higher levels of TST in this sample. Furthermore, the sample was opportunistic with the potential bias for the overrepresentation of participants who were experiencing poor sleep.

Finally, in terms of generalisability of the findings, it should be noted that the majority of participants in this study were aged 65+ and were Caucasian in ethnic origin. Furthermore, the research was conducted on an acute stroke recovery ward based within the NHS. While this sample is fairly representative of the wider stroke population in the UK in terms of age, gender and type of stroke, it should be emphasised that there was no ethnic diversity in the sample, meaning that results should be interpreted with caution in a more ethnically diverse setting. There is a possibility that sleep and mood may demonstrate a different relationship to participation in rehabilitation between participants who have different types of stroke, cognitive profiles, or functional ability. Future research that compares the relationship of mood and sleep on participation with clearly defined participant characteristic controls would be required to answer this question.

Conclusion

This study is novel in its investigation of the relationship between sleep, mood and pain on participation in rehabilitation in an acute stroke setting. Findings support previous literature on the relationship between mood and participation in rehabilitation post-stroke, as well as offering novel findings regarding the possible motivating factor of pain. SE in the sample was much lower than recommended levels and increased SE had a positive association with participation scores. The low SE of the participants and its relationship with participation in rehabilitation in this study suggests that sleep difficulties remain a factor for consideration in a hospital setting. Further research is required to conceptualise our understanding of the impact of SE as well as the interplay between mood and pain and their relationship with participation in rehabilitation.

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Table 1

Participants Demographics and Scores on Baseline Measures (n=19)

Demographics/ variables	Mean (SD)	Range
Demographics		
Age (years)	74 (11.8)	56-94
Gender Female, n (%)	10 (52.6%)	
Experience Aphasia n (%)	4 (21%)	
Time since stroke (days)	15.5 (14.4)	2-46
Type of stroke, n (%)	-	-
Ischemic	17 (89%)	-
Haemorrhagic	2 (11%)	-
Side of deficit, n (%)	-	-
Left	12 (63.1%)	-
Right	6 (31.6%)	-
Bilateral	1 (5.3%)	-
Number of medications being taken that might impact sleep/mood	1.2 (1.2)	0-4
Baseline Variables		
Depression (HADS)	7.5 (5.3)	0-18
Anxiety (HADS)	8.4 (5.1)	0-16
Pain (FPRS)	2.3 (2.8)	0-8
Cognitive assessment (MOCA)	18.9 (6.9)	11-29
Experience Sampling		
Sleep Efficiency (%)	62.7%(18%)	8.1-100%
Total Sleep Time (minutes)	396 (136)	0-802
Mood*	25.5 (33)	0-100
Pain*	2.4 (2.4)	0-8
Participation*	4.3 (1.2)	1-6

*Note: * Higher score represents lower mood, increased pain, and improved participation.*

Table 2.

Effect of Sleep Efficiency (State and Trait) on Participation in Rehabilitation.

	Participation in rehabilitation				
				95% CI	
Variable	*b*	*Se*	*P*	Lower	Upper
Intercept	3.78	0.98	0.00	1.85	5.72
Time	-0.01	0.03	0.77	-0.07	0.05
Sleep Efficiency (state)	1.58	0.76	0.04	0.08	3.08
Sleep Efficiency (trait)	-0.80	1.56	0.62	-4.11	2.51

Table 3.

Effect of Total Sleep Time (State and Trait) on Participation in Rehabilitation.

	Participation in rehabilitation				
				95% CI	
Variable	*b*	*Se*	*P*	Lower	Upper
Intercept	4.71	0.80	0.00	3.12	6.29
Time	0.01	0.03	0.83	-0.06	0.07
Total Sleep Time (state)	0.08	0.06	0.12	-0.04	0.21
Total Sleep Time (trait)	-0.15	0.13	0.26	-0.42	0.12

Table 4.

Effect of Sleep Efficiency (State and Trait) on Mood.

	Mood				
				95% CI	
Variable	*b*	*se*	*P*	Lower	Upper
Intercept	23.67	27.19	0.39	-29.97	77.32
Time	-0.40	0.59	0.50	-1.57	0.77
Sleep Efficiency (state)	-19.10	13.25	0.15	-45.26	7.05
Sleep Efficiency (trait)	23.40	43.22	0.59	-68.22	115.02

Table 5.

Effect of Total Sleep Time (State and Trait) on Mood.

	Mood				
				95% CI	
Variable	*b*	*se*	*P*	Lower	Upper
Intercept	5.48	21.40	0.80	-36.78	47.76
Time	-0.70	0.75	0.35	-2.15	0.77
Total Sleep Time (state)	-1.53	1.15	0.18	-3.80	0.74
Total Sleep Time (trait)	4.99	3.33	0.15	-2.08	12.05

Table 6.

Effect of Mood (State and Trait) on Sleep Efficiency.

	Sleep Efficiency				
				95% CI	
Variable	*b*	*se*	*P*	Lower	Upper
Intercept	0.63	0.05	0.00	0.54	0.72
Time	0.00	0.00	0.48	-0.00	0.01
Mood (state)	-0.00	0.00	0.24	-0.00	0.00
Mood (trait)	0.00	0.00	0.89	-0.00	0.00

Table 7.

Effect of Mood (State and Trait) on Total Sleep Time.

	Total Sleep Time				
				95% CI	
Variable	*b*	*se*	*P*	Lower	Upper
Intercept	6.17	0.64	0.00	4.91	7.43
Time	-0.05	0.05	0.26	-0.14	0.04
Mood (state)	-0.01	0.01	0.07	-0.02	0.00
Mood (trait)	0.03	0.02	0.09	-0.01	0.08

Table 8.

The Impact of both State and Trait Mood on Participation in Rehabilitation.

	Participation				
				95% CI	
Variable	*b*	*se*	*P*	Lower	Upper
Intercept	5.05	0.31	0.00	4.46	5.64
Time	-0.01	0.28	0.58	-0.07	0.04
Mood (state)	0.00	0.01	0.95	-0.01	0.01
Mood (trait)	0.02	0.01	0.02	-0.03	-0.01

Table 9

A Stringent model of all Predictor Variables and their effect on Participation in Rehabilitation.

	Participation in rehabilitation				
				95% CI	
Variable	*b*	*se*	*P*	Lower	Upper
Intercept	3.90	0.61	0.00	2.96	5.01
Time	-0.23	0.03	0.43	-0.08	0.03
Sleep Efficiency (state)	0.83	0.60	0.17	-0.35	2.01
Mood (state)	-0.01	0.00	0.02	-0.01	-0.00
Pain (state)	0.12	0.05	0.01	0.03	0.22
Baseline Anxiety	0.00	0.05	0.95	-0.11	0.08
Baseline Depression	-0.01	0.04	0.79	-0.10	0.11

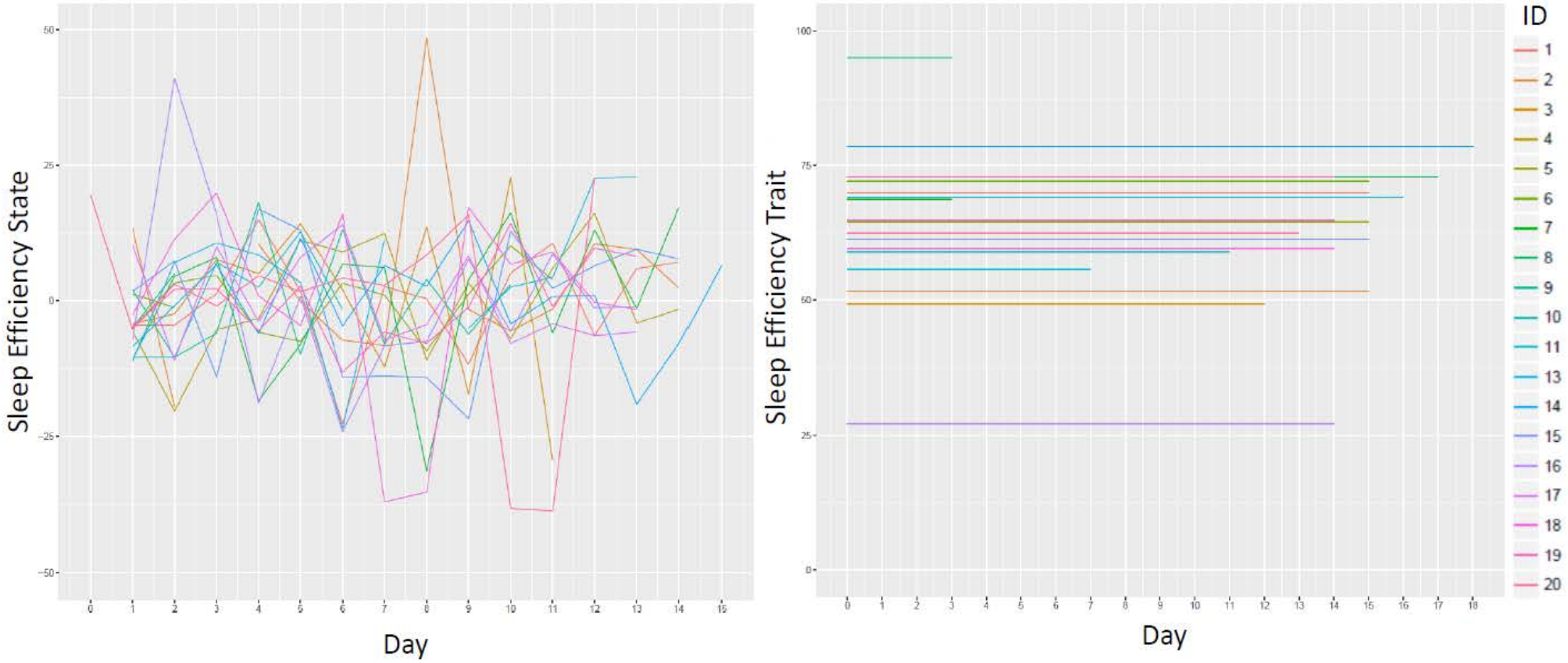

Figure 1. State and trait versions of the data for sleep efficiency: This figure illustrates the level of within and between person variability at both a time variant and time invariant level.

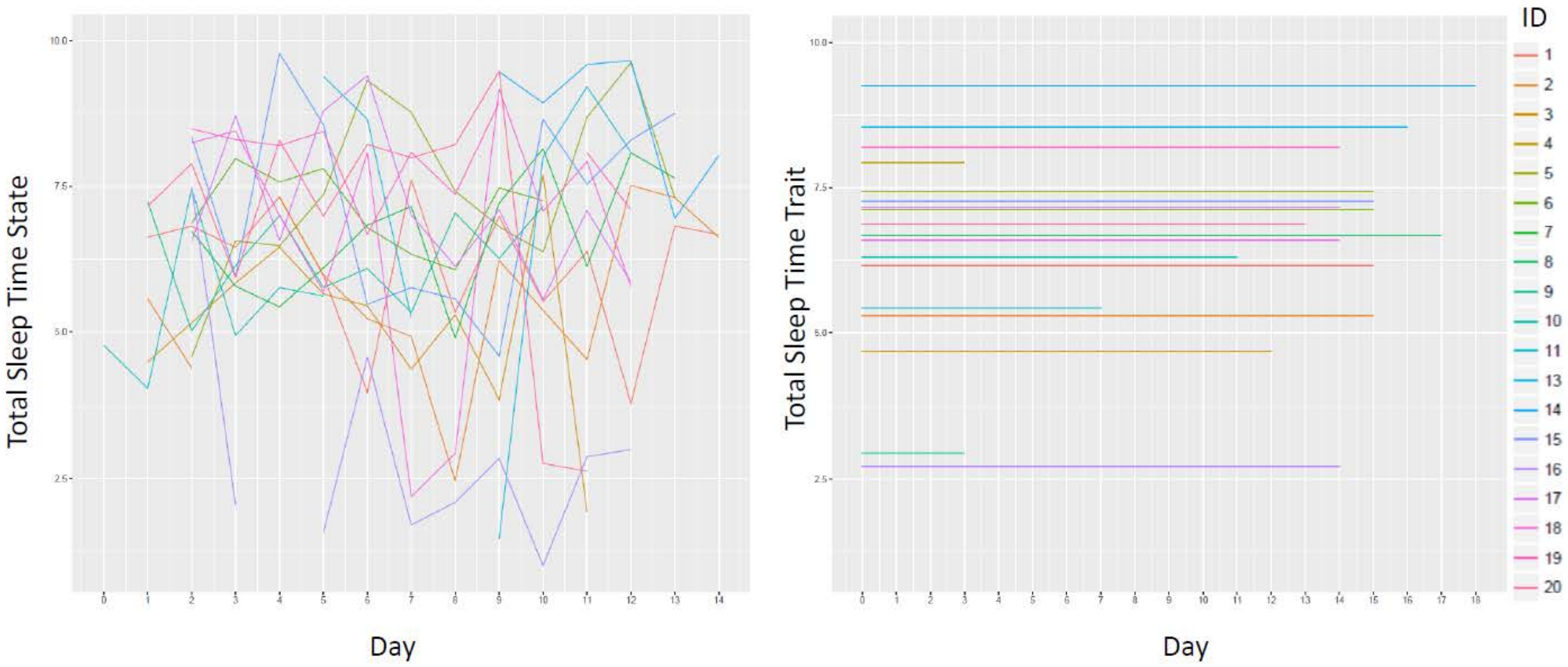

Figure 2. State and trait versions of the data for total sleep time: This figure illustrates the level of within and between person variability at both a time variant and time invariant level.

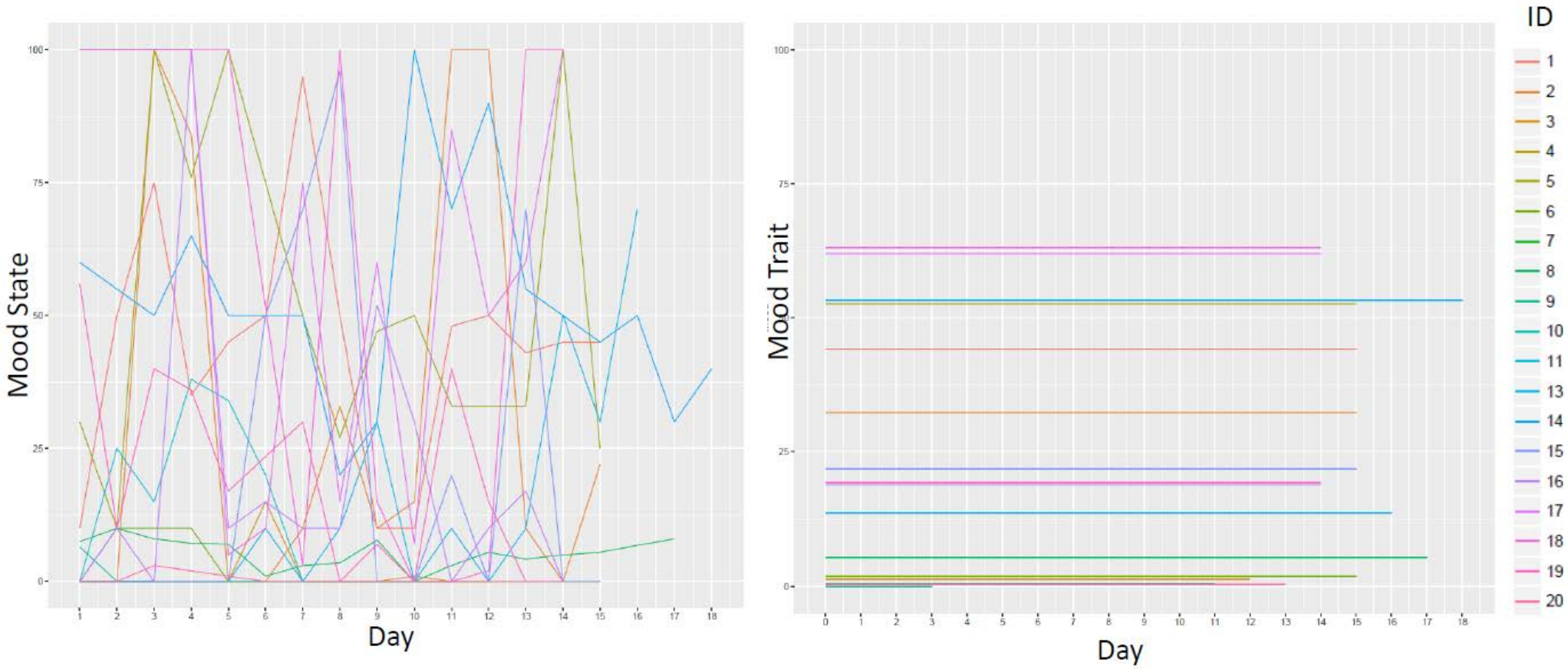

Figure 3. State and trait versions of the data for mood: This figure illustrates the level of within and between person variability at both a time variant and time invariant level.

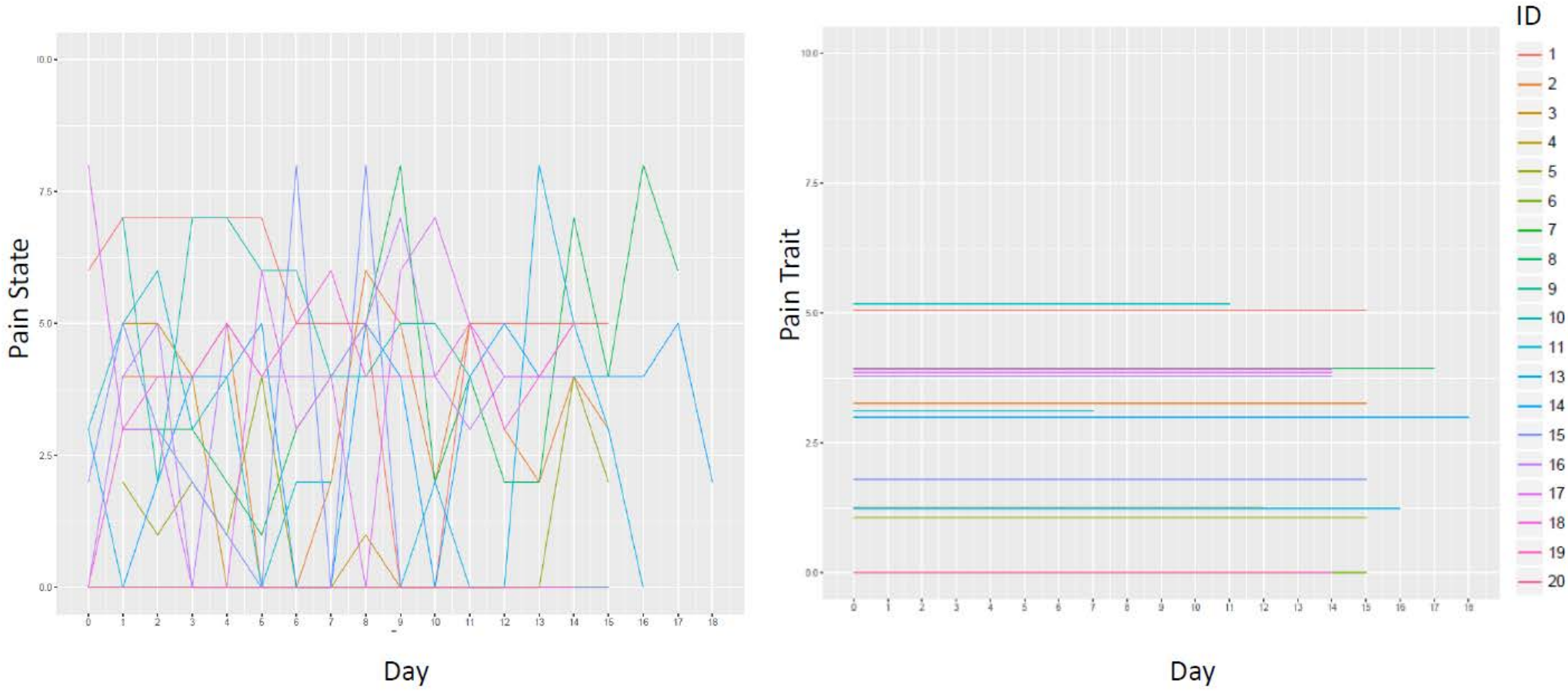

Figure 4: State and trait versions of the data for pain: This figure illustrates the level of within and between person variability at both a time variant and time invariant level.

Doctorate in Clinical Psychology | Lancaster University

Critical Appraisal

Lancaster University

Doctorate in Clinical Psychology

Leona Rose

May 2018

Word Count: 3261, excluding references.

The aim of the critical appraisal is to evaluate both the systematic literature review and the research paper by discussing the salient issues that arose during the completion of this thesis. In the course of reflecting on the systematic review and research paper processes, a number of topics warranted further consideration, however, it was not possible to discuss these in the respective papers. Thus, this critical appraisal will be utilised as a forum for the in-depth consideration of the following topics; the measurement and classification of emotional/psychological distress experienced following stroke; sleep in an acute hospital setting and the opportunities for change; the role of clinical psychology in an acute hospital setting; and conducting an experience sampling study.

This research is particularly timely given the recent publication of the National Clinical Guideline for Stroke [1]. Research has found that the incidence of stroke and its subsequent varying consequences cost the United Kingdom (UK) National Health Service (NHS) approximately £8.9 billion each year, which equates to 5% of the total NHS expenditure [2]. With the prevalence of stroke increasing [3, 4], the pressure to find new methods of supporting stroke survivors in their recovery and subsequent quality of life is mounting.

