Understanding the impact of pre-existing dementia on stroke rehabilitation

A thesis submitted to The University of Manchester for the degree of Doctor of Philosophy in the Faculty of Biology, Medicine and Health

2018

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# Contents

Contents ........................................................................................................................................... 2

List of Tables .................................................................................................................................... 5

List of Figures ..................................................................................................................................... 5

List of Appendices .............................................................................................................................. 6

List of Abbreviations .......................................................................................................................... 7

Declaration .......................................................................................................................................... 9

Copyright statement ............................................................................................................................ 9

Acknowledgements ............................................................................................................................. 10

About the author ................................................................................................................................ 11

Thesis Format ...................................................................................................................................... 11

1 Chapter One: Introduction ................................................................................................................ 12

1.1 Overview of thesis structure ......................................................................................................... 12

1.2 Background .................................................................................................................................. 13

1.3 What is stroke rehabilitation? ....................................................................................................... 13

1.3.1 Benefits of stroke rehabilitation ............................................................................................... 14

1.3.2 Changes in stroke care .............................................................................................................. 15

1.3.3 Access to stroke rehabilitation .................................................................................................. 16

1.3.4 Stroke rehabilitation summary .................................................................................................. 18

1.4 What is dementia? .......................................................................................................................... 18

1.4.1 Alzheimer’s disease .................................................................................................................... 20

1.4.2 Vascular cognitive impairment .................................................................................................. 21

1.4.3 Vascular dementia....................................................................................................................... 21

1.4.4 Post-stroke dementia .................................................................................................................. 24

1.4.5 Small vessel disease .................................................................................................................... 25

1.4.6 Mild cognitive impairment .......................................................................................................... 26

1.4.7 Mixed dementia .......................................................................................................................... 26

1.4.8 Dementia summary ..................................................................................................................... 27

1.5 Distinguishing pre- and post-stroke dementia .............................................................................. 28

1.5.1 Post-stroke cognitive impairment ............................................................................................. 28

1.5.2 Incidence of pre-stroke dementia ............................................................................................... 29

1.5.3 Incidence of post-stroke dementia ............................................................................................. 30

1.5.4 Assessment of cognition in stroke ............................................................................................. 31

1.5.5 Timing of cognitive assessment ................................................................................................ 33
List of Tables
Table 1.1: DSM-5 criteria for major and mild neurocognitive disorder (American Psychiatric Association, 2013) ................................................................................................................. 19
Table 1.2: Section of the DSM-5 criteria for probable Alzheimer's disease .................. 20
Table 1.3: Comparison of vascular dementia diagnostic criteria ................................... 24
Table 3.1: Summary of included studies ........................................................................ 61
Table 3.2: Summary of factors influencing decisions ....................................................... 64
Table 4.1: Summary demographic information of participants ....................................... 79
Table 4.2: Summary of information sources used to identify pre-existing cognitive impairment .................................................................................................................. 81
Table 4.3: Strategies used to support people with pre-existing cognitive impairment or dementia .................................................................................................................. 88
Table 5.1: Participant characteristics .............................................................................. 102
Table 5.2: Amount of therapy received by group ......................................................... 105

List of Figures
Figure 1.1: The typical specialised stroke pathway ......................................................... 16
Figure 1.2: Diagram created to illustrate overlap of vascular cognitive impairments and Alzheimer's disease (not to scale) ................................................................. 22
Figure 2.1: Map of Greater Manchester inpatient stroke services .................................. 42
Figure 3.1: Flowchart of literature searches ................................................................... 58
List of Appendices

Appendix 1: Study two protocol – Health professionals’ experience of diagnosing and managing stroke patients with cognitive impairment: a qualitative study ............ 143
Appendix 2: Qualitative study information sheet ................................................. 143
Appendix 3: Qualitative study consent form ...................................................... 143
Appendix 4: Qualitative study topic guide ........................................................ 143
Appendix 5: COREQ checklist ........................................................................ 143
Appendix 6: Study three protocol - Examining process of care and experience of stroke-specific rehabilitation for people with pre-existing cognitive difficulties ....... 143
Appendix 7: Cohort study standard information sheet ...................................... 143
Appendix 8: Cohort study standard consent form ............................................. 143
Appendix 9: Cohort study aphasia friendly information sheet ......................... 143
Appendix 10: Cohort study aphasia friendly consent form ............................... 143
Appendix 11: Cohort study consultee information sheet .................................... 143
Appendix 12: Cohort study consultee declaration ............................................. 143
Appendix 13: STROBE checklist ..................................................................... 143

Word count: 36689
List of Abbreviations

ADL – Activities of Daily Living
ASU – Acute Stroke Unit
CLAHRC - Collaboration for Leadership in Applied Health Research and Care
CNRT – Community Neurological Rehabilitation Team
CONSORT – Consolidated Standards of Reporting Trials
CRN – Clinical Research Network
CST - Community Stroke Team
DSC – District Stroke Centre
ESD – Early Supported Discharge
HASU – Hyper Acute Stroke Unit
HRA – Health Research Authority
MCI – Mild Cognitive Impairment
MDT – Multi-Disciplinary Team
mRS - Modified Rankin Scale
NHS – National Health Service
NIHR – National Institute for Health Research
NIHSS - National Institutes of Health Stroke Scale
ODN – Operational Delivery Network
OT – Occupational Therapy/Therapist
PPI – Patient and Public Involvement
PSC – Primary Stroke Centre
PSD - Post-Stroke Dementia
PT – Physiotherapy/Therapist
STROBE - Strengthening the Reporting of Observational Studies in Epidemiology
VASCOG – International Society for Vascular Behavioural and Cognitive Disorders
VCI – Vascular Cognitive Impairment
Thesis Abstract
Verity Longley, University of Manchester.

Understanding the impact of pre-existing dementia on stroke rehabilitation

Pre-existing dementia is associated with poorer functional outcome after stroke. It is unclear however whether this is due to lack of access to, or inequality in, stroke rehabilitation. This PhD used mixed methods to understand whether pre-existing dementia is a factor considered by clinicians when referring/admitting patients for rehabilitation, when providing rehabilitation interventions, and whether there is a difference in rehabilitation received by patients with and without pre-existing dementia.

A background literature review informed the first study, which was a systematic review examining factors influencing clinical decision-making about access to stroke rehabilitation. The systematic review suggested that pre-stroke cognition influenced referrals/admission to rehabilitation, however, no studies examined this specifically. The qualitative study therefore used interviews (n=23) to explore clinicians’ experiences of decision-making about rehabilitation for patients with pre-existing dementia/cognitive impairments. The findings highlighted that clinicians’ own knowledge influenced their decision-making, with a common perception that people with pre-existing cognitive impairment lack potential to benefit from rehabilitation. The third study, a prospective cohort study, examined differences in rehabilitation received by patients with and without pre-existing cognitive impairments (n=139). People with pre-existing cognitive impairments received less rehabilitation than those without, particularly physiotherapy and referral to community therapies and more non-patient facing occupational therapy.

This PhD identified that people with pre-existing dementia/cognitive impairment receive less rehabilitation when compared to those without. This may be, in part, due to clinicians’ decision-making about which patients should receive stroke rehabilitation. These findings have multiple clinical implications, particularly around the number of patients in stroke services with undiagnosed pre-existing cognitive impairment. Decisions can become more equitable by ensuring clinicians have access to relevant education, training and skills to work alongside patients with pre-existing dementia/cognitive impairments.
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.

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Acknowledgements

This PhD was funded by the National Institute for Health Research Collaboration for Leadership in Applied Health Research and Care (NIHR CLAHRC) Greater Manchester as part of the NIHR Research Capacity in Dementia Care Programme (RCDCP). The NIHR CLAHRC Greater Manchester is a partnership between providers and commissioners from the NHS, industry and the third sector, as well as clinical and research staff from the University of Manchester. This work was supported by the Stroke Association. The views expressed in this thesis are those of the author and not necessarily those of the NHS, NIHR, or the Department of Health and Social Care or Stroke Association.

I would like to thank my supervisors Professor Audrey Bowen, Dr Sarah Peters and Dr Caroline Swarbrick for all their advice, support and positive encouragement over the past three years. Thanks also go to the NIHR CLAHRC for enabling me to attend so many events throughout my PhD.

I am grateful to all of my participants, the stroke teams and Clinical Research Network (CRN) staff without whom this research would not have been possible.

Final thanks go to all the friends I have made on this journey and enjoyed it with; it would not have been the same without you.
**About the author**

Verity is a qualified Occupational Therapist, who worked clinically in an acute hospital prior to starting this PhD. She has a background in Psychology, and has worked on a number of stroke research projects.

During this PhD she received the Verna Wright Prize for best oral presentation at the Society for Research in Rehabilitation winter meeting (2018), and the British Stroke Research Group Oral Prize for highest scoring oral abstract submitted to the UK Stroke Forum (2018).

**Thesis Format**

This thesis is presented in journal (alternative) format. Three studies are presented in a format suitable for publication in a peer reviewed journal, with the introduction and discussion chapters presented in line within traditional thesis format. The guidelines for journal format thesis acknowledge there will be overlap within sections of this thesis due to publication-style sections.

The qualitative study presented in chapter four has been published:

1 Chapter One: Introduction

1.1 Overview of thesis structure

This introductory chapter outlines the background literature to the thesis to provide the rationale for the studies. First, stroke rehabilitation is described. Second, the literature surrounding the terms dementia, vascular dementia and associated vascular causes for cognitive impairment is discussed. Third, this chapter discusses the literature differentiating pre- and post-stroke dementia in order to understand how dementia is identified in stroke research and clinical practice. The final section of this chapter synthesises what is currently known about the experience of pre-stroke dementia, and the impact of pre-existing dementia on stroke care, and particularly stroke rehabilitation. The research aims of the thesis are then presented.

Chapter two provides details of the mixed methods used for three studies presented in this thesis in greater detail than word limits allowed for the study papers. Chapter three presents the first study, a detailed systematic review of factors influencing clinical decision-making about access to stroke rehabilitation, which was identified as a priority following the review of background literature. This identified pre-existing cognitive impairment was a factor influencing referral/admission to rehabilitation; however no studies specifically examined this. Chapter four contains the first of the two empirical studies presented within this thesis; a qualitative study of factors influencing clinicians’ decision-making for stroke rehabilitation for people with pre-existing dementia, and the impact of this on clinical practice. Decision-making was influenced by the clinician’s own knowledge and skills, and people with pre-existing cognitive impairment are often perceived by clinicians to lack potential to benefit from rehabilitation. Chapter five presents the second empirical study, a quantitative observational cohort study examining stroke-specific rehabilitation received by people with and without pre-existing cognitive impairment or dementia. It found that people with pre-existing cognitive impairment received fewer therapy sessions than those without. The discussion in chapter six synthesises the main findings from the thesis as a whole, discuss the strengths and limitations of this thesis and provides recommendations for future research based on the findings.
1.2 **Background**

Stroke is caused by a disruption in the blood supply to the brain and is the largest cause of complex disability in the UK (Stroke Association, 2018). An estimated 100,000 people experience a stroke every year and over 1.2 million stroke survivors live in the UK (Stroke Association, 2018; Royal College of Physicians, 2017). Worldwide, 15 million people have a stroke each year (Mackay and Mensah, 2004). Stroke can cause physical difficulties, changes in cognition and communication, visual problems, incontinence, and can lead to long-term disability and poor quality of life. Stroke often co-occurs with other major health conditions, one of which is dementia; evidence suggests around one in ten people have a diagnosis of dementia prior to first stroke (Pendlebury and Rothwell, 2009). Dementia represents a progressive syndrome encompassing a range of neurodegenerative diseases that affect a person’s ability to carry out activities of daily living due to significant cognitive decline. It is estimated 35.6 million people worldwide are living with dementia (World Health Organisation, 2012). Incidence of dementia is increasing worldwide with an ageing population (Prince et al., 2014), alongside a reduction in post-stroke morbidity in the past twenty years due to improvements in treatment, therefore co-occurrence of both conditions is likely to increase (Feigin et al., 2008; Stroke Association, 2018). Diagnosis of dementia pre-stroke negatively impacts on outcome post-stroke (Saposnik et al., 2011), but despite this, there is very little research exploring the two conditions together and the best rehabilitation and care pathways for these patients are unknown. This issue is increased in complexity due to the fact only 61% of people ever receive a dementia diagnosis (Kane and Terry, 2015); this co-occurrence may affect many more people than is currently identified. This thesis therefore aims to develop knowledge of the impact of dementia on stroke rehabilitation, starting with a review of background literature.

1.3 **What is stroke rehabilitation?**

There is no universal definition of stroke rehabilitation. It can be defined broadly as:

> An educational, problem-solving process that focuses on activity limitations and aims to optimise patient social participation and well-being, and so reduce stress on carer/family.

(Wade 2005 p. 814)
Rehabilitation after stroke improves rate of recovery and functional outcome, therefore guidelines recommend all patients should have access to rehabilitation that helps meet their goals for recovery (Intercollegiate Stroke Working Party, 2016a). Definitions of stroke rehabilitation differ in their focus; for example Langhorne et al. (2011) emphasise the purpose of rehabilitation is to reduce disability resulting from a stroke, whereas the above definition focuses more broadly on optimising well-being. Generally, the purpose of rehabilitation is to limit the impact of stroke on a person’s life, whether this is through specific reduction of disability (and therefore improving function) or by enhancing participation in activities of daily living (Young and Forster, 2007). The definition presented above will be used for the purposes of this thesis. The UK National Clinical Guidelines for Stroke set out recommendations for delivery and frequency of rehabilitation and suggest all patients should receive rehabilitation whilst they are still able to participate and demonstrate benefit from treatment (Intercollegiate Stroke Working Party, 2016a). Detailed descriptions of stroke care and rehabilitation are available elsewhere (Young and Forster, 2007).

1.3.1 Benefits of stroke rehabilitation
There is much evidence supporting use of rehabilitation after stroke, and rehabilitation on specialised stroke units has been found to benefit all patients (Young and Forster, 2007; Langhorne et al., 2011; Stroke Unit Trialists Collaboration, 2013). A large Cochrane review found people who receive specialised inpatient stroke unit care and rehabilitation have higher rates of survival, higher levels of independence and are more likely to remain living at home than those who do not receive it (Stroke Unit Trialists Collaboration, 2013). In addition, these benefits were found for all patients regardless of age, sex, stroke severity or stroke type, indicating that all patients should be eligible to receive specialised care and rehabilitation after stroke (Stroke Unit Trialists Collaboration, 2013). However, some trials included in this review are over twenty years old, therefore may be less relevant due to significant changes in stroke service provision. Despite this, evidence of the benefits of rehabilitation is not limited to inpatient care. Early Supported Discharge (ESD) services, which provide community stroke rehabilitation, have been found to reduce length of hospital stay, increase independence and reduce likelihood of admission to institutional care for patients with
mild to moderate stroke-related disability when compared with standard care (Langhorne et al., 2017; Langhorne et al., 2005).

1.3.2 Changes in stroke care
Stroke care in the UK has improved over the past twenty years after the introduction of organised care and rehabilitation on stroke units (Stroke Unit Trialists Collaboration, 1997; Stroke Unit Trialists Collaboration, 2013). Specialised stroke units improve patient outcomes; multidisciplinary care and rehabilitation on a stroke unit starting as soon as possible after stroke has been found to improve mortality, independence and maintain the residential status of patients, and reduces healthcare costs (Langhorne et al., 2011; Stroke Unit Trialists Collaboration, 2013). The specialised stroke pathway is illustrated in Figure 1.1. Alongside improvements in care, there has been a significant reduction in stroke mortality worldwide since 1990 (Feigin et al., 2014) and public education campaigns have seen a reduction in delay to seeking medical attention and more people being admitted to hospital following a stroke (Wolters, 2015). Consequently, more people are surviving stroke worldwide than twenty years ago (Feigin et al., 2014).

The stroke population is also changing. Since 1990 more people over 75 are surviving stroke, alongside an increase in incidence of stroke for people under 75 (Feigin et al., 2014). This is particularly relevant when considering the co-morbidities people may have, such as dementia. The risk of developing dementia doubles every five years after the age of 65 (Prince et al., 2014) and stroke more than doubles the risk of subsequently developing vascular dementia (Ivan et al., 2004). Stroke and dementia also share many risk factors, for example hypertension, rates of which have risen consistently since 2005 (Stroke Association, 2018). It seems likely therefore that stroke services will see an increase in the number of patients with comorbid dementia. This has implications for service delivery and access to rehabilitation, which will now be discussed.
1.3.3 Access to stroke rehabilitation

Whilst the aforementioned benefits of stroke rehabilitation have been well documented, there is still disparity as to who does, or does not, receive stroke rehabilitation (Lynch et al., 2017a). There is evidence of inequality in access to stroke rehabilitation both in the UK and worldwide, with estimates ranging between 13%-57% of stroke patients receiving inpatient rehabilitation (Lynch et al., 2017a). Exclusions to rehabilitation services vary across current international clinical guidelines; in Canada, patients must demonstrate the potential ability to return to pre-stroke levels of function or to increase post-stroke functional level (Hebert et al., 2016); in the US patients must aim to be discharged into the community in order to be eligible to receive inpatient rehabilitation (Winstein et al., 2016). In Spanish guidelines, rehabilitation is not recommended for patients with severe stroke and ‘poor recovery prognosis’ (Lynch et al., 2017a). Conversely, many clinical guidelines do not define which patients should receive stroke rehabilitation (Jolliffe et al., 2018). The most recent UK clinical guidelines do not specifically exclude any types of patients, however there are no criteria for who should access rehabilitation either (Intercollegiate Stroke Working Party, 2016a; Lynch et al., 2017a).
The decision of who should access rehabilitation is therefore often left to clinicians, part of which involves clinicians deciding whether a patient possesses ‘rehabilitation potential’ (Burton et al., 2015). Rehabilitation potential is a controversial concept that has been described as a patient’s functional capacity for change through rehabilitation, dependent on a number of factors such as medical condition and lifestyle (Enderby et al., 2016). Information that predicts rehabilitation potential is scarce, with clinicians often relying on past experience, personal attributes of the patient, and prioritisation to inform judgements (Doyle et al., 2013; Burton et al., 2015). Perceptions of a patient’s potential for change may influence the rehabilitation they receive from therapists (Enderby et al., 2016). Decisions about rehabilitation potential may be affected by lack of opportunity to observe long-term improvement of individual patients in current models of stroke care (Burton et al., 2015). As such, clinical judgements about a lack of potential can be self-fulfilling, with patients perceived by staff as lacking in potential receiving less therapy and therefore making smaller gains in improvement (Demain et al., 2006). It is thought however that the most dependent individuals after stroke, who may be seen as having the least potential to change, are in fact the patients that benefit most from early rehabilitation (Enderby et al., 2016; Saposnik et al., 2011). This is particularly relevant when considering factors that may influence decisions about who should access rehabilitation.

The most recent systematic review addressing factors influencing access to rehabilitation identified 79 studies of patient-related factors that guided decision-making (Hakkennes et al., 2011). It was found that age, cognition and post-stroke function were the most important associations with functional outcome and were therefore likely to influence admission to stroke rehabilitation units (Hakkennes et al., 2011). This review included a variety of studies addressing prognostic indicators of patient outcomes, predictors of discharge destination and how patients are selected for rehabilitation. Whist there was large heterogeneity in study design for studies about selection for rehabilitation, it was found that impaired pre-stroke functioning was associated with a lower likelihood of a patient being accepted for rehabilitation. Other influential factors on selection for rehabilitation were age, amount of social support, pre-stroke cognition, level of consciousness and an absence of behavioural problems. It concluded that pre-stroke function and pre-stroke cognition are important aspects of rehabilitation acceptance criteria but there was little evidence addressing these
specifically, and as such their value as a measure of prognosis for rehabilitation is currently unknown (Hakkennes et al., 2011). A systematic review of factors influencing clinical decision-making around access to stroke rehabilitation was therefore essential (contained in chapter three). This was particularly important in order to identify how decisions are made given disparity in clinical guidance, and to identify whether dementia is an influential factor in decision-making.

1.3.4 Stroke rehabilitation summary
The benefits of stroke rehabilitation within hospital and community settings are well documented. However it is apparent there may be inequalities in access to rehabilitation, with many factors that may impact on acceptance to rehabilitation and unclear clinical guidelines about who should receive it (Jolliffe et al., 2018). This PhD focused on how pre-existing dementia influences stroke rehabilitation. The following sections therefore outline what dementia is, how pre-stroke and post-stroke dementia are distinguished, and what is known about the impact of dementia on stroke.

1.4 What is dementia?
The term dementia is an umbrella for a group of symptoms caused by certain brain diseases or conditions. These conditions can be grouped into the most common forms: Alzheimer’s disease, vascular dementia, mixed dementia, frontotemporal dementia, dementia with Lewy bodies, and rarer causes of dementia, for example dementia caused by Parkinson’s disease. It is estimated 850,000 people have a probable diagnosis of dementia in the UK, and this figure is expected to rise (Prince et al., 2014). Around 62% of people with dementia are diagnosed with probable Alzheimer’s disease, 17% of people with vascular dementia, and 10% with mixed dementia (predominately Alzheimer’s and vascular mixed aetiology) (Prince et al., 2014). The remaining 11% are diagnosed with frontotemporal dementia, dementia with Lewy bodies or dementia with other rarer causes (Prince et al., 2014). The definitions in this thesis focus on vascular causes of dementia due to the associations with stroke, however it is necessary to briefly outline Alzheimer’s disease due to its prevalence and contribution to mixed dementia (which tends to include vascular dementia).

It is useful to clarify the diagnostic criteria for dementia in order to understand the differences between the various terms. The American Psychiatric Association DSM-5
(2013) classification has introduced the term major neurocognitive disorder to define and replace the term ‘dementia’, and has distinctions between major and mild neurocognitive disorders. They state the reason for the change is to encompass cognitive impairments secondary to non-degenerative causes, such as trauma or HIV. The recognition of a cognitive impairment that is of concern to an individual or family member that does not meet the criteria for dementia is covered by the term mild neurocognitive disorder. The term dementia is still commonly used for research into pre- and post-stroke cognitive impairment, therefore will be used for this thesis. The criteria for a major and mild neurocognitive disorder are outlined in Table 1.1.

Table 1.1: DSM-5 criteria for major and mild neurocognitive disorder (American Psychiatric Association, 2013)

<table>
<thead>
<tr>
<th>DSM-5 Criteria</th>
<th>Major neurocognitive disorder</th>
<th>Mild neurocognitive disorder</th>
</tr>
</thead>
</table>
| A             | Evidence of **significant** cognitive decline from a previous level of performance in one or more cognitive domains (complex attention, executive function, learning and memory, language, perceptual-motor, or social cognition) based on:  
1. Concern of the individual, a knowledgeable informant, or the clinician that there has been a significant decline in cognitive function; and  
2. A **substantial impairment** in cognitive performance, preferably documented by standardized neuropsychological testing or, in its absence, another quantified clinical assessment. | Evidence of **modest** cognitive decline from a previous level of performance in one or more cognitive domains (complex attention, executive function, learning and memory, language, perceptual-motor, or social cognition) based on:  
1. Concern of the individual, a knowledgeable informant, or the clinician that there has been a mild decline in cognitive function; and  
2. A **modest impairment** in cognitive performance, preferably documented by standardized neuropsychological testing or, in its absence, another quantified clinical assessment. |
| B             | The cognitive deficits **interfere with independence** in everyday activities (i.e., at a minimum, requiring assistance with complex instrumental activities of daily living such as paying bills or managing medications). | The cognitive deficits **do not interfere with capacity for independence** in everyday activities (i.e., complex instrumental activities of daily living such as paying bills or managing medications are preserved, but greater effort, compensatory strategies, or accommodation may be required). |
| C             | The cognitive deficits do not occur exclusively in the context of a delirium. | The cognitive deficits do not occur exclusively in the context of a delirium. |
| D             | The cognitive deficits are not better explained by another mental disorder (e.g., a major depressive disorder). | The cognitive deficits are not better explained by another mental disorder (e.g., major depressive disorder). |
1.4.1 Alzheimer’s disease

Alzheimer’s disease is commonly characterised by its progressive nature and the most recognised symptom of short-term memory loss. It is caused by the build-up of proteins in the brain forming amyloid plaques and neurofibrillary tangles which interfere with the structure of nerve cells, leading to tissue loss (Alzheimer’s Society, 2014). Alzheimer’s disease can be categorised into sub-types to distinguish pathology however as it is peripheral to the topic, this section will only give a brief overview of general diagnostic criteria. The American Psychiatric Association DSM-IV (1994) criteria for a diagnosis of Alzheimer’s disease has been recognised as the most widely used criteria since its inception (Dubois et al., 2007; Jack Jr et al., 2011). Part of the updated DSM-5 criteria is outlined in Table 1.2.

**Table 1.2: Section of the DSM-5 criteria for probable Alzheimer’s disease.**

<table>
<thead>
<tr>
<th>DSM-5 criteria</th>
<th>To be diagnosed with probable Alzheimer’s, all three of the following must be present:</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>Clear evidence of decline in memory and learning and at least one other cognitive domain (based on detailed history or serial neuropsychological testing).</td>
</tr>
<tr>
<td>B</td>
<td>Steadily progressive, gradual decline in cognition, without extended plateaus</td>
</tr>
<tr>
<td>C</td>
<td>No evidence of mixed etiology (i.e., absence of other neurodegenerative or cerebrovascular disease, or another neurological, mental, or systemic disease or condition likely contributing to cognitive decline).</td>
</tr>
</tbody>
</table>

The criteria also states a person must meet with criteria for a major neurocognitive disorder, as previously outlined in Table 1.1. Evidence surrounding the use of biomarkers to diagnose Alzheimer’s disease has been used to update criteria, however these are only currently used in research settings and are not used as general diagnostic tests (McKhan et al., 2011; Dubois et al., 2014). The DSM-5 also states evidence of a genetic mutation either from family history or tests should be used in diagnosis of probable diagnosis of Alzheimer’s disease. The key differentiation between Alzheimer’s disease and vascular dementia criteria is the fact memory impairment is required for a diagnosis of Alzheimer’s and it progresses steadily. All criteria state there should be no evidence of ‘mixed aetiology’, and that the cognitive decline is not better explained by another disease. The most important reason for distinguishing Alzheimer’s disease from other dementias is the pharmacological treatments available to slow the progression of Alzheimer’s have not been found to be effective for other sole causes of dementia and are not readily available for other subtypes.
1.4.2 **Vascular cognitive impairment**

The term vascular cognitive impairment (VCI) is broad, referring to all forms of cognitive impairment attributable to cerebrovascular disease (O'Brien et al., 2003; Gorelick et al., 2011). It includes vascular dementia, post-stroke cognitive impairment, cognitive impairment associated with small vessel disease to even cognitive deficits found in people with diabetes (Birns and Kalra, 2007; Seshadri et al., 2015). Similar to the term dementia, VCI is a syndrome rather than a diagnosis in itself. Not all causes of VCI are progressive and some argue that the term vascular dementia be reserved for those with types of VCI who have a progressive decline in cognition regardless of the specific cause, in order to distinguish the terms VCI and vascular dementia (de Haan et al., 2006). The American Heart Association and American Stroke Association (AHA-ASA, 2011) joint statement on VCI states:

VCI is a syndrome with evidence of clinical stroke or subclinical vascular brain injury and cognitive impairment affecting at least one cognitive domain. (p. 2677)

It goes on to state that the most severe form of VCI is vascular dementia (Gorelick et al., 2011). Vascular cognitive impairment also encompasses the interchangeable terms ‘vascular mild cognitive impairment’ and ‘vascular cognitive impairment no dementia’, which are both used to describe a mild cognitive impairment related to cerebrovascular disease which does not meet the criteria for dementia (Moorhouse and Rockwood, 2008).