Systematic Literature Review (Paper 1)

The aim of the review was to examine the effects and where possible the effectiveness of third-wave psychological interventions on the experience of emotional distress following stroke. Third-wave therapies are part of an emerging evidence base in psychological research with participants who experience chronic health difficulties [5]. Given that stoke can lead to chronic and persistent difficulties, third-wave approaches within this group warranted further investigation. Moreover, third-wave approaches are argued to be trans-diagnostic as they tend to

focus on quality of life rather than symptom reduction. These approaches therefore may be beneficial to people who experience a range of emotional difficulties post-stroke.

Previous reviews of interventions targeting emotional distress in stroke have been limited to cognitive behavioural therapy interventions (CBT), mindfulness only interventions, or medication-based treatment options. Therefore, a systematic review was warranted to examine the effects of third-wave approaches. Ten articles were identified and all were systematically appraised. Overall, the included studies demonstrated the positive impact of third-wave approaches in supporting individuals with experiences of emotional distress following stroke. However, existing evidence was weak-to-moderate in quality. Due to the emerging nature of the research, most studies in the review were cohort or case study design. The need for better quality research as well as the development of an adequate and sensitive measure of distress was highlighted.

Empirical Paper (Paper 2)

Paper two examined the relationship between sleep parameters and their temporal relationship with participation in activities of rehabilitation in a hospital based acute stroke setting. A longitudinal analysis was employed using actigraphy and daily measurements of pain, mood and participation over a period of between 3-15 days and nights. The findings indicated that decreased mood predicted lower levels of participation. This association remained significant after controlling for baseline mood scores, as well as pain and sleep. Findings also showed that there was a significant relationship between increased experiences of pain and improved rate of participation. A relationship between poor sleep efficiency (SE) and lower levels of participation in rehabilitation was found. However, once mood and pain were considered in the model alongside SE, only pain and mood were found to significantly and independently predict

participation. Mood should be considered a key target for therapeutic intervention as participation in rehabilitation has been linked with improved rates of functional recovery. Moreover, this recommendation is directly related to the Mental Health Strategy for England, policy, 'There is no Health without Mental Health' (2011) [6].

The assessment of emotional/psychological distress following stroke

Throughout the process of this thesis, both in topic selection (empirical and systematic review papers), and research design, the issue of how best to measure and quantify the distress experienced by individuals following stroke has been challenging. One of the major challenges was deciding which measure of emotional distress would be most suitable for the target population. Currently there is a scarcity of validated tools available for this purpose, and certainly this was even more apparent when brevity of the measure was also an important factor.

For the empirical study aspect of this thesis, two measures of mood were utilised. The Hospital Anxiety and Depression Scale (HADS) [7], as a baseline mood measure and the Revised Visual Analogue Mood Scale – sad item (VAMS-R) [8], as the daily measure of mood. The empirical evidence currently available suggests that both of these measures are reliable and valid in a post-stroke population, however, the author acknowledges that despite empirical evidence, these measures are not without their flaws. The chosen measures did not allow participants to identify their distress across the range of the emotional experiences, instead considering only the constructs of anxiety and depression. In this respect the author was subject to the same limitations as were the studies included in the systematic review (paper 1). The lack of a well-designed and validated measure of emotional distress, which is not narrowly defined by psychiatric diagnosis, has resulted in researchers falling into the trap of measuring

experiences of distress within the diagnostic category of anxiety and depression. This categorical choice is then forced upon participants involved with research. It is possible that when individuals are provided with limited options by which to quantify their distress that they will either choose the best fit option, or perhaps will not indicate their distress at all.

Measuring emotional distress within the constraints of the restrictive constructs of anxiety or depression is not without its controversies. An example of this is that the prevalence rates for post stroke depression (PSD) and post stroke anxiety (PSA) vary considerably within the literature with estimates ranging from 10.6-31.1% [9]. Although these categories are established to increase internal validity there is still variability as to how they are operationalised. One possible reason for this variance is due to how PSD and PSA are conceptualised and assessed, be that with measures based on diagnostic criteria such as the fifth edition of the Diagnostic and Statistical Manual of Mental Disorders [10] or the tenth edition of the International Classification of Diseases [11], or through structured clinical interviews. Ayerbe and colleagues (2014) [12] argue that studies using measures to assess for the presence of mood difficulty may overestimate the prevalence in comparison to clinical interviews. One possible explanation for this is that the psychometric scales may not be nuanced enough to account for the range of emotional expression following a traumatic event such as stroke. Distress can therefore be recorded as either an experience of depression or anxiety when it is possible that the individual is actually experiencing a range of emotions that fall in the sub-clinical level and are likely to resolve without additional intervention. Additionally, the measurement of PSD is not consistent across the literature with different self-rating scales being used to identify its presence [13].

A further possible implication for the way distress is currently measured in the post-stroke population is that we remain unclear as to what the actual experiences are for individuals. That is, we do not know which aspects of the post-stroke emotional sequelae are causing the individual the most distress. Without knowing whether a person needs support with anger, sadness, frustration, shame, or loss, it will be very difficult for current interventions to target the most pertinent emotional difficulties. Moreover, it is likely that a person is not just experiencing one emotion in relation to their experience of stroke, but rather they are dealing with a range of emotions, and that it is the compounded effect of these experiences that causes the distress.

There is a danger that by not engaging with this range of emotional responses in research and by pathologizing them as either anxiety of depression, that we are perpetuating the problematic narrative that emotional distress is not a normal part of the human experience. In doing so we are locating the problem within the person, rather than normalising their experience of distress as a common and understandable response to this traumatic life event.

In summary, there is a need for a more nuanced and suitable measure of emotional distress to be developed; one which can encompass the full spectrum of emotional responses and can offer a shared language for both the client and the clinician to be able to talk about the subtleties of their emotional experience, rather than this experience being separated into specific categories. This measure is needed so that individuals may have a meaningful way to identify their emotional experiences as well as to support the move towards an acceptance of distress as a common experience rather than an abnormal reaction. The measure would also allow clinicians to be able to distinguish when patients need the additional support of interventions and to then be able to target these interventions successfully.

Sleep in an acute hospital setting – opportunities for change

Throughout the process of data collection, the researcher kept a reflective research diary, which included notes from the daily interactions with participants and details of more qualitative accounts of their experiences of sleep. This qualitative information may provide some context for the rate of sleep efficiency (SE) in this sample being 65% which is representative of poor sleep across the sample [14]. Participants in this study largely reflected on how they had slept poorly the night before, indicating that they had woken up several times in the night, or that they had struggled to fall asleep despite the lateness of the hour. The most common reasons provided by participants were environmental in nature, with the most discussed reason for poor sleep being noise on the ward. This is in keeping with previous literature considering hospital sleep environments [15, 16]. Noise disruption was a consistent complaint irrespective of whether participants were in a side room or on a shared ward. However, the reasons for the noise disruption were notably different. Participants on a shared ward noted that noise disruption was due to the medical needs of other patients, such as the need for a respirator or pain relief throughout the night. Additionally, patients who needed attention would press the nurse call alarm and this would sound until a nurse arrived. Some participants complained of other patients talking or snoring loudly in their sleep as being a reason of the night time disruption.

For participants in the single side rooms, they described that noise disruption was due to human traffic in the corridor, as well as staff talking with each other and conducting handovers. These participants noted that although they were in a side room, they were not able to close the door as staff required assess for continued observation. This is interesting to note given that

modern hospital deigns are showing a preference towards single occupancy [17] rooms rather than wards. This move is already somewhat controversial [18] given the increased demand on staff teams to provide continuous care in a fragmented setting, as well as patients experience of loneliness without the companionship of other patients [19]. Future research into sleep in a hospital environment should investigate the possible differences between ward-based and single-room based experiences of sleep.

The second most commonly reported reason for sleep disruption was the ward-imposed sleep opportunity window. Sleep on the ward is often dependant on staff hand over in terms of the transition between night staff and day staff, as well as how quickly staff are able to conduct the nightly check on patients, for both physical observations as well as the dispensing of medication. Staff reported that this was often the result of staffing issues, for example, if there had been an incident during the day, then staff were running behind in the evening, resulting in patients often being woken from their sleep-in order to take medications. Moreover, with day staff usually commencing their shift at 6am, medication was dispensed to patients shortly after this time, which required patients being awoken in order to take medication. Often participants described this process of being woken up to be most disruptive, resulting in an increased difficulty with re-establishing sleep once the medication had been taken. This is not surprising given what we know of sleep architecture [20], which indicates that rapid eye movement (REM) sleep tends to occur in the early hours of the morning or in the later stages of sleep. REM sleep has been found to support memory consolidation and the development of neural pathways of new learning and these processes will be especially relevant in the context of cognitive rehabilitation [21, 22]. This sleep disruption due to ward-based staffing patterns warrants further

investigation, in terms of both the impact of the disruption, as well as exploring the opportunity of using a sleep-hygiene informed approach when staffing the wards.

Finally, the third most commonly reported reason for sleep disruption was lighting. Many of the participants reported that they found it difficult to sleep at night due to the lighting on the ward, and although this lighting was dimmed or switched off at night, staff often needed to switch it back on again when they were carrying out observations on patients. These findings are in line with previous research which suggests that lighting alone is not a significant factor of poor sleep, but rather it is the combination of lights being switched on to facilitate the process of patient monitoring that is disruptive [23]. This process of around-the-clock care is clearly necessary in an acute hospital setting. however, the consequence of sleep disruption and the possible longer-term implications on recovery and participation in rehabilitation require further investigation.

Role of clinical psychologists in an acute clinical setting

Conducting research on an acute stroke rehabilitation ward was both insightful and challenging for a number of reasons. Often the needs of the patients on the wards were complex and susceptible to rapid change in terms of treatment and condition. Ward staff invariably have a series of complex and time-consuming tasks to juggle in providing care to their patients and understandably, physical health needs often supersede psychological wellbeing. One suggested reason for this is that professionals may have some difficulty in recognising the symptoms of mood difficulties due to the nature of stroke and the subsequent hospitalisation [24]. Additionally, at times staff can feel overwhelmed and underequipped to deal with the emotional distress of patients [25]. This distress is then viewed as a role for psychological or medical intervention, when perhaps a human connection of empathy and sitting alongside the

patient may be most beneficial [26]. For this reason, it is especially important for clinical psychologists to support the ward staff to feel equipped to work with emotional distress. Additionally, working in an acute medical setting can be personally demanding for staff, involving working long hours and various shift patterns. Furthermore, as patients are often very unwell in an acute setting the experience of loss is likely to be more frequent, which in turn will increase the emotional burden placed on staff, both by supporting family members as well as the possible interaction with their own life experiences. Consequently, experiences of vicarious trauma, and compassion fatigue are common [27, 28]. Clinical psychologists are uniquely placed to work in this area given the complexity of issues that may present on a stroke or stroke rehab ward, being able to provide support to both staff and patients. This can be done by taking an overview of the reciprocal relationship between the distress of patients and the emotional burden to the staff team and offering both consultation about patients as well as supervision to the ward staff.

Experience Sampling method.

A review of the existing literature highlighted the need for better quality research considering the possible role of sleep and mood on participation in rehabilitation. The application of experience sampling (ES) has increased rapidly over the last fifteen years [29]. ES allows for the exploration of relationships between variables and has high ecological validity. It facilitates the exploration of subjective experiences, whilst minimising recall bias [30]. The experience sampling method utilised in this research facilitated the examination of the link between sleep, mood and participation in rehabilitation in ‘real-time’.

Prior to engaging in the research, the author considered several options for data collection. The number of times the participants were required to provide ratings of their pain

and mood was a significant consideration that was discussed in supervision with the research team. The possible burden on the participants as well as that on the staff team were considered at length. Prior to recruitment it was noted that the general demographics of the post-stroke population were adults over the age of 65 who may be experiencing some level of cognitive difficulty [31]. Taking into account recommendations for research with older people [32], it was decided that the daily measures would be conducted by a researcher with the participants once per day. This would reduce the cognitive load on the participants in terms of the number of ratings and the necessity to remember to note their experiences of mood and pain. Given the often complex and busy working environment outlined above, it was also decided that the author, would endeavour to collect the daily measures of mood and pain herself, rather than adding additional tasks to the nursing staff who were already under pressure. Although this method of data collection was successful in terms of the low rate of missing data across the study, it was at times a challenging task to juggle alongside placement and teaching commitments. While these data collections methods were acceptable for this exploratory study it may be that for larger studies that the experience sampling aspect of investigation could be incorporated into the daily checks of the nursing staff in terms of patient observations. This would potentially allow for data to be collected over a longer period of time, which may provide additional opportunity for analysis in terms of the possible links between sleep, mood and pain in a post-stroke population.

Personal reflections on the research process

Designing and executing an experience sampling study was a substantial challenge alongside other doctoral training duties, however, the author believes this has resulted in novel and interesting research paper. The research process enabled the author to develop new skills

using the statistical packages SPSS and R. Although at times this process felt overwhelming, it allowed the author to reflect on the importance of seeking supervision in order to scaffold new learning and perspective. The author's personal understanding of sleep, mood, pain and the impacts of stroke has grown substantially throughout the research process, which will undoubtedly inform their clinical work.

Conclusion

In summary, the author's wider reflections on the issues covered in this critical appraisal have resulted in several key conclusions. Firstly, the importance of finding a method of understanding individuals' experience of emotional distress is essential to the future development and evaluation of psychological interventions. A second, but equally important function of this measure will be to provide patients with a language around their experiences of distress, rather than current process of a forced choice between anxiety and depression. This language will assist the shared process of understanding between patients and clinical staff, allowing both staff and patients to tolerate the distress within the context of common and understandable human emotions. Secondly, while the role of sleep in an acute hospital setting and its possible impact on patients' ability or desire to participate in their rehabilitation activities requires further exploration, it is clear that sleep disruption plays an important role in patient wellbeing.

Finally, it is important to note that qualitative investigation of patient's experiences may provide a guide to clinical services on where best to intervene for maximum impact in terms of sleep promotion.

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Letters of Ethical Approval, IRAS, and HRA.

NHS
Health Research Authority

South Central - Berkshire Research Ethics Committee
Bristol REC Centre
Whitefriars
Level 3, Block B
Lewins Mead
Bristol
BS1 2NT

Telephone: 0207 104 8043

Please note: This is the favourable opinion of the REC only and does not allow you to start your study at NHS sites in England until you receive HRA Approval

08 August 2017

Ms Leona Rose
Trainee Clinical Psychologist (student)
Lancashire Care Foundation Trust
Division of Health Research
Furness Building
Lancaster University
LA1 4YW

Dear Ms Rose

Study title:	**An examination of sleep and mood in predicting rehabilitation participation in an inpatient stroke population**
REC reference:	**17/SC/0421**
IRAS project ID:	**229207**

The Proportionate Review Sub-committee of the South Central - Berkshire Research Ethics Committee reviewed the above application on 05 August 2017.

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

Ethical opinion

On behalf of the Committee, the sub-committee gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, 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.

1. **IRAS Form:**
   a) Add 'patients lacking the capacity to provide valid consent' to the exclusion criteria.
   b) Remove the plan to inform GPs.
2. **PIS:**
   a) There is no need to inform GPs or treating clinicians – the latter will be informed routinely anyway and the former need not be involved. The Information Sheets can be adjusted by removing the full paragraph near the top of page three.
   b) In the PIS, 'Collecting information….' there is a missing 'day' in the first sentence. Also in the third sentence of 'Questionnaires' there is an extraneous 'at'. Please adjust accordingly.
   c) The maximum number of days of participation is not consistent – the protocol refers to 15 whereas the PIS states 14 – please adjust documents accordingly.
   d) Please add contact details for PALS – in the complaints section.
   e) Please adjust contact information – it will not be easily possible for a patient to telephone or email you. You should suggest that they make contact with you whilst you are on the ward or via ward staff
3. **Consent Form:**

a) Remove clause 11 and 3.
b) Add a line for a witness signature, which might be used in the event of a patient who has capacity not being able to sign the form as a result of their stroke.

Advisory Points:
All documents should be proof read as there are a few typographical errors.

You should notify the REC once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers. Revised documents should be submitted to the REC electronically from IRAS. The REC will acknowledge receipt and provide a final list of the approved documentation for the study, which you can make available to host organisations to facilitate their permission for the study. Failure to provide the final versions to the REC may cause delay in obtaining permissions.

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 HRA Approval (England)/ 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. This should be before the first participant is recruited but no later than 6 weeks after recruitment of the first participant.

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

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

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

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

Ethical review of research sites

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").

Approved documents

The documents reviewed and approved were:

Document	*Version*	*Date*
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [insurance]	0.1	26 July 2017

IRAS Application Form [IRAS_Form_26072017]		26 July 2017
IRAS Checklist XML [Checklist_26072017]		26 July 2017
Letter from sponsor [Sponsorship letter]	0.1	26 July 2017
Other [insurance Doc]	0.1	26 July 2017
Participant consent form [Consent form]	0.1	16 June 2017
Participant consent form [Aphasia Consent form]	0.1	16 June 2017
Participant information sheet (PIS) [Participant information sheet]	0.2	27 June 2017
Participant information sheet (PIS) [Aphasia information sheet]	0.1	16 June 2017
Research protocol or project proposal [Research Protocol]	0.2	27 June 2017
Summary CV for Chief Investigator (CI) [Chief Investigator CV]	0.1	26 July 2017
Validated questionnaire [Depression identity scale]	0.1	
Validated questionnaire [Hospital Anxiety Depression Scale Questionnaire]	0.1	26 July 2017
Validated questionnaire [Behavioural Outcomes of Anxiety Scale Questionnaire]	0.1	26 July 2017
Validated questionnaire [Pain Scale Questionnaire]	0.1	26 July 2017
Validated questionnaire [Visual Anologue mood Scale Questionnaire VAMS]	0.1	26 July 2017
Validated questionnaire [Pittsburgh Rehabilitation Scale Questionnaire]	0.1	26 July 2017

Membership of the Proportionate Review Sub-Committee

The members of the Sub-Committee who took part in the review are listed on the attached sheet.

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/

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

17/SC/0421	**Please quote this number on all correspondence**

Yours sincerely

PP
Mr David Carpenter
Chair

Email: nrescommittee.southcentral-berkshire@nhs.net

Enclosures: *List of names and professions of members who took part in the review*

Copy to: *DR Diane Hopkins*
Ms Cathy Spence, University Hosiptals of South Manchester Trust
Ms Leona Rose, Lancashire Care Foundation Trust

South Central - Berkshire Research Ethics Committee

Attendance at PRS Sub-Committee of the REC meeting on 05 August 2017

Committee Members:

Name	*Profession*	*Present*	*Notes*
Mr David Carpenter (Chair)	Social Scientist	Yes	
Mr Richard Merewood	Director	Yes	
Ms Susan Tonks	Senior Research Support Associate	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Mr Arun Prathapan	REC Assistant
Miss Charlotte Ferris	REC Assistant

Health Research Authority

Ms Leona Rose
Trainee Clinical Psychologist (student)
Lancashire Care Foundation Trust
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LA1 4YW

Email: hra.approval@nhs.net

11 September 2017

Dear Ms Rose

Letter of HRA Approval

Study title:	**An examination of sleep and mood in predicting rehabilitation participation in an inpatient stroke population**
IRAS project ID:	**229207**
REC reference:	**17/SC/0421**
Sponsor	**University of Lancaster**

I am pleased to confirm that **HRA Approval** has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications noted in this letter.

Participation of NHS Organisations in England

The sponsor should now provide a copy of this letter to all participating NHS organisations in England.

Appendix B provides important information for sponsors and participating NHS organisations in England for arranging and confirming capacity and capability. **Please read *Appendix B* carefully**, in particular the following sections:

- *Participating NHS organisations in England* – this clarifies the types of participating organisations in the study and whether or not all organisations will be undertaking the same activities
- *Confirmation of capacity and capability* - this confirms whether or not each type of participating NHS organisation in England is expected to give formal confirmation of capacity and capability. Where formal confirmation is not expected, the section also provides details on the time limit given to participating organisations to opt out of the study, or request additional time, before their participation is assumed.
- *Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria)* - this provides detail on the form of agreement to be used in the study to confirm capacity and capability, where applicable.

Further information on funding, HR processes, and compliance with HRA criteria and standards is also provided.

IRAS project ID	229207

It is critical that you involve both the research management function (e.g. R&D office) supporting each organisation and the local research team (where there is one) in setting up your study. Contact details and further information about working with the research management function for each organisation can be accessed from www.hra.nhs.uk/hra-approval.

Appendices

The HRA Approval letter contains the following appendices:

- A – List of documents reviewed during HRA assessment
- B – Summary of HRA assessment

After HRA Approval

The document *"After Ethical Review – guidance for sponsors and investigators",* issued with your REC favourable opinion, gives detailed guidance on reporting expectations for studies, including:

- Registration of research
- Notifying amendments
- Notifying the end of the study

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

In addition to the guidance in the above, please note the following:

- HRA Approval applies for the duration of your REC favourable opinion, unless otherwise notified in writing by the HRA.
- Substantial amendments should be submitted directly to the Research Ethics Committee, as detailed in the *After Ethical Review* document. Non-substantial amendments should be submitted for review by the HRA using the form provided on the HRA website, and emailed to hra.amendments@nhs.net.
- The HRA will categorise amendments (substantial and non-substantial) and issue confirmation of continued HRA Approval. Further details can be found on the HRA website.

Scope

HRA Approval provides an approval for research involving patients or staff in NHS organisations in England.

If your study involves NHS organisations in other countries in the UK, please contact the relevant national coordinating functions for support and advice. Further information can be found at http://www.hra.nhs.uk/resources/applying-for-reviews/nhs-hsc-rd-review/.

If there are participating non-NHS organisations, local agreement should be obtained in accordance with the procedures of the local participating non-NHS organisation.

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

IRAS project ID	229207

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 research management staff at our training days – see details at http://www.hra.nhs.uk/hra-training/

Your IRAS project ID is **229207**. Please quote this on all correspondence.

Yours sincerely

Maeve Ip Groot Bluemink
Assessor

Email: hra.approval@nhs.net

Copy to: *Dr Diane Hopkins, University of Lancaster – Sponsor Contact*
Ms Cathy Spence, University Hospitals of South Manchester Trust – Lead R&D Contact

IRAS project ID	229207

Appendix A - List of Documents

The final document set assessed and approved by HRA Approval is listed below.

Document	*Version*	*Date*
Contract/Study Agreement template [data protection agreement]		
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [PL & EL 2017-18]		30 June 2017
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [PN 2017-18]		30 June 2017
HRA Schedule of Events	2 (HRA final)	11 September 2017
HRA Statement of Activities	2 (HRA final)	11 September 2017
IRAS Application Form [IRAS_Form_09082017]		09 August 2017
Letter from sponsor [Sponsorship letter]	0.1	26 July 2017
Participant consent form [Aphasia Consent form]	0.2	08 August 2017
Participant consent form [Consent form]	0.2	08 August 2017
Participant information sheet (PIS) [Participant information sheet]	0.4	22 August 2017
Participant information sheet (PIS) [Aphasia information sheet]	0.4	22 August 2017
Research protocol or project proposal [Research Protocol]	0.2	27 June 2017
Summary CV for Chief Investigator (CI) [Chief Investigator CV]	0.1	26 July 2017
Summary CV for supervisor (student research) [Supervisor CV]	0.1	26 July 2017
Validated questionnaire [Depression identity scale]	0.1	
Validated questionnaire [Hospital Anxiety Depression Scale Questionnaire]	0.1	26 July 2017
Validated questionnaire [Behavioural Outcomes of Anxiety Scale Questionnaire]	0.1	26 July 2017
Validated questionnaire [Pain Scale Questionnaire]	0.1	26 July 2017
Validated questionnaire [Visual Anologue mood Scale Questionnaire VAMS]	0.1	26 July 2017
Validated questionnaire [Pittsburgh Rehabilitation Scale Questionnaire]	0.1	26 July 2017

IRAS project ID	229207

Appendix B - Summary of HRA Assessment

This appendix provides assurance to you, the sponsor and the NHS in England that the study, as reviewed for HRA Approval, is compliant with relevant standards. It also provides information and clarification, where appropriate, to participating NHS organisations in England to assist in assessing and arranging capacity and capability.

For information on how the sponsor should be working with participating NHS organisations in England, please refer to the, *participating NHS organisations*, *capacity and capability* and *Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria)* sections in this appendix.

The following person is the sponsor contact for the purpose of addressing participating organisation questions relating to the study:

Name: Dr Diane Hopkins
Tel: 01524592838
Email: ethics@lancaster.ac.uk

HRA assessment criteria

Section	HRA Assessment Criteria	Compliant with Standards	Comments
1.1	IRAS application completed correctly	Yes	No comments
2.1	Participant information/consent documents and consent process	Yes	Changes were made to the PIS and CF by non-substantial amendment after the REC opinion to align them with HRA Approval standards.
3.1	Protocol assessment	Yes	No comments
4.1	Allocation of responsibilities and rights are agreed and documented	Yes	A Statement of Activities has been submitted and it is intended for this to be used as the contract between the Sponsor and NHS sites. The Sponsor has submitted a separate agreement titled 'data protection agreement' for the transfer of data. No judgement on the cost attributions

IRAS project ID	229207

Section	HRA Assessment Criteria	Compliant with Standards	Comments
			has been made
4.2	Insurance/indemnity arrangements assessed	Yes	Sponsor's insurance policy will cover the design and management of the study. NHS indemnity will apply for the conduct of the study while on NHS premises/under the duty of care of the NHS. Where applicable, independent contractors (e.g. General Practitioners) should ensure that the professional indemnity provided by their medical defence organisation covers the activities expected of them for this research study
4.3	Financial arrangements assessed	Yes	No application for external funding has been made. There will be no financial provisions to the sites.
5.1	Compliance with the Data Protection Act and data security issues assessed	Yes	No comments
5.2	CTIMPS – Arrangements for compliance with the Clinical Trials Regulations assessed	Not Applicable	No comments
5.3	Compliance with any applicable laws or regulations	Yes	No comments
6.1	NHS Research Ethics Committee favourable opinion received for applicable studies	Yes	REC Favourable Opinion was issued by the South Central – Berkshire REC.
6.2	CTIMPS – Clinical Trials Authorisation (CTA) letter received	Not Applicable	No comments
6.3	Devices – MHRA notice of no	Not Applicable	No comments

IRAS project ID	229207

Section	HRA Assessment Criteria	Compliant with Standards	Comments
	objection received		
6.4	Other regulatory approvals and authorisations received	Not Applicable	No comments

Participating NHS Organisations in England

This provides detail on the types of participating NHS organisations in the study and a statement as to whether the activities at all organisations are the same or different.
There is one type of participating NHS organisation in England; therefore, there is only one site type. The Chief Investigator or sponsor should share relevant study documents with participating NHS organisations in England in order to put arrangements in place to deliver the study. The documents should be sent to both the local study team, where applicable, and the office providing the research management function at the participating organisation. For NIHR CRN Portfolio studies, the Local LCRN contact should also be copied into this correspondence. For further guidance on working with participating NHS organisations please see the HRA website. If chief investigators, sponsors or principal investigators are asked to complete site level forms for participating NHS organisations in England which are not provided in IRAS or on the HRA website, the chief investigator, sponsor or principal investigator should notify the HRA immediately at hra.approval@nhs.net. The HRA will work with these organisations to achieve a consistent approach to information provision.

Confirmation of Capacity and Capability

This describes whether formal confirmation of capacity and capability is expected from participating NHS organisations in England.
Participating NHS organisations in England **will be expected to formally confirm their capacity and capability to host this research**. • Following issue of this letter, participating NHS organisations in England may now confirm to the sponsor their capacity and capability to host this research, when ready to do so. How capacity and capacity will be confirmed is detailed in the *Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria)* section of this appendix. • The Assessing, Arranging, and Confirming document on the HRA website provides further information for the sponsor and NHS organisations on assessing, arranging and confirming capacity and capability.

IRAS project ID	229207

Principal Investigator Suitability

This confirms whether the sponsor position on whether a PI, LC or neither should be in place is correct for each type of participating NHS organisation in England and the minimum expectations for education, training and experience that PIs should meet (where applicable).
Principal Investigators (PIs) are expected for this type of study. Bethan Charles (Stroke Research Practitioner) has been identified as the PI for University Hospitals of South Manchester Trust. The training expectations are detailed in the Statement of Activities. GCP training is not a generic training expectation, in line with the HRA statement on training expectations.

HR Good Practice Resource Pack Expectations

This confirms the HR Good Practice Resource Pack expectations for the study and the pre-engagement checks that should and should not be undertaken
Use of identifiable patient records held by an NHS organisation to identify potential participants without their prior consent should be undertaken by a member of the direct care team for the patient, so it would not normally be acceptable for this to be done by staff not employed by that organisation. Where contractual arrangements are not already in place, external staff (or similar) undertaking research activities would be expected to obtain Honorary Research Contracts on the basis of a Research Passport (if university employed) or a Letter of Access on the basis of an NHS to NHS confirmation of pre-engagement checks letter (if NHS employed). Standard DBS checks and occupational health clearance would be appropriate.

Other Information to Aid Study Set-up

This details any other information that may be helpful to sponsors and participating NHS organisations in England to aid study set-up.
The applicant has indicated that they do not intend to apply for inclusion on the NIHR CRN Portfolio.

University Hospital of South Manchester NHS
NHS Foundation Trust

Research & Development
First Floor, The NIHR Building
Tel: 0161 291 5770
evelin.peil@manchester.ac.uk

Wythenshawe Hospital
Southmoor Road
Wythenshawe
Manchester
M23 9LT
Tel: 0161 998 7070

25th September 2017

Leona Rose
Trainee clinical Phychologist
Faculty of Health and Research
Furness building
Lancaster University
Lancaster
LA1 4YT

Dear Leona

Letter of access for research

We have received copies of:

- *Your CV*
- *GCP Training Certificate*
- *Validated Research passport*
- *DBS*
- *Occupational Health*

I am pleased to offer you a Letter of Access for University Hospital of South Manchester NHS Foundation Trust based on the documents mentioned above.

In accepting this letter, University Hospital of South Manchester confirms your right of access to conduct research through their organisation for the purpose and on the terms and conditions set out below. This right of access commences on **1st October 2017** and ends on **1st September 2018** unless terminated earlier in accordance with the clauses below.

Your right of access is for the following research projects:

- ***An examination of sleep and mood in predicting rehabilitation participation in an inpatient stroke population***

Please note that you cannot start the research until the Principal Investigator for the research project has received a letter from us giving confirmation from the individual organisation(s) of their agreement to conduct the research.

The information supplied about your role in research at the organisation(s) has been reviewed and you do not require an honorary research contract with the organisation(s). We are satisfied that such pre-engagement checks as we consider necessary have been carried out. Evidence of checks should be available on request to the organisation(s).

You are considered to be a legal visitor to the University Hospital of South Manchester NHS Foundation Trust premises. You are not entitled to any form of payment or access to other benefits provided by the organisation(s) or this organisation to employees and this letter does not give rise to any other relationship between you and the organisation(s), in particular that of an employee.

While undertaking research through at **University Hospital of South Manchester NHS Foundation Trust** you will remain accountable to your substantive employer but you are required to follow the reasonable instructions of the organisation(s) or those instructions given on their behalf in relation to the terms of this right of access.

Where any third party claim is made, whether or not legal proceedings are issued, arising out of or in connection with your right of access, you are required to co-operate fully with any investigation by the organisation(s) in connection with any such claim and to give all such assistance as may reasonably be required regarding the conduct of any legal proceedings.

You must act in accordance with theUniversity Hospital of South Manchester NHS Foundation Trust policies and procedures, which are available to you upon request, and the Research Governance Framework.

You are required to co-operate with the organisation(s) in discharging its/their duties under the Health and Safety at Work etc Act 1974 and other health and safety legislation and to take reasonable care for the health and safety of yourself and others while on the organisations premises. You must observe the same standards of care and propriety in dealing with patients, staff, visitors, equipment and premises as is expected of any other contract holder and you must act appropriately, responsibly and professionally at all times.

If you have a physical or mental health condition or disability which may affect your research role and which might require special adjustments to your role, if you have not already done so, you must notify your employer and each organisation prior to commencing your research role at that organisation.

You are required to ensure that all information regarding patients or staff remains secure and *strictly confidential* at all times. You must ensure that you understand and comply with the requirements of the NHS Confidentiality Code of Practice and the Data Protection Act 1998. Furthermore you should be aware that under the Act, unauthorised disclosure of information is an offence and such disclosures may lead to prosecution.

You should ensure that, where you are issued with an identity or security card, a bleep number, email or library account, keys or protective clothing, these are returned upon termination of this arrangement. Please also ensure that while on the organisations premises you wear your ID badge at all times, or are able to prove your identity if challenged. Please note that the organisation(s) do not accept responsibility for damage to or loss of personal property.

This organisation may revoke this letter and any organisation(s) may terminate your right to attend at any time either by giving seven days' written notice to you or immediately without any notice if you are in breach of any of the terms or conditions described in this letter or if you commit any act that we reasonably consider to amount to serious misconduct or to be disruptive and/or prejudicial to the interests and/or business of the organisation(s) or if you are convicted of any criminal offence. You must not undertake regulated activity if you are barred from such work. If you are barred from working with adults or children this letter of access is immediately terminated. Your employer will immediately withdraw you from undertaking this or any other regulated activity and you MUST stop undertaking any regulated activity immediately.

Your substantive employer is responsible for your conduct during this research project and may in the circumstances described above instigate disciplinary action against you.

No organisation will indemnify you against any liability incurred as a result of any breach of confidentiality or breach of the Data Protection Act 1998. Any breach of the Data Protection Act 1998 may result in legal action against you and/or your substantive employer.

If your current role or involvement in research changes, or any of the information provided in your Research Passport changes, you must inform your employer through their normal procedures. You must also inform your nominated manager in each participating organisation and [the R&D office] in this organisation.

Yours sincerely

Evelin Peil
Research and Development Intern
Research and Development - UNIVERSITY HOSPITAL OF SOUTH MANCHESTER

Welcome to the Integrated Research Application System

IRAS Project Filter

The integrated dataset required for your project will be created from the answers you give to the following questions. The system will generate only those questions and sections which (a) apply to your study type and (b) are required by the bodies reviewing your study. Please ensure you answer all the questions before proceeding with your applications.

Please complete the questions in order. If you change the response to a question, please select 'Save' and review all the questions as your change may have affected subsequent questions.

Please enter a short title for this project (maximum 70 characters)
Sleep & Mood in Stroke Rehab

1. Is your project research?

(●) Yes ( ) No

2. Select one category from the list below:

( ) Clinical trial of an investigational medicinal product

( ) Clinical investigation or other study of a medical device

( ) Combined trial of an investigational medicinal product and an investigational medical device

( ) Other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice

(●) Basic science study involving procedures with human participants

( ) Study administering questionnaires/interviews for quantitative analysis, or using mixed quantitative/qualitative methodology

( ) Study involving qualitative methods only

( ) Study limited to working with human tissue samples (or other human biological samples) and data (specific project only)

( ) Study limited to working with data (specific project only)

( ) Research tissue bank

( ) Research database

If your work does not fit any of these categories, select the option below:

( ) Other study

2a. Will the study involve the use of any medical device without a CE Mark, or a CE marked device which has been modified or will be used outside its intended purposes?

( ) Yes (●) No

2b. Please answer the following question(s):

a) Does the study involve the use of any ionising radiation?	( ) Yes	(●) No
b) Will you be taking new human tissue samples (or other human biological samples)?	( ) Yes	(●) No
c) Will you be using existing human tissue samples (or other human biological samples)?	( ) Yes	(●) No

d) Will the study involve any other clinical procedures with participants (e.g. MRI, ultrasound, physical examination)? ○ Yes ◉ No

3. In which countries of the UK will the research sites be located? *(Tick all that apply)*

- ☑ England
- ☐ Scotland
- ☐ Wales
- ☐ Northern Ireland

3a. In which country of the UK will the lead NHS R&D office be located:

- ◉ England
- ○ Scotland
- ○ Wales
- ○ Northern Ireland
- ○ This study does not involve the NHS

4. Which applications do you require?

IMPORTANT: If your project is taking place in the NHS and is led from England select 'IRAS Form'. If your project is led from Northern Ireland, Scotland or Wales select 'NHS/HSC Research and Development Offices' and/or relevant Research Ethics Committee applications, as appropriate.

- ☑ IRAS Form
- ☐ Confidentiality Advisory Group (CAG)
- ☐ National Offender Management Service (NOMS) (Prisons & Probation)

For NHS/HSC R&D Offices in Northern Ireland, Scotland and Wales the CI must create NHS/HSC Site Specific Information forms, for each site, in addition to the study wide forms, and transfer them to the PIs or local collaborators.

For participating NHS organisations in England different arrangements apply for the provision of site specific information. Refer to IRAS Help for more information.

Most research projects require review by a REC within the UK Health Departments' Research Ethics Service. Is your study exempt from REC review?

○ Yes ◉ No

5. Will any research sites in this study be NHS organisations?

◉ Yes ○ No

5a. Are all the research costs and infrastructure costs (funding for the support and facilities needed to carry out research e.g. NHS Support costs) for this study provided by a NIHR Biomedical Research Centre, NIHR Biomedical Research Unit, NIHR Collaboration for Leadership in Health Research and Care (CLAHRC), NIHR Patient Safety Translational Research Centre or a Diagnostic Evidence Co-operative in all study sites?

Please see information button for further details.

○ Yes ◉ No

Please see information button for further details.

5b. Do you wish to make an application for the study to be considered for NIHR Clinical Research Network (CRN) Support and inclusion in the NIHR Clinical Research Network Portfolio?

Please see information button for further details.

○ Yes ◉ No

The NIHR Clinical Research Network provides researchers with the practical support they need to make clinical studies happen in the NHS e.g. by providing access to the people and facilities needed to carry out research "on the ground".

If you select yes to this question, you must complete a NIHR Clinical Research Network (CRN) Portfolio Application Form (PAF) immediately after completing this project filter question and before submitting other applications. Failing to complete the PAF ahead of other applications e.g. HRA Approval, may mean that you will be unable to access NIHR CRN Support for your study.

6. Do you plan to include any participants who are children?

○ Yes ◉ No

7. Do you plan at any stage of the project to undertake intrusive research involving adults lacking capacity to consent for themselves?

○ Yes ◉ No

Answer Yes if you plan to recruit living participants aged 16 or over who lack capacity, or to retain them in the study following loss of capacity. Intrusive research means any research with the living requiring consent in law. This includes use of identifiable tissue samples or personal information, except where application is being made to the Confidentiality Advisory Group to set aside the common law duty of confidentiality in England and Wales. Please consult the guidance notes for further information on the legal frameworks for research involving adults lacking capacity in the UK.

8. Do you plan to include any participants who are prisoners or young offenders in the custody of HM Prison Service or who are offenders supervised by the probation service in England or Wales?

○ Yes ◉ No

9. Is the study or any part of it being undertaken as an educational project?

◉ Yes ○ No

Please describe briefly the involvement of the student(s):
The principal investigator is completing this project as part of a Clinical Psychology Doctorate Degree.

9a. Is the project being undertaken in part fulfilment of a PhD or other doctorate?

◉ Yes ○ No

10. Will this research be financially supported by the United States Department of Health and Human Services or any of its divisions, agencies or programs?

○ Yes ◉ No

11. Will identifiable patient data be accessed outside the care team without prior consent at any stage of the project (including identification of potential participants)?

○ Yes ◉ No

Integrated Research Application System
Application Form for Basic science study involving procedures with human participants

The Chief Investigator should complete this form. Guidance on the questions is available wherever you see this symbol displayed. We recommend reading the guidance first. The complete guidance and a glossary are available by selecting Help.

Please define any terms or acronyms that might not be familar to lay reviewers of the application.

Short title and version number: (maximum 70 characters - this will be inserted as header on all forms)
Sleep & Mood in Stroke Rehab

PART A: Core study information

1. ADMINISTRATIVE DETAILS

A1. Full title of the research:

An examination of sleep and mood in predicting rehabilitation participation in an inpatient stroke population

A2-1. Educational projects

Name and contact details of student(s):

Name and contact details of academic supervisor(s):

Academic supervisor 1

	Title	Forename/Initials	Surname
	Mr	Guillermo	Perez Algorta
Address	Division of Health Research Furness Building University of Lancaster		
Post Code	LA1 4YW		
E-mail	g.perezalgorta@lancaster.ac.uk		
Telephone			
Fax			

Please state which academic supervisor(s) has responsibility for which student(s):
Please click "Save now" before completing this table. This will ensure that all of the student and academic supervisor details are shown correctly.

Student(s)	Academic supervisor(s)

A copy of a current CV for the student and the academic supervisor (maximum 2 pages of A4) must be submitted with the application.

A2-2. Who will act as Chief Investigator for this study?

- (●) Student
- ( ) Academic supervisor

The Department of Health's Research Governance Framework for Health and Social Care and the research governance frameworks for Wales, Scotland and Northern Ireland set out the requirement for registration of trials. Furthermore: Article 19 of the World Medical Association Declaration of Helsinki adopted in 2008 states that "every clinical trial must be registered on a publicly accessible database before recruitment of the first subject"; and the International Committee of Medical Journal Editors (ICMJE) will consider a clinical trial for publication only if it has been registered in an appropriate registry. Please see guidance for more information.

International Standard Randomised Controlled Trial Number (ISRCTN):

ClinicalTrials.gov Identifier (NCT number):

Additional reference number(s):

Ref.Number Description	Reference Number

A5-2. Is this application linked to a previous study or another current application?

○ Yes ◉ No

Please give brief details and reference numbers.

2. OVERVIEW OF THE RESEARCH

To provide all the information required by review bodies and research information systems, we ask a number of specific questions. This section invites you to give an overview using language comprehensible to lay reviewers and members of the public. Please read the guidance notes for advice on this section.

A6-1. Summary of the study. *Please provide a brief summary of the research (maximum 300 words) using language easily understood by lay reviewers and members of the public. Where the research is reviewed by a REC within the UK Health Departments' Research Ethics Service, this summary will be published on the Health Research Authority (HRA) website following the ethical review. Please refer to the question specific guidance for this question.*

The research is seeking to explore patient's level of engagement in rehabilitation activities such as physiotherapy and speech and language therapy following stroke. The study is interested in whether the mood of the patient or the quality of the sleep they have had the night before will impact on how much they are able to engage with rehabilitation. It will be conducted at Wythenshawe Hospital Manchester, which is part of the University Hospitals of South Manchester NHS Trust.
Research indicates that engaging with rehabilitation activities can have a positive impact on the patient's recovery. Increased engagement in rehabilitation sessions leading to improved recovery rates for patients. There are a number of factors that can have an impact on a person's ability to engage with rehabilitation activities, and research indicates that sleep and mood are both key elements.
However, we remain unclear about which factor will have the most impact on a patients abilities to participate in rehabilitation, and if this factor (sleep or mood) is stable over time. If we know more about the impact of sleep and mood then we will be able to direct interventions in hospital which will give patients the best chance of increased engagement in rehabilitation activities.