There is a large amount of literature addressing the concept and definition of vascular cognitive impairment that is beyond the scope of this thesis. For the purpose of this thesis, the term ‘vascular cognitive impairment’ will refer to any form of cognitive disorder in which vascular disease is the presumed primary cause (Sachdev et al., 2014).

1.4.3 **Vascular dementia**

Vascular dementia is characterised by a sudden or gradual onset, with a typically stepped progression that worsens with ischaemic events. This differs to Alzheimer’s disease, in which progression is gradual and has no known vascular cause (Román,
Vascular dementia often consists of greater impairment in executive function than memory, which differs from the traditional perception of dementia as memory loss. Some of the diagnostic tools do not require a memory impairment at all for a diagnosis of vascular dementia, as illustrated in Table 1.3 (Blackburn et al., 2013). Figure 1.2 illustrates how vascular dementia fits into the wider concept of vascular cognitive impairments.

Figure 1.2: Diagram created to illustrate overlap of vascular cognitive impairments and Alzheimer’s disease (not to scale).

There are a number of diagnostic tools which seek to define the diagnostic criteria for vascular dementia. There appears to be no consensus on how to define vascular dementia, or even what term should be used to describe the condition. Vascular dementia has traditionally been known as multi-infarct dementia, in which cognitive impairment caused by vascular disease is due to multiple cortical infarcts (Hachinski et al., 1974). The concept of single-infarct dementia emerged from the discovery that a single infarct (an ischaemic stroke) can cause dementia, depending on the location of the infarct (Seshadri et al., 2015). The term vascular dementia is therefore traditionally used to describe any form of dementia occurring after a clinically recognised stroke,
However the cause can be more subtle than this. Improvements in imaging techniques can now detect micro bleeds and microscopic unnoticed infarcts in the brain, which although not clinically recognised as a stroke can be linked to vascular dementia (Seshadri et al., 2015).

There have been at least six different sets of criteria used for the diagnosis of vascular dementia in the past 40 years (Seshadri et al., 2015). These multiple classifications have been found to have little agreement when compared. A comparison using six classifications to diagnose 1879 people with vascular dementia found a wide range of disagreement between criteria (Erkinjuntti et al., 1997). 3.1% to 29.1% of total participants were diagnosed as having dementia depending on the criteria used. Only 20 participants in total were given a diagnosis with all six criteria. Similar results have been found in other comparisons over a number of years, therefore the more general DSM criteria are the most commonly used due to the discrepancies between specific vascular dementia criteria (Pohjasvaara et al., 2000). The recent International Society for Vascular Behavioural and Cognitive Disorders (VASCOG) criteria attempts to harmonise all previous criteria and take new research into account (Sachdev et al., 2014). Table 1.3 compares the key features of the four most commonly used classifications in research settings. Although the VASCOG definition is very similar to the widely used DSM-5 definition, it does not require evidence of stroke or memory loss, and allows a mixed diagnosis whereas DSM-5 does not. The VASCOG criteria for establishing a vascular cause for a neurocognitive disorder are summarised as:

- The onset of cognitive deficit is temporally related to one or more stroke.
- Cognitive deficits persist for 3 months after stroke.
- In the absence of stroke/TIA there is a slowing of information processing, decline in attention and executive function plus a gait disturbance, urinary symptoms or personality change.
- There is neuroimaging evidence of cerebrovascular disease – one large vessel infarct; extensive or strategic single infarct; multiple lacunar infarcts; extensive white matter lesions; one strategically placed or multiple intracerebral haemorrhage; or a combination of all these.

(Sachdev et al., 2014)
Table 1.3: Comparison of vascular dementia diagnostic criteria.

<table>
<thead>
<tr>
<th>Criteria required for diagnosis</th>
<th>VASCOG (1)</th>
<th>DSM-5 (2)</th>
<th>ICD-10 (3)</th>
<th>NINDS-AIREN (4)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Term used</td>
<td>Major vascular neurocognitive disorder</td>
<td>Major neurocognitive disorder</td>
<td>Vascular dementia</td>
<td>Vascular dementia</td>
</tr>
<tr>
<td>Cognitive domains assessed</td>
<td>Attention and processing, executive function, learning and memory, language, visuoconstructional-perceptual, praxis-gnosiss-body scheme, social cognition</td>
<td>Complex attention, executive function, learning and memory, language, perceptual-motor, social cognition</td>
<td>Memory and learning, executive function, social cognition, behaviour change</td>
<td>Attention, orientation, executive functions, language, visuospatial, motor control, praxis</td>
</tr>
<tr>
<td>Memory loss required for diagnosis</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Evidence of stroke required</td>
<td>Yes, or executive/processing/attention decline with gait disturbance, urinary frequency or personality change</td>
<td>Yes, or evidence of sufficient cerebrovascular disease</td>
<td>Yes, or clinical evidence of focal brain damage</td>
<td>Yes</td>
</tr>
<tr>
<td>Mixed diagnosis allowed</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Exclusions</td>
<td>Presence of delirium, or other conditions of sufficient severity to cause cognitive problems</td>
<td>Delirium, other mental disorders</td>
<td>Delirium</td>
<td>Delirium, other mental disorders, severe aphasia, major sensorimotor impairment</td>
</tr>
</tbody>
</table>

1. International Society for Vascular Behavioural and Cognitive Disorders (VASCOG) (Sachdev et al., 2014)

1.4.4 Post-stroke dementia

As previously stated, multi or single infarct dementia is often used to describe dementia following a stroke. The term post-stroke dementia (PSD) refers to a cognitive impairment that classifies as meeting the criteria for vascular dementia after diagnosis of a clinical stroke, and the term is often used interchangeably with vascular dementia in the literature (Ankolekar et al., 2010).
The VASCOG criteria states cognitive deficits must persist for at least three months after stroke in order to be diagnosed with a vascular neurocognitive disorder. A widely accepted three month cut-off for persisting cognitive impairment after stroke is often used to define PSD, but there appears to be little evidence surrounding where the three month figure originated, only general consensus in the literature (Kalaria et al., 2016). Studies have found cognitive impairment in at least one domain that is not significant enough to meet the criteria for vascular dementia (i.e. not interfering with independence in activities of daily living) is often still present three months after stroke, indicating that timing of assessment needs consideration when diagnosing dementia (Jokinen et al., 2015). This will be discussed further in section 1.5.5.

The criteria for vascular dementia overlaps with PSD because clinical stroke is not necessary for a diagnosis of vascular dementia (Ankolekar et al., 2010). Some define PSD as all types of dementia that occur directly after stroke, not just limited to dementia of a vascular origin (Leys et al., 2005). Alzheimer’s disease pathology is often also present in those with cerebrovascular disease although due to the complexity in diagnosing mixed dementia it is difficult to subtype the dementia classification post-stroke if there was no prior diagnosis. In fact, all dementia subtypes are probable and can only be confirmed post-mortem (Dubois et al., 2014).

Whilst the different types of vascular cognitive impairment are not always clearly distinguished in the literature and frequently overlap, it is clear that stroke has a significant impact on causing dementia.

1.4.5 **Small vessel disease**
Cerebral small vessel disease (SVD) is a general term for a variety of processes affecting or blocking small blood vessels in the brain. The most common causes of SVD are hypertension and cerebral amyloid angiopathy (Rodríguez García and Rodríguez García, 2015). Cerebral amyloid angiopathy refers to the accumulation of amyloid proteins in the walls of blood vessels in the brain and is associated with haemorrhagic stroke as well as Alzheimer’s disease (Kalaria, 2002). SVD can result in ischaemic white matter lesions (sometimes termed leukoaraisis) and lacunar infarcts, and is associated with the development of all dementias (Kalaria, 2002; Prins et al., 2005). Lacunar
infarcts are small, subcortical infarcts and commonly cause cognitive impairment (Makin et al., 2013). SVD can cause problems with cognition, mood and behaviour disturbances, and gait problems; SVD can also be present in those with no signs of cognitive impairment (Rodríguez García and Rodríguez García, 2015).

The term subcortical ischaemic vascular dementia is sometimes used to describe vascular dementia with SVD as the main identified cause (O'Brien et al., 2003). SVD is thought to be the most common vascular cause for cognitive impairment and its presence can predict risk of stroke or dementia (Debette and Markus, 2010; Makin et al., 2013; Caratozzolo et al., 2016).

1.4.6 **Mild cognitive impairment**

Mild cognitive impairment (MCI) is a "cognitive decline greater than expected for an individual's age and education level but that does not interfere notably with activities of daily life" (Gauthier et al., 2006). It is defined in the DSM-5 as a mild neurocognitive disorder and represents cognitive changes that are not part of the normal aging process, but that do not reach the full criteria for a diagnosis of dementia (Petersen et al., 2014). 'Normal' aging can be thought of as an absence of any age-related condition that may affect cognitive function, with an expected decline in processing speed and episodic memory (Fjell et al., 2014). MCI can include amnestic and non-amnestic symptoms, and may have behavioural symptoms such as anxiety or depression (Lyketsos et al., 2002). The DSM-5 definition of mild neurocognitive disorder is very similar to the widely used 2003 International Working Group on MCI criteria (Winblad et al., 2004), which emphasises a decline in cognition over time, and that cognitive decline is not just limited to memory.

1.4.7 **Mixed dementia**

The multiple criteria used to define both Alzheimer's disease and vascular dementia generally appear to neglect that a person may have a mixed element to their dementia. The co-occurrence of cerebrovascular disease and Alzheimer's disease has been recognised by large pathological studies (Snowdon, 2003; Toledo et al., 2013), however this is not acknowledged by most of the diagnostic criteria (for example the DSM-5 or ICD-10) (Korczyn and Vakhapova, 2010). The DSM-5, ICD-10 and NINDS-AIREN all specify there should be no better explanation for the cognitive impairment
than the identified cause, which automatically excludes the possibility of both Alzheimer’s and vascular changes causing cognitive impairment.

Research into the interaction between Alzheimer’s disease and vascular changes has increased in recent years, and it is widely considered that vascular causes of dementia have been underestimated (Smith, 2017). Pathological studies have demonstrated that many patients with clinical dementia have both Alzheimer’s and vascular changes, and those with both pathologies tend to have more severe cognitive impairment than those with a similar degree of either (Snowdon, 2003). These studies have also demonstrated that with increasing age the risk of cerebrovascular disease and Alzheimer’s disease co-occurring increases (Snowdon, 2003; Schneider et al., 2009; Toledo et al., 2013). Age is the strongest risk factor for both stroke and all types of dementia (Seshadri et al., 2006; Prince et al., 2014).

There are arguments against separating dementia into vascular and neurodegenerative categories due to the growing evidence supporting a mixed pathology (Korczyn and Vakhapova, 2010). This has significant implications for treatment, because pharmacological treatments for Alzheimer’s disease have been shown to benefit patients with probable mixed vascular and Alzheimer’s dementia with cerebrovascular disease, although this treatment is not yet widely available due to the complexities in diagnosis (Erkinjuntti et al., 2002).

1.4.8 Dementia summary
There is evidently substantial overlap and lack of clarity surrounding the definitions of vascular dementia. Moreover, there is a growing recognition for mixed causes of dementia, which has implications for treatment due to the pharmacological management of Alzheimer’s disease (Erkinjuntti et al., 2002). Diagnosis of two chronic conditions, such as stroke and dementia, may create further complexities into both the management of each, and of the lived experience of the conditions (Prince et al., 2014). The literature linking the two conditions will now be presented, in particular how pre-existing dementia and post-stroke dementia are differentiated.
1.5 **Distinguishing pre- and post-stroke dementia**

As discussed, there is much overlap among terms addressing vascular causes for dementia, which potentially leads to confusion when discussing dementia after stroke. It is sometimes difficult to ascertain whether research is addressing a pre-stroke diagnosis of dementia or progressive dementia after stroke. In addition, many people may have SVD or MCI prior to a stroke which may impact on their subsequent development and diagnosis of dementia. This section will address the ways in which pre- and post-stroke dementia are differentiated in the literature.

1.5.1 **Post-stroke cognitive impairment**

It is important to note the difference between post-stroke cognitive impairment and post-stroke dementia. Cognition is a broad concept that encompasses multiple domains. These can be generally categorised as complex attention, executive function, learning and memory, language, and visuospatial ability (Cumming et al., 2013). Most patients experience some form of cognitive impairment early after stroke, and prolonged cognitive impairment is associated with poorer rehabilitation outcomes (Intercollegiate Stroke Working Party, 2016a). Prolonged impairment in one or more cognitive domain can impact on all areas of cognition and functioning because the domains generally work together when performing tasks. Identification of cognitive impairment is important in order for patients to receive appropriate rehabilitation interventions (Intercollegiate Stroke Working Party, 2016a).

Stroke research and clinical guidance tends to focus on single domains rather than the general concept of cognitive impairment (Jokinen et al., 2015). As shown in Table 1.3, different methods of assessment of impairment might focus on one domain over another, or categorise them differently. Post-stroke cognitive impairment and post-stroke dementia appear to differ in that the term dementia indicates a progressive declining condition, whereas cognitive impairment refers to a state that may remain static or improve which does not meet the aforementioned criteria for dementia (del Ser et al., 2005; Sachs-Ericsson and Blazer, 2015). This difference in progression is especially true in those who are diagnosed with PSD after recurrent stroke or who have pre-stroke cognitive impairment (del Ser et al., 2005). There is a wealth of literature surrounding assessment of post-stroke cognitive impairment and recommendations for
domain specific rehabilitation; however that is beyond the scope of this thesis (Cicerone et al., 2011; Bowen and Patchick, 2013).

1.5.2 **Incidence of pre-stroke dementia**
Currently, around 10% of people are estimated to have dementia before their first stroke (Pendlebury and Rothwell, 2009). Pre-stroke dementia is associated with greater stroke severity and increased mortality (Pendlebury, 2009), and pre-stroke cognitive decline is associated with development of dementia post-stroke (Pohjasvaara et al., 1998; Hénon et al., 2001; Caratozzolo et al., 2016). Significant memory decline over time is also associated with risk of stroke (Wang et al., 2012).

A systematic review and meta-analysis of prevalence of pre- and post-stroke dementia found only eleven out of thirty studies included rates of pre-stroke dementia (Pendlebury and Rothwell, 2009). They reported higher rates of pre-stroke dementia in hospital-based studies (14%) versus community-based (9%) due to community-based studies restricting to first ever stroke. Many hospital-based studies used retrospective methods of assessing for pre-stroke dementia, which is an identified limitation. Often the Informant Questionnaire on Cognitive Decline in the Elderly (IQCODE) (Jorm et al., 1989) is used as the sole method of identifying pre-existing dementia. This is a well validated measure in non-stroke populations and has been found to be a good predictor of dementia in patients post-stroke (Tang et al., 2004), however rates of pre-stroke dementia are likely to be underestimated due to the small amounts of data. There is also no validation of using the IQCODE as a measure of pre-stroke cognition in stroke (McGovern et al., 2016).

It has also been estimated that only 61% of people with dementia in England ever have a formal diagnosis, which varies regionally with some areas having diagnosis rates of only 50% (Kane and Terry, 2015). Cognitive impairment is often undiagnosed prior to stroke, with stroke revealing underlying SVD for the first time for that patient (Caratozzolo et al., 2016). As discussed, diagnosing dementia is a complex process. For this reason, research and statistics may be likely to under represent all people living with dementia and perhaps even overlook individuals with less clear diagnosis. There is also a risk of over or misdiagnosing dementia as highlighted by the increase in diagnosis rates following introduction of a financial incentive for the GP Quality
Outcome Framework recording, although this increase is not necessarily a causal link (Mukadam et al., 2014).

1.5.3 Incidence of post-stroke dementia

Stoke more than doubles the risk of developing vascular dementia (Ivan et al., 2004). A case-control study of prospective risk of 212 participants found risk of all types of dementia doubled after ischaemic stroke over 10 years after adjustment for age, gender, education and individual risk factors (Ivan et al., 2004). Similarly, a study of the medical records of 971 community dwelling people found any type of dementia developed at twice the expected rate over 25 years following ischaemic stroke (Kokmen et al., 1996). Stroke location and severity have been found to affect incidence of PSD (Moulin et al., 2016). A study of 218 patients found 14.2% developed PSD within one year, but incidence differed depending on stroke location in the brain. PSD has been found to be associated with older age, more severe stroke, previous stroke, and recurrent stroke during follow up (Moulin et al., 2016).

Pendlebury and Rothwell’s (2009) meta-analysis estimated around 10% of people develop a new cognitive impairment that can be classified as dementia three or more months post-stroke, and a third of people develop dementia after recurrent stroke. This paper did not specify type of dementia, but as discussed it is usually presumed vascular due to the difficulty subtyping post-stroke (Leys et al., 2005). Between 16-29% of people living with any dementia have also been estimated to have had a stroke (Bunn et al., 2014). Estimates of prevalence of post-stroke cognitive impairment are variable due to differences in assessment methods, ranging between 22%-83%, and post-stroke cognitive impairment can develop into dementia (Douiri et al., 2013; Jokinen et al., 2015; Moulin et al., 2016). Many studies exploring the incidence of post-stroke dementia fail to account for levels of pre-stroke dementia, or exclude patients with pre-existing dementia entirely (e.g. Patel et al., 2002), which may impact on recorded incidence rates (Pendlebury and Rothwell, 2009). A recent study of 404 patients into prevalence of post-stroke neurocognitive disorder categorised 10% of participants with dementia using the VASCOG criteria, and 39% with mild neurocognitive disorder, although people with pre-stroke dementia were again excluded (Barbay et al., 2018).
PSD also has similar risk factors to pre-stroke dementia. Age, female sex, low education, and vascular risk factors such as diabetes and atrial fibrillation (AF) are all associated with both (Pendlebury, 2009). Pendlebury and Rothwell’s (2009) review found hypertension, ischemic heart disease and prior TIA were only associated with pre-stroke dementia, not post-stroke. They hypothesise that vascular risk is significant in the development of a pre-stroke degenerative cognitive impairment but after a stroke, the impairment is more dependent on the stroke itself (Pendlebury and Rothwell, 2009).

1.5.4 Assessment of cognition in stroke
Historically in research settings, the most commonly used assessments for post-stroke cognitive impairment/dementia have been the Mini Mental State Examination (MMSE) and the Montreal Cognitive Assessment (MoCA). The MMSE is often used to assess for dementia but this has been found to have poor validity in assessment of cognitive impairment post-stroke (Nys et al., 2005b). The MoCA has been found to be valid in assessment post-stroke, and for Alzheimer’s and MCI (Nasreddine et al., 2005). The MMSE is therefore not the most appropriate assessment post-stroke but it is still often used (e.g. Patel et al. (2002)). There are numerous papers comparing the use of the MoCA and MMSE in the acute stroke setting (e.g. Dong et al. 2010; Blackburn et al. 2013).

Guidelines on early assessment of cognitive impairment after stroke are outlined by the UK National Clinical Guidelines for Stroke. These state every patient should be expected to experience an element of cognitive impairment initially post-stroke, and recommend the use of a standardised measurement such as the MoCA or the Oxford Cognitive Screen as a routine screening tool for general cognitive functioning (Intercollegiate Stroke Working Party, 2016a). Further cognitive assessment is recommended if indicated, although the guidelines provide no detail about assessing cognitive decline associated with cerebrovascular disease. The American Heart Association guidelines on stroke rehabilitation do not recommend any one particular measure to screen for cognitive impairment, and the MoCA is not included in the list of suggested tools (Miller et al., 2010). The guidelines do suggest screening for dementia when planning care but no time point or measure is suggested.
Diagnosis of cognitive impairment or dementia post-stroke in the literature is often dependant on the assessment used (Rasquin et al., 2005). Also, differences in assessment method seem to be confounded by the amount of diagnostic criteria to diagnose vascular dementia, and the mixing of the tools for assessment and diagnosis. For example, in Patel et al.’s (2002) study cognitive impairment after stroke was assessed using the MMSE. The author’s acknowledge they were assessing cognitive impairment rather than dementia, and yet the results are included in Pendlebury and Rothwell’s (2009) meta-analysis of PSD. Studies using MMSE scores as indicative of dementia identify higher rates of dementia in post-stroke populations than those using standardised criteria (Pendlebury and Rothwell, 2009).

This variety of assessment tools in research is not limited to the MMSE. A longitudinal study into progression of cognitive impairment over two years post-stroke found the majority of participants’ cognition remained stable, and in others it improved or progressively worsened (del Ser et al., 2005). In this study of 193 people, participants were followed up at 3, 6, 12 and 24 months post stroke. The authors found 78.2% of participants remained cognitively stable over 24 months, 21.8% worsened and 7.8% improved. Five participants assessed as having dementia at three months improved to no dementia or cognitive decline (indicating initial misdiagnosis), and seven participants with cognitive impairment subsequently worsened to a diagnosis of dementia. Participants who worsened had high rates of illiteracy, previous cognitive impairment and were older, which has been associated with post-stroke vascular dementia by other studies (Desmond et al., 2002; Pendlebury, 2009). The measure used to assess stage of cognition however, the Clinical Dementia Rating (CDR), does not appear to be validated in populations post-stroke and is normally used to define stages of Alzheimer’s type dementia (Hughes et al., 1982). This may therefore lead to misrepresentations of levels of dementia. Additionally, patients with pre-existing diagnosis of dementia were excluded from this study, therefore it is unknown whether their dementia deteriorated after stroke (del Ser et al., 2005).

This highlights the difficulty in identifying whether a person has cognitive impairment or dementia when solely based on the assessment used. The use of a variety of cognitive assessments is not exclusive to research and can be found in clinical practice. For example, Lees et al. (2014) surveyed stroke clinicians and found 45 different cognitive screening tools were being used across stroke services in Scotland to identify
cognitive impairments, with the MMSE being the most used. One area that was therefore important to address in the qualitative study presented in this thesis (chapter four) was how clinicians identify cognitive impairment and whether they use this information in clinical practice.

Despite this, Pendlebury and Rothwell’s (2009) systematic review of PSD identified substantial variance of results related to differences in study design rather than assessment used. Studies involved in the review included those which assessed dementia using standard criteria such as the DSM-IV or ICD-10 or used the results of the MMSE as an outcome. They found substantial variation in rates of PSD measured using different assessment criteria, but when studies were stratified by setting, recurrent stroke inclusion or by pre-stroke dementia, rates of variation decreased. They concluded that study heterogeneity is due to differences in study design rather than assessment used.

1.5.5 Timing of cognitive assessment
The time point at which cognitive assessment is conducted after stroke can affect rate and type of diagnosis. Cognitive assessments performed in the acute hospital environment post-stroke identify a high (over 70%) proportion of people as cognitively impaired (Blackburn et al., 2013). Around two thirds of people are identified as cognitively impaired when assessed on an acute stroke unit (Nys et al., 2005a). However as previously highlighted, this can be dependent on the assessment used. Spontaneous recovery is also common after stroke, which has implications for timing of assessments used to inform care (Ballard et al., 2003).

As seen in the criteria for vascular dementia, it is important to exclude other causes of cognitive impairment when diagnosing dementia or cognitive impairment. Delirium is common in up to one third of patients admitted to hospital with acute stroke (Shi et al., 2012). For this reason, in Pendlebury and Rothwell’s (2009) systematic review they excluded all studies with less than a three month follow up post-stroke. Whilst PSD is often defined by an onset within three months after stroke, cognitive impairment can persist for more than three months after stroke and not necessarily develop into dementia, which is important when identifying the most appropriate time for assessment (del Ser et al., 2005; Kalaria et al., 2016; Sachs-Ericsson and Blazer, 2015).
Cognitive impairment has also been observed in patients who had otherwise regained function three months post-stroke using specific assessments (Jokinen et al., 2015). In Jokinen et al.’s study into prevalence of domain specific cognitive impairment at three months, the authors found 83% of 409 participants had cognitive impairment in at least one domain using neuropsychological tests rather than if assessed with a general measure such as the MMSE. A subgroup of 152 physically well recovered participants was still found to be cognitively impaired (71%). Although they note a significant association of cognitive impairment and reduced functional independence at 15 months, it is not specified whether any participants were subsequently diagnosed with dementia (Jokinen et al., 2015).

1.5.6 **Pre- and post-stroke dementia summary**

The boundary differentiating pre- and post-stroke dementia is unclear. Identification of both is important because presence of prolonged cognitive impairment affects functional outcomes after stroke, and may develop into dementia (Intercollegiate Stroke Working Party, 2016a). Stroke rehabilitation services may provide treatment for someone who has cognitive impairment following a stroke, although it unknown whether clinicians distinguish between pre-stroke dementia, PSD or cognitive impairment. Stroke and dementia are inextricably linked therefore it is important to acknowledge the limited research into pre- or post-stroke dementia. Studies often exclude patients with pre-existing dementia, however these appear to be a significant proportion of patients. The next section will discuss what is known about people with pre-existing dementia within stroke services.

1.6 **What is known about the experience of pre-stroke dementia?**

It is clear many patients within stroke services are likely to have pre-existing cognitive impairment or dementia (Caratozzolo et al., 2016). There is a lack of research into pre-stroke dementia specifically and the impact on rehabilitation, service delivery or the experience of patients. Although dementia has seen an increased focus and significant financial investment from the UK government since 2009 through policy (Department of Health, 2009), as yet there are no specific recommendations in place for people with dementia after stroke. In fact, the National Clinical Guidelines for Stroke
(Intercollegiate Stroke Working Party, 2016a) acknowledge that the information on
cognition is not directly related to cerebrovascular disease. People living with dementia
or stroke often have multiple comorbidities to manage and cardiovascular risk factors
(for example, high blood pressure or diabetes), therefore connecting up of services is
vital.