A6-2. Summary of main issues. *Please summarise the main ethical, legal, or management issues arising from your study and say how you have addressed them.*

Not all studies raise significant issues. Some studies may have straightforward ethical or other issues that can be identified and managed routinely. Others may present significant issues requiring further consideration by a REC, R&D office or other review body (as appropriate to the issue). Studies that present a minimal risk to participants may raise complex organisational or legal issues. You should try to consider all the types of issues that the different reviewers may need to consider.

This study requires consent from participants that my have some difficulty with speech and comprehension following stoke. In order to mitigate this difficulty and ensure that these participants have the option to participant should they wish to all participant information has been written in an aphasia friendly format, and guidance has been sought on these documents from experts by experience in the form of a Speakeasy group.

The power-imbalance between participants who are users of the hospital service and the interviewer may inhibit their

The Department of Health's Research Governance Framework for Health and Social Care and the research governance frameworks for Wales, Scotland and Northern Ireland set out the requirement for registration of trials. Furthermore: Article 19 of the World Medical Association Declaration of Helsinki adopted in 2008 states that "every clinical trial must be registered on a publicly accessible database before recruitment of the first subject"; and the International Committee of Medical Journal Editors (ICMJE) will consider a clinical trial for publication only if it has been registered in an appropriate registry. Please see guidance for more information.

International Standard Randomised Controlled Trial Number (ISRCTN):

ClinicalTrials.gov Identifier (NCT number):

Additional reference number(s):

Ref.Number	Description	Reference Number

A5-2. Is this application linked to a previous study or another current application?

○ Yes ◉ No

Please give brief details and reference numbers.

2. OVERVIEW OF THE RESEARCH

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Research indicates that engaging with rehabilitation activities can have a positive impact on the patient's recovery. Increased engagement in rehabilitation sessions leading to improved recovery rates for patients. There are a number of factors that can have an impact on a person's ability to engage with rehabilitation activities, and research indicates that sleep and mood are both key elements.
However, we remain unclear about which factor will have the most impact on a patients abilities to participate in rehabilitation, and if this factor (sleep or mood) is stable over time. If we know more about the impact of sleep and mood then we will be able to direct interventions in hospital which will give patients the best chance of increased engagement in rehabilitation activities.

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The power-imbalance between participants who are users of the hospital service and the interviewer may inhibit their

population. A surprising finding, considering the clear links observed between sleep and mood out with the stroke population (Ptaoek, Ying-Hui, & Krystal, 2016; Talbot et al., 2012; Wong et al., 2012).

There remains a lack of experimental investigation into the possible relationship between sleep and mood on participation in rehabilitation activities. Previous methodological limitations mean that as yet we have not been able to make a clear distinction on either the direction of the main effect (sleep or mood). As such further investigation into this area is required.

This study will be an experimental, longitudinal, design which will make use of prospective measures of sleep, mood, and participation in in activities of rehabilitation. We will be measuring the temporal relationships between variables over time, which is a novel approach given that research in this area is dominated by cross- sectional designs. We aim to explore the effect that both (sleep and mood) may have on engagement with rehabilitation. Identifying dynamic mechanisms of both sleep and mood in the post stroke population may lead to more specific therapeutic interventions (Robinson & Jorge, 2016) allowing for a targeted approach to recovery based rehabilitation activities.

A13. Please summarise your design and methodology. *It should be clear exactly what will happen to the research participant, how many times and in what order. Please complete this section in language comprehensible to the lay person. Do not simply reproduce or refer to the protocol. Further guidance is available in the guidance notes.*

All participants will be asked to complete three baseline measures:
-Mood (anxiety and depression)
-Pain
-Cognitive function

Baseline measures will be administered by the principle investigator and will take no longer than 30minutes to complete.

Daily measures:

-Each participant will be asked to wear an actigraph watch on their dominate wrist for a period of 3-15 days (depending on length of stay on the ward, this watch will be looking at the sleep patterns of the participants.
-Participants will be asked to complete mood and pain questionnaires for every day that they are wearing the actigraph, the questionnaire will be administered to the participant by a member of the research team. The questionnaire will take no longer than five minutes to complete.
-Participants will routinely be engaging in rehabilitation activities during their time on the ward, following participant participation in these activities the practitioner will be asked to complete a questionnaire measure of participation. The questionnaire will take no longer than five minutes to complete.

In addition to the above participants will be asked to give consent for the research team to have access to the medical details about their stroke, this is information that is already routinely recorded by the stroke ward and does not present as an additional burden to the participants.

A14-1. In which aspects of the research process have you actively involved, or will you involve, patients, service users, and/or their carers, or members of the public?

- [x] Design of the research
- [ ] Management of the research
- [ ] Undertaking the research
- [ ] Analysis of results
- [x] Dissemination of findings
- [ ] None of the above

Give details of involvement, or if none please justify the absence of involvement.
The speakeasy group reviewed the Participant Information Sheet, and the Consent Form, for the study. They provided recommendations on the format and content of the materials.

They stated that once the recommended amendments were made the materials would be suitably adapted for communication with them and their fellow service-users.

4. RISKS AND ETHICAL ISSUES

RESEARCH PARTICIPANTS

A15. What is the sample group or cohort to be studied in this research?

Select all that apply:

- ☐ Blood
- ☐ Cancer
- ☐ Cardiovascular
- ☐ Congenital Disorders
- ☐ Dementias and Neurodegenerative Diseases
- ☐ Diabetes
- ☐ Ear
- ☐ Eye
- ☐ Generic Health Relevance
- ☐ Infection
- ☐ Inflammatory and Immune System
- ☐ Injuries and Accidents
- ☑ Mental Health
- ☐ Metabolic and Endocrine
- ☐ Musculoskeletal
- ☑ Neurological
- ☐ Oral and Gastrointestinal
- ☐ Paediatrics
- ☐ Renal and Urogenital
- ☐ Reproductive Health and Childbirth
- ☐ Respiratory
- ☐ Skin
- ☐ Stroke

Gender:	Male and female participants
Lower age limit: 18	Years
Upper age limit: 100	Years

A17-1. Please list the principal inclusion criteria (list the most important, max 5000 characters).

Inclusion:
• Command of the English language sufficient to complete assessments and able to provide informed consent for participation
• Expected to remain on the inpatient ward for the duration of the data collection phase (3-15 days)
• Experienced a stroke (both ischaemic & haemorrhagic)
• Fully conscious, somnolent, able to awaken to fully conscious
• Orientated to time (month), place and person
• Be between the ages of 18 and above

A17-2. Please list the principal exclusion criteria (list the most important, max 5000 characters).

Exclusion:
• Unable to participant in meaningful conversation or to point out response alternatives on an interview schedule.
• Significant difficulties with mobility that would inhibit the use of the actigraph (this will be assessed by Physiotherapy colleagues)
• Have a diagnosis of sleep apnoea

RESEARCH PROCEDURES, RISKS AND BENEFITS

A18. Give details of all non-clinical intervention(s) or procedure(s) that will be received by participants as part of the research protocol. *These include seeking consent, interviews, non-clinical observations and use of questionnaires.*

Please complete the columns for each intervention/procedure as follows:

1. Total number of interventions/procedures to be received by each participant as part of the research protocol.
2. If this intervention/procedure would be routinely given to participants as part of their care outside the research, how many of the total would be routine?
3. Average time taken per intervention/procedure (minutes, hours or days)
4. Details of who will conduct the intervention/procedure, and where it will take place.

Intervention or procedure	1	2	3	4
Daily Questionnaires for mood, and pain	16	0	5 minutes	the principle investigator will administer the questionnaires at baseline as well as the daily administration. this will happen by the patients bedside [redacted] Hospitals, University Hospitals of South Manchester Trust
Rehabilitation activities.	1-4	1-4	1-4 hours	Conducted by employed members of clinical staff at University Hospitals of South Manchester Trust.
Baseline measure of mood, pain and cognitive functioning	1	0	30minutes	the PI at University Hospitals of South Manchester Trust.

A21. How long do you expect each participant to be in the study in total?

the participants will be involved in the study for as long as they wish to be for the period of time they remain on the stroke ward, up to a maximum of 15 days. The range of days that a participant can be involved in the study can be 3-15.

A22. What are the potential risks and burdens for research participants and how will you minimise them?

For all studies, describe any potential adverse effects, pain, discomfort, distress, intrusion, inconvenience or changes to lifestyle. Only describe risks or burdens that could occur as a result of participation in the research. Say what steps would be taken to minimise risks and burdens as far as possible.

This research is aimed at understanding the possible relationship between and sleep and mood and the impact that this may have on a patients ability to take part in rehabilitation activities following stroke. It is not anticipated to cause any distress to participants. However all members of the research team will use their clinical expertise to address this appropriately should distress arise during the course of the study.
If any of the research team become concerned that a participant poses a risk of serious harm (to themselves or others) they will inform the treating clinician who will access if any further intervention is necessary.
Participants will also be given advice on the participant information sheet about who to contact if they are experiencing distress.

The contact details for the university's associate dean for research is also provided on the information sheet should participants wish to discuss the project or make a complaint.

A24. What is the potential for benefit to research participants?

Taking part may highlight some difficulties with a participants sleep, if so it is possible that some targeted guidance

can be offered which could improve the patients care.

RECRUITMENT AND INFORMED CONSENT

In this section we ask you to describe the recruitment procedures for the study. Please give separate details for different study groups where appropriate.

A27-1. How will potential participants, records or samples be identified? Who will carry this out and what resources will be used? *For example, identification may involve a disease register, computerised search of social care or GP records, or review of medical records. Indicate whether this will be done by the direct care team or by researchers acting under arrangements with the responsible care organisation(s).*

A briefing will be provided to all clinical staff who work on the stroke ward at [redacted] Hospital regarding the study.
Participants who have experienced a stroke and who have been admitted onto the Stroke ward will be recruited and identified by a members of the research team who have honary contacts with UHSM NHS Trust, and by health professionals in their care team, team who are based on the Stroke Ward at [redacted] Hospital.
All staff will be briefed by Leona Rose (trainee clinical psychologist) and Dr Viki Teggart (clinical neuropsychologist).
The staff will identify whether a patient who has been admitted onto the ward meets the inclusion criteria and if so, the patient will be approached by Leona Rose or Viki Teggart to give the patients information on the research. Participants will be given the participant information sheet (appendix A). These participants will indicate their consent to be contacted again by a member of research team at a later date once they have had an opportunity to consider the information.
Each participant will then be followed up by a member of the research team Leona Rose or Dr Viki Teggart who is based on site at [redacted] Hospital. Participants will be provided with information about the study and will have the opportunity to ask any questions. During this process the participant is welcome to have a friend or family member present; this will be made clear to the participant.
If the participants are still interested in taking part then either Leona Rose or Dr Viki Teggart will check once again that the participant understands the information given in the relevant participant information sheet and then the researcher will take written consent (appendix B). Once consent has been provided, the initial (baseline) questionnaires will be completed (this will be paper based). This gives the participants an opportunity to ask any questions about the study or the questionnaires. In addition, participants will be given an actigraph watch to wear on their most mobile arm for the duration of their involvement in the study.

A27-2. Will the identification of potential participants involve reviewing or screening the identifiable personal information of patients, service users or any other person?

○ Yes ◉ No

Please give details below:

A28. Will any participants be recruited by publicity through posters, leaflets, adverts or websites?

○ Yes ◉ No

A29. How and by whom will potential participants first be approached?

The potential participants will either be approached by the PI personally or by a member of staff as outlined in the recruitment strategy above. This consist of information provision to the patient, if the patient wishes to know more information about the study they will be invited to agree time for meeting the researcher to discuss the study further. this meeting will involve answering any questions the individual has, assessing whether certain inclusion criteria are met and discussing consent.

A30-1. Will you obtain informed consent from or on behalf of research participants?

◉ Yes ○ No

If you will be obtaining consent from adult participants, please give details of who will take consent and how it will be

done, with details of any steps to provide information (a written information sheet, videos, or interactive material). Arrangements for adults unable to consent for themselves should be described separately in Part B Section 6, and for children in Part B Section 7.

If you plan to seek informed consent from vulnerable groups, say how you will ensure that consent is voluntary and fully informed.

consent will be sought during the meeting between the researcher and the patient (and their family member if they wish). The researcher will talk the participant through the consent form and will provide a written copy in which ever format (original or aphasia adapted) is most accessible for the patient. If voluntary informed consent is not gained the participant will not be able to take part in the study.

During the initial meeting between the researcher and the participant it will be made clear to the participant that a refusal to take part in the study will not impact on the care they receive while in hospital. This message will be further reinforced using the participant information sheet.

If you are not obtaining consent, please explain why not.

Please enclose a copy of the information sheet(s) and consent form(s).

A30-2. Will you record informed consent (or advice from consultees) in writing?

(●) Yes ( ) No

A31. How long will you allow potential participants to decide whether or not to take part?

Once participants have been approached by a member of the research team and have been given details of the study they will have 36 hours to make their decision on whether to take part. This will allow time to consult their family or carer's as well as ask any questions of the research team.

A32. Will you recruit any participants who are involved in current research or have recently been involved in any research prior to recruitment?

( ) Yes
(●) No
( ) Not Known

A33-1. What arrangements have been made for persons who might not adequately understand verbal explanations or written information given in English, or who have special communication needs?*(e.g. translation, use of interpreters)*

All of the participant information materials have been adapted to make them accessible to those patients who may be experiencing aphasia.

all research materials and questionnaires will be in English (the language of the researcher). Should a non-English speaking patient wish to participate funding will be sought to translate the research material and employ a translator to conduct initial study interview and obtain consent.

A35. What steps would you take if a participant, who has given informed consent, loses capacity to consent during the study? *Tick one option only.*

( ) The participant and all identifiable data or tissue collected would be withdrawn from the study. Data or tissue which is not identifiable to the research team may be retained.
(●) The participant would be withdrawn from the study. Identifiable data or tissue already collected with consent would be retained and used in the study. No further data or tissue would be collected or any other research procedures carried out on or in relation to the participant.
( ) The participant would continue to be included in the study.

◯ Not applicable – informed consent will not be sought from any participants in this research.

◯ Not applicable – it is not practicable for the research team to monitor capacity and continued capacity will be assumed.

Further details:

If you plan to retain and make further use of identifiable data/tissue following loss of capacity, you should inform participants about this when seeking their consent initially.

CONFIDENTIALITY

In this section, personal data means any data relating to a participant who could potentially be identified. It includes pseudonymised data capable of being linked to a participant through a unique code number.

Storage and use of personal data during the study

A36. Will you be undertaking any of the following activities at any stage (including in the identification of potential participants)?*(Tick as appropriate)*

- ☑ Access to medical records by those outside the direct healthcare team
- ☐ Access to social care records by those outside the direct social care team
- ☐ Electronic transfer by magnetic or optical media, email or computer networks
- ☐ Sharing of personal data with other organisations
- ☐ Export of personal data outside the EEA
- ☐ Use of personal addresses, postcodes, faxes, emails or telephone numbers
- ☐ Publication of direct quotations from respondents
- ☐ Publication of data that might allow identification of individuals
- ☐ Use of audio/visual recording devices
- ☐ Storage of personal data on any of the following:
  - ☑ Manual files (includes paper or film)
  - ☐ NHS computers
  - ☐ Social Care Service computers
  - ☐ Home or other personal computers
  - ☑ University computers
  - ☐ Private company computers
  - ☐ Laptop computers

Further details:
This study will record demographic information from the participants, as well as accessing their medical records (with consent) to gather details specific to their stroke. The study will use questionnaires to gather information from participants about their pain, and mood daily. We will also ask clinical staff involved in the rehabilitation activities with the participants to complete a questionnaire following each rehabilitation session regarding the participants engagement.

Participants will also be asked to wear an actigraphy watch which will measure their sleeping patterns for the length of time they are involved in the study (between 3-15 days). Data will initially be stored on the actigraph, but will be transferred to a secure device once the data has all be collected for that participant.

A37. Please describe the physical security arrangements for storage of personal data during the study?

The data from the questionnaires as well as the demographic information will be transferred from paper format to the researcher's university account and then the paper copy will be destroyed. This data transfer will happen on site at UHSM trust, as so the paper copies will not leave the hospital secure site. The researcher's university account is password protected and is in an encrypted environment. A password protected word document containing the names and corresponding numbers of each participant will also be stored on this secure account, to which only the lead researcher will have access.

The actigraph data will be Transferred from the potable watch to the researchers secure university environment, this transfer will happen on site at UHSM. Once the data has been transferred from the actigraph the data stored on the actigraph will be permanently deleted. Only the researcher will have full access to all the materials. The academic and field supervisors will have access to the anonymised data.

A38. How will you ensure the confidentiality of personal data?*Please provide a general statement of the policy and procedures for ensuring confidentiality, e.g. anonymisation or pseudonymisation of data.*

During the initial consent phases of the research the participant will be assigned a number for identification, this will ensure that the participants data will be kept together while at the same time their anonymity is protected. Only the lead researcher will have access to the identities f the participants which will be stored in the form of a password protected work document, on the researchers secure university account.

A40. Who will have access to participants' personal data during the study? *Where access is by individuals outside the direct care team, please justify and say whether consent will be sought.*

The study will seek consent from the participants to access their medical record for the purposes of gathering information specific to their stroke. This medical record will not be removed from the hospital site and will not be accessed by anyone other than the lead researcher who is a trainee clinical psychology operating within the remit of an honorary research contract with the UHSM trust.

Storage and use of data after the end of the study

A41. Where will the data generated by the study be analysed and by whom?

The information will primarily be analysed by the lead researcher. Several sections will also be analysed by the academic research for quality purposes. The field supervisor will advise on outcomes and interpretation of the analysis. The analysis of the data will take place at Lancaster university and the home of the lead researcher, this will be conducted using a secure virtual private network (VPN)environment, on a password protected computer. The lead researchers home is secured by a house alarm.

A42. Who will have control of and act as the custodian for the data generated by the study?

Title	Forename/Initials	Surname
Mr	Bill	Selwood

Post	Programme Director, Doctorate in Clinical Psychology, Lancaster University
Qualifications	PHD
Work Address	Division of Health Research
	Furness College, Lancaster University, Lancaster
	Lancaste University, Lancaster
Post Code	LA1 4YG
Work Email	b.selwood@lancaster.ac.uk
Work Telephone	01524593398
Fax	01524592401

A43. How long will personal data be stored or accessed after the study has ended?

- (●) Less than 3 months
- ( ) 3 – 6 months
- ( ) 6 – 12 months
- ( ) 12 months – 3 years
- ( ) Over 3 years

A44. For how long will you store research data generated by the study?

Years: 10
Months:

A45. Please give details of the long term arrangements for storage of research data after the study has ended. *Say where data will be stored, who will have access and the arrangements to ensure security.*

Following the completion of the study the data will be stored by the doctorate in clinical psychology programme at the University of Lancaster.

All the data will be saved electronically, including consent forms which will be scanned and saved. The paper copies of all the forms will be securely destroyed following scanning.

All the data will be saved in password protected file space on the university sere in an encrypted environment. Following the researcher's completion of the doctorate access to the data will be transferred to a research coordinator who will have access to the information. For this project this will be the academic supervisor.

INCENTIVES AND PAYMENTS

A46. Will research participants receive any payments, reimbursement of expenses or any other benefits or incentives for taking part in this research?

( ) Yes (●) No

A47. Will individual researchers receive any personal payment over and above normal salary, or any other benefits or incentives, for taking part in this research?

( ) Yes (●) No

A48. Does the Chief Investigator or any other investigator/collaborator have any direct personal involvement (e.g. financial, share holding, personal relationship etc.) in the organisations sponsoring or funding the research that may give rise to a possible conflict of interest?

( ) Yes (●) No

NOTIFICATION OF OTHER PROFESSIONALS

A49-1. Will you inform the participants' General Practitioners (and/or any other health or care professional responsible for their care) that they are taking part in the study?

(●) Yes ( ) No

If Yes, please enclose a copy of the information sheet/letter for the GP/health professional with a version number and date.

A49-2. Will you seek permission from the research participants to inform their GP or other health/ care professional?

(●) Yes ( ) No

It should be made clear in the participant's information sheet if the GP/health professional will be informed.

PUBLICATION AND DISSEMINATION

A50-1. Will the research be registered on a public database?

The Department of Health's Research Governance Framework for Health and Social Care and the research governance frameworks for Wales, Scotland and Northern Ireland set out the requirement for registration of trials. Furthermore: Article 19 of the World Medical Association Declaration of Helsinki adopted in 2008 states that "every clinical trial must be registered on a publicly accessible database before recruitment of the first subject"; and the International Committee of Medical Journal Editors (ICMJE) will consider a clinical trial for publication only if it has been registered in an appropriate registry. Please see guidance for more information.

( ) Yes (●) No

Please give details, or justify if not registering the research.
If the report of this study gets published then the research will be accessible from multiple academic databases.

Please ensure that you have entered registry reference number(s) in question A5-1.

A51. How do you intend to report and disseminate the results of the study? *Tick as appropriate:*

- [x] Peer reviewed scientific journals
- [ ] Internal report
- [x] Conference presentation
- [ ] Publication on website
- [ ] Other publication
- [ ] Submission to regulatory authorities
- [ ] Access to raw data and right to publish freely by all investigators in study or by Independent Steering Committee on behalf of all investigators
- [ ] No plans to report or disseminate the results
- [x] Other (please specify)

The research will seek to publish the study in peer reviewed journal. The target journal identified for this study is Stroke.

The researcher will seek to present at an appropiate conference, this is in addition to presenting the study to university colleagues at a research presentation event. The findings will also be presented to interested staff and service-users at the trust in which the study was conducted.

A52. If you will be using identifiable personal data, how will you ensure that anonymity will be maintained when publishing the results?

no identifiable personal data will be used in the final published study.

A53. Will you inform participants of the results?

(●) Yes ( ) No

Please give details of how you will inform participants or justify if not doing so.

The finding will be presented to interested staff and service user groups within the Trust in which the study will be conducted. Participants taking part in the study will be sent a copy of the final report should they want access to it. They are able to indicate this on the consent form.

5. Scientific and Statistical Review

A54-1. How has the scientific quality of the research been assessed? *Tick as appropriate:*

- ☐ Independent external review
- ☐ Review within a company
- ☐ Review within a multi−centre research group
- ☑ Review within the Chief Investigator's institution or host organisation
- ☐ Review within the research team
- ☑ Review by educational supervisor
- ☑ Other

Justify and describe the review process and outcome. If the review has been undertaken but not seen by the researcher, give details of the body which has undertaken the review:
The academic quality of the research has been assessed by a number of parties. These include Dr. Gullimero Algorta the projects academic supervisor. Dr. Guillermo Algorta who has extensive experience in the supervision of doctoral research and clinical psychology at the University of Lancaster. Dr. Viki Teggart clinical neuropsychologist Greater Manchester Mental Health Trust is acting as field supervisor alongside as Dr. Lee Mulligan at Greater Manchester Mental Health Trust, both Dr. Teggart and Dr. Mulligan have accessed the scientific quality of the research. The research has also been assessed but the University's Research support office and the Trusts Research and Development Department.

For all studies except non-doctoral student research, please enclose a copy of any available scientific critique reports, together with any related correspondence.

For non-doctoral student research, please enclose a copy of the assessment from your educational supervisor/ institution.

A56. How have the statistical aspects of the research been reviewed? *Tick as appropriate:*

- ☐ Review by independent statistician commissioned by funder or sponsor
- ☐ Other review by independent statistician
- ☐ Review by company statistician
- ☐ Review by a statistician within the Chief Investigator's institution
- ☐ Review by a statistician within the research team or multi−centre group
- ☑ Review by educational supervisor
- ☐ Other review by individual with relevant statistical expertise
- ☐ No review necessary as only frequencies and associations will be assessed – details of statistical input not required

In all cases please give details below of the individual responsible for reviewing the statistical aspects. If advice has been provided in confidence, give details of the department and institution concerned.

	Title	Forename/Initials	Surname
	Dr	Guillermo	Perez Algorta
Department	Division of Health and Research		
Institution	Lancaster University		
Work Address	Division of Health and Research Furness College		

	lancaster University
Post Code	LA1 4YG
Telephone	+44 (0)1524 594711
Fax	01524592401
Mobile	
E-mail	g.perezalgorta@lancaster.ac.uk

Please enclose a copy of any available comments or reports from a statistician.

A57. What is the primary outcome measure for the study?

The level of engagement in rehabilitation activities as measured by the Pittsburgh Rehabilitation Participation Scale (PRPS)

A58. What are the secondary outcome measures?*(if any)*

Mood as assessed by the Visual Anologue Mood Scale -Revised (VAMS-R)
Pain as assessed by the Numerical pain rating scale supplemented with the Faces pain scale - NPRS-FPS.
Sleep as measured by actigraph

A59. What is the sample size for the research? *How many participants/samples/data records do you plan to study in total? If there is more than one group, please give further details below.*

Total UK sample size:	20
Total international sample size (including UK):	20
Total in European Economic Area:	20

Further details:

A60. How was the sample size decided upon? *If a formal sample size calculation was used, indicate how this was done, giving sufficient information to justify and reproduce the calculation.*

Using guidance from other ESM studies, we plan to recruit 20 individuals. Therefore, the study could potentially yield 140 sets of data. For the regression, we will have 1 variable as a predictor (sleep score) and 3 variables held as covariates (see statistical procedure). With 4 variables, a data size of 84 would be sufficient to yield a power of around 0.8. As we cannot predict the degree of missing data or participant drop-out rates, we believe a sample of 20 will ensure that at least 84 data sets are gathered to explore our hypotheses

A61-1. Will participants be allocated to groups at random?

○ Yes ◉ No

A62. Please describe the methods of analysis (statistical or other appropriate methods, e.g. for qualitative research) by which the data will be evaluated to meet the study objectives.

Descriptive data on the participants will be assessed and tabulated. Scaled data will be checked for normality and other parametric data assumptions and, where necessary transformed. Statistical analysis will be performed using SAS version 9.4. As the ESM measures have a 3-level hierarchical structure (entry points nested within days nested within participant) we will use multilevel modelling in the analysis to account for the clustering in outcomes within participants. We will calculate summary statistics (mean and variability) of participation for each day. In order to test the hypotheses of this study, and to take into account the nested nature of the data, two multilevel models for discrete outcomes will be generated, with sleep and mood as the independent (predictor) variables in the separate models, participation in rehabilitation activities will form the dependant variable. To account for possible confounding, we will include baseline measures of anxiety, depression, and pain as additional covariates in all the models.

6. MANAGEMENT OF THE RESEARCH

A63. Other key investigators/collaborators. *Please include all grant co-applicants, protocol co-authors and other key members of the Chief Investigator's team, including non-doctoral student researchers.*

	Title Forename/Initials Surname
	Dr Viki Teggart
Post	Clinical Neuropsychologist
Qualifications	BSc. MSc. DClinPsy
Employer	Greater Manchester Mental Health Trust
Work Address	Stroke Rehabilitation Ward, UHSM, [redacted]
Post Code	[redacted]
Telephone	[redacted]
Mobile	
Work Email	Viki.teggart@gmmh.nhs.uk

	Title Forename/Initials Surname
	Dr Lee Mulligan
Post	Clinical Psychologyist
Qualifications	BSC, MSc, DClinPsy
Employer	Greater Manchester Mental Health Trust
Work Address	Community Mental Health Team, Cromwell House CMHT, Cromwell Rd Eccles Manchester
Post Code	M30 0GT
Telephone	+44 (0) 161 787 6000
Fax	
Mobile	
Work Email	Lee.mulligan@gmmh.nhs.uk

	Title Forename/Initials Surname
	Dr Guillermo Perez Algorta
Post	Lecturer in Mental Health
Qualifications	BSc. PHD
Employer	Lancaster University
Work Address	Division of Health Research Furness College Lancaster University, Lancaster
Post Code	LA1 4YG
Telephone	+44 (0)1524 594711
Fax	
Mobile	
Work Email	g.perezalgorta@lancaster.ac.uk

A64. Details of research sponsor(s)

A64-1. Sponsor

Lead Sponsor

Status:
- ○ NHS or HSC care organisation
- ◉ Academic
- ○ Pharmaceutical industry
- ○ Medical device industry
- ○ Local Authority
- ○ Other social care provider (including voluntary sector or private organisation)
- ○ Other

Commercial status: Non-Commercial

If Other, please specify:

Contact person

Name of organisation	University of Lancaster
Given name	Diane
Family name	Hopkins
Address	B floor, Boland Main, Lancaster University
Town/city	Lancaster
Post code	LA1 4WY
Country	UNITED KINGDOM
Telephone	01524595605
Fax	
E-mail	ethics@lancaster.ac.uk

Is the sponsor based outside the UK?

○ Yes ◉ No

Under the Research Governance Framework for Health and Social Care, a sponsor outside the UK must appoint a legal representative established in the UK. Please consult the guidance notes.

A65. Has external funding for the research been secured?

- ☐ Funding secured from one or more funders
- ☐ External funding application to one or more funders in progress
- ☑ No application for external funding will be made

What type of research project is this?

- ◉ Standalone project
- ○ Project that is part of a programme grant
- ○ Project that is part of a Centre grant

◯ Project that is part of a fellowship/ personal award/ research training award

◯ Other

Other – please state:

A66. Has responsibility for any specific research activities or procedures been delegated to a subcontractor (other than a co-sponsor listed in A64-1) ? *Please give details of subcontractors if applicable.*

◯ Yes ◉ No

A67. Has this or a similar application been previously rejected by a Research Ethics Committee in the UK or another country?

◯ Yes ◉ No

Please provide a copy of the unfavourable opinion letter(s). You should explain in your answer to question A6-2 how the reasons for the unfavourable opinion have been addressed in this application.

A68-1. Give details of the lead NHS R&D contact for this research:

	Title Forename/Initials Surname
	Ms Cathy Spence
Organisation	University Hosiptals of South Manchester Trust
Address	Research & Development Directorate First Floor, [redacted]
Post Code	, Manchester [redacted]
Work Email	Cathy.Spence@UHSM.NHS.UK
Telephone	0161 291 4650
Fax	
Mobile	

Details can be obtained from the NHS R&D Forum website: http://www.rdforum.nhs.uk

A69-1. How long do you expect the study to last in the UK?

Planned start date: 01/09/2017

Planned end date: 01/09/2018

Total duration:

Years: 1 Months: 0 Days: 1

A71-1. Is this study?

◉ Single centre

◯ Multicentre

A71-2. Where will the research take place? *(Tick as appropriate)*

☑ England

☐ Scotland
☐ Wales
☐ Northern Ireland
☐ Other countries in European Economic Area

Total UK sites in study

Does this trial involve countries outside the EU?
◯ Yes ◉ No

A72. Which organisations in the UK will host the research? *Please indicate the type of organisation by ticking the box and give approximate numbers if known:*

☑ NHS organisations in England	1
☐ NHS organisations in Wales	
☐ NHS organisations in Scotland	
☐ HSC organisations in Northern Ireland	
☐ GP practices in England	
☐ GP practices in Wales	
☐ GP practices in Scotland	
☐ GP practices in Northern Ireland	
☐ Joint health and social care agencies (eg community mental health teams)	
☐ Local authorities	
☐ Phase 1 trial units	
☐ Prison establishments	
☐ Probation areas	
☐ Independent (private or voluntary sector) organisations	
☐ Educational establishments	
☐ Independent research units	
☐ Other (give details)	
Total UK sites in study:	1

A73-1. Will potential participants be identified through any organisations other than the research sites listed above?

◯ Yes ◉ No

A76. Insurance/ indemnity to meet potential legal liabilities

***Note:** in this question to NHS indemnity schemes include equivalent schemes provided by Health and Social Care (HSC) in Northern Ireland*

A76-1. What arrangements will be made for insurance and/or indemnity to meet the potential legal liability of the sponsor(s) for harm to participants arising from the management of the research? *Please tick box(es) as applicable.*

Note: Where a NHS organisation has agreed to act as sponsor or co-sponsor, indemnity is provided through NHS schemes. Indicate if this applies (there is no need to provide documentary evidence). For all other sponsors, please describe the arrangements and provide evidence.

☐ NHS indemnity scheme will apply (NHS sponsors only)

☑ Other insurance or indemnity arrangements will apply (give details below)

Lancaster University Legal liability cover will apply

following approval by the University's research support office, the office will issue a letter confirming sponsorship of the project.

Please enclose a copy of relevant documents.

A76-2. What arrangements will be made for insurance and/ or indemnity to meet the potential legal liability of the sponsor(s) or employer(s) for harm to participants arising from the design of the research? *Please tick box(es) as applicable.*

Note: Where researchers with substantive NHS employment contracts have designed the research, indemnity is provided through NHS schemes. Indicate if this applies (there is no need to provide documentary evidence). For other protocol authors (e.g. company employees, university members), please describe the arrangements and provide evidence.

☐ NHS indemnity scheme will apply (protocol authors with NHS contracts only)

☑ Other insurance or indemnity arrangements will apply (give details below)

Lancaster University legal liability cover will apply.

Please enclose a copy of relevant documents.

A76-3. What arrangements will be made for insurance and/ or indemnity to meet the potential legal liability of investigators/collaborators arising from harm to participants in the conduct of the research?

Note: Where the participants are NHS patients, indemnity is provided through the NHS schemes or through professional indemnity. Indicate if this applies to the whole study (there is no need to provide documentary evidence). Where non-NHS sites are to be included in the research, including private practices, please describe the arrangements which will be made at these sites and provide evidence.

☑ NHS indemnity scheme or professional indemnity will apply (participants recruited at NHS sites only)

☐ Research includes non-NHS sites (give details of insurance/ indemnity arrangements for these sites below)

Please enclose a copy of relevant documents.

A78. Could the research lead to the development of a new product/process or the generation of intellectual property?

◉ Yes ○ No ○ Not sure

PART C: Overview of research sites

Please enter details of the host organisations (Local Authority, NHS or other) in the UK that will be responsible for the research sites. *For further information please refer to guidance.*

Investigator identifier	Research site	Investigator Name

Full Set of Project Data IRAS Version 5.5.0

IN1

(•) NHS site
( ) Non-NHS site

Country: England

Organisation name	UNIVERSITY *HOSPITAL* OF SOUTH MANCHESTER NHS FOUNDATION TRUST
Address	[redacted] HOSPITAL [redacted] [redacted] MANCHESTER GREATER MANCHESTER
Post Code	[redacted]

Forename	Leona
Middle name	Ann
Family name	Rose
Email	l.magee1@lancaster.ac.uk
Qualification (MD...)	BSc.MSc
Country	UNITED KINGDOM

HRA Statement of Activities

Health Research Authority

for Participating NHS Organisations in England (template version 4.1)

For non-commercial studies, one Statement of Activities should be completed as a template for each site-type in the study. Each Statement of Activities should be accompanied by a completed HRA Schedule of Events, as part of the submission via IRAS for HRA Approval.

Blue shaded fields (also marked with an asterisk) should be completed by the sponsor/applicant prior to submission to the HRA.*
Where appropriate, for the purpose of confirming capacity and capability, green shaded fields (also marked with a caret^) should be completed by the participating organisation before returning the document to the sponsor.
Other questions may be completed either by the sponsor/applicant or participating organisation (or collaboratively between both parties), as appropriate.

For participating organisations in Northern Ireland, Scotland or Wales, the sponsor should transfer a Site Specific Information Form to each local research team for completion and submission to their research management support function.

To provide an answer in the form, click in a box with the blue text and over-write this text, or select the relevant option if presented with drop-down text. A separate guidance document is provided and should be consulted prior to completion of this template. Please also read the question specific guidance where present.

IRAS ID*	229207
Short Study Title*	Sleep & Mood in Stroke Rehab
Full Study Title*	An examination of sleep and mood in predicting rehabilitation participation in an inpatient stroke population
Contact details of sponsor, or sponsor's delegated point of contact (e.g. Study Manager), for questions relating to study set-up*	Dr Diane Hopkins ethics@lancaster.ac.uk +44 (0) 1524 592838
Site Type*	All Site Activities *Select one option. If 'Other', give details.* If 'Other', insert details here

Name of Participating Organisation	*Where this statement is to be used as the agreement between sponsor and participating organisation, the name of the participating organisation should be entered here prior to agreement. If this Statement is being agreed to cover multiple separate entities (e.g. multiple GP practices within a single LCRN geography) please make this clear here.* [redacted]
Location/s within Participating Organisation	*Where the research is planned to take place only at specified hospitals or other locations within the participating organisation (as may be the case in an NHS Trust comprised of more than one hospital) please name those hospitals/locations here.* [redacted]

Date *HRA Office Use Only*	*Date template assessed by HRA*
Version Number	Applicant version assessed by HRA

HRA Office Use Only	

1. Does the sponsor intend that this document forms the agreement between itself and the participating organisation/s in England?*

For non-commercial studies other than clinical trials and clinical investigations, the HRA encourages use of the Statement of Activities as the only form of agreement between sponsor and an English participating organisation, in place of bespoke agreements created by sponsors. For research in primary care settings, the Statement may be used for a geographical area, e.g. at the LCRN level, although agreement should be between the sponsor and independent legal entity (e.g. GP Practice). For clinical trials and clinical investigations the HRA expects that sponsors will use the relevant model agreement, where one exists.

Yes

2. Date this Statement of Activities confirmed by participating organisation, if applicable.^

Enter date confirmed

3. Confirmation on behalf of participating organisation provided by (insert name and job title), if applicable.^

Enter name and job title

It is not intended that this confirmation requires wet-ink signatures, or a passing of hard copies between the sponsor and participating organisation. Instead, sponsors are expected to accept confirmation by email from an individual empowered by the participating organisation to agree to the commencement of research (including any budgetary responsibility, where the study involves the transfer of funds).

4. If this Statement is not intended to form the agreement with the participating organisation/s in England, will the sponsor be using an unmodified model non-commercial agreement?*

Select 'yes' or 'no'

5. If no, please provide details of the modifications made to the model agreement and the reasons for them. If the sponsor intends to use an agreement not based on the model agreement, please provide detailed justification for this (templates of all 'site agreements' to be used, including for sites in the devolved administrations (where applicable) should be provided as part of the submission for HRA Approval).*

Provide details of modification made to model agreement and the reasons for them

6. Predicted Participant Recruitment, if applicable.

This is recruitment or identification at participating organisation, not overall for the study. Please clarify if this refers to participants, samples or data. Please clearly state if this is per month, per year, overall etc. Leave blank if not applicable to this site type.

20 participants to be resruited in total

7. Proposed start date of research/participant identification activity at participating organisation.

Where it might otherwise be open to interpretation, please specify whether this date refers to the commencement of screening, the recruitment of the first participant, etc.

Enter proposed start date (05/10/2017) of research/participant identification activity

Identification and recruitment

8. Predicted end date of research/participant identification activity at participating organisation.

Where it might otherwise be open to interpretation, please specify whether this date refers to the recruitment of the final participant, the final visit of the final participant, database lock, etc.

Enter the proposed end date (05/01/2018) of research/participant identification activity

Completion of recruitment and data collection

9. Person responsible for research activities at site.*

Chief Investigator (Central Study Team)

The HRA expects Principal investigators to be in place at participating organisations where locally employed staff take responsibility for research procedures. Where this is not the case, the HRA expects Local Collaborators to be in place where central study staff will be present at site to undertake research procedures (the role of the Local Collaborator is to support practical arrangements for the presence of research staff under Letters of Access or Honorary Research Contracts). Where existing data is being provided for research purposes without additional research procedures and without the presence of central research team members at site, the HRA does not expect that a Principal Investigator or Local Collaborator is appointed and you should select Chief Investigator.

10. Are you requesting support to identify a Principal Investigator or Local Collaborator?*

Please indicate whether support from the host organisation is being requested to identify a Principal Investigator/Local Collaborator and provide further information on expectations below. Where a Principal Investigator or Local Collaborator has already been identified, their details appear on Part C of the IRAS Form.

No

11. Further Information (where applicable).*

Please provide further information on sponsor expectations for a Principal Investigator/Local Collaborator, to help participating organisations identify an appropriate individual if required (e.g. Profession, specialty, seniority etc.)

Provide information on the support required

12. The following capabilities and capacity are needed locally in order to deliver the study, e.g. specific equipment, patient/participant groups, service support nursing time, excess treatment costs, etc.*

Any funding or support from the sponsor/funder to the participating organisation is set out in the Finance Schedule.

No funding is required. Clinicians involved in the rehabilitation activies (physiotherapy, speech and language therapy) with the participants of the study are required to complete a short (5min) questionnaire about the participants engagment during the rehabilitation session.

13. Projected NHS Treatment Cost savings at this site type, if applicable.*

Although many studies incur Excess Treatment Costs (see AcoRD for information on cost attribution) many studies also give rise to treatment cost savings during the study (e.g. a two armed study comparing standard care to a less intensive, and less expensive, alternative treatment). Please describe below any projected treatment cost savings, so your participating organisations may include this information when considering the overall treatment costs/cost savings of their portfolio of research. Any funding or support from the sponsor/funder to the participating organisation is set out in the Finance Schedule. Excess Treatment Costs will be indicated above (question 12) and in the HRA Schedule of Events.

Provide information on projected treatment cost savings (or leave blank if not applicable)

14. The following training for local staff will be provided by the sponsor. Where only specific team members (e.g. the Principal Investigator) will receive this training, this is described below.*

No specific training is required. Staff at the site will be invited to a briefing with the PI who will discuss the study and how to complete questionnaire materials if required.

15. In addition to the above training, to be provided by the sponsor, the sponsor also expects that the following local research team members will undertake or have already undertaken the following training.*

It would not be usual for the sponsor to expect study specific training additional to that which it will provide, this section does however allow sponsors to state that they will accept, for example, NIHR CRN training in Good Clinical Practice where the study is a Clinical Trial of an Investigational Medicinal Product etc.

No additional training is required

Schedule 1 (Finance) (template version 4.1)

Please select one of the following*	
There are no funds/resources/equipment, etc. being provided to this/these organisation/s by the sponsor. *This schedule should be left blank.**	☒
The following funding/resources/equipment, etc. is to be provided to this/these local participating organisation/s. However, the finance schedule to cover such transfer is detailed in a separate agreement. *Please complete the information below but leave the schedule blank and submit your separate agreement to the HRA.**	☐
Enter information on funding, resource and/or equipment etc. to be provided to the site by the sponsor but do not complete the schedule below	
The following funding/resource/equipment, etc. is to be provided to this local participating organisation. This Statement of Activities is intended by the sponsor to form the agreement between them and the participating organisation. The finance schedule below details the funds to be provided to the site by the sponsor. *Please complete the information and the schedule below.[1]**	☐
Enter information on funding, resource and/or equipment etc. to be provided to the site by the sponsor and also complete the schedule below	

1 Payment Schedule (i.e. frequency or trigger for payments)*
Enter details of payment schedule
2 Area of Cost (e.g. set-up, procedure, overall cost, etc.)*
Enter details on area of cost

Payment Details:

If VAT is payable, then the Sponsor shall pay the VAT in addition to the payment on presentation of a VAT invoice. If VAT is not payable, then the Sponsor shall issue a VAT exemption certificate.