1.6.1 Long-term outcomes
Cognitive impairment and dementia are associated with poorer long-term outcomes
Both PSD and pre-existing dementia have been found to increase the risk of death one
year post-stroke (Appelros et al., 2003; Tatemichi et al., 1994). In a study of 9304
stroke patients in Canada, researchers found the 9% of patients with pre-existing
dementia had higher rates of disability at discharge. People with pre-existing dementia
were less likely to be discharged to their pre-stroke place of residence, 24% compared
with 45% of people without (Saposnik et al., 2011). Disability was assessed using the
modified Rankin scale (van Swieten et al., 1988), a 6-point scale rating disability
related to level of mobility and ability to complete activities of daily living. It was
concluded that pre-existing dementia was associated with higher rates of disability and
institutionalisation after stroke. Saposnik et al.’s (2011) study was restricted to first
ever stroke, and it is known that PSD is associated with recurrent stroke (Pendlebury
and Rothwell, 2009). Participants were diagnosed with any type of dementia pre-stroke
(including vascular) so those with vascular dementia are likely to have a decline in
motor or executive function post-stroke due to the nature of the disease. It is possible
that with recurrent stroke, patients with dementia would exhibit even higher rates of
disability post-stroke.

A study comparing short-term outcomes for 919 stroke patients found that whilst the
11.5% of patients with pre-existing dementia had a higher level of disability at baseline
and discharge than patients without, they made similar daily gains in motor function as
measured using the Functional Independence Measure, a validated tool within stroke
rehabilitation (Mizrahi et al., 2016). This suggests that patients with pre-existing
dementia are able to benefit from stroke rehabilitation, at least in the short term
(measured up to 50 days). It was also found they had shorter lengths of hospital stay,
however no data was collected about discharge destination (Mizrahi et al., 2016).
It appears unclear whether poorer long-term outcomes are related to limited opportunity for rehabilitation received after stroke, or other factors. Little is known about the impact of dementia or cognitive impairment on referral to stroke rehabilitation, and the influence it has on decisions made about patient care, which will ultimately influence long-term outcomes. There is no guidance or recommendations specific for people with dementia prior to stroke or how best to approach rehabilitation for these patients. The American Heart Association acknowledges that cognitive assessment may impact on choice of interventions provided by clinicians, although do not detail how or in what way (Duncan et al., 2005; Miller et al., 2010).

1.6.2 Support needs of people with pre-stroke dementia
Presence of cognitive impairment or dementia can affect outcomes after stroke, therefore stroke services should take this into account when designing services. An Alzheimer’s Society survey of 570 of carers and families of people with dementia found that only 2% felt hospital staff understood the specific needs of people with dementia, indicating a divisive gap in service provision (Boaden, 2016).

Diagnosis allows patients to access post-diagnostic support. An Alzheimer’s Society poll of over 1000 GP’s found that 27% would be less likely to refer or diagnose patients if there is a lack of post-diagnostic support in place (Kane and Terry, 2015). When estimating the cost of dementia, it was assumed by Prince et al (2014) that people without a diagnosis are less likely to use formal support services, which has implications for care sectors as well as research (Prince et al., 2014).

When considering the support needs of people with pre-existing dementia after stroke, post-stroke difficulties need to be taken into account alongside cognitive impairments. Communication problems are common after stroke and can also contribute to difficulty engaging with others (Code and Herrmann, 2003). Dealing with communication difficulties has been reported to be a major priority for carers of people after stroke and can contribute to social problems for both stroke survivors and carers (Mackenzie et al., 2007). People with severe aphasia are also often excluded from trials into cognitive impairment after stroke, which needs to be accounted for when developing methods to support people with cognitive impairments (Pohjasvaara et al., 1997). Communication problems can lead to a person having little opportunity to assert choice.
and control over their lives, and excluded from some services due to being them inaccessible or inappropriate (Parr, 2007). Therefore a person with both dementia and communication problems is at risk of becoming even more isolated after stroke.

1.6.2.1 Managing comorbid conditions
Co-morbidities may affect patient outcomes after stroke and experience of services. Evidence suggests around three-quarters of patients with acute stroke in the UK have at least one co-morbid medical condition, and one in ten of those have at least three (Intercollegiate Stroke Working Party, 2016a). The Alzheimer’s Society reported 72% of people with dementia have another medical condition or disability (Dowrick and Southern, 2014). A scoping literature review into prevalence and delivery of services for people with dementia and comorbid diabetes, stroke or visual impairment found significant numbers of comorbid conditions (Bunn et al., 2014). This study found despite a high level of comorbidity, there was evidence that people with dementia have restricted access to treatment and monitoring for their conditions compared to those without. One study of 1006 people with dementia plus one or more vascular risk factor found the level of care for vascular risk (for example, regular cholesterol monitoring as a risk factor for stroke) was significantly lower than the care provided for people without dementia matched for risk (Connolly et al., 2013). It has been hypothesised that clinicians may be reluctant to investigate and treat patients with dementia due to treatments being seen as inappropriate for older patients with multiple conditions (Bunn et al., 2014). Dementia may also become the clinically dominant condition and clinicians might concentrate on treating behavioural or psychological symptoms of dementia rather than other conditions (Bunn et al., 2014). There is currently very little research into how dementia influences treatment decisions and the experience of people with dementia living with and managing comorbid conditions such as stroke, which has implications for the commissioning and delivery of stroke services. It therefore seems relevant to acknowledge this gap when considering the impact of dementia on stroke care pathways.

1.6.3 Patient experience of pre-stroke dementia
No research currently exists specifically exploring the experience of stroke from the perspective of people with pre-existing dementia (as opposed to post-stroke cognitive problems). Despite this, the measurement of subjective experience of cognitive decline
has been found to be an early identifier of actual cognitive decline (Geerlings et al., 1999). A study of patients with SVD presenting at a memory clinic found those reporting experience of subjective cognitive decline were at an increased risk of progression to clinical dementia over a year than those who did not report it (Benedictus et al., 2015). Studies into the outcome of patients’ experience of subjective cognitive decline after stroke have been less conclusive. A systematic review of subjective cognitive complaints after stroke identified that cognitive complaints are common after stroke, and when present they tend to increase over time (van Rijsbergen et al., 2014). Common concerns focused on memory, processing speed and concentration. It was also found that subjective cognitive complaints were not always associated with objective performance on cognitive tests or with progressive decline. This review related to cognitive impairment rather than dementia, however it is still useful when considering the long term effect of chronic cognitive impairment on stroke. A recent study investigated the effect of subjective cognitive complaints on quality of life and everyday function after stroke, however participants with pre-existing dementia were excluded (van Rijsbergen et al., 2018).

1.6.4 Specialist services for people with dementia and stroke

There is very little literature about specialist stroke teams working with people with dementia, or mental health teams working with people after stroke. A study of 663 Occupational Therapists working in stroke services in Canada found that when treating post-stroke cognitive impairment most therapists did not address executive function, which is often affected by vascular dementia (Korner-Bitensky et al., 2011). Cognition was also rarely reassessed by those working in the community, indicating that progression of cognitive impairment was not regularly monitored. A reason for this was suggested to be the lack of clinical trial data to guide best practice (Korner-Bitensky et al., 2011), and this is issue has not been explored at all in the UK. Indeed, many of the UK National Guidelines for Stroke on cognition are based on consensus rather than definitive evidence (Intercollegiate Stroke Working Party, 2016a). Korner-Bitensky et al.’s (2011) study did not look directly at how clinicians work with people with dementia, therefore research is needed into how clinicians change their treatment or rehabilitation after stroke if the patient has dementia.
Dedicated services for dementia and stroke are rare. Ciolli et al. (2012) describe an outpatient clinic in Italy accepting referrals for patients with cognitive impairment associated with cerebrovascular disease or stroke, such as memory complaints, language deficits and general cognitive decline. Their paper goes into detail about clinical assessment and neuroimaging used to facilitate diagnosis of cognitive impairment. However, no description is given of treatment or interventions that may take place in the clinic. They acknowledge the importance such a clinic may have on secondary prevention and managing aspects of daily living, and report patients have requested an increase in the number of visits they receive. This reflects an assumed benefit or at least, appreciation of the service, however there is a need for data about the impact of a dedicated VCI clinic on the lives of people attending in order to inform care globally.

1.7 Summary and rationale for studies
People with pre-existing dementia have poorer outcomes after stroke than those without. Whilst there is increasing research on improving dementia care, still more is needed to improve quality of life for people living with dementia (Dowrick and Southern, 2014; Alzheimer’s Society, 2017). Equally, research into stroke rehabilitation is increasing (Intercollegiate Stroke Working Party, 2016a), however there is a need for greater research into the most appropriate rehabilitation and care for people with both dementia and stroke. Worldwide inequality in access to stroke rehabilitation has been acknowledged (Lynch et al., 2017a), but it is unknown whether having a diagnosis of dementia or PSD influences subsequent access to and receipt of stroke services and whether it is linked to outcomes.

Therefore in order to identify whether pre-existing dementia is a factor considered to influence access to stroke rehabilitation, a systematic review of factors influencing clinical decisions about stroke rehabilitation was carried out as the first study in this thesis. A qualitative study about clinicians’ decision-making process when working with people with pre-existing dementia was also identified as an area for research in order to explore how dementia influences clinicians’ perceptions of their clinical practice. Finally, a quantitative study comparing usual stroke rehabilitation processes for people with and without dementia was undertaken in order to understand whether diagnosis of dementia actually influences stroke care in practice.
1.7.1 Thesis aim and study objectives

Thesis aim: To identify the impact of pre-existing dementia on stroke rehabilitation.
This aim was met through a series of studies:

1. Study One: Systematic review of clinical decision-making about stroke rehabilitation (chapter three)

   Objective:
   - To identify factors that affect clinical decision-making about who should receive stroke rehabilitation.

2. Study Two: Qualitative interviews with clinicians about their decision-making and expectations around the concept of rehabilitation potential (chapter four).

   Objectives:
   To identify:
   - Factors influencing clinical decision-making about rehabilitation for people with pre-existing dementia/cognitive impairment.
   - How these factors influence clinical practice.

3. Study Three: Prospective cohort study examining differences in amount of stroke-specific rehabilitation received by patients with and without pre-existing dementia (chapter five).

   Objective:
   - To examine whether undiagnosed pre-existing cognitive impairment or diagnosed dementia is associated with amount of stroke-specific rehabilitation received.
2 Chapter Two: Methods

This chapter gives an overview of the study setting, outlines how study protocols were developed and gives justification of methods chosen for each study. Further methods can be found in the individual study chapters and the study protocols which are included as appendices.

2.1 Study context

This PhD is based at the University of Manchester, funded by the National Institute for Health Research (NIHR) Collaboration for Leadership in Applied Health Research and Care (CLAHRC) Greater Manchester. It is embedded within the CLAHRC Greater Manchester Stroke Programme, therefore the project was carried out within the Greater Manchester area. Greater Manchester has a population of 2.7 million people, and the Greater Manchester Built-up Area is the second most populated urban area in the UK after London (Office for National Statistics, 2015). Stroke services in both Greater Manchester and London are designed on a centralised model, which has been shown to reduce length of hospital stay and in the case of London, mortality (Morris et al., 2014; Fulop et al., 2016). Centralised systems are more likely to use evidence-based interventions which are generally associated with better clinical outcomes (Ramsay et al., 2015). It therefore was appropriate to carry out research within this model, and the limitations of this are acknowledged in section 6.3.

2.1.1 Stroke services in Greater Manchester

Acute stroke services in Greater Manchester were centralised in 2010 and reconfigured again in 2015 (Turner et al., 2016). All patients who present with a recent stroke are admitted to one of three Hyper Acute Stroke Units (HASUs) dependent on residence: Salford Royal Hospital in Salford, Fairfield General Hospital in Bury and Stepping Hill Hospital in Stockport (see Figure 2.1). Salford Royal Hospital is the region’s main HASU and open 24/7 seven days a week for residents within the catchment area. Fairfield General Hospital and Stepping Hill Hospital serve as a Primary Stroke Centres (PSCs), providing hyper acute care from 06.45am to 22.45pm seven days a week for residents within their catchment areas. Outside of these hours, patients are admitted to Salford. If well enough, patients normally remain in the HASU for up to 3 days and are either discharged with community services directly, or transferred to their local District Stroke
Centre (DSC) for ongoing rehabilitation. All three PSCs have a DSC on site providing rehabilitation for local residents. The DSC rehabilitation units are located at Salford Royal Hospital, Fairfield General Hospital, Stepping Hill Hospital, University Hospital of South Manchester, Manchester Royal Infirmary, Trafford General Hospital, Tameside General Hospital, Royal Bolton Hospital and Royal Albert Edward Infirmary. Some patients are discharged into the community from the DSC with Early Supported Discharge (ESD) specialist stroke support or general community neurological rehabilitation/stroke services (CNRT/CST). Figure 1.1 (section 1.3.2) illustrates this pathway.

Figure 2.1: Map of Greater Manchester inpatient stroke services. Salford Royal Hospital is labelled in dark blue, Fairfield General Hospital and Stepping Hill Hospital (PSCs) in purple, local DSCs in light blue (Copyright Greater Manchester ODN).

2.2 Stakeholder involvement

Patient and Public Involvement (PPI) is vital when conducting healthcare research to ensure the research is relevant to the groups it addresses. It is defined by carrying out research ‘with’ stakeholders (patients or members of the public) rather than ‘on’ or ‘about’ them (INVOLVE, 2018). Stakeholder involvement has been found to have a positive impact on quality and appropriateness of healthcare research (Brett et al.,
This is particularly crucial in early stages of research, in order to identify relevant research questions and shape studies (Brett et al., 2012). With this in mind, scoping and networking meetings were carried out in October 2015, April, May and June 2016 with stroke services to assess the feasibility of the PhD aims and gain clinician’s opinions. Local multi-disciplinary team (MDT) meetings were observed within stroke rehabilitation wards, ESD teams, and a day was spent shadowing a senior Occupational Therapist (OT) on an acute stroke unit. Informal discussions also took place with the Greater Manchester Stroke Operational Delivery Network (ODN) manager, senior OTs, stroke nurses, and psychologists.

It became clear that the stroke services within one area had challenges around the flow of patients with cognitive impairment. A key finding that arose from these meetings was around organisational issues. A senior OT was auditing the flow of patients with cognitive impairment through their service, because it was felt some patients were discharged with inappropriate services. Issues were discussed around patients presenting with mild stroke symptoms with chronic cognitive impairments due to SVD, who were undiagnosed with dementia. As discussed, there are no specific policies or guidelines in place linking dementia and stroke services together. This influenced the qualitative study, which was an opportunity to discuss the barriers and facilitators to decisions made about which services patients are discharged with. In addition, clinicians on at one rehabilitation unit estimated around 80% of their patients have a pre-existing cognitive impairment. This raised an interesting disparity with the literature, which states around 10% of patients have pre-existing dementia (Pendlebury and Rothwell, 2009), although as discussed, dementia and cognitive impairment have different diagnostic criteria. This was one reason why the cohort study aimed to describe this patient population. Opinions of these stakeholders were taken into account and used to develop study protocols (see appendices), and also influenced the decision to include patients with undiagnosed pre-existing dementia/cognitive impairment throughout the work.
2.3 **Summary of research methods**
A mixed methods approach was chosen for the studies. An advantage of mixed methods research is the use of multiple data collection and analysis strategies can result in complementary strengths that address the same research aims, balance the disadvantages of single methods, and add depth to findings (Johnson and Onwuegbuzie, 2004). Equally, complex topics are well suited to mixed methods due the need for a variety of methods to gain a wider understanding (Creswell et al., 2003). This section outlines the choice of methods for each of the studies. The approaches used in each study are described in order to provide rationale for the methods in greater detail than word limits allowed in the study papers (reported in chapters three, four and five).

2.3.1 **Study One: What factors affect clinical decision-making about access to stroke rehabilitation? A systematic review (chapter three)**

Study aim: To identify factors that affect clinical decision-making about who should receive stroke rehabilitation.

2.3.1.1 **Design**
Systematic reviews are a rigorous method of synthesising evidence, using a pre-defined approach (Moher et al., 2015). They are used to refine and critically evaluate large amounts of information, and some argue systematic reviews of existing evidence are essential in order to justify new research and identify research questions (Lund et al., 2016). Systematic reviews are of particular utility in healthcare and can be used to efficiently integrate data in order to inform practice guidelines and decision-making (Moher et al., 2015). A systematic review evaluating current literature on clinicians’ decision-making about access to stroke rehabilitation was justified; the only existing review on the topic was of patient studies therefore this was an identified gap in research.

Cochrane reviews are the gold standard of quantitative systematic reviews in healthcare, synthesising and combining results from randomised controlled trials. Multiple methods of synthesising qualitative research exist, alongside standards for reporting qualitative research (Carroll, 2017; Tong et al., 2007). It was evident from reviewing the background literature that a mix of study methods would be found on the topic; therefore a mixed study review was carried out, which can provide detailed
understanding of a diverse topic (Pluye and Hong, 2014). A mixed methods study appraisal tool was identified in order to facilitate the quality appraisal of quantitative, qualitative and mixed methods studies using generic quality criteria (Pluye et al., 2009).

### 2.3.1.2 Data collection

It was clear following the background literature that no literature appeared to exist specifically about the influence of dementia on stroke rehabilitation. Therefore the search terms used for this review were purposefully not specific to dementia; all the factors influencing clinical decision-making for stroke rehabilitation were explored in order to identify whether pre-existing dementia was one of them. Clinician-focused rather than patient studies were chosen in order to explore the decision-makers themselves rather than patient-focused prognostic indicators, on which a systematic review already exists (Hakkennes et al., 2011). Advice was sought from the University of Manchester Library systematic review service prior to implementation to ensure the search strategy was suitable. The search terms were adapted to terminology used by each database and were combinations of the Mesh headings: Stroke OR cerebrovascular accident OR CVA AND rehabilitation OR therapy AND decision making OR clinical reasoning OR clinical judgement. Themes were identified across the included studies in order to provide a narrative synthesis of results.

Further details for the full study and methods are presented in chapter three.
2.3.2 Study Two: What influences decisions about ongoing stroke rehabilitation for patients with pre-existing dementia or cognitive impairment? A qualitative study (chapter four)

The aims of this study were to identify:

a) Factors influencing clinicians’ decision-making about rehabilitation for people with pre-existing dementia/cognitive impairment
b) How these factors influence clinical practice.

2.3.2.1 Design

There was no previous literature on this topic therefore a deductive qualitative methodology was adopted because it allows for an in-depth investigation of participants’ views and experiences without testing a priori assumptions (Peters, 2010). Qualitative research uses meaning and words rather than numbers and statistics to capture and interpret data and is ideal for research exploring experiences (Braun and Clarke, 2013). Qualitative research is of particular utility for exploring a topic without being driven by a pre-existing hypothesis, and attempts to understand, rather than control, the context of participants (Peters, 2010).

Qualitative data collection of opinions and experiences can be collected via interviews, questionnaires or focus groups. Focus groups can be a logistical challenge for healthcare professionals due to the demands of their role, and can have issues with confidentiality and power within groups where participants work together or manage each other (Kitzinger 2006). Interviews were chosen because this research aimed to investigate personal experiences and perceptions in detail; required participants to have an involvement with the topic; and required sensitivity in order for participants to disclose working practices with vulnerable groups, all which focus groups and questionnaires cannot always demonstrate (Peters, 2010; Braun and Clarke, 2013). Semi-structured interviews use a list of questions as a guide but can deviate to allow unexpected issues to be explored, rather than questionnaires or structured interviews which are more restrictive (Braun and Clarke, 2013). This approach allows for flexibility within the interview to ensure all areas relevant to the participant are discussed in detail, and therefore has more scope to explore causal influences than structured interviews (Peters, 2010). This format also gives participants the opportunity to disclose information of importance to them relevant to the topic that may not be
anticipated by the interview schedule, and interviews use open questions in order to encourage participants to provide a detailed response (Braun and Clarke, 2013).

2.3.2.2 Sample

Purposive sampling was used to recruit staff working within stroke services for interviews. This is a method of identifying participants due to their knowledge or experience (as opposed to random or statistical sampling) and is an efficient method of acquiring relevant experience and understanding (Peters, 2010), in this case of making decisions about patient’s cognition. The sample was derived from members of local stroke teams who played a role in assessing cognition and making decisions about cognition-based interventions and rehabilitation. The professional mix of each team influenced sampling; Occupational Therapists often have the role of assessing cognition in stroke settings (Intercollegiate Stroke Working Party, 2016b) and therefore were more highly represented in the sample. A mix of years of experience within professions was sought in order to represent a range of experience, and equal numbers from each different team were sought in order to minimise bias towards one service. Participants (staff) were recruited from the Hyper-acute Stroke Unit (HASU), inpatient rehabilitation (DSCs), Early Supported Discharge (ESD) and Community Stroke Rehabilitation teams from two hospital Trusts in two different areas of Greater Manchester. The decision was made to sample from two sites because they are quite different in size of service, Trust management, and community team organisation, possibly highlighting some contrast between the two and aiming to provide results that were applicable not only within Greater Manchester but also outside of it.

2.3.2.3 Data collection

The interviews were carried out face-to-face, individually, in a quiet room on the hospital site. Interview location can affect qualitative data therefore it was important to ensure participants were located in their workplace in order to elicit responses reflective of their working practices (Edwards and Holland, 2013). Telephone interviewing was offered also; these can offer privacy, give access to hard to reach participants and require less time to conduct and participate, however they can restrict development of rapport which is important when interviewing (Sturges and Hanrahan, 2004).
2.3.2.4 Analysis

The method of analysis for qualitative data is influenced by the approach to data collection (Ritchie et al., 2014). Thematic analysis was chosen rather than Interpretive Phenomenological Analysis or grounded theory because it allows a flexible approach to data collection not linked to any theoretical framework; it provides an introduction to qualitative methods for those new to it; and it provides accessible results that can be directly disseminated to wide audiences, especially within healthcare settings (Peters, 2010; Braun and Clarke, 2006; Braun and Clarke, 2013). For this reason an inductive perspective was taken, which does not require any hypothesis or existing theory to inform analysis (Braun and Clarke, 2013). Thematic analysis also can be used with larger sample sizes than other methods, which was required when interviewing a range of different professionals (Braun and Clarke, 2013). Thematic analysis follows a six stage, iterative process: data familiarisation; generation of initial codes; identification of themes; reviewing themes; definition of themes; and report production (Braun and Clarke, 2006).

2.3.2.5 Patient and public involvement

The stakeholders for this study were clinicians working in stroke services. Following initial consultation for the study as detailed in section 2.2, a summary of the proposed method was presented to a meeting of clinicians at the Greater Manchester Stroke Operational Delivery Network Rehabilitation (ODN) sub-group in June 2016. Their feedback was used to develop the protocol further by adapting the recruitment process. Consultation was an appropriate level of involvement for the study due to the need for a range of views in order to refine the research question, aims, and recruitment strategy (INVOLVE, 2015).

Further details for the full study and methods are presented in chapter four.
2.3.3 **Study Three: Differences in stroke rehabilitation for people with pre-existing cognitive impairment: an observational cohort study (chapter five)**

Study aim: To examine whether undiagnosed pre-existing cognitive impairment or diagnosed dementia is associated with amount of stroke-specific rehabilitation received.

2.3.3.1 **Design**

This study was addressing current practice within rehabilitation services therefore an observational design was chosen, which seeks to indicate what is happening within a setting when an experimental design is not appropriate (von Elm et al., 2008). The study was not addressing the benefit of a specific intervention, but whether people receive rehabilitation interventions at all, therefore an experimental design would not have suited the research aims (Black, 1996; von Elm et al., 2008). Observational studies can be a cohort, case-control or cross-sectional design. A cohort design was chosen because it involves following a chosen population (in this case stroke patients) to measure outcome over a time period (Song and Chung, 2010). Case-controls require specific matched groups of control patients, which restrict inclusion criteria and therefore can be difficult to recruit to, and cross-sectional designs only collect data at one time-point and therefore cannot provide information about sequence of events (Song and Chung, 2010).

A number of different approaches to data collection were considered when designing the study. The Sentinel Stroke National Audit Programme (SSNAP) is a readily available data set from all stroke units in the UK and measures processes of care provided to stroke patients, including amount of rehabilitation therapies. In particular, the SSNAP audit reports total average minutes of therapy received by patients (Royal College of Physicians, 2017). This would have been appropriate for a retrospective cohort study examining total rehabilitation received for people with and without dementia (Sedgwick, 2013). However, whilst the SSNAP collects data on a large number of variables, nothing is recorded about cognitive status or dementia. Gathering data at the point of input into SSNAP in order to link it to individual patient notes to identify cognitive status was considered but this would have involved collecting data from duplicate sources and a complex consent process. A prospective cohort study was
therefore chosen, using only patient notes to gather data on consecutive admissions during a set time period on both rehabilitation therapies received and cognitive status.

The intention was for this study to also include a nested qualitative element to understand patient’s experience of receiving (or not) rehabilitation (see appendix 6). Gathering service user perspectives is important when conducting research within healthcare. Patient experience serves a vital role in facilitating service design (Mockford et al., 2012), and qualitative research can explore a problem from the perspective of those experiencing it (Clarke, 2003). It was thought these data would provide greater depth to the cohort study. However, identifying and consenting potential participants for an additional interview study proved untenably resource-intensive. Therefore early on the decision was made to focus entirely on the cohort study, which would quantify differences in rehabilitation experience of participants and ensure its success within the timeframe.

2.3.3.2 Sample
The study was supported by the Greater Manchester Clinical Research Network (CRN), who assisted in identifying and approaching sites. All nine stroke rehabilitation units in Greater Manchester were approached in order to maximise participant availability, and four sites participated. Consecutive sampling was used in order to recruit as many participants as possible within the study timeframe. The sample size was calculated by identifying the number of proposed sites and mean number of admissions; nine sites were approached, with a mean number of 60 patients admitted to each site every three months (Royal College of Physicians, 2017). This gave approximately 540 patients available for recruitment within a three month period. With a conservative 50% consent rate this suggested a possible 270 participants. The literature suggests around 10% of patients have a dementia diagnosis prior to first stroke (Pendlebury and Rothwell, 2009), therefore 27 patients with dementia were anticipated. However as described in chapter five, the final sample size was smaller than anticipated due to the number of participating sites.

2.3.3.3 Capacity and consent
An awareness of issues around capacity and informed consent was required due to the research involving patients who may lack capacity. The study used accessible format information sheets and consent forms for patients with communication, visual or
specific cognitive difficulties, and the consent procedure was witnessed by a member of the clinical or research team, or by a carer/family member of the patient. Both written and verbal information was provided to the patient, and adapted to suit the needs of the patient (Dewing, 2007).

Some participants had either known or suspected dementia (or cognitive impairment) however this did not necessarily mean that they lacked capacity to provide informed consent. In line with the Mental Capacity Act (2005), patients were deemed to have capacity to consent unless a clinician involved in their care determined otherwise. If there were doubts as to whether a participant had capacity to consent, a capacity assessment form was used by the person taking consent. The consent process described is a recognised way of working in the dementia research field.