3 Invoices to be submitted to (insert job title, name of body and address)*
Enter address details

4 Payment to be made by cheque to^
Enter cheque payable details
4.1 AND remitted to (insert job title/position and address)
Enter job title/position and address
OR
5 Arrange BACS transfer to: Bank Name
Enter bank name

[1] The Statement of Activities is not intended for use with participating organisations in Northern Ireland, Scotland or Wales

5.1 Sort Code

Enter sort code

5.2 Account Number

Enter account number

5.3 And send the relevant paper work to the following address

Enter address details

Invoices should be presented promptly. No payment shall be made in the case where invoices are not presented in a complete, accurate and timely fashion and funding from an external funding body has been irrecoverably reclaimed by such external funding body as a result of such delay or inadequacy.

Schedule 2 (Material Transfer Provisions)

(template version 4.1)

These provisions do not remove the responsibility for a sponsor to clearly lay out in their protocol (and to potential participants in the patient information sheet/s) at a minimum the following information for all human biological material taken: 1) The nature of the materials, 2) The reason that the material is being taken, 3) where the material is to be sent, 4) what will happen to any remaining material once it has been processed/analysed, etc. for the purposes of this study (e.g. return, retention or destruction).

Detailed guidance on what information should be included in a protocol may be found on the HRA website http://www.hra.nhs.uk

Please select one of the following*	
This study does not involve the transfer of human biological material from this participating organisation to the sponsor or its agents. ***This schedule does not form part of this agreement.****	☒
The Sponsor has separately provided to the HRA and participating organisation an agreement for the transfer of human biological material. ***This schedule does not form part of this agreement.****	☐
These provisions form part of the agreement between the sponsor and this participating organisation. ***Select this option if no other agreement is provided, and the terms below constitute the arrangements for this study.**[2]	☐

1 Where the protocol requires the participating organisation to supply material to the sponsor/joint sponsor(s)/either of the co-sponsors, these provisions shall apply if stated above.

2 In accordance with the protocol, the participating organisation shall send material to the sponsor/joint sponsor(s)/a co-sponsor or, in accordance with provision 8 below, a third party nominated by the sponsor/joint sponsor(s)/either of the co-sponsors.

3 The participating organisation warrants that all material has been collected with appropriate informed consent and has been collected and handled in accordance with applicable law (including, without limitation, the Human Tissue Act 2004 or the Human Tissue (Scotland) Act 2006[3] (as the case may be)) and as required by the protocol.

4 Subject to provision 3 above, the materials are supplied without any warranty, expressed or implied including as to their properties, merchantable quality, fitness for any particular purpose, or that the materials are free of extraneous or biologically active contaminants which may be present in the Materials.

5 The sponsor/joint sponsor(s)/one of the co-sponsors shall ensure, or procure through an agreement with the sponsor/joint sponsor(s)/co-sponsors nominee as stated in provision 2 above that.

5.1 the material is used in accordance with the protocol, the consent of the participant, and the HRA Approval for the Study,

[2] The HRA Statement of Activities is not intended for use with participating organisations in Northern Ireland, Scotland or Wales.

[3] Although the HRA Statement of Activities is not intended for use with participating organisations in Scotland, studies taking place in England might involve transfer of Human Tissue to Scotland for (for example) analysis in a central technical facility.

5.2 the material is handled and stored in accordance with applicable law,

5.3 the material shall not be redistributed or released to any person other than in accordance with the protocol or for the purpose of undertaking other studies approved by an appropriate ethics committee and in accordance with the participant's consent, and

5.4 no alteration shall be made to the title, coding or acronym of the material.

6 The parties shall comply with all relevant laws, regulations and codes of practice governing the research use of human biological material.

7 The participating organisation and the sponsor/joint sponsors(s)/a co-sponsor shall each be responsible for keeping a record of the material that has been transferred according to these provisions.

8 To the extent permitted by law the participating organisation and its staff shall not be liable for any consequences of the supply to or the use by the sponsor/joint sponsors//co-sponsor of the material or of the supply to or the use by any third party to whom the sponsor/joint sponsors/co-sponsor subsequently provides the material or the Sponsor's/Joint Sponsors/Co-Sponsor's nominee as stated in provision 2 above, save to the extent that any liability which arises is a result of the negligence of the participating organisation.

9 The sponsor/joint sponsors/co-sponsor undertake(s) that, in the even that material is provided to a third party in accordance with provision 2 above, it/they shall require that such third party shall undertake to handle any data and Material related to the Study in accordance with all applicable statutory requirements and codes of practice and under terms no less onerous than those set out in these provisions.

10 Any surplus material that is not returned to the participating organisation or retained for future research (in line with participant consent) shall be destroyed in accordance with applicable law (including, without limitation, the Human Tissue Act 2004).

Schedule 3 (Confidentiality, Data Protection and Freedom of Information) (template version 4.1)

Please select one of the following*	
This study does not involve the transfer of Personal Data from this participating organisation to the sponsor or its agents, nor is there transfer of confidential information between the parties. ***This schedule does not form part of this agreement.****	☐
The Sponsor has separately provided to the HRA and participating organisation another agreement for the transfer of data. ***This schedule does not form part of this agreement.****	☐
These provisions form part of the agreement between the sponsor and this participating organisation. ***Select this option if no other agreement is provided, and the terms below constitute the arrangements for this study.**[4]	☒

1. Participant Confidentiality
   1.1. The parties agree to adhere to all applicable statutory requirements and mandatory codes of practice in respect of confidentiality (including medical confidentiality) in relation to participants
   1.2. Personal Data shall not be disclosed to the sponsor by the participating organisation, save where this is required directly or indirectly to satisfy the requirements of the Protocol, or for the purpose of monitoring or reporting adverse events, or in relation to a claim or proceeding brought by a participant in connection with the study.
   1.3. Neither the sponsor nor the participating organisation shall disclose the identity of participants to third parties without the prior written consent of the participant except in accordance with applicable statutory requirements and codes of practice, including HSCIC Code of Practice on Confidential Information.
   1.4. The sponsor agrees to act as Data Controller in relation to any processing of Personal Data under this agreement. This extends to all processing that would not have taken place but for this agreement regardless where that processing takes places. In particular, it extends to processing by the participating organisation where that processing is undertaken solely for the purposes of the study.
   1.5. The sponsor agrees to comply with the obligations placed on a Data Controller by the Data Protection Act 1998. This is not limited to, but includes, ensuring that:
      1.5.1. Personal Data shall be obtained only for one or more specified and lawful purposes, and shall not be further processed in any manner incompatible with that purpose or those purposes
      1.5.2. Personal Data are adequate, relevant and not excessive in relation to the purpose or purposes described within the protocol.
      1.5.3. Personal Data shall be accurate and, where necessary, kept up to date.
      1.5.4. Personal Data shall be processed in accordance with the rights of data subjects under the Data Protection Act 1998.
   1.6. The Sponsor agrees to ensure appropriate training. In particular:
      1.6.1. To ensure that any persons (excluding employees, honorary employees, students, researchers, consultants and subcontractors of the Participating Site) processing

[4] The HRA Statement of Activities is not intended for use with participating organisations in Northern Ireland, Scotland or Wales.

Personal Data are subject to annual mandatory training in the information governance responsibilities and have appropriate contracts including sanctions, including for breach of confidence or misuse of data;

1.6.2. To ensure that the Senior Information Risk Owners, e.g. Caldicott Guardians, senior partners and board members of the sponsor (or organisational equivalent of each of these) complete additional data security training annually.

1.7. The participating organisation agrees to ensure that its employees, honorary employees, students, researchers, consultants and subcontractors processing Personal Data are subject to annual mandatory training in the information governance responsibilities and have appropriate contracts including sanctions, including for breach of confidence or misuse of data;

1.8. The sponsor agrees to use Personal Data solely in connection with the operation of this agreement and the study and not otherwise. In particular;

1.8.1. Not to disclose Personal Data in whole or in part to any person without the participating organisation's prior written consent;

1.8.2. Not to disclose other than pursuant to a data sharing agreement that conforms to the requirements set out in the Information Commissioner's data sharing code of practice.

1.9. The participating organisation agrees to act as Data Processor on behalf of the sponsor as Data Controller for processing undertaken under this agreement solely for the purposes of the study. The participating organisation agrees to comply with the obligations placed on it as the data controller by the seventh data protection principle ("the Seventh Principle") set out in the Data Protection Act 1998, namely:

1.9.3. to maintain technical and organisational security measures sufficient to comply at least with the obligations imposed on the Data Controller by the Seventh Principle;

1.9.4. only to process Personal Data for and on behalf of the Data Controller, in accordance with the instructions of the Data Controller and for the purpose of the study and to ensure the Data Controller's compliance with the Data Protection Act 1998;

1.9.5. to allow the sponsor to audit the participating organisation's compliance with the requirements of this clause on reasonable notice and/or to provide the Data Controller with evidence of its compliance with the obligations set out in this clause;

1.9.6. the participating organisation shall obtain prior agreement of the sponsor to store or process Personal Data at sites outside the European Economic Area (comprising the countries of the European Community, Norway, Iceland and Liechtenstein).

2. Freedom of Information

2.1. Parties to this agreement which are subject to the Environmental Information Regulations 2004 (EIR) and the Freedom of Information Act 2000 (FOIA) or the Freedom of Information (Scotland) Act 2002 (FOI(S)A) and which receive a request under EIR, FOIA or FOI(S)A to disclose any information that belongs to another party shall notify and consult that party, as soon as reasonably practicable, and in any event, not later than seven (7) calendar days after receiving the request.

2.2. The parties acknowledge and agree that the decision on whether any exemption applies to a request for disclosure of recorded information under EIR, FOIA or FOI(S)A is a decision solely for the party responding to the request.

2.3. Where the party responding to an EIR, FOIA or FOI(S)A request determines that it will disclose information it will notify the other party in writing, giving at least four (4) calendar days' notice of its intended disclosure.

3. Confidential information

3.1. The receiving party agrees to take all reasonable steps to protect the confidentiality of the confidential information and to prevent it from being disclosed otherwise than in accordance with this agreement.
3.2. Subject to clause 3.4 below, the participating organisation agrees to treat the results, excluding any clinical data of the study, as confidential information disclosed by the sponsor and the sponsor agrees to treat Personal Data as confidential information disclosed by the participating organisation.
3.3. The receiving party agrees:
    3.3.1. To ensure that any of its employees, students, researchers, consultants or sub-contractors who participate in the operation of the study are made aware of, and abide by, the requirement of this clause 3 and, where relevant, clause 2.
    3.3.2. To use confidential information solely in connection with the operation of the agreement and not otherwise.
    3.3.3. Not to disclose confidential information in whole or in part to any person without the disclosing party's prior written consent.
3.4. The provision of clause 3 shall not apply to the whole or any part of the confidential information that is:
    3.4.1. lawfully obtained by the receiving party free of any duty of confidentiality;
    3.4.2. already in the possession of the receiving party and which the receiving party can show from written records was already in its possession (other than as a result of a breach of clause 3.1 or 3.2);
    3.4.3. in the public domain (other than as a result of a breach of clause 3.1 or 3.2);
    3.4.4. independently discovered by employees of the receiving party without access to or use of confidential information;
    3.4.5. necessarily disclosed by the receiving party pursuant to a statutory obligation;
    3.4.6. disclosed with prior written consent of the disclosing party;
    3.4.7. necessarily disclosed by the receiving party by virtue of its status as a public authority in terms of the Freedom of Information Act 2000;
    3.4.8. published in accordance with HRA expectations on research transparency.
3.5. The restrictions contained in clauses 2 and 3 shall remain in force without limit in time in respect of Personal Data or which relates to a patient, his or her treatment and/or medical records. Save as aforesaid and unless otherwise expressly set out in this Agreement, these clauses shall remain in force for a period of 10 years after the termination or expiry of this Agreement.

Appendix 1 (Staff signature and delegation log) (template version 4.1)

This Appendix is for use at the discretion of the sponsor and participating organisation, to record the roles and responsibilities of the local research team (where applicable) and the authorisation of the Principal Investigator (PI) for this.

Please select one of the following*	
The sponsor intends to use this template as the delegation log for this participating organisation	☒
The sponsor intends to use a delegation log based on another template for this participating organisation	☐
The sponsor is not proposing that a delegation log is completed for this participating organisation	☐

IRAS ID	Name of Participating Organisation
229207	University Hospitals of South Manchester Trust

Name of Principal Investigator	PI's Signature[1]	PI's Initials	Start (dd/mmm/yy)	End (dd/mmm/yy)
Leona Rose			05/10/2017	05/01/2018

[1]My signature confirms/acknowledges that the information contained in this delegation log is accurate and that:

a. I will conduct the study in accordance with the protocol and remain responsible for the overall study conduct at the participating organisation and for the reported data.
b. I will ensure study oversight.
c. I will authorise the delegation of study-related tasks to each individual as listed.
d. The study tasks listed will only be delegated by me to skilled and qualified staff appropriately trained for the role.
e. I will ensure that all personnel assisting in the conduct of the study are informed about their obligations and will not have performed any delegated study-related tasks prior to appropriate delegation and completion of study training appropriate to the role.
f. I will ensure that participating organisation staff receive, in a timely manner, the appropriate information and training.
g. I am not involved in any regulatory or misconduct litigation or investigation by any regulatory authority and no data produced by me in any previous clinical Study has been rejected because of concerns as to its accuracy or because it was generated by fraud.
h. Neither I, nor any dependents, have entered into and will not enter into arrangements, financial or otherwise, with any third party providing support, products and/or services to the study that would present a conflict of interests
i. I will ensure that any and all changes in staff or delegated study-related task will be recorded in a timely manner.
j. I consent to the sponsor, and to any relevant third party providing support, products and/or services to the Study, holding my name and other relevant details on an appropriate database for the purpose of communicating with me in relation to the study.

[2]My signature confirms/acknowledges that I accept the assigned study task/s and that:

- I am not involved in any regulatory or misconduct litigation or investigation by any regulatory authority, and no data produced by me in any previous clinical Study has been rejected because of concerns as to its accuracy or because it was generated by fraud.
- I consent to the sponsor, and to any relevant third party providing support, products and/or services to the study, holding my name and other relevant details on an appropriate database for the purpose of communicating with me in relation to the study.

I confirm that the information contained in this delegation log is accurate and complete. (To be completed by the PI at the end of the study).

PI name: Leona Rose Signature: Date: 11.07.2017

HRA Schedule of Events

Template Version 3.2.2

NHS
Health Research Authority

What is the HRA Schedule of Events?

The HRA Schedule of Events is part of the document submission pack, to be submitted via IRAS for non-commercial studies applying for HRA Approval. It also forms part of the local document pack that sponsors should provide to participating organisations once the templates submitted to the HRA have been agreed and this agreement recorded in the HRA Initial Assessment Lettter (or HRA Approval letter, where no Initial Assessment letter is issued).

For non-commercial studies, one HRA Schedule of Events should be completed as a template for each site-type in the study. Each HRA Schedule of Events should be accompanied by a completed Statement of Activities for the same site-type, as part of the submission via IRAS for HRA Approval. Once agreed by the HRA, the sponsor/applicant should provide each participating organisation with the agreed Schedule and related agreed Statement relevent for its site-type. Applicants should refer to the guidance document for the Statement of Activities template for further information on use of the two tools.

Together with the Statement of Activities, the Schedule is designed to facilitate the conversation between sponsor/applicant and their partcipating organisations through which local capacity and capability to undertake the study are assessed and arranged and thereafter confirmed as being in place. The Schedule is designed to allow the sponsor/applicant to detail the activities to take place at the participating organisations that come under the site-type covered by the document and to indicate the cost attribution of each activity.

Each activity recorded in the Schedule should be given a cost attribution by the sponsor/applicant, in line with the DH AcoRD guidance available here: https://www.gov.uk/government/publications/guidance-on-attributing-the-costs-of-health-and-social-care-research

Each completed Schedule should reflect the activities to be undertaken at the organisations to be covered by the document. Studies where the activities undertaken at different organisations differ (i.e. there is more than one 'site-type' in the study) should have one Schedule submitted to the HRA per site type, with each Schedule reflecting the activities to be undertaken at one site-type.

What is a 'Site Type'?
Many research studies take place at more than one participating organisation. Where this is the case, each participating organisation may be undertaking the same research procedures, e.g. identifying, consenting, treating and following-up research participants. In such cases the study has only one 'site-type' and only one Schedule and one accompanying Statement are required. In other cases, different participating organisations may be undertaking different sub-sets of the overall set of research procedures that make up the study, e.g. some participating organisations may identify and consent participants whilst others treat and follow-up. In such a case there would be two 'site-types' and two Schedules of Events and two Statements of Activities would be submitted, with each Shedule/Statement covering one site-type. It is important to note that the number of Schedules to be submitted by the sponsor for HRA Approval is determined by the number of site-types, not by the number of sites.

How Do I Complete this Document?
Please answer the first four questions in the Study Information tab. Complete one HRA Schedule of Events per site-type, specifying the site-type under questions 3 (and 4, if necessary) of the Study Information tab.

Please complete the General Activities and Per-Participant tabs for the site-type covered by this document. Select an item from "Area of Activity" first, before selecting an item from

"Specific Activity" (the "Specific Activity" drop-down box is only present once an "Area of Activity" is selected). Activities should be selected from the drop-down lists where possilble (for ease of reference, activities in the drop downs are listed alphabetically on the List of Activities tab). Where an activitiy is not listed, it should be entered in free-text. Only activities that take place per-participant should be listed on the per-participant tab. Where the study has more than one arm, or the activities otherwise differ between groups of participants, the tab may be copied and each arm/group recorded as a new tab. For each instance of each activity, a cost attribution should be selected from the drop-down list (e.g. Research Cost (Part A), Research Cost (Part B) etc.). Where an activity does not occur at a particular visit, the box may be left blank or "No Activity" may be selected. Each box may be populated individually from the drop down, or cost types may be 'pulled across' an entire row (see Hints and Tips tabs for further details).

Hints and Tips
Please read the Hints and Tips tab before completing the General Activities and Per-Participant tabs.

List of Activities
This section provides definitions of / more information on activities given in the General Activities and Per-Participan drop-down lists. It is not an exhaustive list of all possible activities associated with a research project and applicants may enter additional activities by free-text in the general activities and/or participant activities tabs. Applicants are invited to use the User Feedback tab to comment on the usefulness of the activities given and to suggest the inclusion of additional activities in future versions of this tool.

How do I submit my HRA Schedule of Events to the HRA?
All submissions for HRA Approval should be made electronically through IRAS. The Schedule of Events forms part of the document set that should be uploaded to the IRAS Form checklist tab prior to submission. To upload your Schedule/s please select 'Add New Row' at the bottom of the checklist tab . Please attach one Schedule per 'Other (please specify)' row.

Accessing Help and Support Completing this Document
Please refer in the first instance to the guidance below and the Hints & Tips tab. Additional queries may be addressed to hra.approval@nhs.net

User Feedback
The HRA wants to hear from you about this document. Whether you work for a sponsor or organisation hosting research, whether within cohort 3 or not, we want your views. Formal feedback may be provided by completing the User Feedback tab in this spreadsheet and returning it to hra.approval@nhs.net

End of General Guidance.

Research Protocol.

An examination of sleep and mood in predicting rehabilitation participation in an inpatient stroke population

Version 0.2 – 27.06.17

Applicants

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Introduction

Stroke impacts approximately 17 million people worldwide each year (Feigin, Forouzanfar, & Krishnamurthi, 2014) and one person every five minutes in the UK alone (stroke Association, 2016). As prevalence rates of strokes increase (16.2 million survivors worldwide, representing a 68% increase since 1990) (Feigin et al., 2014) so too does our knowledge of how to treat people who have experienced stroke. As a result of increased survival rates (Hackett, Köhler, O'Brien, 2014), we have seen increasingly more people and their families live with the long terms consequences of stroke, such as physical disability, cognitive impairment, psychological problems such as anxiety and depression as well as fatigue (Wolfe et al., 2011). The number of people experiencing a stroke is growing due to lifestyle implications such as an increase in diabetes and obesity (Krishnamurth et al., 2013) as well as, in part the number of people living to old age (Wang, Rudd, & Wolfe, 2013).

Recovery pathways following stroke have been widely researched and investigated (Betani, Melegari, De Cola, Bramanti & Calabro, 2017; Jin, Guo, Zhang, & Chen, 2017). Recovery from stoke relies on a number of individualistic factors such as a person's age, weight, location of stroke and size of the lesion. However, a recent meta-analysis by Bindawas, Vennu & Moftah (2017) concluded that following engagement with rehabilitation activities, patients had an overall higher functional capacity (as well as being discharged from hospital earlier. As such it appears that increasing a patient's ability to engage with activities of rehabilitation will in turn have a positive effect on recovery levels.

There are a number of factors that impact on a person's ability to engage with rehabilitation activities following a stroke: communication difficulties; cognitive impairment; fatigue, sleep difficulties and mood (Plant, Tyson, Kirk & Parsons, 2016). This study will attempt to look at the impact of two of these factors mood and sleep.

Alongside functional capacity mood has been reported to be one of the main factors which contribute to health-related quality of life for people who have experienced stroke (Almborg, Ulander, Thuline, & Berg, 2010). Indeed, Gray et al. (2011) found an increase in the number of people experiencing mental health difficulties in the stroke population, including both survivors of stroke and their carer's. Prevalence rates of mood difficulties in the post stroke population are as high as 40-50% in the 12 months following stroke (Creed, Swanwick, & O'Neill, 2004). Individuals who experience mood difficulties following stroke also report poor outcomes in terms of recovery, participation in rehabilitation, quality of life and indeed mortality (Parikh, Robinson, Lipsey, 1990; Williams, Ghose & Swindle, 2004).