Capacity to consent was assessed using the following principles:

- Does the person have a general understanding of what decision they need to make and why they need to make it?
- Does the person have a general understanding of the likely consequences of making, or not making, this decision?
- Is the person able to understand, use and weigh up the information relevant to this decision?
- Can the person communicate their decision (by talking, using sign language or any other means)?

(Office of the Public Guardian 2007)

If a person is only able to retain information relevant to a decision for a short period this does not prevent them from being able to make the decision (HM Government, 2005), which is especially pertinent when assessing capacity in people with memory problems or dementia. For potential participants deemed not to have capacity, the British Psychological Society approach was taken (Dobson 2008), adopting the following steps:

1. Identify a family member/friend who knows the person, who will act in the capacity of personal consultee. If no family or friends are willing or able to be consulted, a nominated professional consultee will be sought (a person with whom the potential participant has a professional relationship who is not
involved in the research, for example a member of staff in a care home in which the person lives).

2. Present the consultee information sheet to the consultee, giving the opportunity to ask questions.

3. If the consultee is satisfied, they will be asked to sign a declaration form.

4. Following successful completion of the declaration form, the researcher will include data from the person who lacks capacity as a participant in the cohort study. Should the declaration form not be signed, no further steps will be taken.

The consultee was asked to give their advice on whether the participant would wish to participate in the research, or whether they would be likely to decline had they the capacity (Dobson, 2008). Consultees unavailable during normal working hours were given the option to receive the information sheet via email or post via the consent to contact form, with a postal consent form for return in a ready stamped and addressed envelope.

2.3.3.4 Data collection
Routinely collected data was extracted from medical notes for the eight week period post-stroke for each participant. Eight weeks was chosen to allow reasonable time for patients to receive rehabilitation services. Average length of stay was examined for the potential sites using national audit data (Royal College of Physicians, 2017) and it appeared eight weeks captured a reasonable and practical amount of time following stroke onset to explore the process of care in those referred for post-HASU rehabilitation. Clinical notes were reviewed manually by the research team on NHS sites using electronic or paper based records. Alongside routine demographic, clinical and therapy data, data on pre-stroke cognitive functioning were extracted i.e. whether or not pre-existing dementia or cognitive impairment were documented and if so, by which member of the multidisciplinary team and from what source.

2.3.3.5 Patient and public involvement
PPI groups were consulted during the design and dissemination stages of the study. The study was presented to the Salford Royal Hospital Cardiovascular PPI group for consultation on the overall topic of the study and to ensure all logistical aspects of the protocol were considered, for example methods of contacting participants and the
personal consultee process. The patient information sheets, consent forms and dissemination plans were presented and adapted following feedback also. Relevant dementia PPI groups were contacted however they declined to be involved. The majority of PPI input for this study was around the nested qualitative element (see appendix 6) to ensure questions were worded appropriately, relevant to participants, and well-timed (Brett et al., 2014). The impact of the consultation on the research design was fed back to the group when presenting the findings and they were also consulted on the patient dissemination summary sheet.

Further details for the full study and methods are presented in chapter five.
3 Chapter Three: What factors affect clinical decision-making about access to stroke rehabilitation?: A systematic review (study one)

Presented in a format suitable for publication. This article has been accepted for publication in Clinical Rehabilitation (in press). This review includes the qualitative study (chapter four) as one of the included papers.

This study has been accepted for presentation at:
UK Stroke Forum (poster), 2018
Abstract

Objectives: To determine the factors affecting clinical decision-making about which patients should receive stroke rehabilitation.

Methods: Data sources (MEDLINE, CINAHL, AMED and Psychinfo) were searched systematically from database inception date to August 2018. Full text English language studies of data from stroke clinicians were included. Studies of patients were excluded. Included studies were any design focused on clinical decision-making for referral or admission into stroke rehabilitation. Summary factors were compiled from each included study. The quality of included studies was assessed using the Mixed Methods Appraisal Tool.

Results: After removing duplicates 1915 papers were identified, of which thirteen met the inclusion criteria. Eight included studies were qualitative, one used mixed methods. A total of 292 clinicians were included in the studies. Quality of included studies was mixed. Patient-level and organisational factors, as well as characteristics of individual clinicians contributed to decisions about rehabilitation. The most often described factors were patients’ pre- and post-stroke function (n=6 studies), presence of dementia (n=6), patients’ social/family support (n=6), organisational service pressures (n=7) and the decision-making clinician’s own knowledge (n=5) and emotions (n=5).

Conclusion: The results highlight a lack of clinical guidance to aid decision-making, and reveal a subjective approach to rehabilitation decision-making influenced by patient-level and organisational factors alongside clinicians’ characteristics occurs across services and countries.

Introduction

Although coordinated multidisciplinary rehabilitation for patients following stroke improves mortality and independence, not every patient is selected to receive this intervention even though there is no evidence to indicate that certain patients will or will not benefit from rehabilitation (Langhorne et al., 2011; Stroke Unit Trialists Collaboration, 2013). The benefits of stroke rehabilitation have been found in patients regardless of gender, age, stroke type and severity (Stroke Unit Trialists Collaboration, 2013), however internationally, there is disparity as to who does, or does not, receive...
stroke rehabilitation (Lynch et al., 2017a). Exclusions to rehabilitation services vary across current international clinical guidelines; in Canada, patients must demonstrate the potential ability to return to pre-stroke levels of function or to increase post-stroke functional level (Hebert et al., 2016); in the US patients must aim to be discharged into the community in order to receive inpatient rehabilitation (Winstein et al., 2016). In Spanish guidelines, rehabilitation is not recommended for patients with severe stroke and 'poor recovery prognosis' (Lynch et al., 2017a). Conversely, many clinical guidelines do not define which patients should receive stroke rehabilitation (Jolliffe et al., 2018). The most recent UK clinical guidelines do not specifically exclude any types of patients, however there are no criteria for who should access rehabilitation either (Intercollegiate Stroke Working Party, 2016a; Lynch et al., 2017a). The decision of who should receive stroke rehabilitation therefore requires complex deliberation on the part of clinicians.

An increasing body of literature examines how clinicians choose which patients to refer or admit for stroke rehabilitation; however this often focuses on patient factors and prognostic indicators, rather than investigating the clinician’s role in decision-making (Hakkennes et al., 2011; Ilett et al., 2010; Jolliffe et al., 2018). The most recent systematic review of this topic is over seven years old and only used patient studies (Hakkennes et al., 2011). Qualitative investigation reveals decision-making about rehabilitation is a complex process requiring clinicians’ interpretation of clinical and non-clinical factors (Longley et al., 2018). Synthesising the current literature on clinicians’ perspectives will help inform clinicians’ own decision-making process, and also understand biases that may lead to inequalities in access (Higgs and Jones, 2005).

The aim of this review is to identify factors that affect clinical decision-making about who should receive stroke rehabilitation.

### 3.3 Methods

Searches were completed on four electronic databases that focus on medical, allied health and psychology journals (all from inception date to August 2018): Cumulative Index to Nursing and Allied Health Literature (CINAHL, via Ebsco search platform), PsychINFO (via Ovid), MEDLINE (via Ebsco) and AMED Allied and Complementary Medicine (via Ovid). Additionally the Cochrane Central Register of Controlled Trials (CENTRAL) (Issue 8, 2018), and Cochrane Stroke Group Trials Register (August 2018).
were also searched. No restrictions were placed on study design or publication date, with English language being the only restriction. The search terms were adapted to terminology used by each database.

Studies were eligible for inclusion if they were full text primary research published in peer-reviewed journals in which participants provided any type of stroke service (i.e. acute, rehabilitation or community). Studies were included that focused on clinical decision-making for referral/admission to stroke rehabilitation, or that examined clinicians’ prioritisation criteria for stroke rehabilitation or decision-making about rehabilitation potential; in essence any type of decision-making influencing subsequent access to stroke rehabilitation services. Studies focused on decision-making between specific interventions or treatments were excluded, for example decisions about which patients should receive a home visit (Whitehead et al., 2014). Studies that included a mixed diagnosis case-load (i.e. participants working in generic services) were excluded unless separate results for stroke were reported. Studies with patient participants were excluded. No restrictions were placed on included study design.

The first author (VL) reviewed studies against the inclusion criteria by title. All abstracts and full text were then reviewed for eligibility by VL and a reviewer independent to the research team in order to minimise selection bias. Two discrepancies in inclusion were resolved through discussion. Reference lists of included studies and relevant review papers were hand-searched for studies not already identified in the searches. We extracted all factors from included studies and organised them into patient (e.g. patient’s age), organisational (e.g. staffing levels) and clinician (e.g. experience) level factors.

In order to appraise the quality of studies, the Mixed Methods Appraisal Tool (Pluye et al., 2009) was used. This allows for the appraisal of qualitative and quantitative study designs simultaneously and scores studies on design, sampling, appropriateness of outcome measures and analysis method, randomisation (when appropriate) and completeness of data. Studies are scored in four domains and total scores range from 0-100%. All studies were assessed by VL and an independent reviewer and scores compared. Two discrepancies were resolved through discussion. Studies were included regardless of quality rating.
3.4 Results

After removing duplicates 1915 papers were identified, of which thirteen met the inclusion criteria and were included (see Figure 3.1). Eight of these were qualitative and one was mixed methods. The remaining quantitative studies all used questionnaires/surveys (see Table 3.1).

Figure 3.1: Flowchart of literature searches.
Most included studies were conducted in Australia (n=5) (Luker et al., 2014; Lynch et al., 2016; Lynch et al., 2017b; Hakkennes et al., 2013; Kennedy et al., 2012). Two studies sampled from stroke units in more than one country (Daniëls et al., 2002; Putman et al., 2007). Three studies sampled clinicians involved in admitting patients to inpatient rehabilitation facilities and examined their admission criteria (Hakkennes et al., 2013; Kennedy et al., 2012; Putman et al., 2007), the others sampled referring clinicians. Two studies examined factors influencing perceptions of rehabilitation potential after stroke, a complex concept sometimes used as a determinant for referring patients onto rehabilitation (Burton et al., 2015; Lam Wai Shun et al., 2017).

292 clinicians in total were included in the studies. Study size varied, from an ethnographic study of one multidisciplinary team (Johnson et al., 2015) to a survey of 77 discharge planners (Magdon-Ismail et al., 2016). 671 patients were included across three of the studies (Hakkennes et al., 2013; Lynch et al., 2016; Putman et al., 2007), for example in meetings observed about individual patients.

As shown in Table 3.1, the quality of studies was mixed. One mixed methods study received a quality rating of 25%, three received a rating of 50%, seven received 75% and three met the full quality criteria of 100%. The eight qualitative studies were generally well conducted and reported and all achieved a quality score of at least 75%. They needed greater clarity about their analysis process (Putman et al., 2007); how the findings may have related to researcher influence (Burton et al., 2015; Lynch et al., 2016; Lam Wai Shun et al., 2017; Lynch et al., 2017b; Luker et al., 2014) and how the findings may have related to context of the research (Daniëls et al., 2002). Three of the four quantitative studies had poor response rates (under 60%) (Hasenbein et al., 2002; Magdon-Ismail et al., 2016; Putman et al., 2007); some had an unrepresentative sample of the study population, for example some participants were sampled due to participation in previous research (Hasenbein et al., 2002) or reasons for non-participation from eligible individuals were not explained (Kennedy et al., 2012; Magdon-Ismail et al., 2016); and there was a lack of clarity about measures used (Putman et al., 2007).

Patient-related factors (n=8), organisational factors (n=2), and the characteristics of individual clinicians (n=4) were all found to influence clinicians’ decision-making for stroke rehabilitation. These key factors are described in Table 3.2 and organised thematically for clarity, however categories were not mutually exclusive. Where
possible the positive or negative influences are described, however some studies did not always specify the specific influence of factors (Hakkennes et al., 2013; Hasenbein et al., 2002; Lam Wai Shun et al., 2017; Magdon-Ismail et al., 2016).
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<th>Author and country</th>
<th>Design</th>
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<th>Key findings</th>
<th>Study quality appraisal score</th>
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<td>Burton et al., (2015) UK</td>
<td>Focus groups</td>
<td>To investigate meaning and influence of rehabilitation potential on clinical practice</td>
<td>2 inpatient and 5 community rehabilitation teams</td>
<td>12 clinicians (OT, physiotherapy, speech and language therapy, rehabilitation assistant)</td>
<td>Rehabilitation potential is predicted by observation of carry-over and functional gain. Judgement of rehabilitation potential influenced by prioritising workload, working around the system, balancing optimism and realism. Impacts on patients and staff.</td>
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<td>Daniëls et al., (2002) the Netherlands and Belgium</td>
<td>Focus groups</td>
<td>Identifying occupational therapists (OTs) deliberations in stroke rehabilitation</td>
<td>12 rehabilitation units</td>
<td>13 OTs</td>
<td>Difficulties for OTs were around: focusing on adaption whilst the patient is focused on recovery, being client-centred and protective simultaneously, setting meaningful goals in an institutional environment.</td>
<td>75%</td>
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<tr>
<td>Johnson et al., (2015) Canada</td>
<td>Ethnography</td>
<td>Examining factors influencing team decision-making when choosing post-stroke discharge destination</td>
<td>One acute stroke unit</td>
<td>One team, 12 multidisciplinary team members (psychiatrist, speech therapist, OT, physiotherapy, nurses, social worker, discharge planner)</td>
<td>Decisions about discharge destination influenced by social, economic and policy factors, interactions between team members, condition of patient and social support.</td>
<td>100%</td>
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<tr>
<td>Lam Wai Shun et al., (2017) Canada</td>
<td>Focus group</td>
<td>Identifying factors influencing OT’s perception of rehabilitation potential after stroke</td>
<td>3 acute and 3 rehabilitation hospitals</td>
<td>12 OTs</td>
<td>Agreed on 11 most important patient-related factors to consider when assessing rehabilitation potential, and additional factors of organisational context and clinician’s expertise.</td>
<td>75%</td>
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<tr>
<td>Study</td>
<td>Method</td>
<td>Research Questions</td>
<td>Setting</td>
<td>Participants</td>
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<tr>
<td>Longley et al., (2018) UK</td>
<td>Semi-structured interviews</td>
<td>To identify factors influencing clinicians decision-making about rehabilitation for people with pre-existing cognitive impairment</td>
<td>Four inpatient and two community stroke teams</td>
<td>23 clinicians (OT, physiotherapy, speech and language therapy, psychology, nursing, physicians)</td>
<td>Decisions influenced by understanding of the individual patient, clinician’s knowledge of dementia/cognitive impairment, predicting rehabilitation potential, organizational constraints, and clinician’s perceptions of their role within the team. Impacts on clinical practice.</td>
<td>100%</td>
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<tr>
<td>Luker et al., (2014) Australia</td>
<td>Semi-structured interview</td>
<td>Exploring factors influencing Allied Health Professionals decision-making when prioritising stroke rehabilitation</td>
<td>3 acute stroke units</td>
<td>15 Allied Health Professionals (physiotherapy, OT, speech and language therapy, dietician, social worker, psychologists)</td>
<td>Predicted discharge destination was a powerful driver of care decisions. Clinicians considered pre-stroke status, nature and severity of stroke, course of recovery and multiple factors within healthcare system to aid decisions.</td>
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<tr>
<td>Lynch et al., (2017) Australia</td>
<td>Focus groups</td>
<td>Exploring factors perceived to affect why patients are referred to stroke rehabilitation, and how assessments were completed</td>
<td>8 acute stroke units</td>
<td>32 clinicians (mixed discipline)</td>
<td>Rehabilitation assessment and referral varied between units. People with stroke symptoms not consistently referred for rehabilitation. Perceived roles, beliefs about consequences, relationships with rehabilitation service providers and knowledge influenced decisions and referral practices.</td>
<td>75%</td>
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<tr>
<td>Lynch et al., (2016) Australia</td>
<td>Observations and focus groups</td>
<td>Investigating how staff determine who to refer to rehabilitation</td>
<td>8 acute stroke units</td>
<td>32 clinicians (nurse, physiotherapy, OT, speech therapy, dietician, unit manager)</td>
<td>Factors influencing referrals for rehabilitation: anticipated discharge destination, stroke severity, staff expectations, family advocacy; clinicians referred patients who they considered would be accepted</td>
<td>75%</td>
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<td>Quantitative</td>
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<td>Most important items for acceptance into rehabilitation: pre-morbid cognition, pre-</td>
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<tr>
<td>Hakkennes et al., (2013) Australia</td>
<td>Prospective observational cohort</td>
<td>Identifying factors important in</td>
<td>5 acute hospitals</td>
<td>14 rehabilitation assessors</td>
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<td>100%</td>
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<tr>
<td>Study, Questionnaire</td>
<td>Decision-Making for Rehabilitation</td>
<td>Morbid Mobility, Pre-Morbid Communication. For non-acceptance most important items: current mobility, social support, current cognition.</td>
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<tr>
<td>Hasenbein et al., (2002) Germany</td>
<td>Case-based survey</td>
<td>Analysis of medical decisions of allocation to stroke rehabilitation</td>
<td>Acute and rehab hospitals (unknown number)</td>
<td>33 physicians</td>
<td>Physician expertise and patient age influenced choice between in or outpatient rehabilitation.</td>
<td>50%</td>
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<tr>
<td>Kennedy et al., (2012) Australia</td>
<td>Questionnaire</td>
<td>Exploring factors influencing decisions for rehabilitation</td>
<td>12 rehabilitation units</td>
<td>17 physicians</td>
<td>Most influential clinical factors for accepting patients to rehabilitation: prognosis, social support, anticipated discharge destination, age, anticipated length of stay. Key non-clinical factors: priority, patient residence, workforce capacity.</td>
<td>75%</td>
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<tr>
<td>Magdon-Ismail et al., (2016) USA</td>
<td>Survey</td>
<td>Investigating factors influencing selection of post-acute discharge destination</td>
<td>471 acute hospitals</td>
<td>77 discharge planners</td>
<td>Factors influencing post-discharge care destination: insurance, quality of care facility, pressure to discharge patient. Patients and families more influential than physicians in choosing care facility. Non-clinical factors perceived to have major influence in decision-making.</td>
<td>50%</td>
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<tr>
<td>Putman et al., (2007) Europe</td>
<td>Mixed methods: assessment, questionnaire, interview</td>
<td>Exploring factors involved in decision-making for admission to stroke rehabilitation</td>
<td>6 stroke rehabilitation units in 4 European countries (UK, Belgium, Germany, Switzerland)</td>
<td>532 patients, medical consultants (unknown number)</td>
<td>Clinical criteria for admission evaluated differently between units: UK only used diagnosis of stroke as admission criteria, Belgian, German and Swiss units all considered pre-stroke status, and likelihood of discharge home in Swiss units.</td>
<td>25%</td>
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Study quality is scored and ranges from 0-100% according to % of criteria met in 25% intervals (Pluye et al., 2009).
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<tr>
<th>Studies</th>
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<th>Pre- and post-stroke function</th>
<th>Type/ severity of stroke</th>
<th>Presence of dementia</th>
<th>Social/family support</th>
<th>Motivation</th>
<th>Demonstration of progress</th>
<th>Predictions about recovery/discharge</th>
<th>Service pressures</th>
<th>Insurance</th>
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<td>Magdon-Ismail et al. (2016)</td>
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<td>Putman et al. (2007)</td>
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</table>
3.4.1 **Patient-related factors**

Five studies identified patient age as a factor perceived to influence decision-making (see Table 3.2), three of which described older age as negatively affecting rehabilitation services received by patients (Hasenbein et al., 2002; Johnson et al., 2015; Luker et al., 2014). Older age was identified as a barrier for referral into some rehabilitation services although the reasons why were unexplored (Johnson et al., 2015). Patient age was also used as a proxy for associated disability, for example older people being assumed to have a lower baseline functioning (Luker et al., 2014).

Pre- and post-stroke functioning were factors both influencing decisions to refer and to admit (or decline) patients to rehabilitation. Putman et al.’s (2007) observational study of six stroke units across Europe found higher levels of pre-stroke disability meant patients were less likely to be admitted. Similarly, Hakkennes et al.’s (2013) cohort study found higher pre-morbid levels of function resulted in a higher likelihood of acceptance to rehabilitation, whilst post-stroke factors were more important in not admitting patients (Hakkennes et al., 2013). Lam Wai Shun et al.’s (2017) focus group study of occupational therapists found pre- and post-stroke function were two of eleven essential factors to consider when assessing a patient’s rehabilitation potential, although they did not state how this would affect decisions. Equally, pre- and post-stroke status were considered important when prioritising patients for rehabilitation by clinicians in Luker et al.’s (2014) interview study, especially when post-stroke deficits such as swallowing difficulties increased patients’ risk of deterioration; higher priority was given to patients at risk. Additionally, type and severity of stroke and interacting comorbidities were found to impact on decisions about rehabilitation, with patients with severe stroke being less likely to be referred for rehabilitation (Burton et al., 2015; Luker et al., 2014; Lynch et al., 2017b). Older patients with higher levels of pre-stroke disability or severe stroke appear less likely to be accepted or referred for rehabilitation.

A specific element of pre-stroke function, whether patients have pre-existing dementia, was identified as an influential factor in decision-making not only affecting admission for rehabilitation, but also initial referrals. Lynch et al. (2016) found that clinicians were less likely to refer patients for rehabilitation when they believed the patient would not be accepted, for example patients with a diagnosis of dementia. Similarly, Lam Wai Shun et al. (2017) identified patients with severe memory problems (although not
specifically dementia) may be perceived to have low rehabilitation potential, as clinicians felt they would be less likely to be accepted for rehabilitation. Neither study explored the reasons why staff believed this, however, in their other included study, Lynch et al. (2017b) found that some participants considered that rehabilitation was not suitable for certain patients, particularly those with severe stroke or those with cognitive deficits/dementia. Clinicians perceived these types of patients would never gain from rehabilitation, although the reasons why this was believed were not explored (Lynch et al., 2017b). Burton et al. (2015) found that some clinicians considered a pre-morbid diagnosis of dementia would indicate little rehabilitation potential and therefore limit the amount of rehabilitation that patients receive. Equally, clinicians in Longley et al.’s (2018) interview study found clinicians perceived patients with dementia would lack rehabilitation potential or capacity to change unless they proved otherwise.

Putman et al. (2007) found in four out of six stroke rehabilitation units studied, pre-morbid cognitive disability reduced the likelihood of a decision to admit. One Belgian unit specifically screened patients for advanced dementia, although the study does not detail how the result of screening would influence admission and the methodological quality of this study was rated poorly when appraised. Additionally, Hakkennes et al. (2013) surveyed assessors from rehabilitation units, and they viewed pre-morbid cognition as the most important item to consider when accepting patients for rehabilitation. It is not clear, however, whether the pre-morbid cognition specifically refers to dementia. The National Institutes of Health Stroke Scale (NIHSS) (Brott et al., 1989) score was used to gather information about cognition which has no way of indicating a pre-morbid diagnosis of dementia. Again, it was not specified whether cognition would positively or negatively influence a decision for rehabilitation, just that it would be taken into account.

Social/family support was a factor that was considered to affect decisions about access to rehabilitation. A lack of social support, which may prevent patients from returning home, meant that patients were less likely to be admitted to one Swiss stroke unit in Putman et al.’s (2007) study when compared with other units in the study, although details remain unclear. Clinicians felt that families sometimes pressurised services into providing ongoing rehabilitation (Luker et al., 2014; Putman et al., 2007) and influenced decisions about discharge destination (Magdon-Ismail et al., 2016). Home environment was also influential when deciding rehabilitation plans; patients from
residential care were often not considered as candidates for rehabilitation unless families asked (Lynch et al., 2016).

Staff perceptions about patient-related factors also affected decision-making. Staff perception of patient motivation to engage in rehabilitation was found to affect decisions in five studies (see Table 3.2). Occupational therapists in Daniëls et al.’s (2002) focus group study identified that patient motivation influenced their approach to rehabilitation, and aided decisions on when to proceed with rehabilitation. Whilst Daniëls et al.’s (2002) study focused on ongoing rather than access to rehabilitation, another study found that when participants were unmotivated to participate in therapy sessions, they were less likely to be referred for post-acute rehabilitation in the first place (Luker et al., 2014). Two studies identified barriers to judging motivation, such as post-stroke depression and attention (Burton et al., 2015; Luker et al., 2014), with some clinicians in Luker et al.‘s (2014) acknowledging that low motivation would prevent access to rehabilitation but also feeling unable to influence it.

Patients were required to demonstrate progress with rehabilitation or have therapy-led goals in order to be referred for rehabilitation in five studies (see Table 3.2). Observed improvement in the acute phase was an important factor in clinicians’ decision-making about whether a patient possessed rehabilitation potential (Lam Wai Shun et al., 2017). Lynch et al. (2016) found that a lack of improvement within the first two weeks post-stroke was linked to decisions about referral onto a residential care rather than an inpatient rehabilitation pathway.

Similarly to observed improvement, five studies found clinician’s predictions about improvement (or rehabilitation potential) were an important and sometimes overriding factor in decision-making. Predicting discharge destination determined clinical priority and the care patients would receive; patients for discharge into residential care would become low priority for rehabilitation (Luker et al., 2014; Lynch et al., 2016).

### 3.4.2 Organisational factors

Organisational factors, such as service acceptance criteria and workforce capacity, were found to influence decisions about stroke rehabilitation. Service pressures were discussed in seven studies from four different countries using a mix of methods (see Table 3.2). This predominantly related to bed shortages; some participants described
having to discharge patients before they felt they reached the end of inpatient rehabilitation (Johnson et al., 2015), and limited bed availability was identified as a barrier to referring patients for post-acute rehabilitation (Magdon-Ismail et al., 2016; Luker et al., 2014). Participants in Lam Wai Shun et al.’s (2017) study described having limited time to assess patients, creating pressure for quick decision-making based on a single encounter with patients. Similarly, participants in Longley et al.’s (2018) study described the challenges of working with people with cognitive impairments within time limited services, when they may require longer to progress with rehabilitation. Johnson et al. (2015) observed multidisciplinary team meetings and found that a barrier to decision-making about discharge destination was lack of time for some members of staff to actually attend meetings. Staffing shortages were also found to be barrier for admitting patients for rehabilitation (Kennedy et al., 2012), and restricted the amount of time clinicians were able to spend with each patient (Luker et al., 2014).

In a study from the United States (Magdon-Ismail et al., 2016), insurance was found to be the biggest barrier in referring patients to the appropriate level of post-acute care, thus affecting the decision of whether patients would receive ongoing rehabilitation. Insurance was also a factor in decisions to admit to some European stroke rehabilitation units (Putman et al., 2007), however this was not found in countries with universal healthcare such as the UK. Proximity was a factor affecting decisions to refer to specific units; patients were more likely to be admitted to rehabilitation units in the same hospital as the acute unit in three sites in Putman et al.’s (2007) study. Clinicians were also aware proximity to family was a factor influencing choice of rehabilitation unit (Magdon-Ismail et al., 2016; Kennedy et al., 2012).