In addition to mood difficulties, studies have also reported that poor sleep can have a negative impact on the recovery levels of the stroke survivor. For example, reduced sleep may impact as many as 50% of stroke patients (Hermann & Bassetti, 2016). Sleep

disturbances have been strongly correlated with experiences of depression and anxiety both in the post stroke population as well as healthy control groups (Naess, Lunde, Brogger, & WajeAndreassen, 2012; Leppavuuori et al., 2002). Poor sleep is also correlated with reports of poor life satisfaction, and post stroke recovery and rehabilitation activities (Hermann & Bassetti, 2009; 2016; Siengsukon & Boyd, 2008). Current research on the relationship between sleep and stroke, indicates that the main sleep variables involved in impaired sleep are: poor sleep efficiency (Siccoli & Bassetti, 2008); sleep fragmentation (Terzoudi et al., 2009) and insomnia (Sieminski, Gojska, Nitka-Sieminska, & Nyka, 2006).

Studies that have examined the impact of sleep on next day functioning in healthy controls found that poor sleep had a negative impact on functioning (Walker, 2008) this affect would most likely be exacerbated in stroke survivors due to possible impairments in both cognitive and physical functioning. Together with the findings outlined above this highlights the important role of sleep in the post stroke population, and their ability to engage in rehabilitation activities. Sleep remains an unknown factor within the stoke population, as example of this the UK National Institute of Clinical Excellence recently published guidance on stroke care, the guidance accounts for medical, physical, and psychological needs of the patients but makes no reference to sleep (NICE, 2013).

As outlined above research has shown that there are clear links between poor sleep and engagement with rehabilitation, as well as links between low mood and engagement in the stroke population. However, as far as we know to date there has been no research conducted into the impact of sleep or mood and the effect t that this may have on a persons' ability to engage with rehabilitation activities, within a stoke population. A surprising finding, considering the clear links observed between sleep and mood out with the stroke population (Ptaoek, Ying-Hui, & Krystal, 2016; Talbot et al., 2012; Wong et al., 2012).

There remains a lack of experimental investigation into the possible relationship between sleep and mood on participation in rehabilitation activities. Previous methodological limitations mean that as yet we have not been able to make a clear distinction on the direction of the main effect (sleep or mood). As such further investigation into this area is required.

This study will be an experimental, longitudinal design which will make use of prospective measures of sleep, mood, and participation in activities of rehabilitation. We will be measuring the temporal relationships between variables over time, which is a novel approach given that research in this area is dominated by cross- sectional designs. We aim to explore the effect that both (sleep and mood) may have on engagement with rehabilitation.

Identifying dynamic mechanisms of both sleep and mood in the post stroke population may lead to more specific therapeutic interventions (Robinson & Jorge, 2016) allowing for a targeted approach to recovery-based rehabilitation activities.

Method

Participants

Participants who have experienced stroke will be recruited from the Acute Stroke Unit within [redacted] Hospital as part University Hospitals of South Manchester Trust, which provides specialist care to patients who have experienced stroke in the greater Manchester area.

Details of power calculation:

Using guidance from other ESM studies, we plan to recruit 20 individuals. Therefore, the study could potentially yield 140 sets of data. For the regression, we will have 1 variable as a predictor (sleep score) and 3 variables held as covariates (see statistical procedure). With 4 variables, a data size of 84 would be sufficient to yield a power of around 0.8. As we cannot predict the degree of missing data or participant drop-out rates, we believe a sample of 20 will ensure that at least 84 data sets are gathered to explore our hypotheses

All participants will have experienced a stroke (ischaemic or haemorrhagic) and will have been admitted onto the acute stroke ward, patients will have been on the ward for a minimum of 48 hours prior to being approached about the research. All participants will be expected to remain on the stroke ward for the duration of data collection; this can be between 3-15 days depending on the length of stay on the ward. Participants are required to have a command of the English language that will be sufficient to complete assessments and provide informed consent for participation. Participants will need to be fully conscious or able to awaken to fully consciousness during all assessments for the research. Participants are required to be orientated to time (year) and place Participants will also be aged 18 or over and will not have any significant issues with mobility that would inhibit the use of the actigraph watch (mobility will be assessed by a Physiotherapist). Participants will also not have a previous or existing diagnosis of sleep apnoea.

Design

This study will collect quantitative data.

Individuals who have experienced a stroke

The primary outcome measures will be sleep, mood and level of participation in rehabilitation activities. The mood measure will be administered once per day for the number of days that the participant is active in the study (between 3-15 days). Sleep will be measured using actigraphy, each participant will wear an actigraph watch on their most mobile wrist (assessed by physio) for the period they are participating in the study (between 3-15 days).

A possible confounder in the data may be the participants experience of pain, and the impact that this pain may have on their ability to participate in rehabilitation activities. As a result, a daily measure of pain will be administered.

Baseline outcome measures for mood and pain will be administered prior to the study. In addition to this descriptive characteristics of the participants will be gathered from their medical record, these will include:

- Age
- Sex
- Time since stroke
- Location of lesion
- Side of deficit
- Size of lesion
- Barthel index
- Medication
- Co-morbid medical conditions

Participation in rehabilitation will be measured using an objective measure completed by clinical staff who conduct the rehabilitation activity.

Materials

The following questionnaire measures will be used:

Baseline measures:

Mood

Hospital Anxiety and Depression Scale
The HADS is a validated, widely-used, 14-item self-report scale designed to briefly measure current anxiety and depressive symptoms in non-psychiatric hospital patients (Zigmond & Snaith, 1983). It excludes somatic symptoms, therefore avoiding potential confounding factors. The HADS comprises two independent seven-item subscales for anxiety and depression. The HADS has been normed and validated within the stroke population and demonstrated useful application as an acceptable screening instrument (Sagen et al., 2009).

Depression Identity Scale Circles
For participants who wish to participate but are experiencing aphasia, mood will be assessed using the Depression Identity Scale Circles (DISCS). This instrument was developed within the context of brain injury setting, as has been validated within an aphasia population (Turner-Stokes, Kalmus, Harani, & Clegg, 2005).

Visual Anxiety Measure

For participants where it has been established that Aphasia is present then we will use the Behavioural outcomes of anxiety scale to measure anxiety (Adams, Morris & Kneeborn, 2015. BOA). This measure has been validated within the stroke population, and is a observational measure of anxiety, which can be completed by a family member or carer for the participant.

Pain

Numerical pain rating scale supplemented with the Faces pain scale - NPRS-FPS
The NPRS-FPS is a validated and reliable measure of pain in people with stroke, with good relative and absolute reliability (Chuang, Wu, Lin & Hsieh, 2014). Pain is a relevant variable to measure as it has been shown to impact both on mood and social engagement within a stroke population (Almenkerk et al., 2015).

Cognitive Impairment

Montreal Cognitive Assessment – MoCA (Nasreddine et al., 2005)
The MoCA contains items which assess stroke-relevant domains and has been shown to have good sensitivity in detecting global impairment (Blackburn, Bafadhel & Randall, 2013). For participants who have been identified as aphasic the Oxford Cognitive Scale (OCS) will be used to assess cognition. This scale has been validated against an aphasic population (Demeyere et al., 2015). These are currently routine measures on the ward so data may be pre-existing. Where this is not the case a MoCA or an OCS assessment will be carried out by the researcher. This measure is within the competencies of the Trainee Clinical Psychologist (principle investigator), further to this field supervisor Dr Viki Teggart will offer supervision for this measure. Where the participant's communication difficulties significantly inhibit a cognitive assessment then they will no longer be able to be involved in the research.

Daily Measures:

Sleep

Objective measurement of sleep-wake patterns will be conducted using wrist actigraphy over a period of between 3-15 days and nights, utilising an epoch of thirty seconds (i.e. categorisation of movements will occur every 30 seconds). Actigraphy provides a recording of continuous motor activity and has been validated for use within the stroke population Cavalcanti et al., 2013). Three sleep variables will be extracted from actigraphy data: sleep efficiency (SE), sleep onset latency (SOL), and wake after sleep onset (WASO). These variables have been selected as they have been identified by previous research to be the most impaired functions following stoke (e.g. Siccoli et al., 2008; Bakken et al., 2012; Terzoudi et al., 2009).

Mood

Visual Analogue Mood Scale -Revised (VAMS-R) will be administered to participants by the researcher once per day during the time they are wearing the actigraph The VAMS is a reliable and valid measure of eight specific mood states: (Afraid, Confused, Sad, Angry, Energetic, Tired, Happy, and Tense), although we are interested in the 'sad' mood construct for this research design, the measure results in eight scores between 0-100. It places minimal cognitive or linguistic demands on the respondent and is appropriate for neurologically impaired individuals (Kontou, Thomas & Lincoln, 2012). The VAMS has

been normed against 425 healthy adults and 290 psychiatric inpatients and outpatients and represents reliable measure of mood.

Pain

A daily measure of pain will be administered to participants, this will allow researchers to control for this variable within the model. We will use the same measure as outlined above for baseline, the Numerical pain rating scale supplemented with the Faces pain scale - NPRS-FPS.

Rehabilitation

The Pittsburgh Rehabilitation Participation Scale (PRPS)
The scale will be completed by clinicians following rehabilitation sessions with the participants, a scale can be completed following each session and takes less than 5 minutes to complete. The PRPS is a clinician-rated 6-point Likert-type item measuring patient participation in inpatient rehabilitation sessions. The PRPS has been validated and normed against a stroke population and has been shown to collate with functional outcomes for patients (Lenze at al., 2002). A mean score of the six items will be calculated from the total PRPS scores for each participant, it will be this score that is used as the daily score.

Procedure

Roles of the research team in the procedure

Leona Rose will be involved in the recruitment (taking consent) and data collection with participants (daily measures of mood and pain) and will be involved in the data analysis.

Dr Viki Teggart may be involved in the recruitment (taking consent) and data collection (mood and pain) and will be involved in the data analysis.

In addition, an assistant psychologist and research practitioner who hold positions with [redacted] Hospital and University Hospital of South Manchester Trust (UHSM) may be involved in recruitment and data collection.

Dr Lee Mulligan and Dr Gullimero Perez Algorta will both be involved in the data analysis.

Clinicians involved in rehabilitation will complete the objective rehabilitation participation questionnaire following each rehabilitation session that a participant is scheduled to complete for the duration of the participants involvement in the research study.

Recruitment

Participants will be recruited and identified by the participant information centre (PIC): [redacted] Hospital.

Procedure at [redacted]

A briefing will be provided to all clinical staff who work on the stroke ward at [redacted] Hospital regarding the study.

Participants who have experienced a stroke and who have been admitted onto the Stroke ward will be recruited and identified by a members of the research team who have honary contacts with UHSM NHS Trust, and by health professionals in their care team, team who are based on the Stroke Ward at [redacted] Hospital.

All staff will be briefed by Leona Rose (trainee clinical psychologist) and Dr Viki Teggart (clinical neuropsychologist). The staff will identify whether a patient who has been admitted onto the ward meets the inclusion criteria and if so, the patient will be approached by Leona Rose or Viki Teggart to give the patients information on the research. Participants will be given the participant information sheet (appendix A). These participants will indicate their consent to be contacted again by a member of research team at a later date once they have had an opportunity to consider the information.

Each participant will then be followed up by a member of the research team Leona Rose or Dr Viki Teggart who is based on site at [redacted] Hospital. Participants will be provided with information about the study and will have the opportunity to ask any questions. During this process the participant is welcome to have a friend or family member present; this will be made clear to the participant.

If the participants are still interested in taking part then either Leona Rose or Dr Viki Teggart will check once again that the participant understands the information given in the relevant participant information sheet and then the researcher will take written consent (appendix B). Once consent has been provided, the initial (baseline) questionnaires will be completed (this will be paper based). This gives the participants an opportunity to ask any questions about the study or the questionnaires. In addition, participants will be given an actigraph watch to wear on their most mobile arm for the duration of their involvement in the study.

A letter will be send to the GP of the participant (unless the participant has expressed a wish for this not to happen) with a copy sent to their treating clinician to inform them that their patient is taking part in the research (appendix).

Those clinical staff involved in the rehabilitation activities for the participants will be given details by the principle investigator Leona Rose about the Pittsburgh Rehabilitation Participation Scale (PRPS), including guidance on its completion. They will have an opportunity to ask any questions during the briefing as well as having access to a member of the research team who is based on site at [redacted] Hospital. Clinical staff will be informed of which patients are participating in the research to ensure they are able to complete the necessary objective measure of rehabilitation engagement.

Administering measures
Questionnaires

The baseline questionnaire measures will be administered immediately after taking consent (see recruitment section above). The daily questionnaire measures will be completed with the participant by a member of the research team, these measures will take no longer than 5 minutes to complete. The daily measures of rehabilitation engagement will be completed by the clinicians involved in the participants rehabilitation activities. This questionnaire measure will take no longer than 5 minutes to complete.

Actigraph

The actigraph watch will be assigned to the participant following consultation with physio colleagues about which arm (left or right) is the most mobile. The watch will be given to participants following consent and will be worn by them for the remainder of the research, this could be between 3-15 days.

Analysis

Quantitative Analysis

Descriptive data on the participants will be assessed and tabulated. Scaled data will be checked for normality and other parametric data assumptions and, where necessary transformed. Statistical analysis will be performed using SAS version 9.4. As the ESM measures have a 3-level hierarchical structure (entry points nested within days nested within participant) we will use multilevel modelling in the analysis to account for the clustering in outcomes within participants. We will calculate summary statistics (mean and variability) of participation for each day. In order to test the hypotheses of this study, and to take into account the nested nature of the data, two multilevel models for discrete outcomes will be generated, with sleep and mood as the independent (predictor) variables in the separate models, participation in rehabilitation activities will form the dependant variable. To account for possible confounding, we will include baseline measures of anxiety, depression, and pain as additional covariates in all the models.

Dissemination

These findings will be presents t the medical team within [redacted] Hospital and fed back to patients and support groups via formal and informal presentations. The data will also be published in relevant journals such as Stroke and Clinical Neuropsychology. Participants will also receive a copy of the findings if they request this.

Practical Issues

Permissions for use of copyrighted scales has been sought where necessary. The licences for all the necessary statistical analyses are already available through Lancaster University.

Ethical concerns

Risk to participants

This research is aimed at understanding the possible relationship between and sleep and mood and the impact that this may have on a patient's ability to take part in rehabilitation activities following stroke. It is not anticipated to cause any distress to participants. However all members of the research team will use their clinical expertise to address this appropriately should distress arise during the course of the study.

If any of the research team become concerned that a participant poses a risk of serious harm (to themselves or others) they will inform the treating clinician who will access if any further intervention is necessary.

Participants will also be given advice on the participant information sheet about who to contact if they are experiencing distress.

Risk to researchers

The researcher will not be alone with a participant on any occasion, as the research is due to be conducted at the patient's bedside while they are an inpatient on the ward. All research will be conducted within [redacted] hospital. The research team will adhere to the health and safety policies of the research site.

Timeline for study competition.

Submit ethics proposal: April 2017
Data collection: Sep - Dec 2017
Data analysis: Dec 17 - Jan 18
Comment on first draft of literature review: Oct 2017
Comment on first draft of research paper: Dec 2017
Comment on second draft of literature review: Jan 2018
Comment on second draft of research paper: Feb 2018
Comment on first draft of critical review: March 2018
Comment on second draft of critical review: April 2018
Submit thesis: May 2018
Submit papers for publication

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Consent Forms

Lancaster University

Consent Form

An examination of sleep and mood on predicting participation in rehabilitation activities in an inpatient stroke population.

We are asking if you would like to take part in a research study to investigate whether sleep and mood have an impact on a person's ability to engage with rehabilitation activities during an impatient hospital stay following a stroke.

Before you consent to participating in the study we ask that you read the participant information sheet and mark each box below with a tick if you agree. If you have any questions or queries before signing the consent form please speak to a member of the research team.

	Please tick box after each statement
1. I confirm that I have read the participant information sheet and fully understand what is expected of me within this study	
2. I confirm that I have had the opportunity to ask any questions and to have them answered.	
3. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my medical care or legal rights being affected.	
4. I understand that relevant sections of my medical notes and data collected during the study may be looked at by individuals from Lancaster University, from regulatory authorities or from the NHS Trust where it is relevant to my taking part in the research. I give permission for these individuals to have access to my records.	
5. I agree to the treating clinician at the hospital being informed of my participation in the study.	
6. I understand that the information from my questionnaires and actigraphy data will be pooled with other participants' responses, anonymised and may be published.	

7. I consent to information from the being used in reports, conferences and training events.	
8. I understand that any information I give will remain strictly confidential to the researchers unless it is thought that there is a risk of harm to myself or others, in which case this information may need to be shared with appropriate persons.	
9. I consent to Lancaster University keeping the data from the study for up to 10 years after the study has finished.	
10. I consent to take part in the above study.	

Name of Participant_____ Signature_____ Date _____

Name of Researcher _____Signature _____Date _____

Consent to contact GP

	Please tick the box if you agree with the statement
11. I agree to my GP being informed of my participation in the study	

Name of Participant_____ Signature_____ Date _____

Name of Researcher _____Signature _____Date _____

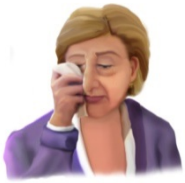
Researcher

Leona Rose

Lancaster University

Taking part in **research**

about **sleep** and **mood** following **stroke.**



I have **read** the **information** about the **research**

yes ☐ no ☐

I have had the **chance** to **ask questions** about the research

yes ☐ no ☐

I am **happy** with the **answers** to my questions

yes ☐ no ☐

I understand that **I can stop being in the research** at any time

yes ☐ no ☐

If I stop I do not have to **give a reason**

...and I will still **get my normal care**

yes ☐ no ☐

I understand that **researchers** will need **information** from my **medical records**

yes ☐ no ☐

I understand that my **GP** (doctor) **will be told** that I am **taking part** in the research

yes ☐ no ☐

I understand that researchers may **share my results** with other **researchers in this country**

yes ☐ no ☐

I understand that researchers may **share my results** with **researchers** in **other countries**

yes ☐ no ☐

I understand that **information** about me will be **kept safe**

yes ☐ no ☐

It will **not** be **shared** with **anyone outside the research**

yes ☐ no ☐

I am **happy** for **Lancaster University** to keep my **information** for up to **10 years**

yes ☐ no ☐

I agree to take part in the research

yes ☐ no ☐

Name_____

Signature _____ **Date**_____

I give my consent to

Name _____

Signature_____ **Date**_____

Participant Information Sheet

An examination of sleep and mood on predicting participation in rehabilitation activities in an inpatient stroke population.

My name is Leona Rose, I am a trainee clinical psychologist at Lancaster University. This study will form part of my doctoral research and is an academic requirement for my course. Myself and my supervising tutors 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 feel free to talk to others about the study when making up your mind. One of our team will also go through the information sheet with you and answer any questions you have before you decide whether you want to take part.

What is the study about?

When a person experiences a stroke they may be asked to take part in some rehabilitation activities such as physiotherapy and speech and language therapy. We know that if a person is able to engage with rehabilitation activities that they may have an improved rate of recovery compared with those people who find it difficult to engage with them. We are interested in what might be getting in the way of a person's ability to take part in rehabilitation sessions. People who have had a stroke often experience some difficulties with sleep and mood (feeling sad or frightened). Sometimes issues with sleep and mood can make taking part in rehabilitation activities more difficult because you may be tired or not feel able. The aim of this study is to find out if it is sleep or mood that is having the biggest impact on a person's ability to participate in rehabilitation.

Why have I been approached?

You have been approached because the study is for people who have experienced a recent stroke and are being treated on an inpatient ward. We are approaching people who are taking part in rehabilitation activities to see if mood or sleep is having an impact on their ability to participate.

Do I have to take part?

No. It's completely up to you to decide whether or not you take part. If you decide not to take part it will not affect your clinical care in any way. If you agree to take part, you can still stop and withdraw at any time without giving a reason.

What will I be asked to do if I take part?

Opting in
If you are possibly interested in taking part then first you contact Leona from the research team (more details are given at the end of this information sheet) who will tell you more about the research. If you are still interested in taking part, a member of the research team will come and meet with you at the hospital so you can sign a consent form and you will also complete some questionnaires (see below).

Collecting information about your sleep and mood
If you decide to go ahead and participate then we will collect some data from you each that you are on the ward for a maximum of 14 days (data collection will stop after 14 days even if you remain on the ward). We want to do this in two ways: by questionnaires and using an actigraphy (sleep) watch.

Questionnaires
We will ask you to complete some questionnaires: before the research starts, and then every day you are taking part in the research for a maximum of 14 days. The questionnaires we will complete at before the research starts will take about 30 minutes to complete. The questionnaires that we will complete every day will take no longer than 5 minutes to complete. A researcher will be with you every time you complete a questionnaire.

We will also ask the professionals who are completing your rehabilitation sessions with you to complete a questionnaire. This will be about their opinion on your ability to engage with the rehabilitation activity. This questionnaire will not impact on your level of care.

Actigraphy Watch

Actigraphy is a non-invasive method of monitoring human rest/activity cycles. A small actigraph unit is worn on the wrist for a period of time between 2-15 days to measure how you sleep The movements the actigraph (sleep watch) unit undergoes are continually recorded. The data can be later read to a computer and analysed offline. The actigraph will not inhibit your movement and you will be able to carry on with your normal activities. We will ask you to wear the actigraph (sleep) watch on your wrist with the most movement, and you will wear this 24/7 for the length of time you take part in the study (between 3-15 days).