3.4.3 Characteristics of individual clinicians

Awareness of clinicians’ own professional clinical discipline was cited as a factor that helped focus evaluation of rehabilitation potential, and sometimes was used to advocate for a patient to receive rehabilitation (Lam Wai Shun et al., 2017; Longley et al., 2018). Discharge planners found non-physician clinicians to be more influential than physicians when referring for rehabilitation in one study (Magdon-Ismail et al., 2016), indicating professional discipline may have an important role, however no detail is given about the specific roles of non-physicians therefore it is unclear what type of expertise is preferred in this setting (Magdon-Ismail et al., 2016).
Occupational therapists in Lam Wai Shun et al.’s (2017) study described how their clinical experience was a factor that influenced their decision-making. Assessment of rehabilitation potential and recovery was made by drawing on experiential knowledge. Experience, or lack thereof, was cited as a factor that challenged decisions regarding rehabilitation and participants expressed additional skills were required when working in acute stroke (Longley et al., 2018; Luker et al., 2014).

Clinician’s knowledge and awareness influenced decisions. Lam Wai Shun et al. (2017) found clinicians referred to scientific evidence and clinical guidelines to aid decisions (although did not detail the guidance specifically), however Lynch et al. (2017b) found lack of knowledge was a barrier for participants to refer patients to rehabilitation. They highlighted a belief from clinicians that rehabilitation was not suitable for patients with severe stroke, despite education sessions being provided demonstrating otherwise. Lack of knowledge about comorbid conditions (specifically dementia) was found to influence decisions about ongoing stroke rehabilitation for patients in Longley et al.’s (2018) study, with participants highlighting a lack of availability of extra training. Clinicians’ awareness of rehabilitation services also influenced which services patients were referred to and when (Lam Wai Shun et al., 2017; Luker et al., 2014). Johnson et al. (2015) identified clinicians’ lack of knowledge about rehabilitation services available in the community resulted in delays in discharge, or patients not being referred for rehabilitation at all. Additionally, fear of damaging relationships with rehabilitation providers prevented some clinicians from referring patients when they considered them unlikely to be accepted (Lynch et al., 2017b).

Finally, five qualitative studies identified an emotional element to decision-making for clinicians, with participants wanting to give all patients a chance with rehabilitation whilst not challenging limited resources (see Table 3.2). Participants in Longley et al.’s (2018) study described an element of ‘gut instinct’ informed decision-making, particularly for less experienced clinicians. Luker et al. (2014) identified an ‘ethical strain’ when attempting to provide equal levels of care; participants stated they were aware certain demographics of patients (for example, severe stroke, older age) had more difficulty in acquiring post-acute rehabilitation and yet also acknowledged they provided more rehabilitation to younger patients (Luker et al., 2014).
3.5 **Discussion**

This systematic review of clinical decision-making about access to stroke rehabilitation found that a combination of patient and organisational factors, and characteristics of the decision-makers can influence decisions. It appeared that the most important patient-related factors were patients’ pre- and post-stroke functioning (particularly whether they have pre-stroke dementia) and level of social support. Service pressures and clinicians’ own knowledge also influenced whether patients would be referred or admitted for rehabilitation. Surprisingly, five studies described an emotional element to decision-making, which highlights the challenge faced by clinicians when formal guidance is lacking. This review reveals the complexity of decision-making, and the delicate balance of factors that may lead to a patient receiving, or not receiving post-stroke rehabilitation.

The limitations of this review require consideration due to the mix of included studies. The low quality appraisal scores of some included quantitative studies reflect a need for clearer reporting and more representative samples of participants in this area, for example researchers could invite all people involved in discharge planning to participate from sampled services. Caution should be used when comparing their results to the highly appraised studies. There was heterogeneity in the organisation of rehabilitation services and referral systems across the included studies which may limit the applicability of results, for example, some relied on external assessors selecting patients rather than patients being referred; some studies were carried out in generic acute or rehabilitation settings rather than stroke specific; and insurance was an influential factor in studies from countries requiring insurance to access healthcare. Organisation of stroke services influences clinicians’ consideration about when to refer/admit patients for rehabilitation; service organisation affects patient outcomes (Stroke Unit Trialists Collaboration, 2013; Foley et al., 2007), therefore consideration needs to be made when applying these results across services.

This review did find similarities across all nine countries covered by included studies, which increases our confidence in the generalisability of our findings. The patient-related factors identified in this review are similar to those identified in a systematic review of patient level studies that looked at prognostic factors influencing selection for rehabilitation (Hakkennes et al., 2011), which supports our findings. This review builds
on the existing literature by summarising research from clinicians’ perspectives and addressing the organisational and individual clinician level factors as well.

The review itself has a number of limitations. For one, search results were limited to English language. In addition, the search terms may have resulted in records being overlooked; the terms decision-making, clinical reasoning or clinical judgement were used based on previous studies and suggested search terms in databases, but despite this alternatives may still be used by some authors. There may have been ambiguity about what studies to include given the nature of the topic and the inclusion criteria, although all abstracts were reviewed by a researcher independent to the team in order to minimise this. One of the included studies was written by the authors of this review, which introduces elements of bias to the quality rating and importance given to certain factors. Again, quality was rated by an independent reviewer in order to minimise this bias.

Seven studies in this review were limited to single disciplines. Two were directly related to the experience of occupational therapists (Daniëls et al., 2002; Lam Wai Shun et al., 2017), with the others focused on the perspective of rehabilitation assessors or discharge planners i.e. the clinician deciding whether to refer or accept patients for rehabilitation. These roles are reflective of different healthcare systems, and therefore not necessarily generalizable to all countries e.g. the UK. Evidence suggests decisions to accept patients to rehabilitation (including patients with stroke) are variable across clinical disciplines (Cunningham et al., 2000), which indicates a need for multidisciplinary guidance about rehabilitation potential. Stroke rehabilitation is multidisciplinary (Langhorne et al., 2011), therefore the decision of whether a patient receives rehabilitation should be informed by all perspectives and future research needs to reflect this.

An important finding was that no service reported using formal criteria to aid decisions for rehabilitation. In fact, Lynch et al. (2017b) specifically explored whether a nationally recommended assessment tool (Australian Stroke Coalition Rehabilitation Working Group, 2012) was being used in practice to guide assessment and referral for rehabilitation. They determined that only one out of eight sites studied used the recommended tool as criteria to determine rehabilitation requirements, and four sites did not consistently use any type of assessment criteria. They recommended more
interdisciplinary guidance is required in order to ensure patients receive equal access to stroke rehabilitation (Lynch et al., 2017b). Our findings reveal this subjective approach to rehabilitation decision-making occurs across services and countries, and more comprehensive methods of supporting decision-making are required.

Information about inconsistencies in access to rehabilitation has implications for clinical practice. Evidence suggests older stroke patients are less likely to receive evidence-based stroke care processes than younger patients (Luker et al., 2011b), and this review identified age was a barrier for acceptance into rehabilitation services (Johnson et al., 2015). Similarly, pre-stroke dementia has been associated with poorer outcomes (Intercollegiate Stroke Working Party, 2016a), however it is unknown whether this is due to lack of opportunities for rehabilitation. Whilst there is some recent evidence suggesting pre-stroke dementia influences clinical decisions for stroke rehabilitation (Longley et al., 2018), this review has identified the need to further explore this in order to close gaps in inequality of access. There is no evidence to restrict access to stroke rehabilitation for certain patients (Stroke Unit Trialists Collaboration, 2013), therefore there is a need to challenge these barriers to stroke rehabilitation.

This review highlights other barriers around access to stroke rehabilitation, particularly regarding clinicians’ own knowledge. Clinical decision-makers need to be aware that their perspective of patient level and organisational factors, as well as their own individual characteristics, influence their decisions about stroke rehabilitation. Some of these barriers to rehabilitation are potentially modifiable by addressing staff knowledge deficits and attitudes to rehabilitation potential. Further studies on this topic require consideration of researcher influence, more representative samples of the study population and more specificity as to how factors positively or negatively influence decisions.

3.6 Clinical messages

- Decisions about referring/accepting patients into stroke rehabilitation are not only influenced by patient factors, but also organisational factors and characteristics of the clinician.
- Clinical decisions appear to take a subjective approach due to lack of clinical guidance about which patients should receive stroke rehabilitation.
3.7 **Acknowledgements**

The authors would like to thank Amber Muhinyi from the University of Manchester for help evaluating articles. VL was responsible for writing the paper, initiating and designing the study, data collection, and analysis. SP, AB, CS made substantial contributions to the conception or design of the work; analysis and interpretation of data for the work; revising the work critically for important intellectual content; and final approval of the version to be published.

3.8 **Source of funding**

This project was funded by the National Institute for Health Research Collaboration for Leadership in Applied Health Research and Care (NIHR CLAHRC) Greater Manchester. The NIHR CLAHRC Greater Manchester is a partnership between providers and commissioners from the NHS, industry and the third sector, as well as clinical and research staff from the University of Manchester. Audrey Bowen is part funded by the Stroke Association and the NIHR CLAHRC Greater Manchester. The views expressed in this article are those of the authors and not necessarily those of the NHS, NIHR, the Department of Health and Social Care or the Stroke Association.

3.9 **Conflict of interests**

The Authors declare that there is no conflict of interest. The authors alone are responsible for the content and writing of the paper.
4 Chapter Four: What influences decisions about ongoing stroke rehabilitation for patients with pre-existing dementia or cognitive impairment?: a qualitative study (study two)

Presented in a format suitable for publication. This study has been published:


This study has been presented at:
Alzheimer's Research UK North West Science Day (oral), 2017
University of Manchester Doctoral Academy PhD conference (poster), 20217
University of Manchester Postgraduate Summer Research Showcase (poster), 2017
Organisation into Psychological Research in Stroke (OPSYRIS) annual conference (oral), 2017
UK Dementia Congress (poster), 2017
UK Stroke Forum (poster), 2017
Society for Research in Rehabilitation (SRR) winter meeting (oral), 2018
4.1 Abstract

Objective: To identify factors influencing clinicians decision-making about ongoing stroke rehabilitation for people with pre-existing dementia/cognitive impairment, and the impact on clinical practice.

Design: Qualitative semi-structured interviews with stroke specialist healthcare professionals analysed using Thematic Analysis.

Setting: Acute stroke unit, inpatient stroke rehabilitation units and community stroke services.

Participants: Twenty three professionals from six multi-disciplinary stroke teams involved in decision-making about stroke patients’ rehabilitation potential and clinical pathways.

Results: Factors influencing decision-making about ongoing rehabilitation were: 1) gaining understanding of the individual patient, 2) clinician’s knowledge of dementia/cognitive impairment, 3) predicting rehabilitation potential, 4) organisational constraints, 5) clinician’s perceptions of their role within the team. Decision-making led to two outcomes, either accommodating the pre-existing dementia/cognitive impairment within delivery of rehabilitation, or ending rehabilitation for that patient to allocate limited resources where they were perceived more likely to be effective. Participants felt that patients with pre-existing dementia/cognitive impairment had difficulty demonstrating the required rehabilitation potential within the short timescales available in the current model of service delivery. Participants identified a need for training to improve their knowledge and confidence for decision-making and delivery of rehabilitation for this growing population.

Conclusions: Clinicians’ decision-making about ongoing rehabilitation for patients with pre-stroke dementia/cognitive impairments is influenced by gaps in their knowledge and by service constraints. Increased training and more flexible, patient-centred services would enable clinicians to better accommodate these patients in rehabilitation.
4.2 Introduction

Debates about the suitability of stroke rehabilitation for patients with pre-existing or current cognitive deficits occur regularly in clinical practice and the literature (Lynch et al., 2017b). An estimated 10% of patients have a diagnosis of dementia prior to first stroke (Pendlebury and Rothwell, 2009) and others may have undiagnosed cognitive impairment (Prince et al., 2014). Pre-existing dementia/cognitive impairment is associated with poorer functional outcome, discharge to institutional care, and increased risk of death after stroke when compared with those without (Tatemichi et al., 1994; Appelros et al., 2003; Saposnik et al., 2011). It is unclear whether these poorer outcomes are inevitable or are partly a consequence of limited access to stroke rehabilitation. If inadequate rehabilitation is a contributory factor, then that is modifiable through service reorganisation. Increasing rehabilitation could improve life after stroke because, although patients with pre-existing dementia/cognitive impairment often start at lower functional baselines, evidence suggests that they benefit from rehabilitation (Mizrahi et al., 2016).

UK models of stroke care require professionals to make early predictions about a person’s ‘rehabilitation potential’ for initiating or continuing with rehabilitation (Burton et al., 2015; Lam Wai Shun et al., 2017). The term rehabilitation potential sits uncomfortably with many but is understood as the ability to benefit from rehabilitation (Enderby et al., 2016); a broad process which aims to reduce impairment, increase independence and autonomy, and enhance wellbeing (Enderby et al., 2016). Rehabilitation potential is difficult to predict due to the fact that some patients demonstrate their potential later than others (Enderby et al., 2016). Enderby et al. (2016) call for research into decision-making about rehabilitation potential after stroke. It is unclear whether, and if so how, pre-existing dementia/cognitive impairment influences decision-making about rehabilitation potential and treatment plans after stroke (Enderby et al., 2016; Burton et al., 2015).

The present research aimed to identify a) factors influencing the clinicians making decisions about rehabilitation for people with pre-existing dementia/cognitive impairment, and b) how these factors influence clinical practice.
4.3 Methods

The consolidated criteria for reporting qualitative research (COREQ) checklist was used to develop and report this study (Tong et al., 2007) (see appendix 5), which was approved by the University of Manchester ethics committee (reference 16438) and relevant UK NHS bodies. Clinicians working in stroke services as part of multidisciplinary teams (MDT) and who were involved in making decisions about rehabilitation were eligible for inclusion. Teams were approached with information about the study and clinicians volunteered to participate. We sought a purposive sample to include a range of settings and disciplines, for example hyper acute, rehabilitation and community in two different NHS Trusts in order to gain as wide a range of perspectives as possible and cover the entire stroke pathway.

One-off individual semi-structured interviews using open and closed questions were undertaken in a private room in the participant’s workplace, and followed a topic guide (see Appendix 4). The guide was initially piloted on two clinicians working in different services to those sampled from, and was reviewed and refined throughout the interview process to ensure it was as relevant as possible. Field notes were made following each interview to aid the topic guide. The choice of face-to-face or telephone interviews were offered to minimise logistical challenges for healthcare professionals (Sturges and Hanrahan, 2004). Informed consent was gained prior to interview. Interviews were conducted by VL, an Occupational Therapist with experience of delivering clinical services to people with stroke and dementia, and of research. This was disclosed to participants prior to interview, and participants were unknown to the interviewer. With consent, interviews were audio recorded and transcribed verbatim by a University approved transcription service. Transcripts were checked for accuracy prior to deletion of audio recordings.

Data were analysed using Thematic Analysis (Braun and Clarke, 2006). Analysis started after the first interview and followed constant comparison of each interview with the ones preceding, guiding the point of data saturation (Boeije, 2002). Data were managed using NVivo 11 software. All identifiable data (e.g. names and places) were removed from the transcripts, which were then read repeatedly in order to increase familiarity. Themes were derived using an iterative process of data familiarisation; generation of initial codes; identification of themes; reviewing themes; definition of themes; and report production (Braun and Clarke, 2006). VL analysed the transcripts.
and generated initial codes. A subset of transcripts were analysed by the co-authors, a multidisciplinary team of health service researchers with expertise in stroke rehabilitation and dementia. Emerging themes were then discussed by all co-authors at each stage of analysis to agree final themes.

### 4.4 Results

Six multidisciplinary stroke teams across two NHS Trusts in the North of England were approached. Twenty three clinicians from six professions volunteered to participate in the study (see Table 4.1 for demographics). Interviews ranged in length from 15 to 50 minutes (mean=30, SD=10.1), and one was conducted via telephone. Occupational therapists (OT) were most highly represented in the sample (n=11) due to often having the role of assessing cognition in stroke settings. Four physiotherapists, one Speech and Language Therapist (SLT), one Assistant Psychologist and one Clinical Psychologist, three Nurses, and two Physicians were also recruited.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>N</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Sex</strong></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>20</td>
</tr>
<tr>
<td>Male</td>
<td>3</td>
</tr>
<tr>
<td><strong>Age (years), mean and min/max</strong></td>
<td>36.25 (22 – 55)</td>
</tr>
<tr>
<td><strong>Service setting</strong></td>
<td></td>
</tr>
<tr>
<td>Hyper acute/acute stroke unit</td>
<td>5</td>
</tr>
<tr>
<td>Inpatient stroke rehabilitation</td>
<td>11</td>
</tr>
<tr>
<td>Community stroke service</td>
<td>7</td>
</tr>
<tr>
<td><strong>Years worked in stroke service mean and min/max</strong></td>
<td>4 (2 months – 12 years)</td>
</tr>
<tr>
<td><strong>Years since qualifying mean and min/max</strong></td>
<td>11 (2 years – 25 years)</td>
</tr>
</tbody>
</table>

Five themes were identified as factors influencing decision-making about rehabilitation with links between them illustrated in Figure 4.1. Quotes have been aggregated to OT/Physiotherapy, SLT/Medicine, or Nursing/Medical in order to maintain confidentiality.
4.4.1 **Theme 1: Gaining understanding of the individual patient.**

Information gathering on the patient’s pre- and post-stroke physical and cognitive functioning formed part of the initial assessment by participants and was a key feature in planning rehabilitation. Participants described how several sources of information were used to determine whether a patient had pre-existing dementia/cognitive impairment (see Table 4.2). Social history from family was perceived to be the most reliable source of information for identifying any pre-existing cognitive issues. Participants spoke of then triangulating this with observations and formal assessments in order to identify pre- and post-stroke impairments.
### Table 4.2: Summary of information sources used to identify pre-existing cognitive impairment

<table>
<thead>
<tr>
<th>Type of information</th>
<th>Information source</th>
<th>Example</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Formal assessment</strong></td>
<td>Result of assessment during current admission</td>
<td>Functional assessment and cognitive screens</td>
</tr>
<tr>
<td></td>
<td>Results of past assessments</td>
<td>Repeating cognitive screens carried out in the past</td>
</tr>
<tr>
<td><strong>Report from others</strong></td>
<td>Social history from family</td>
<td>Asking family/carers whether any impairments are new/old</td>
</tr>
<tr>
<td></td>
<td>Conversation with patient</td>
<td>Asking the patient their previous level of functioning</td>
</tr>
<tr>
<td></td>
<td>Discussion with MDT</td>
<td>Discussing assessments with other colleagues</td>
</tr>
<tr>
<td></td>
<td>Liaison with other services</td>
<td>Contacting GP for history</td>
</tr>
<tr>
<td><strong>Other sources</strong></td>
<td>Medical notes</td>
<td>Admission notes/MDT notes, past medical history, repeat admissions</td>
</tr>
<tr>
<td></td>
<td>Gut feelings</td>
<td>“They feel more dementia-ry than they do cognitive but I can’t really explain how I get that feel.” P18 (OT/Physiotherapy)</td>
</tr>
<tr>
<td></td>
<td>Environmental clues</td>
<td>Observing signs patients are struggling to look after themselves</td>
</tr>
</tbody>
</table>

Participants discussed the complexity of identifying cognitive impairments, and the importance of teasing out pre-stroke and post-stroke impairments in order to identify rehabilitation needs. Participants discussed how patients with existing impairments have different rehabilitation needs to those with new post-stroke cognitive impairments. However, participants from some professions revealed a more nuanced view than others.

*We’ve got a lady at the minute that did have dementia before she came in, and [everyone in the team is saying], ‘she’s really confused, she doesn’t have a clue what’s going on...she’s not safe to go home’. Actually I’ve been and assessed her and there’s a lot more cognitive going on than a worsening dementia, like*
perceptually she has no awareness of her left side. P16 (OT/Physiotherapy, inpatient rehabilitation)

4.4.2 **Theme 2: Clinician’s knowledge of dementia and cognitive impairment.**

Decisions around ongoing rehabilitation for patients with pre-existing dementia/cognitive impairment were influenced by participants’ own knowledge of dementia. Whilst most participants observed that many of the patients they see had pre-existing dementia/cognitive impairments, some were unable to identify patients with dementia.

*To be honest, in three months we’ve not really had a real dementia. We’ve had a few mild dementias but not had a proper dementia with a stroke.* P5 (OT/Physiotherapy, hyper acute/acute stroke unit)

Whilst this view was not commonplace, it implies that some participants understood dementia as a singular condition rather than a complex one with differing presentations.

In contrast to post-stroke cognitive impairments, participants expressed feeling that they had a lack of knowledge of dementia, which affected their ability to make decisions about ongoing rehabilitation for these patients. Most participants recognised their limited understanding of dementia, attributing this to a lack of training. Instead they relied on "common sense" P15 (OT/Physiotherapy, inpatient rehabilitation) and opportunistic learning:

*At uni I think it was quite limited, I’ve learnt most of what I know from cognitive impairment in placements at uni or from work, just shadowing senior staff and things like that.* P3 (OT/Physiotherapy, inpatient rehabilitation, 1.3 years in clinical practice)

Participants also highlighted the lack of formal structure and priority available for extra training, especially for ward nurses. Some participants had had specialist dementia training funded by their workplace; however it was acknowledged that working within
stroke services requires a broad spectrum of knowledge, some of which was perceived to be best gained through experience.

4.4.3 **Theme 3: Predicting rehabilitation potential.**

Participants’ knowledge about dementia influenced decision-making about rehabilitation potential. Participants initially described giving all patients the opportunity to have a "fair chance" P4 (OT/Physiotherapy, hyper acute/acute stroke unit) at rehabilitation, but balanced this with their perceptions about the individual patient’s potential to benefit from rehabilitation.

*It would be a disservice to say to someone, because you’ve got a dementia you can’t possibly have stroke rehab.* P9 (OT/Physiotherapy, hyper acute/acute stroke unit)

Participants discussed their belief that patients need to possess carry-over in order to benefit from rehabilitation: “*the idea of rehab is that you can build on something and carry over [to the next] session*” P5 (OT/Physiotherapy, hyper acute/acute stroke unit). Carry-over was viewed as an area in which patients with pre-existing dementia/cognitive impairments have difficulty and participants had lower expectations of the patient’s ability to change.

*If there’s pre-existing cognitive impairment there that might be memory related... I would probably then start to think, well what's this person’s capacity for learning and improving?... the thing we should be doing for that person is discharge planning.* P13 (OT/Physiotherapy, hyper acute/acute stroke unit)

Whilst participants expressed the desire to provide fair chances at rehabilitation, these perceptions were associated with a broad belief that having a diagnosis of dementia equated to lack of rehabilitation potential or capacity to change, unless the patient demonstrated otherwise.

*I wouldn’t expect anything to improve [if a patient has a pre-existing cognitive impairment]... I just wouldn’t expect [them] to change.* P18 (OT/Physiotherapy, community stroke service)
Some also expressed difficulty in determining whether patients possessed rehabilitation potential, and were mindful that "people have also completely bucked the trend" P22 (Nursing/Medical, inpatient rehabilitation). Participants described a lack of rehabilitation potential as patients being unable to achieve therapy goals and "starting to plateau" P1 (OT/Physiotherapy, community stroke service) with progress. However rehabilitation potential was typically assessed within the first few days of admission and participants felt obliged "to make a decision pretty quickly and I find that can be quite hard as well" P8 (OT/Physiotherapy, hyper acute stroke unit).

Previous experience of working with patients with dementia or pre-existing cognitive impairments was used to inform decision-making about rehabilitation potential. Junior participants with less experience in particular highlighted difficulty when determining rehabilitation potential and acknowledged that these decisions held a great deal of weight if they resulted in a patient being discharged into residential care.

But, yeah, I think it’s been so difficult for me to describe who has got rehab potential, it is really difficult. Sometimes it is a gut instinct as well and, yeah, I think it would be good if we did have maybe a bit more guidance on that, you know, what to look out for. P8 (OT/Physiotherapy, hyper acute stroke unit, 3.5 years in clinical practice)

That’s what is scary with the rehab potential part, so if you say this person’s got no rehab potential anymore, then they could essentially have things decided for them… it’s difficult, isn’t it, how long is a piece of string. P3 (OT/Physiotherapy, inpatient rehabilitation, 1.3 years in clinical practice)

Participants also expressed concern that rehabilitation potential is unpredictable. Accurately determining an individual’s rehabilitation potential was viewed as an impossible task and one in which training was lacking.

Nobody’s ever sat down and said, this is how you decide if somebody’s got rehab potential. You kind of get taught that if something’s not working, if you’ve tried it three times and it’s not improving then try something else. P5 (OT/Physiotherapy, hyper acute/acute stroke unit)
4.4.4  **Theme 4: Organisational constraints.**

Participants described how assessing patients with pre-existing dementia/cognitive impairments was challenging, and that patients needed increased time to demonstrate progression in rehabilitation which was limited within current service delivery models.

> [It is difficult] when we are trying to do our first assessments and then maybe someone with a dementia that’s quite advanced maybe can't follow instruction, can't participate with your assessment, maybe is just not very engaged with you... It makes it hard because then you can't just give them an instruction to follow. P9 (OT/Physiotherapy, hyper acute/acute stroke unit)

Examples were given of how participants worked with patients with pre-existing dementia/cognitive impairment. Participants observed that such patients sometimes required longer to make equivalent progress in rehabilitation than patients without pre-existing impairments.

> Rehab as a journey in terms of weeks with people getting better takes longer, but equally individual sessions take longer because you often have to repeat commands, take things really slowly, give people time for delayed processing, so I think it definitely takes more time. P3 (OT/Physiotherapy, inpatient rehabilitation)

Participants described an awareness of management strategies for working with people with dementia but were struggling to provide these due to service limitations, and expressed the opinion that stroke services were not necessarily the most appropriate service for patients with pre-existing dementia/cognitive impairments:

> We're a service that's very much based around potential to improve, we're not really a management service and we've only got 6 weeks, with those patients I think it's only fair that we try and get them into the right service. P1 (OT/Physiotherapy, community stroke service)

In addition to this, participants expressed the opinion that the model of rehabilitation they were working within i.e. that rehabilitation led to improvement in function, was
not suited to patients with pre-existing dementia/cognitive impairments. It was acknowledged that dementia is a progressive condition that requires a different approach to rehabilitation.

*I know a lot of the people with vascular dementia get put on the stroke pathway and it's actually not the right place for them and they're not getting the service that they need. They're also getting a potentially incorrect message in terms of you're on a rehabilitation ward which means that you're going to get better, and people with dementias...are potentially going to deteriorate and we can do what we can to support them but we're not able to rehabilitate them in the sense that they're going to improve.* P14 (SLT/Psychology, inpatient rehabilitation)

### 4.4.5 Theme 5: Clinician’s perceptions of their role within the team.

Participants’ perception of their own role within the team influenced decision-making for patients. Collaborative working was frequently cited as an important factor in decision-making; "not just a single thing that we do, we do it as an MDT” P10 (OT/Physiotherapy, inpatient rehabilitation). Some disciplines perceived a lack of understanding within the team about the scope of their role when working with patients with pre-existing cognitive impairments.

*Sometimes they’ll think it’s [our] role to psychologically analyse that person and to provide a full treatment plan for cognitive impairment and to be a psychiatrist and be a psychologist. I think that can be sometimes quite frustrating because they look at us and go, so what we thinking then, do you think they’ve got dementia? And it’s like I’m looking at it in terms of function, do they remember to take their medication, I’m not looking at it to diagnose.* P16 (OT/Physiotherapy, inpatient rehabilitation)

Teamwork and gaining specialist knowledge from others was an important factor when making decisions about rehabilitation, and participants used opinions from other disciplines to inform decisions: "*[I] don't feel confident to make that decision on my own at all, and I think it is meant to be an MDT decision as well*” P8 (OT/Physiotherapy, hyper acute/acute stroke unit). This was not without difficulty;
some professions sampled perceived their colleagues as having different attitudes about rehabilitation potential to themselves which limited decision-making:

*I think us as therapists – physio and OT, we do work obviously very closely on stroke, so it is good because you’re bouncing ideas off each other, but I think [medical staff] can be quite quick to be like, she’s not got rehab potential, they’ve had this stroke and that’s it kind of thing.* P4 (OT/Physiotherapy, hyper acute/acute stroke unit)

The previous five themes reveal the factors influencing whether patients would receive ongoing rehabilitation. As shown in Figure 4.1 these influence decisions about whether to i) accommodate cognitive impairments into rehabilitation or ii) ending rehabilitation for the patient with pre-existing dementia/cognitive impairment.

### 4.4.6 Outcome i: Accommodating cognitive impairments in rehabilitation.

Participants described focusing on compensatory strategies in order to accommodate patients with pre-existing dementia/cognitive impairments, to maintain function and address safe discharge instead of attempting to improve abilities.

*For people where already you’re starting to get a feel that it’s more about a management approach, it’s more about long term potential deterioration rather than improvement. There might be some level of improvement but that will normally be environmental or compensatory rather than doing rehab.* P1 (OT/Physiotherapy, community stroke service)

Participants also talked about strategies they used to tailor their approach to rehabilitation for individuals with pre-existing dementia/cognitive impairments (see Table 4.3).
Table 4.3: Strategies used to support people with pre-existing cognitive impairment or dementia

<table>
<thead>
<tr>
<th>Category</th>
<th>Strategy</th>
<th>Illustrative quote</th>
</tr>
</thead>
</table>
| Environmental                | • Reduce distractions  
• Utilise quiet rooms and spaces  
• Use home visit assessments | I am very conscious of the fact that it’s a very busy, noisy environment and it’s horrendous for a cognitive patient.  
P4 (OT/Physiotherapy)                                                                                           |
| Patient-centred approaches   | • Spread therapy time throughout the day to minimise fatigue  
• Ensure patient has eaten, had medication, opened bowels prior to therapy  
• Use familiar objects during functional assessments  
• Ensure assessment is meaningful to patient  
• Engage family with rehabilitation | I’ve done making just a cordial if someone doesn’t make tea because it’s that being meaningful to them, so if someone never made a cup of tea before and I ask them to do it now, it’s just not going to be relevant.  
P3 (OT/Physiotherapy)                                                      |
| Communication                | • Clear, concise instructions  
• Use closed rather than open questions  
• Avoid rhetorical questions | You need to be just be asking a yes or no, simple sentence structure, again using really clear, concise language.  
P10 (OT/Physiotherapy)                                                                                          |

Whilst participants expressed feeling that they had a lack of knowledge and skills for working with patients with pre-existing dementia/cognitive impairment, they actually described a variety of methods that they used to support patients. These were acquired through trial and error and would be reviewed alongside the decision to continue with rehabilitation.

*Trying to get strategies to work on [the deficit], so whether that’s compensatory or teaching or equipment or further practice or things like that, ...it’s going to be trial and error I think really on your treatment, but trying to think what might be useful to help them overcome that deficit, and then just keep trying until you find something that works or you get to a point where you think, I don’t think this person’s going to be able to get that back. P3 (OT/Physiotherapy, inpatient rehabilitation)*
4.4.7 **Outcome ii: Ending rehabilitation for the patient.**

Ultimately, participants described how rehabilitation would have to end for some patients with pre-existing dementia/cognitive impairments. Participants discussed how they would give priority to patients making faster progress in rehabilitation because working with patients with pre-existing dementia/cognitive impairments "does add pressure onto the staffing levels" P11 (Nursing/Medical).

So if I have 18 patients on one ward and I have half of me for that day ...if somebody’s got quite significant cognitive problems and I feel that they are not going to make massive difference by [...] giving daily therapy, then I will de-prioritise them over...somebody who would benefit from daily input. P23 (SLT/Psychology, hyper acute/acute stroke unit)

Participants discussed how decisions had to be based on outcomes from previous patients in order to facilitate continuing or ending rehabilitation:

*When you have such a flow of patients through, all requiring such demanding input... all requiring equal rights and access to this service, there has to be a point when you look at rehab potential and outcome and who was best placed.*

P11 (Nursing/Medical, inpatient rehabilitation)

Participants talked about service pressures, and a reduced ability to provide extensive support when having a large number of patients; treatment became reactive rather than focused on long-term outcome. This ultimately impacted on how patients who are taking longer to improve would be prioritised within the service. Participants working within time-limited services adapted their rehabilitation to fit within their limits i.e. taking a compensatory approach rather than focusing on improvement within a short time-frame.

*I think it's difficult really and I think sometimes that pressure we've got this [six week] window, we know we've got the provision to do more but then if we've got lots of referrals and we've got a big caseload then we're kind of reduced to what we can do with our patients.* P1 (OT/Physiotherapy, community stroke service)
Time limits on services intend to focus interventions and enable prioritisation, however this means that some individuals are not given the opportunity to demonstrate progression within the timeframe. Participants discussed how they felt current stroke pathways were ill-suited for patients with pre-existing dementia/cognitive impairments due to this.

4.5 Discussion
The findings demonstrate the way information, confidence, service models and team-working inform decision-making about stroke rehabilitation for people with pre-existing dementia/cognitive impairment and their impact on clinical practice. Clinicians attempted to distinguish pre-stroke from post-stroke cognitive impairments in order to determine rehabilitation needs and potential when working to a somewhat narrow concept of rehabilitation (functional improvement) and towards goals that appeared service-led rather than patient-centred. Often this was based on information from family members and intuition rather than systematic assessment. This identification was influenced by participants’ own knowledge and understanding of dementia, often acknowledged to be limited. Participants expected patients with dementia to have difficulty demonstrating rehabilitation potential, which was confounded by limitations of the model of rehabilitation they were working within. Participants reported patients needed longer to progress with rehabilitation compared to those without pre-stroke cognitive impairments, but clinicians were required to make early decisions about potential to progress. Additionally, misconceptions over roles limited shared decision-making.

The decision of whether a patient will receive ongoing rehabilitation was expressed in two ways. Participants described positive strategies of how they would support patients with pre-existing dementia/cognitive impairments and engaged in an iterative process of reviewing their decision to continue with rehabilitation, shifting their focus from improvement to maintenance. Participants also described how they would have to end rehabilitation for patients with pre-existing dementia/cognitive impairments due to service constraints.

This study has strengths and limitations. A qualitative approach to this topic allowed a relatively unexplored area of clinical practice to be investigated and this was done from the perspectives of clinicians from a range of relevant disciplines and stroke services.
The contextual issues highlighted in this study around working in high pressured environments could be applicable to services nationally. The level of self-reflection from staff demonstrates an awareness of areas for improvement whilst attempting to work to the best of their current abilities given the imposed service constraints.

This was a difficult topic to discuss in some cases due to sensitivity around sharing working practices caring for vulnerable patients and in an area in which participants felt they lacked skills, knowledge and resources to provide ideal services for patients. Sampling from two Trusts within one geographical area may limit the transferability of the findings, however the six sampled services were as different as possible and covered a large population. Whilst the sample was more professionally diverse than related studies (Burton et al., 2015), 47% of participants still came from one profession (OT). This was expected due to their role in assessing cognition, however greater representation from other professions could improve transferability of the findings. The overrepresentation of OTs could underestimate the training needs of this population, because whilst as a discipline they had received the most training of those sampled and have a role in assessing cognition (Intercollegiate Stroke Working Party, 2016b), some still lacked confidence. Additionally, the fact the lead author (VL) is an OT could introduce bias to the study, although every attempt was made to mitigate this. Participant’s awareness of the researcher’s role can effect results, however the mutual understanding of services may have allowed participants to speak more freely (Richards and Emslie, 2000).

Whilst this is to our knowledge the first study exploring decision-making for stroke rehabilitation for people with pre-existing dementia/cognitive impairment, some comparisons to other studies can be drawn. In this study there was inconsistency over the amount of training and experience participants had about dementia amongst all disciplines. A lack of knowledge about the aetiology of dementia may impact on the success of interventions in the long-term (Turner et al., 2004). Education on dementia has been found to be inadequate for adult nursing, occupational therapy and social work courses in some UK Higher Education Institutions (Pulsford et al., 2007), as highlighted by clinicians in this study. Clinical experience has been found to be one of the most important factors influencing decision-making in stroke rehabilitation, therefore training to support those with less experience may be beneficial (Burton et al., 2015; Doyle et al., 2013; Lam Wai Shun et al., 2017; Luker et al., 2014). Clinicians
in the current study indicated their own desire to further develop their knowledge; however there is limited guidance on working with this patient group, as highlighted in the UK National Clinical Guidelines for Stroke (Intercollegiate Stroke Working Party, 2016a).

Some clinicians in this study saw rehabilitation as an active process leading to improvement in function rather than maintenance of function or wellbeing; if patients did not demonstrate functional improvement they were unable to progress with rehabilitation. This is a somewhat narrow interpretation of rehabilitation, which is defined as restoring, or adapting to loss of, physical and psychological function (NICE, 2013). Adapting to loss could be thought of as maintaining function (Enderby et al., 2016). The UK National Clinical Guidelines (Intercollegiate Stroke Working Party, 2016a) even state over time stroke rehabilitation will shift from a restorative to compensatory approach due to the evolving needs for people post-stroke. It seems therefore that acknowledgment of different approaches for some patients should be made clear from services delivering rehabilitation. In fact, rehabilitation taking a compensatory approach has been found to be effective for people with dementia (Graff et al., 2006) and cognitive rehabilitation can be used to facilitate management of a condition, which is a growing field in dementia care (Clare, 2017). Additionally, no definitive literature has been identified about specific patient groups who do not benefit from stroke rehabilitation (Lynch et al., 2017a). Maintenance and management of function remains a vital part of the rehabilitation process, and stroke services need to make provision for people with pre-existing dementia/cognitive impairments who may require more of a management approach.

The current rehabilitation delivery model in the study settings therefore appears to have a number of constraints which influence clinical practice. As identified in this study, patients requiring longer to progress in rehabilitation or to demonstrate their potential to change become deprioritised due to limitations around availability of services, which is similar to findings in the wider literature (Burton et al., 2015; McGlinchey and Davenport, 2015; Enderby et al., 2016). Clinicians working in inpatient environments suggested they were not always conducive to the demonstration of rehabilitation potential for patients with dementia, and therefore this needs to be considered when deciding if a patient has potential in these settings (Burton et al., 2015). Studies have highlighted challenges in devising meaningful interventions in
clinical environments, which particularly impacts on patients with cognitive difficulties (Daniëls et al., 2002; Whitehead et al., 2014); and thus deferring decisions about rehabilitation potential (i.e. deciding when a patient lacks potential) may be more appropriate for these patients (Burton et al., 2015).

One aspect to emerge from the study findings is the difficulty clinicians have in judging rehabilitation potential for patients with pre-existing dementia/cognitive impairments. The emotional element of decision-making, with clinicians sometimes fulfilling a need to act or feeling ‘torn’ about seeing patients perceived as a lower priority, has been highlighted in the literature (Burton et al., 2015; Doyle et al., 2014). The concept of giving patients a fair chance at rehabilitation is framed by resource availability and patient abilities, which requires resilience on the part of clinicians (Luker et al., 2014; Burton et al., 2015). It is clear more support and revised service models are required in order to deliver care that clinicians feel is in patients’ best interests.

Stroke and dementia are associated with age and incidence of both is increasing (Seshadri et al., 2006; Prince et al., 2014). Improvements in stroke care mean higher survival rates, and an increase in older patients who are surviving strokes (Feigin et al., 2014). Staff in this study identified a lack of training even at university level in working with people with dementia, therefore it is clear improvements in education and training are required in order to ensure clinicians possess the appropriate skills to work alongside patients with pre-existing dementia/cognitive impairments, particularly as patient numbers with dementia are likely to increase (Prince et al., 2014).

Changes to the current model of stroke rehabilitation are required to better suit the needs of stroke patients with pre-existing dementia/cognitive impairments. Patients are currently required to demonstrate their potential for change early in the acute phase of their treatment, however this is not always appropriate for this patient group and more flexibility may be required.

Throughout this study there was little mention of how patients were included in the decision-making process. This could be an area for future study; people with dementia are often excluded from decisions about their care (Kane and Terry, 2015), and exploring how to better involve them in decision-making in the early stages of stroke rehabilitation could potentially facilitate care planning.
4.6 **Clinical messages**

- Clinicians should have access to training in order to increase knowledge of dementia and accommodate cognitive problems in rehabilitation.
- Timeframes need to be more flexible in order for patients to demonstrate rehabilitation potential.
4.7 **Source of funding**

This project was funded by the National Institute for Health Research Collaboration for Leadership in Applied Health Research and Care (NIHR CLAHRC) Greater Manchester. The NIHR CLAHRC Greater Manchester is a partnership between providers and commissioners from the NHS, industry and the third sector, as well as clinical and research staff from the University of Manchester. Audrey Bowen is part funded by the Stroke Association and the NIHR CLAHRC Greater Manchester. The views expressed in this article are those of the authors and not necessarily those of the NHS, NIHR, the Department of Health and Social Care or the Stroke Association.

4.8 **Conflict of interests**

The Authors declare that there is no conflict of interest. The authors alone are responsible for the content and writing of the paper.

4.9 **Contributors**

VL (guarantor) – writing the paper, initiating study, designing study, monitoring progress, data collection, analysis.

SP, AB, CS - Substantial contributions to the conception or design of the work; analysis and interpretation of data for the work; revising the work critically for important intellectual content; Final approval of the version to be published.
5 Chapter Five: Differences in stroke rehabilitation for people with pre-existing cognitive impairment: an observational cohort study (study three)

Presented in a format suitable for publication.

This study has been accepted for presentation at:
UK Stroke Forum (oral), 2018

5.1 Abstract

Objective: To examine whether stroke survivors with pre-existing cognitive impairment receive different amounts of rehabilitation therapies than those without.

Design: Prospective observational cohort.

Setting: Four UK inpatient stroke rehabilitation units.

Participants: 139 stroke patients receiving rehabilitation, able to give informed consent/had an individual available to act as personal consultee. 33 participants were categorised with pre-existing cognitive impairment based on routine documentation by clinicians, 106 without.

Measures: Number of inpatient physiotherapy (PT) and occupational therapy (OT) sessions received during the first eight weeks post-stroke, referral to Early Supported Discharge (ESD) and length of stay.

Results: On average participants with pre-existing cognitive impairment received 40 total PT and OT sessions compared to 56 sessions for those without (mean difference 16.0, 95% CI 2.9 to 29.2) and this difference was not fully explained by adjusting for potential confounders. They received nine fewer single discipline PT sessions (95% CI 3.7 to 14.8). They received similar amounts of single discipline OT, psychology and speech and language therapy sessions; however did receive two more non-patient facing OT sessions (95% CI 0.6 to 4.3) and nine fewer patient-facing OT sessions (95% CI 3.5 to 14.9). There was no evidence to suggest they were discharged earlier from rehabilitation. Of the 85 discharged by eight weeks, those with pre-existing cognitive impairment were less likely to be referred to ESD (p =0.008).

Conclusions: People in stroke rehabilitation with pre-existing cognitive impairments receive less rehabilitation than those without, particularly physiotherapy and referral to ESD, but receive more non-patient facing OT.
5.2 Introduction

Evidence suggests people with a diagnosis of dementia prior to stroke are subject to a number of barriers around access to stroke rehabilitation. It is estimated around 10% of patients have a diagnosis of dementia prior to first stroke, one third of patients develop dementia after recurrent stroke (Pendlebury and Rothwell, 2009), and many others may have undiagnosed pre-stroke cognitive impairment (Prince et al., 2014). Pre-existing dementia is associated with higher levels of disability, risk of death, and likelihood of discharge to institutional care after stroke, when compared to patients without (Tatemichi et al., 1994; Appelros et al., 2003; Saposnik et al., 2011). Patients with dementia often start at lower functional baselines than those without, however, there is evidence to suggest that they are able to benefit from rehabilitation and none to suggest they cannot (Mizrahi et al., 2016; Stroke Unit Trialists Collaboration, 2013; Lynch et al., 2017a). Despite this, people with pre-existing dementia are less likely to be referred or admitted to post-acute stroke rehabilitation than those without, in part due to a perception by clinicians as having limited potential to improve through rehabilitation (Hakkennes et al., 2013; Burton et al., 2015; Longley et al., 2018). Some barriers to stroke rehabilitation have been identified around discharge pressures within services influencing time clinicians are able to provide, with patients with pre-existing dementia perceived as low priority for rehabilitation therapies after being deemed eligible to receive them (Luker et al., 2014; Lam Wai Shun et al., 2017; Longley et al., 2018). Additionally, patients with pre-existing dementia are perceived by clinicians to require longer to demonstrate progress in rehabilitation than patients without, with time limited services unable to accommodate their needs (Longley et al., 2018). There remains limited guidance on how to manage these patients, and how best to deliver rehabilitation services for them. It is unclear whether the aforementioned poorer outcomes are linked to lack of rehabilitation received after stroke.

Only around 61% of people living with dementia receive a formal diagnosis (Kane and Terry, 2015), and many patients may have pre-clinical symptoms of dementia prior to a stroke. Clinicians use a range of sources to identify pre-existing cognitive impairments, and often draw on social histories rather than systematic clinical assessment (Longley et al., 2018). Due to variation in identifying pre-stroke cognitive impairments, it is unclear whether patients with undiagnosed pre-existing dementia/cognitive impairment experience the same barriers to rehabilitation as patients with a diagnosis of dementia. No studies have described patients with pre-
existing cognitive impairments who are seen by stroke services, or have examined whether patients with pre-existing dementia/cognitive impairment who are deemed suitable for admission to post-acute rehabilitation receive different amounts of stroke-specific rehabilitation than those without.

The aim of this study was therefore to examine whether undiagnosed pre-existing cognitive impairment or diagnosed dementia is associated with amount of stroke-specific rehabilitation received in the post-acute phase.

5.3 Method

This prospective observational cohort study used clinical notes to extract data about pre-existing cognitive status and rehabilitation received by participants. Appropriate ethics and NHS permissions were granted (North West Haydock Research Ethics Committee 17/NW/0427). The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) (von Elm et al., 2008) checklist has been used to report the study (see appendix 13).

The study took place within four National Health Service stroke rehabilitation units in the UK and was supported by the UK NIHR local Clinical Research Network (CRN), who aided in identifying and approaching sites and participants. Participants were eligible for inclusion if they were an inpatient on a stroke rehabilitation unit with a clinically confirmed stroke and under the care of the stroke team; capable of giving informed consent or had an individual available to act in the capacity of a personal consultee; and identified by staff as having post-acute rehabilitation needs. Patients were excluded if they were in the last days of life; non-stroke; or unable to give informed consent and did not have an individual available/willing to act in the capacity of a personal consultee. The Mental Capacity Act (2005) (HM Government, 2005) principles and British Psychological Society guidelines (Dobson, 2008) were followed when recruiting participants who lacked capacity to consent.

Consecutive sampling occurred across sites from August 2017 to January 2018. All patients on the stroke rehabilitation units were screened and potentially eligible participants were approached on the ward by CRN practitioners as soon as medically stable in order to receive information about the study, and informed consent gained where able. Standard and accessible/aphasia-friendly information sheets and consent
forms were used, alongside consultee declarations for participants deemed unable to give informed consent by CRN practitioners.

On discharge from inpatient care or eight weeks post-stroke, whichever was sooner, data were extracted from consented participants’ clinical notes for the period up to eight weeks post-stroke. Eight weeks was chosen to allow reasonable time for patients to receive rehabilitation services based on average length of stay from national data (Royal College of Physicians, 2017). Clinical notes from hospital admission were accessed and reviewed manually by the first author (VL) or CRN practitioners, recorded on a paper case report form and input into a custom database by VL. The data collection process was piloted initially with the first five recruits. Every instance of documentation of an offered therapy session or activity by a therapist relating to the patient during the eight week post-stroke data capture period was counted. Distinctions were made between patient-facing or non-patient facing (i.e. phone calls, family meetings etc) activities. Joint sessions were counted as one of each of the present therapies.

Alongside routine demographic, clinical and therapy data, data on pre-stroke cognitive functioning were extracted. Notes were reviewed for dementia diagnosis on admission, or any evidence of pre-existence of cognitive impairment and if so, by which member of the multidisciplinary team and from what source. For example if an occupational therapist (OT) documented a conversation with a relative who stated the patient was struggling to remember appointments, this was categorised as a pre-existing cognitive impairment from social history by OT. If no dementia diagnosis or documentation about pre-existing cognitive impairment were documented, the patient was categorised as having no pre-existing cognitive impairment.

5.4 Analysis
Participants were assigned to one of three groups during analysis based on data collected about their pre-stroke cognitive functioning. Those with a documented diagnosis of dementia on admission were assigned to the ‘dementia’ group. Participants were then either categorised into the ‘pre-existing cognitive impairment’ group or the ‘no pre-existing cognitive impairment’ group. As planned in our protocol, a minimum of 20 participants was required per group for analysis, therefore due to the
small number of patients with diagnosed dementia pre-planned aggregation of the dementia and pre-existing cognitive impairment groups was carried out. Combining these two groups was reasonable due to the fact data were not available about severity of any pre-existing cognitive impairment; therefore there was likely to be a large overlap in severity of cognitive impairment within these groups.

Statistical analyses were conducted using SPSS Statistics 23 for Windows. The primary outcome measure was the total number of therapy sessions calculated by combining total number of physiotherapy (PT) and occupational therapy (OT) sessions offered during the eight week post-stroke data capture period. This was selected because all patients on a rehabilitation ward typically receive these two therapies, whereas not all require speech and language therapy or psychology (Intercollegiate Stroke Working Party, 2016a). Profession-specific sessions were also considered in secondary analyses (i.e. PT only), with further distinctions between patient-facing or non-patient facing therapy sessions.

Descriptive characteristics by groups and the cohort are presented as total numbers and percentages for categorical variables and means, standard deviation (SD) and median for continuous variables. The primary outcome was examined with a linear regression adjusting for the possible confounders of age, sex, National Institutes of Health Stroke Scale (Brott et al., 1989) (NIHSS) (a standard measure of stroke severity) and also pre-stroke modified Rankin score (van Swieten et al., 1988) (mRS) (a standard measure of functional disability). Data were examined to clarify the distribution of residuals in order to meet the assumptions of linear regression. Missing data were handled using multiple imputation as sensitivity analysis using 5 imputed datasets in SPSS. Kaplan-Meier analysis and log rank (Mantel-Cox) test was used to test for differences between pre-existing cognitive impairment group and time until discharge (censored at eight weeks). Chi-squared (2x2) tests were used to test for differences between pre-existing cognitive impairment grouping and referrals to ESD on discharge or not. The level of significance used was $p < 0.05$. We attempted to use mRS to report outcome on discharge however insufficient data were available to calculate differences in outcome post-stroke.
5.5 **Results**

We received complete screening data from three of four participating sites, showing that 219 admissions to stroke rehabilitation units in six months met the study's eligibility criteria (see Figure 5.1) of which 125 (57%) consented. With the inclusion of a fourth site, a total of 139 participants provided primary outcome data for analysis (attrition rate 7%).

Participant baseline demographic and clinical characteristics are presented in Table 5.1. The average age of participants was 75 with a median pre-stroke mRS of 0, which is similar to national audit figures (Royal College of Physicians, 2017). Median NIHSS on admission was 7, slightly higher than the national average (Royal College of Physicians, 2017). One hundred and seven (77%) participants had a routine cognitive screen during admission to rehabilitation, most commonly with the Montreal Cognitive Assessment (MoCA) (Nasreddine et al., 2005).