Will my data be confidential?
The information you provide will be kept confidential. The data collected for this study will be stored securely and only the researchers conducting this study will have access to this data:

- Hard copies of questionnaires will be kept in a locked cabinet.
- The files on the computer will be encrypted (that is no-one other than the researchers will be able to access them) and the computer itself password protected.

- At the end of the study, hard copies of questionnaires and consent forms will be kept securely in a locked cabinet for ten years which gives the researchers time to analyse all the data and publish it. At the end of this period, they will be destroyed.
- At the end of the study, electronic questionnaires, the data from the questionnaires and actigraph will also be kept securely on the computer for ten years.
- Your name will not appear on any of the data stored instead you will be assigned a number, e.g. participant 1.

If you take part we will write to your GP to let them know that you are taking part unless you prefer us not to do this. We will also send a copy of this letter to your treating clinician at the hospital so the team there know too. However, this information will only say that you are taking part in the study and will not contain any of your questionnaires or interview data.

There are some limits to confidentiality. If at any point in the study (filling in a questionnaire or talking to a researcher) you say something that makes us think that you or someone else is at significant risk of harm, we will have to break confidentiality and speak to your treating clinician or a member of the team at the hospital. . If possible, we will tell you if we have to do this.

What will happen if I decide to leave part way through?
You can choose to stop participating in the study at any time. If you leave the study, we will keep the data (questionnaires and actigraphy data) that you have already given us, unless you ask us to destroy them. If you ask us to withdraw your data at any point, every effort will be made to do so, but it may not be possible if your data has been fully anonymised and have already been analysed.

This will not change the usual clinical care that you receive.

What will happen to the results?
The results will be summarised and reported at conferences and local groups and will be submitted for publication in academic and/or professional journals. If you would like a copy of the results, please ask the researchers. The results will also form part of a research project for a doctorate in clinical psychology at Lancaster University.

Are there any risks?
There are minimal risks anticipated with participating in this study. If you experience any distress during the study, please discuss it with the research team. There will be someone from the research team available to you Monday to Friday 9-5.

If you experience any distress following participation and do not wish to discuss them with a member of the research team you are encouraged to contact the resources provided at the end of this sheet.

Are there any benefits to taking part?
Taking part may highlight some difficulties with your sleep, if so it is possible that some targeted guidance can be offered which could improve your care.

Who has reviewed the project?
This study has been approved by the NHS Research Ethics Service, University Hospitals of South Manchester Trust and the Research and Development department and Lancaster University Research department

Where can I obtain further information? How do I opt in?
If you might be interested in participating in the study, please contact Leona Rose who is a trainee clinical psychologist and one of the researchers. You can do this by email: l.magee1@lancaster.ac.uk, by telephone (07715 639 269). You can also let the team at the hospital know that you want to take part and they will pass on your details.

Leona will tell you more about the project and then you can decide whether you are interested in taking part.

Research team
This research is led by Leona Rose at Lancaster University. Other members of the team are Dr Viki Teggart clinical neuropsychologist at [redacted] Hospital, Manchester, Dr Lee Mulligan, clinical psychologist and sleep specialist and Dr Guillermo Perez Algorta from Lancaster University.

Complaints
If you wish to make a complaint or raise concerns about any aspect of this study and do not want to speak to the researchers, you can contact:

Professor Bruce Hollingsworth
Head of Division of Health Research
Lancaster University
Lancaster
LA1 4YG
b.hollingsworth@lancaster.ac.uk
01524 59415

If you would like to make a complaint, and would like to speak with someone outside of the Health Research department, please contact:

Professor Roger Pickup Tel: +44 (0)1524 593746
Associate Dean for Research Email: r.pickup@lancaster.ac.uk
Faculty of Health and Medicine
(Division of Biomedical and Life Sciences)
Lancaster University
Lancaster
LA1 4YG

Resources

It is not anticipated that taking part in this research will cause distress. However, should you feel distressed as a result of taking part you can contact:

Leona who is the lead researcher on this project on 07715 639 269 or l.magee1@lancaster.ac.uk
Viki from the research team on 0161 291 6971
You can also contact a member of your clinical care team at the hospital or your GP.

The following organisations may also provide advice or support.

Stroke association www.stroke.org.
There is lots of advice and information on their website. **If you call the help line on 0303 3033 100, they can offer specialist support and advice. More information about this service and about finding support in your local area is given here:**
https://www.stroke.org.uk/finding-support

The Samaritans www.samaritans.org
The Samaritans offer a non-judgemental listening service. Their phone number is 08457 90 90 90 (charges apply) or you can email them on jo@samaritans.org

Research and more information

Stroke
More about Stroke can be found here:

http://www.nhs.uk/Conditions/Stroke/Pages/Introduction.aspx

Information about ongoing and previous stroke research can be found here:

https://www.stroke.org.uk/research

What is the research?

	We are doing some **research** It is about **stroke** and **sleep** and **mood.**
	Research helps us **learn** We need to **know** more about **how to help**

Why me?

	You **have had a stroke**
	Your stroke may have affected your **sleep** and your **mood**

	You are having **treatment** for your stroke in [redacted] **Hospital**

Who is doing the research?

The **main researcher** is **Leona Rose**

The research is run from the **hospital**

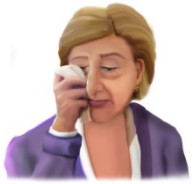
Lancaster University

The **research** is sponsored by **Lancaster University**

Why are we doing the research?

Stroke can make you feel **very tired**

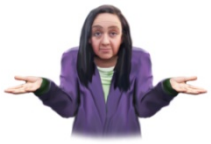
and



stroke can make you feel **depressed**

anxious or **frightened**

sometimes this can **get in the way** of your **recovery activities**

	We **don't know** enough about **it** This **research** will help us to **learn more**

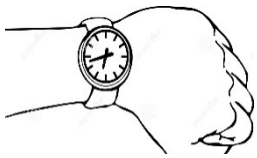
What happens in the research?

	We want to **compare sleep** and **mood** We want to know which has the biggest impact on **your therapy to get better - Rehabilitation** We want **20 people** to take part **All** of **the people** will have the **same tests** This will last **for a maximum of 15 days**

	The researcher will **look at the results** They will **learn** about what **effects** **You getting better**

What will I have to do?

   	In the research you will have an **interview** **answer** some **questions** have some **assessments** We will give you a **questionnaire everyday**

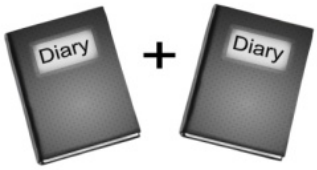
	We will do this for a **maximum** of **15 days**
	You will wear a **watch** which will measure your **sleep**
	**Professionals** will tell us information about your
	**rehabilitation performance**.
	We will look in your **medical records**

	We will keep your information **safe**

Where will the research happen?

	The research will happen in **hospital**
	You will need to **stay in hospital** for this research

How long will the research last?

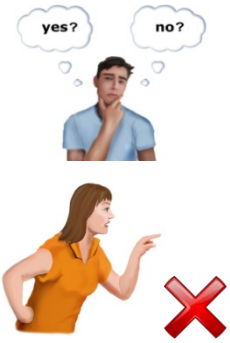
	The **whole research** will last for **12 months** **Your part** will last for **15 days maximum**

	You will have **appointments every day for 15 days**

Will I get paid?

	You will **not get paid** for taking part in the research

Do I have to take part?

	**You can decide** You **don't have to** If you don't take part you will **still get your normal help**
	If you change your mind, **you can stop** at any time You **don't** have to **give a reason**

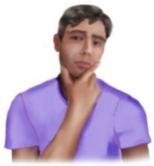
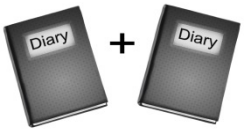
 	**If you stop** you will still get your **normal help**
  	You don't have to decide now, you can **think about it** You can **take your time** You can **read** the information **again** You can **talk to your family** to **help you decide**

Who will see the information about me?

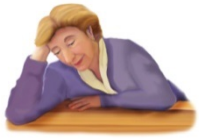
	We will keep the **information** about you **safe** **Only** the **researchers** will see the **information about you**

	We may **share** your information with **other researchers** in this **country**
	We may **share** your information with **researchers** in **other countries**
	This **helps** with **other research** about **stroke**
	We will **take out your name** and **personal details**
Lancaster University	We will share this research with **Lancaster University** as it is part of an
	academic **qualification.**
	We will **tell your doctor** that you are in this research project

What might be good about taking part?

	You may **enjoy** taking part
	You may find it **interesting**
	You will **help** people in the **future** They will get **better help**
	You will help us to **learn** This may **support people with strokes** in the **future**

What might be difficult about taking part?

	We **don't think** it is **dangerous** however the **research may not help** you
  	You may find it **tiring** You may find it **distressing** It will **take** up **your time**

What if I don't take part in the research?

	You will still get your **normal help**

Is the research safe?

A committee **decides if research can happen**

This is the **ethics committee**

They say that **this research can happen**

They say that it is **safe**

They say that it has been **planned properly**

What if something goes wrong?

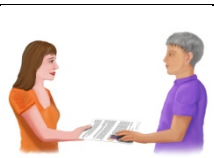
	This is very **unlikely** However, The NHS has set up **a committee** This committee will **monitor the research** The committee has **different people** from those who do this research
  	If you **take part** in the research and **if you think** you were **harmed** there are **people to talk to** **contact** Professor Bruce Hollingsworth **at** Head of Division of Health Research Lancaster University Lancaster LA1 4YG b.hollingsworth@lancaster.ac.uk 01524 59415 **Or** **Stroke association** www.stroke.org.

	**0303 3033 100** **The Samaritans** www.samaritans.org 08457 90 90 90 jo@samaritans.org The University has **insurance**

What will happen after the research?

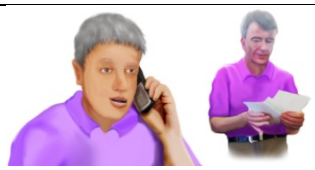
	The **researchers** will **look at the results**
	They will **learn more** about **sleep** and **mood**

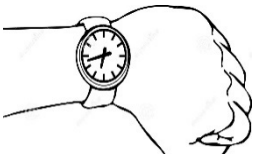
What will happen to the results?

	We will **give you the results** of the research
	We will share the **results** with **other researchers** at **conferences** and **meetings** through **newsletters** and **magazines** in **academic journals**
	
	with **other people** who have a **stroke**
	The results will **not use your name**

What next?

	Do you **want** to **take part?** **You need to decide**
  	You may want **more information** Contact Leona Rose Division of Heath Research Lancaster University Lancaster LA1 4YG l.magee1@lancaster.ac.uk They will **answer your questions** **Let us know** if you want to take part You can **contact us** at Division of Heath Research Lancaster University Lancaster LA1 4YG l.magee1@lancaster.ac.uk Tel: 07715 639 269

 	If you decide to take part you will need to **sign a consent form** This says that **you understand** the research and **you agree** to take part
   	We will **contact you** We will ask for **your decision** **Yes** I want to **No** I don't want to

	If you decide to take part you will have **an appointment** This **appointment** will be in **2 days**
	At this appointment you will be asked to complete some **questionnaires**
	You will be given a **watch** to monitor **sleep**
	The appointment will **last for 30 minutes.**

Measures

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

Scoring:
Total score: Depression (D) _____ Anxiety (A) _____
0-7 = Normal
8-10 = Borderline abnormal (borderline case)
11-21 = Abnormal (case)

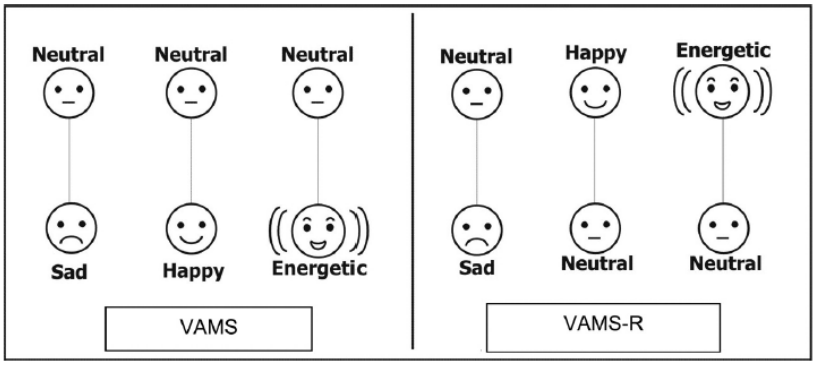
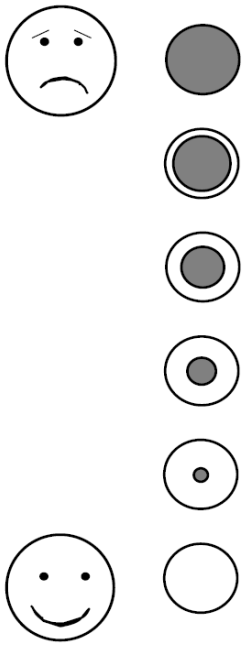


Figure 1. Illustration of changes made to the Visual Analog Mood Scales items on happy and energetic items.

The Depression Intensity Scale Circles (DISCs) – pictorial version



The DISCs is displayed on a laminated card.

- Each circle is 2 cm in diameter.
- The scale measures 15 cm from the centre of the bottom circle to the centre of the top circle.
- A pictorial version also available.

Instructions for administration:
Say to the patient:

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

To the administrator:
In your opinion was the person able to understand this scale?

Yes ☐ No ☐

Comment

Appendix A: Survivor BOA

The following information will be used anonymously in the study. You do not have to answer anything you do not want to. Please read each item and place a tick in the box which comes closest to how you have been feeling in the PAST WEEK. Try not to take too much time over it, as your immediate reaction should be accurate.

Today's Date: _____

	Often 3 points	Sometimes 2 points	Rarely 1 point	Never 0 points	Score (points)
I feel tense or on edge	☐	☐	☐	☐	☐
I have a strained face	☐	☐	☐	☐	☐
I have had trouble falling asleep	☐	☐	☐	☐	☐
I have been getting tired easily	☐	☐	☐	☐	☐
I feel restless as if I have to be constantly on the move (e.g., pacing)	☐	☐	☐	☐	☐
Worrying thoughts go through my mind	☐	☐	☐	☐	☐
I get sudden feelings of panic	☐	☐	☐	☐	☐
I'm scared of falling over	☐	☐	☐	☐	☐
I tend to avoid activities or social engagements	☐	☐	☐	☐	☐
I feel jumpy or easily startled	☐	☐	☐	☐	☐

Note. Adapted from the carer version in "Screening for depression and anxiety after stroke: Developing protocols for use in the community" by I. I. Kneebone, L. Neffgen, and S. Pettyfer, 2012, *Disability and Rehabilitation, 34*, p. 117. Copyright 2012 by Informa UK, Ltd. Items were rendered to the first person and instructions to consider behaviour during the past week were added. All items were rephrased into the past tense and the items on sleep, social activities and panic were simplified.

Appendix B: Carer BOA

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.

Today's Date: _____

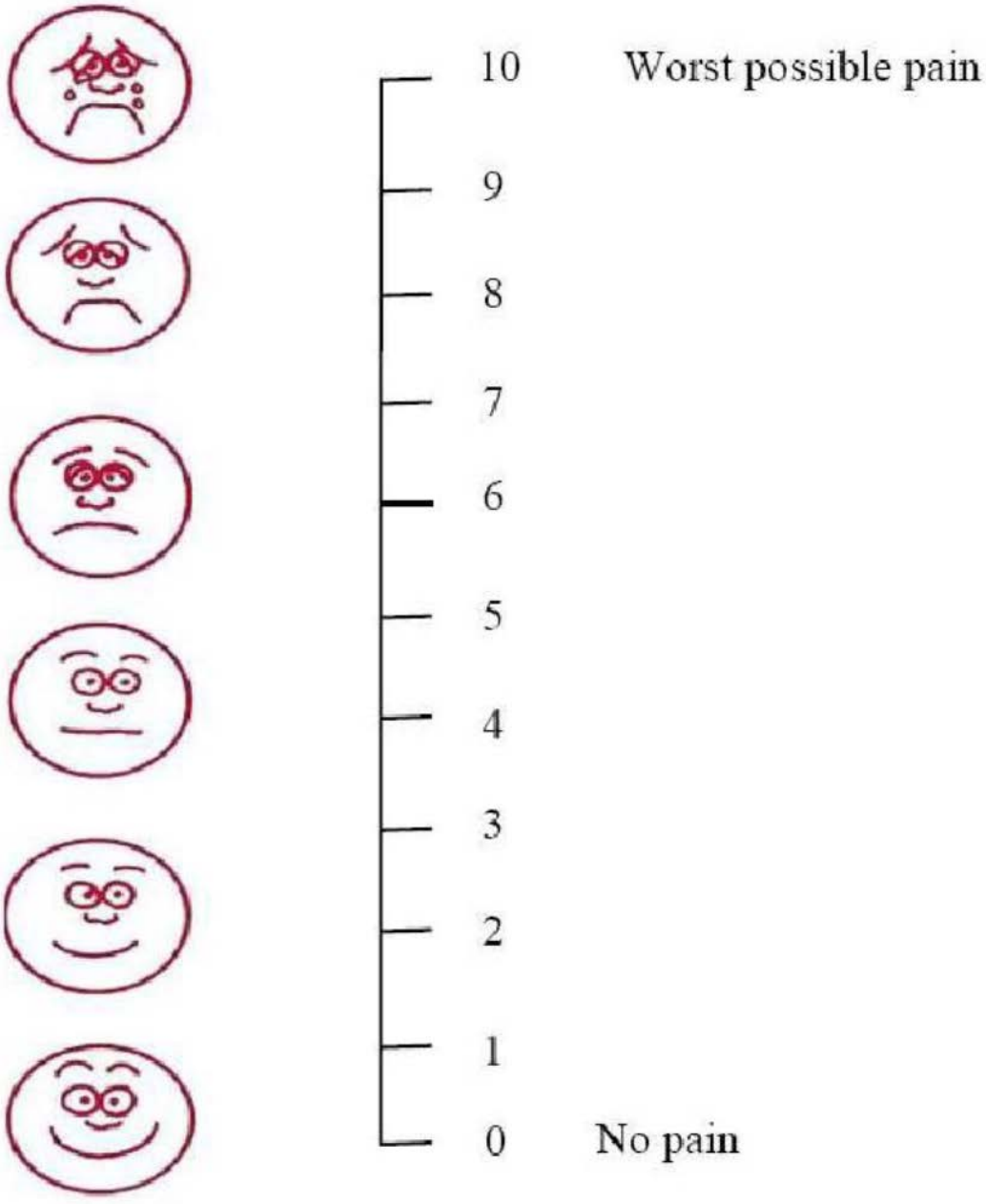
	Often 3 points	Sometimes 2 points	Rarely 1 point	Never 0 points	Score (points)
Has he/she appeared particularly tense or on edge	☐	☐	☐	☐	☐
Has he/she had a strained face	☐	☐	☐	☐	☐

Continued

Appendix B. (*Continued*)

	Often 3 points	Sometimes 2 points	Rarely 1 point	Never 0 points	Score (points)
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	☐	☐	☐	☐	☐

Note. Adapted from the carer version in "Screening for depression and anxiety after stroke: Developing protocols for use in the community" by I. I. Kneebone, L. Neffgen, and S. Pettyfer, 2012, *Disability and Rehabilitation, 34*, p. 117. Copyright 2012 by Informa UK, Ltd. Instructions were altered to refer to behaviour during the past week, all items were rephrased into the past tense and the items on sleep, social activities and panic were simplified.


10
Worst possible pain
9
8
7
6
5
4
3
2
1
0
No pain

PITTSBURGH REHABILITATION PARTICIPATION SCALE

Patient name: _____

Admission date: _____

Instructions to therapist: for each therapy session, please circle one of each of the following to assess the patient's participation (effort and motivation as perceived by you) in the therapy session. Please rate as follows: None: patient refused entire session, or did not participate in any exercises in session. (see Note below)

Poor: patient refused or did not participate in at least half of session.

Fair: patient participated in most or all of exercises*, but did not show maximal effort or finish most exercises*, or required much encouragement to finish exercises*.

Good: patient participated in all exercises* with good effort and finished most but not all exercises* and passively followed directions (rather than actively taking interest in exercises* and future therapy).

Very good: patient participated in all exercises* with maximal effort and finished all exercises, but passively followed directions (rather than actively taking interest in exercises* and future therapy).

Excellent: patient participated in all exercises* with maximal effort, finished all exercises*, and actively took interest in exercises* and/or future therapy sessions.

Note: if patient was unable to attend therapy because of medical test, bed rest order, illness, or scheduling conflict, do not mark any score.

Note: in cases of doubt, choose the lower rating, eg, "good" rather than "very good."

PARTICIPATION:

Session Number	Date	Therapist Initials		None	Poor	Fair	Good	Very good	Excellent
1				1	2	3	4	5	6
2				1	2	3	4	5	6
3				1	2	3	4	5	6
4				1	2	3	4	5	6
5				1	2	3	4	5	6
6				1	2	3	4	5	6
7				1	2	3	4	5	6
8				1	2	3	4	5	6
9				1	2	3	4	5	6
10				1	2	3	4	5	6

NOTE. Available as an electronic file from the corresponding author by request.
*This version is specifically for PT. For the OT form, "exercises" should be replaced by "activities."

Word Count Statement

Thesis word count:

Thesis Abstract: 245

Literature Review: 6,736

Empirical Paper: 6,855

Critical Appraisal: 3,261

Ethics Proposal: 3,663

Total: 20,760

Appendices word count:

Tables: 2,485

Figures: 250

References: 7,623

Other: 11,120

Total: 21,472

Whole Thesis Document: 42,28 words.