**Table 5.1: Participant characteristics**

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Total participants (n=139)</th>
<th>No pre-existing cognitive impairment (n=106)</th>
<th>Pre-existing cognitive impairment (n=33)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>N (%)</td>
<td>N (%)</td>
<td>N (%)</td>
</tr>
<tr>
<td>Age, y, mean (SD)</td>
<td>75 (12.4)</td>
<td>73 (12)</td>
<td>83 (7.5)</td>
</tr>
<tr>
<td>Min and max</td>
<td>30-104</td>
<td>30-94</td>
<td>70-95</td>
</tr>
<tr>
<td>Female sex</td>
<td>83 (59.7)</td>
<td>64 (60.4)</td>
<td>3 (33.3)</td>
</tr>
<tr>
<td>Ethnicity</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>White British</td>
<td>131 (94.2)</td>
<td>100 (94.3)</td>
<td>9 (100)</td>
</tr>
<tr>
<td>White Other</td>
<td>2 (1.4)</td>
<td>2 (1.9)</td>
<td>0</td>
</tr>
<tr>
<td>Mixed White &amp; Black Caribbean</td>
<td>1 (0.7)</td>
<td>1 (0.9)</td>
<td>0</td>
</tr>
<tr>
<td>Asian or Asian British – any Asian background</td>
<td>5 (3.6)</td>
<td>3 (2.8)</td>
<td>0</td>
</tr>
<tr>
<td>Comorbidities</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Congestive heart failure</td>
<td>11 (7.9)</td>
<td>9 (8.5)</td>
<td>1 (11.1)</td>
</tr>
<tr>
<td>Hypertension</td>
<td>79 (56.8)</td>
<td>63 (59.4)</td>
<td>5 (55.6)</td>
</tr>
<tr>
<td>Diabetes</td>
<td>40 (28.8)</td>
<td>30 (28.3)</td>
<td>3 (33.3)</td>
</tr>
<tr>
<td>Previous stroke/TIA</td>
<td>37 (26.6)</td>
<td>25 (23.6)</td>
<td>2 (22.2)</td>
</tr>
<tr>
<td>Atrial fibrillation</td>
<td>26 (18.7)</td>
<td>19 (17.9)</td>
<td>2 (22.2)</td>
</tr>
<tr>
<td>Other neurological condition</td>
<td>3 (2.2)</td>
<td>3 (2.8)</td>
<td>0</td>
</tr>
</tbody>
</table>
Residential status on admission

<table>
<thead>
<tr>
<th></th>
<th>Living alone</th>
<th>Living with partner/others</th>
<th>Sheltered accommodation</th>
<th>Residential care</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>48 (34.5)</td>
<td>33 (31.1)</td>
<td>2 (22.2)</td>
<td>13 (54.2)</td>
</tr>
<tr>
<td></td>
<td>81 (58.3)</td>
<td>67 (63.2)</td>
<td>4 (44.4)</td>
<td>10 (41.7)</td>
</tr>
<tr>
<td></td>
<td>8 (5.8)</td>
<td>5 (4.7)</td>
<td>2 (22.2)</td>
<td>1 (4.2)</td>
</tr>
<tr>
<td></td>
<td>2 (1.4)</td>
<td>1 (0.9)</td>
<td>1 (11.1)</td>
<td>0</td>
</tr>
</tbody>
</table>

Pre-stroke mRS (n=136)

<table>
<thead>
<tr>
<th></th>
<th>Mean (SD)</th>
<th>Median</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>0.82 (1.3)</td>
<td>0</td>
</tr>
<tr>
<td></td>
<td>0.57 (1.1)</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td>1.22 (1.3)</td>
<td>1.78 (1.4)</td>
</tr>
</tbody>
</table>

NIHSS on admission (n=121)

<table>
<thead>
<tr>
<th></th>
<th>Mean (SD)</th>
<th>Median</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>8.56 (6.2)</td>
<td>7</td>
</tr>
<tr>
<td></td>
<td>8.78 (6.3)</td>
<td>7.5</td>
</tr>
<tr>
<td></td>
<td>7.89 (3.3)</td>
<td>7</td>
</tr>
<tr>
<td></td>
<td>7.95 (6.6)</td>
<td>6</td>
</tr>
</tbody>
</table>

Days post-stroke on admission to rehabilitation unit

<table>
<thead>
<tr>
<th></th>
<th>Mean (SD)</th>
<th>Median</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>5.83 (8.3)</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>6.19 (8.9)</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>2.67 (2.8)</td>
<td>5.46 (6.9)</td>
</tr>
</tbody>
</table>

Days spent in rehabilitation unit (up to 56 days)

<table>
<thead>
<tr>
<th></th>
<th>Mean (SD)</th>
<th>Median</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>38.42 (18.5)</td>
<td>43</td>
</tr>
<tr>
<td></td>
<td>39.07 (18.3)</td>
<td>45</td>
</tr>
<tr>
<td></td>
<td>33.78 (19.9)</td>
<td>34</td>
</tr>
<tr>
<td></td>
<td>37.33 (19.1)</td>
<td>39.5</td>
</tr>
</tbody>
</table>

Cognitive screen completed

<table>
<thead>
<tr>
<th></th>
<th>MOCA</th>
<th>MMSE</th>
<th>Other</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>78 (72.9)</td>
<td>3 (2.8)</td>
<td>26 (24.3)</td>
</tr>
<tr>
<td></td>
<td>65 (74.7)</td>
<td>3 (3.4)</td>
<td>19 (21.8)</td>
</tr>
<tr>
<td></td>
<td>2 (40)</td>
<td>0</td>
<td>3 (60)</td>
</tr>
<tr>
<td></td>
<td>11 (73.3)</td>
<td>0</td>
<td>4 (26.7)</td>
</tr>
</tbody>
</table>

106 participants (76%) had no recorded pre-existing cognitive impairments; 9 (7%) had a diagnosis of dementia on admission and 24 (17%) had documented pre-existing cognitive impairment. For the 24 participants with pre-existing cognitive impairment, the most common source of information for this was social history from family (n=16, 67%), followed by results of post-stroke cognitive assessment during current admission (n=6, 25%). OTs were the professionals who most frequently documented existence of pre-existing cognitive impairment (n=13, 54%), followed by physicians (n=9, 38%), psychologists (n=1, 4%) and mental health liaison staff (n=1, 4%).

As planned we combined the dementia and pre-existing cognitive impairment groups for analyses. All subsequent data are presented using two groups: no pre-existing cognitive impairment or pre-existing cognitive impairment. Patients with pre-existing cognitive impairment had lower stroke severity (NIHSS mean difference = 1.8, 95% confidence interval [CI] 0.9, 2.8) and higher pre-stroke disability (mRS mean difference = 0.5, 95% CI 0.6, 10.3) on average.
**Figure 5.1: CONSORT diagram of available screening data**

Total known admissions during study period (n=367)

- Excluded (n=26)
  - Unable to screen due to staff unavailable (n=26)

Assessed for eligibility (n=341)

- Excluded (n=122)
  - Not meeting inclusion criteria (n=77)
    - Not stroke (n=19)
    - End of life (n=19)
    - Lacked capacity & no consultee (n=34)
    - No active rehabilitation (bedbound with full care at baseline) (n=5)
  - Other reasons (n=45)
    - Asked not to approach by clinical team (n=18)
    - Already involved in other research (n=2)
    - Language barrier (n=2)
    - Already recruited on previous admission (n=1)
    - Already recruited at another site (n=1)
    - From overseas (n=1)
    - Other (unspecific) (n=20)

Approached for consent to participate (n=219)

- Excluded (n=94)
  - Declined to participate (n=21)
  - Discharged before approach/consent (n=73)

Consented (n=150)

- Excluded from analysis (n=11)
  - Lost to follow up (n=6) (of which from site 4, n=1)
  - Died before 8 weeks post-stroke (n=5) (of which from site 4, n=3)

Consented from site four (n=25)

Analysed (n=139)
5.5.1 **Primary outcome**

Participants with pre-existing cognitive impairment had on average 16 fewer (PT and OT) sessions than participants with no pre-existing cognitive impairment (see Table 5.2). When analysis was adjusted for NIHSS, sex and age this reduced to an average of 14 fewer sessions for participants with pre-existing cognitive impairment, with both NIHSS ($p < 0.001$) and cognitive impairment grouping ($p = 0.04$) associated with number of sessions. When including pre-stroke mRS in adjusted analysis, difference in number of sessions reduced to an average of 9 fewer therapy sessions for participants with pre-existing cognitive impairment.

**Table 5.2: Amount of therapy received by group**

<table>
<thead>
<tr>
<th>Type of therapy</th>
<th>No pre-existing cognitive impairment (n=106)</th>
<th>Mean (SD), median</th>
<th>Pre-existing cognitive impairment (n=33)</th>
<th>Mean (SD), median</th>
<th>Mean difference (95% confidence interval)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Total Physiotherapy and OT</strong></td>
<td>55.84 (35.3), 50</td>
<td>39.81 (25.5), 37</td>
<td></td>
<td></td>
<td>16.03 (2.89, 29.16) Unadjusted</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>14.1 (0.4, 27.8) Adjusted*</td>
<td></td>
<td>9.89 (-4.5, 24.2) Adjusted†</td>
</tr>
<tr>
<td><strong>Physiotherapy</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patient facing</td>
<td>24.3 (16.2), 21.5</td>
<td>14.6 (10), 16</td>
<td></td>
<td></td>
<td>9.68 (3.7, 15)</td>
</tr>
<tr>
<td>Non-patient facing</td>
<td>3.59 (3.3), 3</td>
<td>4.03 (4.4), 2</td>
<td></td>
<td></td>
<td>-0.4 (-1.8, 0.9)</td>
</tr>
<tr>
<td><strong>Total physiotherapy</strong></td>
<td>27.91 (18.5), 24.5</td>
<td>18.66 (12.3), 18</td>
<td></td>
<td></td>
<td>9.24 (3.67, 14.82)</td>
</tr>
<tr>
<td><strong>OT</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patient facing</td>
<td>22.8 (15.3) 20</td>
<td>13.6 (10.7), 10</td>
<td></td>
<td></td>
<td>9.21 (3.5, 14.9)</td>
</tr>
<tr>
<td>Non-patient facing</td>
<td>5.08 (4.3), 4</td>
<td>7.51 (5.8), 5</td>
<td></td>
<td></td>
<td>-2.4 (-4.3, -0.6)</td>
</tr>
<tr>
<td><strong>Total OT</strong></td>
<td>27.93 (18), 26.5</td>
<td>21.15 (14.9), 19</td>
<td></td>
<td></td>
<td>6.78 (-0.74, 13.63)</td>
</tr>
<tr>
<td><strong>Speech and Language Therapy (SLT)</strong></td>
<td>9.14 (10.3), 5.5</td>
<td>7.64 (8), 5</td>
<td></td>
<td></td>
<td>1.5 (-2.39, 5.4)</td>
</tr>
<tr>
<td><strong>Psychology</strong></td>
<td>1.32 (2.8), 0</td>
<td>0.87 (1.7), 0</td>
<td></td>
<td></td>
<td>0.4 (-0.58, 1.47)</td>
</tr>
</tbody>
</table>

*Adjusted to take into account sex, age, NIHSS
†Adjusted to take into account sex, age, NIHSS and pre-stroke mRS.

Analyses were repeated using mean number of therapy sessions per week in order to account for differing lengths of stay between participants. Participants with pre-existing cognitive impairment had fewer sessions per week (mean difference = 1.7, 95% CI
0.1, 3.4). NIHSS data were missing for 18 participants (not recorded in clinical notes) and assumed to be missing at random. Analysis using multiple imputation did not affect conclusions. Overall, participants with pre-existing cognitive impairments had fewer total therapy sessions and this was not fully explained by demographic and clinical variables.

5.5.2 **Secondary outcomes**

When analysed by single discipline, participants with pre-existing cognitive impairment had nine fewer total physiotherapy sessions than those without pre-existing cognitive impairment (95% CI 3.7, 14.8). The differences in total OT, speech and language therapy (SLT) and psychology sessions were not statistically significant. When examined by specific type of session, participants with pre-existing cognitive impairment had on average nine fewer patient facing OT sessions (95% CI 3.5, 14.9) and on average two *more* non-patient facing sessions than those without (95% CI 0.6, 4.3).

The median time to discharge from the rehabilitation units was 38 days for participants in the pre-existing cognitive impairment group compared to 45 days than those without. A log rank (Mantel-Cox) test revealed no significant differences in the time until discharge for the two groups (p = 0.585). 54 participants were still inpatients at eight weeks. Of the 85 discharged by eight weeks, 47 (75%) of participants without pre-existing cognitive impairment were referred to ESD compared to only 8 (42%) of participants with and this difference was significant (p = 0.008). 54 (84%) of participants without pre-existing cognitive impairment and 15 (71%) of participants with pre-existing cognitive impairment were discharged to their previous residence. Similar proportions between groups were newly admitted to residential care; 6 (9%) without pre-existing cognitive impairment and 2 (10%) with.

5.6 **Discussion**

We found that participants with documented pre-existing cognitive impairments who had been eligible for post-acute rehabilitation received 16 fewer total therapy sessions than participants without, and this was not fully explained by adjusting for potential confounders. There was a small increase in amount of non-patient facing OT received by participants with pre-existing cognitive impairments. These participants were also less likely to be referred to ESD.
This is the first study to describe post-acute stroke rehabilitation for patients with pre-existing cognitive impairments, however it has strengths and limitations. By ensuring consent procedures were accessible we demonstrated that it is possible to successfully recruit people with dementia/cognitive impairments to stroke research, who are often excluded (Livingston et al., 2017; Dewing, 2007). Forty two percent of participants were recruited using the consultee process, either because they were deemed to lack capacity by research staff or stroke-related communication impairments impacted on ability to consent.

Previous estimates suggest 10% of patients have a diagnosis of dementia prior to stroke but only 7% of our participants had a pre-existing diagnosis of dementia and 17% had undiagnosed pre-existing cognitive impairment (Pendlebury and Rothwell, 2009). A limitation of our study is that the population were those deemed eligible for inpatient rehabilitation, from which some stroke patients remain excluded (Lynch et al., 2017a). Some, particularly those with dementia, may never be referred for inpatient rehabilitation due to staff perceptions of their abilities to benefit from it or to rehabilitation unit acceptance criteria (Longley et al., 2018; Lynch et al., 2016; Putman et al., 2007; Hakkennes et al., 2013). We also do not have data on the cognitive status of patients screened out of the study therefore are unable to draw conclusions as to how this may have affected the sample. These may account for the relatively low level of dementia recorded in our sample compared to the broader stroke population in the literature (Pendlebury and Rothwell, 2009), which suggests people with a diagnosis of dementia are less likely to be admitted to stroke rehabilitation in the first place. As our study focuses on patients already admitted to rehabilitation this difference in the amount of therapy received may be underestimated.

A further limitation was the use of existing data may have resulted in lack of validity to the results. This study relied on clinical documentation; some therapy input may have been undocumented, however medical notes are a legal document and thus should contain all relevant information regarding care without bias (General Medical Council, 2014). Some participants may also have had pre-existing cognitive impairment that was not identified or documented by clinicians, which may have affected the cognitive impairment groupings. There is currently no validated assessment of pre-stroke cognition (McGovern et al., 2016) and the purpose of this study was to describe
current care processes. All cognitive assessments utilised in this study (predominately the MoCA) were of post-stroke cognition, rather than informant-based assessments of pre-stroke cognition; no formal assessments of pre-stroke cognition were documented. This reiterates the findings of previous research which found social histories were a more relied upon source of information than formal assessment regarding pre-stroke cognition (Longley et al., 2018).

Our findings reflect those of a number of studies which found clinicians may consider stroke rehabilitation unsuitable for patients with dementia or cognitive impairment (Lynch et al., 2016; Lynch et al., 2017b; Burton et al., 2015; Longley et al., 2018). Factors such as stroke severity and previous level of independence have been found to be associated with quality of care after stroke (Luker et al., 2011a). Our adjusted analysis supports this; stroke severity and previous level of disability were associated with amount of therapy provided. However our measure of pre-stroke disability may be confounded by the existence of pre-existing cognitive impairment itself; mRS is a general measure and has no differentiation between physical or cognitive disability alone so this adjusted analysis using mRS should be treated with caution (van Swieten et al., 1988). Similarly, only cardiovascular comorbidities were recorded therefore presence of other conditions that could impact on recovery are unknown in this sample.

A point to note is whether the seeming inequality in amount of rehabilitation for people with pre-existing cognitive impairment is in fact appropriate. Rehabilitation for people with advanced dementia may be of limited benefit and a more care-focused approach to prevent further deterioration may be required, for example ensuring appropriate assistive devices and support are in place on discharge (Bauer et al., 2009). Whilst there is limited evidence that people with pre-existing dementia are able to benefit from stroke rehabilitation, this has not been examined for people who were very dependent on admission (Stroke Unit Trialists Collaboration, 2013; Mizrahi et al., 2016). Rehabilitation in non-stroke fields has been found to increase function for patients with mild to moderate dementia, although not for those with severe dementia (Huusko et al., 2000). Severity of dementia may therefore limit the success of rehabilitation interventions, although this has not been examined in stroke. Equally, these differences in rehabilitation may be due to clinicians tailoring the pace of interventions within the first eight weeks post-stroke. A recent qualitative study found
clinicians stated they would provide shorter, more frequent sessions for people with pre-existing cognitive impairments (Longley et al., 2018), but our results do not support this; if therapists were providing shorter, more frequent sessions then there would likely have been a smaller difference in amount of therapy received. Whilst therapists report a desire to provide multiple short interventions, provision of these types of sessions is rare (Clarke et al., 2018). The use of existing data should overcome this discrepancy between what people say and what they do, adding strength to the findings (Mays and Pope, 1995). Despite this, lack of data on outcomes and severity of cognitive impairment for patients in this study limits the conclusions that can be drawn about the appropriateness of the difference in amount of therapy; however it does raise some interesting questions and areas for future research.

Another potential reason for this difference in amount of therapy is related to clinicians’ decision-making about observed improvement. Previous research describes the need for patients to demonstrate progress or improvement in order to receive ongoing rehabilitation (Daniëls et al., 2002; Lam Wai Shun et al., 2017; Luker et al., 2014; Lynch et al., 2017b). Evidence suggests patients with pre-existing cognitive impairments require longer to make equivalent progress with rehabilitation than people without, and that highly constrained services are unable to provide for this (Longley et al., 2018). Rehabilitation is defined as a process that aims to optimise social participation and well-being (Wade, 2005); framing rehabilitation as a restorative process requiring improvement rather than an adaptive one excludes patients who may require a more management-focussed approach, and means they may be less likely to have their needs met by services.

This study has a number of implications. First, our findings suggest that a sizeable group of stroke rehabilitation patients (24%) with pre-existing cognitive impairment may receive differences in rehabilitation, and we have demonstrated it is feasible to recruit this group of patients to research. Additionally, we have demonstrated there are a significant number of people (17%) within stroke rehabilitation services with undiagnosed pre-existing cognitive impairments, which is important given that pre-stroke cognitive decline is associated with future development of clinical dementia (Pendlebury and Rothwell, 2009). Increasing awareness of these groups of patients is vital in order for rehabilitation to best meet the needs of patients (Kalaria et al., 2016). We also found that participants with pre-existing cognitive impairments received more
non-patient facing OT (i.e. phone calls, family meetings) than participants without. Stroke services need to be aware that these patients may require different clinical resources in favour of more formal direct intervention, therefore should ensure services are equipped to provide this.

Future research is required to examine whether these observed differences in amount and type of rehabilitation are inequalities that need to be rebalanced or potentially reflect appropriate, personalised care during the first eight weeks post-stroke. To determine this requires examination of long-term outcomes to see whether patients with pre-existing cognitive impairments, who we have shown receive less rehabilitation, have worse outcomes and whether increasing the amount, duration or type of therapy might counter this. Evidence suggests these patients are able to make short-term gains from rehabilitation (Mizrahi et al., 2016), but our study did not address outcome longitudinally and insufficient data were collected to draw any conclusions about differences in short-term outcome.

5.7 Clinical messages

- People with pre-existing cognitive impairment within inpatient stroke rehabilitation received differences in number of therapy sessions than those without, particularly physiotherapy and referral to community therapies.
- There are a significant number of people within stroke rehabilitation services with undiagnosed pre-existing cognitive impairments, suggesting the size of this population has been underestimated.
5.8 **Source of funding**
This project was funded by the National Institute for Health Research Collaboration for Leadership in Applied Health Research and Care (NIHR CLAHRC) Greater Manchester in partnership with the Stroke Association. The NIHR CLAHRC Greater Manchester is a partnership between providers and commissioners from the NHS, industry and the third sector, as well as clinical and research staff from the University of Manchester. Audrey Bowen is part funded by the Stroke Association and the NIHR CLAHRC Greater Manchester. The views expressed in this article are those of the authors and not necessarily those of the NHS, NIHR, the Department of Health or the Stroke Association.

5.9 **Conflict of interests**
The Authors declare that there is no conflict of interest. The authors alone are responsible for the content and writing of the paper.

5.10 **Contributors**
VL (guarantor) – writing the paper, initiating study, designing study, monitoring progress, data collection, analysis.
SP, AB, CS - Substantial contributions to the conception or design of the work; analysis and interpretation of data for the work; revising the work critically for important intellectual content; Final approval of the version to be published.
6 Chapter Six: Discussion

Due to the presentation of studies in this thesis, discussions for individual studies have been provided in their respective chapters. This chapter summarises and integrates the overall findings, discusses the limitations and clinical implications of the body of work presented within the thesis, and identifies future areas for research.

6.1 Overall summary of findings

Prior to this PhD, it was known that all stroke patients are able to benefit from rehabilitation, including those with pre-existing cognitive impairments (Stroke Unit Trialists Collaboration, 2013; Mizrahi et al., 2016). People with pre-existing cognitive impairments are able to make short-term gains from rehabilitation, even though they tend to start at lower functional baselines than those without (Mizrahi et al., 2016). Despite this, patients with pre-existing dementia/cognitive impairment have poorer outcomes than those without (Saposnik et al., 2011; Appelros et al., 2003; Tatemichi et al., 1994). Whilst there is no evidence or guidelines to recommend (or deny) rehabilitation for people with pre-existing cognitive impairment, the literature suggested that diagnosis of dementia may still influence the decision to refer/admit patients to rehabilitation.

The relationship between poorer outcomes and possible lack of opportunities for rehabilitation had not been explored prior to this thesis. The aim of the work was to examine the impact of pre-existing dementia on stroke rehabilitation, carried out through a systematic literature review (chapter three), a qualitative study of clinicians’ experience (chapter four), and a quantitative study examining differences in rehabilitation (chapter five). These studies have found people with pre-existing dementia/cognitive impairment before a stroke do not receive the same opportunity for rehabilitation as those without. This is in part due to clinicians’ decision-making about which patients should receive stroke rehabilitation. The systematic review identified that decision-making to refer/admit patients for rehabilitation is influenced by patient, organisational and clinician level factors, one of which was presence of pre-existing dementia/cognitive impairment. Findings from the qualitative study suggested that decisions about providing rehabilitation for people with pre-existing dementia/cognitive impairment were influenced by clinicians’ own knowledge, which resulted in changes in clinical practice and deprioritising of patients. Clinicians identified a lack of knowledge
and skills around working with patients with pre-existing dementia, which may subsequently contribute to decisions that result in inequality in rehabilitation. The impact of pre-existing dementia/cognitive impairment extends beyond access to rehabilitation; the cohort study found people with pre-existing cognitive impairment who are accepted for inpatient rehabilitation do not receive equal amounts of therapy once there. A further issue explored by this thesis was around undiagnosed cognitive impairment; evidence suggests 39% of people never receive a dementia diagnosis and a stroke admission may be the first time pre-existing cognitive impairment is identified (Kane and Terry, 2015; Caratozzolo et al., 2016). The cohort study identified 17% of participants had undiagnosed cognitive impairment, which is the first time this group of patients has been described. A major strength of this research is that 42% of participants were recruited to the cohort study using the consultee process, which indicates a lack of capacity to consent; this group of participants are often excluded from research (Livingston et al., 2017; Dewing, 2007). Many studies of prevalence and development of post-stroke dementia exclude those with pre-existing cognitive impairment (Pendlebury and Rothwell, 2009), and the figures identified by the cohort study suggest current levels of prevalence may be underestimated.

Some interesting comparisons can be drawn between the studies presented in this thesis. A key finding was around the lack of confidence and experience clinicians from all disciplines have in working with people with dementia, and the impact of this on clinical practice. The qualitative study highlighted a lack of confidence amongst less experienced clinician participants, mainly due to lack of training and education in working with and caring for people with dementia. The systematic review also identified one factor influencing clinical decisions about access to stroke rehabilitation is clinicians’ own knowledge. These findings are relevant for access to rehabilitation; both knowledge and awareness of services were found to affect referrals to rehabilitation (Lynch et al., 2017b; Lam Wai Shun et al., 2017; Luker et al., 2014). This may result in people with pre-existing cognitive impairment being less likely to be admitted/referred for rehabilitation, and could explain the relatively small number of people with dementia in the cohort study (7%) compared with the literature (Pendlebury and Rothwell, 2009).

The systematic review did not identify any studies in which clinicians used formal criteria to aid decisions for rehabilitation. The findings revealed a subjective approach
to decision-making occurs across services and countries, and more interdisciplinary
guidance to ensure patients receive equal access to stroke rehabilitation is
recommended (Lynch et al., 2017b). This finding was supported by the qualitative
study. Clinicians reported using many different sources of information to aid decisions,
and found social histories to be the most reliable information source rather than formal
assessment. The fact that participants reported difficulty with decision-making for
people with pre-existing cognitive impairments indicates more guidance would benefit
clinicians.

Clinicians in the qualitative study also discussed how patients with pre-existing
cognitive impairments/dementia require longer to progress in rehabilitation or to
demonstrate their potential to change. Clinicians highlighted that inpatient
environments are not always conducive to the demonstration of rehabilitation potential
for patients with dementia; patients are sometimes able to respond better to
rehabilitation in their home environment (Burton et al., 2015). In contrast, it was found
in the cohort study that patients with pre-existing cognitive impairments were actually
less likely to be referred to community therapy with ESD (stroke-specific rehabilitation)
than patients without, although it is unknown whether this is due to clinicians’
perceptions about patients’ potential to benefit from rehabilitation.

Participants in the qualitative study stated that they would use strategies to adapt to
working with people with pre-existing cognitive impairments, for example by spreading
therapy throughout the day. Recently, stroke rehabilitation recommendations have
shifted towards frequent, short interventions so this adaption of sessions would adhere
to recommendations (Intercollegiate Stroke Working Party, 2016a). However, the
results of the cohort study provide evidence that provision of these shorter sessions is
unlikely to be happening; if therapists were providing shorter, more frequent sessions
then there would likely have been a smaller difference in amount of therapy received.
Evidence suggests that whilst therapists report a desire to provide multiple short
interventions, provision of these types of sessions is rare (Clarke et al., 2018).
Increasing awareness of this disparity between what clinicians think they provide and
what they do in clinical practice is important to ensure stroke services are actually
meeting the needs of patients, although it remains unknown whether this is actually a
more effective way of delivering rehabilitation to this patient group.
6.2 Comparisons with the wider literature

One theme running throughout the studies is around the concept of rehabilitation, and clinician’s expectations of the purpose of it. Participants in the qualitative study conceptualised rehabilitation as an active process leading to physical improvement rather than maintenance of function or wellbeing; if patients did not demonstrate functional improvement they were perceived as lacking ‘rehabilitation potential’ and hence unable to progress with rehabilitation. Contrary to this, others would argue that the purpose of stroke rehabilitation is to restore, or adapt to loss of, physical and psychological function and optimise participation (Wade, 2005; NICE, 2013). The systematic review identified a body of research describing the need for patients to demonstrate progress in order to be referred for rehabilitation (Daniëls et al., 2002; Lam Wai Shun et al., 2017; Luker et al., 2014; Lynch et al., 2017b). Similarly, observed improvement was an important factor in clinicians’ decision-making about whether a patient possesses rehabilitation potential, which as discussed, influences access to ongoing rehabilitation (Lam Wai Shun et al., 2017). These conflicts may explain the finding that people with pre-existing cognitive impairments receive less therapy than those without; if rehabilitation is framed as a restorative rather than adaptive process, patients who require a more adaptive or management-focused approach will be less likely to have their needs met by services. It appears that the purpose and concept of rehabilitation is not necessarily as clear as it should be from those who provide it.

Furthermore, the definition of rehabilitation presented in section 1.3 emphasises the purpose of rehabilitation is to optimise well-being, whilst adjusting to residual limitations (Wade, 2005). This goes beyond adapting to disability or restoring function; rehabilitation is not just a ‘fix’, as it seems to be conceptualised by some (Longley et al., 2018). This well-being focused definition is comparable to the recovery model in mental health, which shifts focus from the treatment or cure of illness to empowering people to live with a condition and assert self-control over it (Jacobson and Greenley, 2001). Recovery is about having a satisfying and fulfilling life despite the limitations of illness (Anthony, 1993). The recovery approach has also been compared to that of person-centred dementia care, which moves beyond functional ability and emphasises the individual living a valued and meaningful life (Hill et al., 2010; Brooker, 2003). Similarly, the Stroke Association have highlighted the emotional impact of stroke; they state emotional support is as important as physical rehabilitation, and services need to provide this (Stroke Association, 2013). This living-well approach therefore seems
applicable to life after stroke, particularly for people with pre-existing cognitive impairments, and the findings from this thesis suggest stroke rehabilitation would benefit from a similar shift in focus.

It was important to include people with undiagnosed cognitive impairment in the cohort study because of the lack of consensus on how to identify and diagnose vascular cognitive impairment and vascular dementia, as discussed in section 1.4 (Gorelick et al., 2011). SVD is considered the most common cause of vascular cognitive impairment, and its presence predicts risk of stroke, therefore it is likely some of cognitive impairment identified in the study was attributable to SVD and cerebrovascular disease (although data were not collected on this) (O'Brien et al., 2003; Caratozzolo et al., 2016). Furthermore, the definition of VCI does actually include mild cognitive impairments related to cerebrovascular disease not meeting the criteria for dementia (Moorhouse and Rockwood, 2008). The decision was made to combine the groups of participants with documented dementia and undiagnosed cognitive impairment to enable statistical analysis. The fact that data were not available about the severity of any pre-existing cognitive impairment, and the uncertainty about how to identify VCI justifies the combination of groups. 17% of participants in the cohort study were identified with undiagnosed cognitive impairment, which reflects the importance of including this population, especially because pre-stroke cognitive decline is associated with subsequent development of dementia post-stroke (Pohjasvaara et al., 1998; Hénon et al., 2001; Caratozzolo et al., 2016). It appears likely therefore that prevalence rate of pre-stroke dementia is currently underestimated due to the challenges associated with identifying it.

A final consideration from the thesis findings is whether the seeming inequality in amount of rehabilitation for people with pre-existing cognitive impairment is in fact appropriate. As participants in the qualitative study stated, rehabilitation for people with advanced dementia may be of limited benefit and a more care-focused approach to prevent further deterioration may be required, for example ensuring appropriate assistive devices and support are in place on discharge (Bauer et al., 2009). Whilst there is evidence that people with pre-existing dementia are able to benefit from stroke rehabilitation, this has not been examined for people who were very dependent on admission (i.e. already in residential/nursing care) (Stroke Unit Trialists Collaboration, 2013; Mizrahi et al., 2016). Those with severe dementia often appear to
be excluded from trials of non-stroke rehabilitation interventions for people with dementia (Graff et al., 2006). Rehabilitation for orthopaedic patients with mild to moderate dementia has been found to increase the likelihood of returning to independent living, although not for those with severe dementia (Huusko et al., 2000). The severity of dementia may therefore limit the success of rehabilitation interventions, although this has not been tested on stroke patients and as stated, no data were available on severity of cognitive impairment in the cohort study. Equally, participants in the qualitative study stated patients with pre-existing cognitive problems require longer to demonstrate progress in rehabilitation than those without. The differences in rehabilitation found in the cohort study may be due to clinicians tailoring the pace of interventions within the first eight weeks post-stroke. Lack of evidence on outcomes and severity of cognitive impairment for patients in the cohort study limits the conclusions that can be drawn about the appropriateness of this inequality.

### 6.3 Strengths and limitations

This thesis highlights that people with pre-stroke dementia/cognitive impairment in stroke services are a group that are difficult to identify and access, but remain a significant and growing proportion of patients. By ensuring consent procedures were accessible, the cohort study was both able to successfully recruit people with cognitive impairments and become the first study to describe patients with pre-existing cognitive impairments in stroke services who may not have a diagnosis of dementia, which is a major strength. Despite this, recruitment was not without difficulty, as demonstrated in both recruitment numbers and difficulty consenting participants for a planned patient study (see appendix 6).

There were elements of gatekeeping for the cohort study that served as barriers to recruitment, and this may have introduced elements of bias to the study. Common gatekeepers in research are ethical review boards, researchers, service managers, health professionals and family members; all who have responsibility to ensure potential research participants are protected and not exploited (Bartlett and Martin, 2002; McFadyen and Rankin, 2017). The available screening data identified a number of people were not approached about the study. Whilst some reasons were unavoidable (patients being discharged before approach), in 18 cases the clinical team or research practitioner reported they felt the patient should not be approached. These are possible examples of gatekeeping, which is a major barrier for recruiting people to
research and is not exclusive to research involving people with dementia (Patterson et al., 2011). Similarly, Ewing et al. (2004) describe palliative care patients not being approached for a study because recruiting GPs wanted to avoid additional 'upset' for patients, or believed it inappropriate to approach them (irrespective of eligibility). These views, whilst attempting to protect the patient, in fact contribute to exclusion of people with dementia/cognitive impairment in research (Wilkinson, 2002). Additionally, 34 people (10% of potential participants) were excluded due to lack of capacity and having no personal consultee available, which indicates there were many more potential participants. The protocol followed British Psychological Society guidelines (Dobson, 2008) specifying use of a professional consultee was acceptable however no professional consultees were used and the reasons why unknown. This may account for the relatively low level of dementia recorded in the sample (7%) compared with the literature (10%) (Pendlebury and Rothwell, 2009). There is an increasing body of literature on the inclusion of people living with dementia in research, for example through use of PPI and flexible methods of consent (see section 6.5.5) (Wilkinson, 2002). Some argue informed consent relies too much on cognitive ability and involving people with dementia in research should take an inclusionary, context-specific approach (Dewing, 2002; Hellström et al., 2007). Those carrying out the recruitment of people with dementia to research need the appropriate knowledge and skills to do so, which is a consideration when managing a number of research teams recruiting on behalf of a study (McKeown et al., 2010).

My clinical background has guided the research direction, ensured its relevance, and informed decisions and data collection throughout this PhD. Despite this, this perspective may have introduced elements of bias, particularly within the qualitative work. Although participant’s awareness of a researcher’s role can influence data and findings, it was found that the mutual understanding of services can allow participants to speak more openly on a difficult topic (Richards and Emslie, 2000). Use of reflexivity in order to develop rapport was useful (DiCicco-Bloom and Crabtree, 2006), particularly when interviewing junior clinicians; we were able to share mutual lack of knowledge and confidence in decisions about rehabilitation potential which aided participants in sharing their experience. These shared assumptions can be a disadvantage in qualitative research due to the researcher over-emphasising personal similarities with participants and thus limiting the data collected, although this was mediated through the support of a research team with differing perspectives (Holloway, 2017). In
contrast to this full level of involvement, the cohort study depended on others (CRN practitioners) for recruitment at all sites and data collection at half of them. This may have resulted in differences in approach to the research, however quantitative research is less subjective and data were collected from clinical notes therefore interpretation should not be influenced by the research team (Peters, 2010).

The influence of belonging to a clinical group is again relevant when considering the systematic review, which identified seven studies that were limited to single disciplines. Two of these were directly related to the experience of occupational therapists (Daniëls et al., 2002; Lam Wai Shun et al., 2017) with the others focused on the perspective of rehabilitation assessors or discharge planners, so the findings may not apply to all professions. The thesis studies were deliberately designed to be relevant to all stroke clinicians rather than focused directly on occupational therapists. Additionally the mixed methods approach taken in this thesis helped to mediate any issues around subjectivity when synthesising the findings (Johnson and Onwuegbuzie, 2004). One strength of the qualitative study is that it explored the experiences of six different professions; stroke rehabilitation is multidisciplinary therefore it is seems appropriate to research the decision-making processes of all professions involved in order to more accurately reflect clinical practice (Langhorne et al., 2011).

The use of existing rather than experimental data for the cohort study has strengths and limitations. Routine clinical data is readily available, low cost and quick to access due to being collected for other purposes, and is a rich source of a large amount of information (Powell et al., 2003). However in this case it was collected un-blinded, which may affect validity and reliability of the data (Powell et al., 2003). It was also difficult to control data quality due to small amounts of missing or poorly documented data, particularly when working with a number of different sites, which is a disadvantage of observational research (Karahalios et al., 2012). Despite this, a major strength of using existing data is that it minimises modifications in behaviour that having a researcher observing a participant may cause (the Hawthorne Effect) (Mays and Pope, 1995). Equally, the use of existing observational data can overcome the discrepancy between what people say and what they do (Mays and Pope, 1995). Existing data can circumvent potential biases, for example people trying to present themselves in a good light, and uncover actions that participants may be unaware of (Mays and Pope, 1995). As discussed in section 6.1, clinicians said they would provide
shorter, more frequent sessions for people with pre-existing cognitive impairments, but the results of the cohort study did not support this.

A final limitation of the work is that it took place in one geographical location, which may reduce the generalisability of the findings. One way this was mediated was through sampling strategies. As stated in section 2.3.2.2, the qualitative study deliberately sampled from two Trusts that were as different as possible within this centralised model. Whilst all stroke rehabilitation units in Greater Manchester were approached for the cohort study, the four that participated were quite different in both size and organisation to each other. One site admits the highest number stroke patients in the UK (over 600 in a three month period), whereas the smallest site in the study admits around 85 (Royal College of Physicians, 2017). The two larger rehabilitation units were on the same hospital site as a hyper acute/acute stroke unit; the smaller two were not (see Figure 2.1). The data collection period of eight weeks was chosen with these different services in mind in order to capture a reasonable amount of post-HASU rehabilitation; mean length of stay in these services was similar to national audit data (Royal College of Physicians, 2017). There still may have been elements of bias around the study population due to the fact centralised services increase likelihood of people receiving acute evidence-based interventions, which impact positively on patient outcomes (Ramsay et al., 2015). The findings, particularly those from the qualitative study that are specifically relevant to the model of stroke care, are based on a model of ‘best practice’ and demonstrate that this centralised model is still not free from problems (Ramsay et al., 2015). Therefore these findings remain relevant because there are likely to be similar issues found across stroke services.

Although this PhD was UK based, the findings from this thesis may be applicable across similar Western countries. The systematic review identified similarities across nine countries in factors that influence referral/admission to rehabilitation, one of which being pre-existing cognitive status. Inequalities in access to stroke rehabilitation have been found internationally, with different exclusion criteria and lack of clinical guidance on which patients should access rehabilitation (Lynch et al., 2017a; Jolliffe et al., 2018). Dementia is a global condition; therefore it is possible that similar inequalities in rehabilitation for people with pre-stroke cognitive impairment/dementia would be found elsewhere.
6.4 Clinical implications

The work presented in this thesis has multiple clinical implications. It appears people with pre-existing dementia/cognitive impairment before a stroke do not receive the same opportunity for rehabilitation to those without. The qualitative study reveals that this is in part due to clinicians’ decision-making about which patients should receive stroke rehabilitation. Clinical decision-making is influenced by patient-level and organisational factors, as well as the attributes of individual clinicians. Clinicians identified a lack of knowledge and skills around working with patients with pre-stroke dementia, which may contribute to decisions that result in inequality in rehabilitation.

6.4.1 Identification of pre-stroke cognitive impairment

As discussed in chapter one, very little is known about the prevalence of undiagnosed pre-stroke cognitive impairment. The cohort study identified 17% of participants recruited had undiagnosed cognitive impairment, which is an important finding given that pre-stroke cognitive decline is associated with development of post-stroke dementia (Pendlebury and Rothwell, 2009). There is a lack of longitudinal data on the progression of cognitive impairment, particularly from pre-stroke cognitive impairment into diagnosis of dementia, with the majority of studies assessing at stroke onset only rather than accounting for pre-stroke cognition and with limited follow-up (Pendlebury and Rothwell, 2009). Identifying cognitive impairments early after stroke and monitoring progression of the impairment (see section 1.5.5) will enable patients to subsequently receive appropriate diagnosis and post-diagnostic support (Kalaria et al., 2016). Early diagnosis and identification of dementia increases access to support services, lifestyle adjustments and also reduces the cost of health care (McCarten et al., 2010). Identifying patients at possible risk of progression to PSD has benefits for patients, carers and services. The number of people with cognitive impairments suggests there may be a need for increased interagency working with mental health services in order to appropriately support this patient population.

6.4.2 Management approaches in stroke rehabilitation

Some clinician participants in the qualitative study perceived rehabilitation as a process requiring improvement rather than maintenance in function, and discussed how some services were unable to provide condition-management. As stated in the qualitative study, compensatory strategies are acknowledged by the UK National Clinical Guidelines (Intercollegiate Stroke Working Party, 2016a) to be part of the rehabilitation
process. Different approaches for some patients should be provided by services delivering rehabilitation; or alternative services should be made available if time limited services are unable to meet the needs of patients. However, it was found in the cohort study that participants with pre-existing cognitive impairments received slightly more non-patient facing occupational therapy than patients without. Occupational therapists are required to assess a patient’s home environment, and provide and train patients and family in use of equipment (Intercollegiate Stroke Working Party, 2016b). Provision of equipment is frequently used as part of a compensatory approach to rehabilitation (Foster, 2006). The need for non-patient facing or compensatory types of interventions may be greater in this population. As identified in both the qualitative study and cohort study, occupational therapists also spend time gathering information about pre-stroke functioning from families. Patients with pre-existing cognitive impairments may be more demanding of clinician resources due to this need for liaison with families and other such non-patient facing activities involved in discharge planning. Stroke services should ensure they are able to deliver this type of patient-centred practice for people with pre-existing dementia/cognitive impairments who may require more of a management approach, and be aware that this may impact on clinical resources and require alteration of current service goals.

6.4.3 Clinicians’ training needs
A key finding from the studies presented in this thesis is the inconsistency around training and experience clinicians have in dementia amongst all disciplines. Lack of knowledge has been found to be a barrier for clinicians referring patients to rehabilitation (Lynch et al., 2017b), and their awareness of services influences where and when patients are referred for rehabilitation (Lam Wai Shun et al., 2017; Luker et al., 2014). Lack of dementia training in acute environments has been found to be a significant unmet need for all staff (Galvin et al., 2010; Royal College of Psychiatrists, 2011), but training needs to be of sufficient quality in order to make changes to clinical practice. A systematic review of dementia education in hospitals found training in group-based classroom environments rather than online, lasting one or more days rather than one-two hours had positive impact on staff attitudes and knowledge of dementia (Surr and Gates, 2017). As discussed in the systematic review, Lynch et al. (2017b) found that clinicians perceived patients with dementia as unable to benefit from stroke rehabilitation despite receiving one training session on the contrary,
indicating training needs to be of sufficient substance in order to result in attitude change.

It seems therefore that education in working with people with dementia needs to start early. Education on dementia has been found to be inadequate for adult nursing, occupational therapy and social work courses in some UK Higher Education Institutions (Pulsford et al., 2007). Current education programmes need to improve the capabilities, opportunities and motivations of healthcare professionals working with people with dementia in order to meet minimum core requirements (Banerjee et al., 2017; Surr et al., 2017). Banerjee et al. (2017) highlight a need for healthcare education to provide knowledge and understanding of chronic conditions, such as dementia, and management of patients with multi-morbidities. This is particularly relevant when considering the increasing needs of clinicians working with patients with pre-stroke dementia. Understanding about dementia needs to be incorporated into healthcare education in order to challenge negative beliefs.

6.5 Future areas for research

This thesis has provided knowledge on rehabilitation for people with dementia in stroke services through clinician perspectives and observing current processes of care through use of clinical data. The following section will discuss a number of future areas for research in order to build on the findings.

6.5.1 Long-term outcomes

A key area for future research is to identify whether the difference in outcome for people with pre-existing cognitive impairment is caused by inequality in rehabilitation by examining long-term outcomes (Appelros et al., 2003; Tatemichi et al., 1994; Saposnik et al., 2011). Whilst the cohort study identified there is a difference in rehabilitation received, it remains unknown whether patients with pre-existing cognitive impairments would have improved outcomes with equal or more amounts of therapy. Evidence suggests these patients are able to make short-term gains from rehabilitation (Mizrahi et al., 2016), however this evidence is limited and more is required on longitudinal outcomes over time, for example with a randomised controlled trial comparing different models of delivering rehabilitation.
6.5.2 Rehabilitation across the whole stroke pathway
Some patients, particularly those with dementia, may never be referred on for inpatient rehabilitation due to staff perceptions of their abilities to benefit from it or the acceptance criteria of rehabilitation units (Longley et al., 2018; Lynch et al., 2016; Putman et al., 2007; Hakkennes et al., 2013). The cohort study was situated within inpatient rehabilitation units and whilst it provided a new description of service delivery in this setting, it did not provide any information about people who were not admitted to rehabilitation limiting generalisability of the findings across the broader population of stroke survivors. Future research could gather larger scale data across the entire stroke pathway for patients with pre-existing cognitive impairments starting on admission to emergency units. Rehabilitation interventions begin within 24 hours of admission to hospital post-stroke (Intercollegiate Stroke Working Party, 2016a), therefore it seems appropriate to undertake this work in other areas in order to gain more representative samples.

6.5.3 Assessment of pre-stroke cognition
Future research on pre-existing cognitive impairment and rehabilitation could use a standardised method of assessment to identify cognitive impairment, rather than routinely collected clinical data. One limitation of the cohort study is the use of existing data resulted in possible lack of validity to the groupings, which would be mediated by a study collecting new data using a standardised measure. The IQCODE is one method of retrospectively assessing cognition, which asks an informant about the participant’s cognitive decline over the past 10 years (Jorm, 2004). As described in section 1.5.2, this has not yet been validated as a method of assessing pre-stroke cognition (McGovern et al., 2016), although it is a well-validated tool for assessing previous cognitive decline in non-stroke populations (Jorm, 2004). Assessing pre-stroke cognition of all participants as part of the study process might have revealed different proportions of participants as cognitively impaired rather than using observational data from clinical notes; some participants might have had pre-existing cognitive impairment that was just not identified or documented by clinicians. The purpose of this research was to observe current care processes, therefore another area of study could examine the proportion of participants assessed as previously cognitively impaired using a tool (for example IQCODE) compared with the more informal methods used by clinicians described in the qualitative study and cohort study. All cognitive assessments utilised in the cohort study (predominately the MoCA) were of
post-stroke cognition, rather than informant-based assessments of pre-stroke cognition; no formal assessments of pre-stroke cognition were documented. Future research could examine the effectiveness of using a validated tool to identify pre-existing cognitive impairment in stroke rehabilitation.

6.5.4 Content of therapy sessions
Whilst the cohort study has provided insight into number of sessions provided for people with or without pre-existing cognitive impairments, no data were collected on the content of therapy sessions which is a potential area for future research. Clinicians in the qualitative study discussed how they might provide a management approach for people with dementia if able, which could be why patients with pre-existing cognitive impairments had fewer therapy sessions in the cohort study. The cohort study also reflects the findings of a recent observational study of the content of therapy sessions; non-patient facing activity such as administration, phone calls and meetings take up a large proportion of therapy time (Clarke et al., 2018). This activity could be justified as related to taking a management approach, and future research could further illustrate this. Additionally, an examination of whether people with pre-existing cognitive impairments receive recommended therapy time compared to people without could explore potential differences in service delivery further. The UK Clinical Guidelines recommend 45 minutes of each appropriate therapy daily, however physiotherapy and OT provision has been found to be lower in England than other countries (De Wit et al., 2006). As discussed, the provision of frequent short interventions was not reflected in the results of the cohort study. Whilst length of therapy sessions are self-reported as part of SSNAP, clinicians have been found to overestimate session length (Clarke et al., 2018). Future research could explore content of sessions for people with pre-existing cognitive impairment in greater detail using non-routinely collected data such as observations of sessions.

6.5.5 Patient and carer experience
Further work is needed to understand the perspective of patients with pre-existing cognitive impairment about stroke rehabilitation, which is missing from the literature. It would be pertinent to understand whether improving physical and psychological functional is a priority for patients and carers, or if services should focus support on living well with comorbid conditions. A true understanding of a condition can only be gained from a person experiencing it, therefore it is vital to include patient voices in
research about them (Robinson, 2002; McKeown et al., 2010). Whilst steps were taken to rectify difficulty with recruitment into the qualitative patient study (appendix 6), time limitations prevented a more inclusive study redesign, such as changing the consent process or recruiting from a different service. One way inclusion could be improved in future is through more effective use of Patient and Public Involvement (PPI) in order to inform the study design, which has been found to be of particular value when designing experience-type qualitative research (Staley, 2009) and can improve the quality and relevance of research (Edelman and Barron, 2016). A collaborative approach may be suitable as an alternative, which involves a partnership between the researcher and patients/members of the public to share decisions about the study and can be beneficial in the design process (INVOLVE, 2015). Alzheimer Europe’s recent position paper highlights the need for PPI and recommends it in order to facilitate participation in dementia research (Gove et al., 2018).

In order to ensure the success of a patient study in the future, adequate resources and stakeholder engagement would be required, particularly around the consent process. The study required consent on one occasion from patients whilst in an acute phase of illness, which limited the number of people able to give informed consent (required for the interviews). This one-off consent is unsuitable for people with dementia (McKeown et al., 2010); more preparation with the services involved and the ability to establish a basis for consent would likely improve recruitment rates in future. For example McKeown et al. (2010) describe using a process model of consent (Dewing, 2007) in order to involve people with advanced dementia in a qualitative evaluation of service delivery, such as by involving gatekeeper groups (such as care home staff) in protocol design in order to facilitate relationships with potential gatekeepers. Process consent involves adapting to the needs of the individual with dementia and continual monitoring of the person’s choice to be involved instead of relying on one-off consent (Dewing, 2007). A more novel and flexible approach to study design such as this may help to overcome barriers to recruitment. Also participants could be recruited through different routes, for example via community stroke teams working with people with pre-stroke cognitive problems rather than exclusively through acute environments in order to maximise recruitment options.

Future research could also be adapted into an interview study with family/carers of people with pre-existing dementia about stroke rehabilitation from their perspective. It
is known that informal family carers provide an enormous level of support for people with dementia, and also for people after stroke (Kane and Terry, 2015). It is estimated there are over 670,000 people acting as unpaid or informal carers for people with dementia (Prince et al., 2014). Also, there are around 1.2 million stroke survivors in the UK and of those, 1 in 5 is cared for by a family member (Stroke Association 2018). 42% of participants with pre-existing cognitive impairment in the cohort study were living with a partner or family members, therefore this is a potential way of exploring the topic. Their role in supporting rehabilitation and their views regarding the value of rehabilitation may be useful to examine from a carers perspective. However, this would still exclude direct patient experience. Multi-perspective interviews with patients and carers together could be one method of facilitating inclusion of patients with dementia depending on the chosen research direction (Kendall et al., 2009).

6.6 Thesis conclusion

Stroke and dementia are associated with age and incidence of both is rising worldwide, increasing the likelihood of both conditions co-occurring (Seshadri et al., 2006; Prince et al., 2014). Older patients are surviving stroke due to improvements in stroke care (Feigin et al., 2014), which whilst positive, has multiple implications for rehabilitation service delivery some of which have been highlighted by this thesis. Models of rehabilitation need updating in order to reflect the complex needs of the current stroke population, and a shift in focus of the aim of rehabilitation is required. People with pre-existing dementia/cognitive impairment before stroke are subject to a number of barriers around referral and admission to, and opportunity to benefit from, rehabilitation. As a result they receive less rehabilitation than patients without pre-existing cognitive impairments. Decisions around access to rehabilitation can improve and become more equitable by ensuring clinicians possess appropriate education, training and skills to work alongside patients with pre-existing dementia/cognitive impairments.
7 References


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Appendices

Appendix 1: Study two protocol – Health professionals’ experience of diagnosing and managing stroke patients with cognitive impairment: a qualitative study
Appendix 2: Qualitative study information sheet
Appendix 3: Qualitative study consent form
Appendix 4: Qualitative study topic guide
Appendix 5: COREQ checklist
Appendix 6: Study three protocol - Examining process of care and experience of stroke-specific rehabilitation for people with pre-existing cognitive difficulties
Appendix 7: Cohort study standard information sheet
Appendix 8: Cohort study standard consent form
Appendix 9: Cohort study aphasia friendly information sheet
Appendix 10: Cohort study aphasia friendly consent form
Appendix 11: Cohort study consultee information sheet
Appendix 12: Cohort study consultee declaration
Appendix 13: STROBE checklist

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Rationale

Little is known about the effect pre-existing dementia or cognitive impairment has on stroke care. Often patients with dementia or significant cognitive impairment are excluded from research studies due to their cognition (Dewing, 2007), and pre-stroke cognition is often unrecorded in post-stroke dementia (PSD) prevalence studies (Pendlebury and Rothwell, 2009). It is unknown how many participants in prevalence studies have pre-first-stroke dementia across study settings (i.e. community versus hospital based studies), and many hospital based studies use retrospective methods of assessing pre-stroke dementia (Pendlebury and Rothwell, 2009). A stroke may cause a sudden or gradual decline in cognition for someone with underlying vascular cognitive impairment (VCI) or small vessel disease (SVD), due to the stepped progression of vascular dementia (Román, 2003). Not all patients who present with cognitive impairment have a diagnosis of dementia, and a hospital admission presents an opportunity for referral to appropriate services (Kane and Terry, 2015).

Cognitive impairment is also a common consequence of stroke, with the majority of patients experiencing some form of cognitive impairment early after stroke. Cognition can impact on functional outcomes after stroke, and knowledge of a patient’s cognition can be used to make decisions about rehabilitation plans (Heruti et al., 2002). It is not clear, however, how professionals decide whether a patient had a pre-existing
cognitive impairment prior to admission or how these decisions impact on the rehabilitation interventions they provide.

Stroke rehabilitation is defined broadly by Langhorne et al. (2011) as “stroke-care interventions, which are selected after a problem-solving process that aims to reduce the disability and handicap resulting from a stroke” (Langhorne et al., 2011 p. 1695). Rehabilitation potential is a concept that is unclearly defined, and is described as a patient’s functional capacity for change through rehabilitation, dependent on a number of factors such as medical condition and lifestyle (Enderby et al., 2016). The decision about whether or not a patient has rehabilitation potential will influence their journey on the stroke pathway. If a patient is deemed to have no potential through use of therapy assessment, they are unlikely to be referred for rehabilitation services. Patients with dementia are often more severely disabled (both physically and cognitively) following a stroke, however it is thought individuals with the least potential to become less dependent are the patients that benefit most from very early rehabilitation (Enderby et al., 2016; Saposnik et al., 2011). Knowledge of a patient’s potential for change may influence the rehabilitation they receive from the decision-making therapists, for how long and from whom (Enderby et al., 2016). Enderby et al. (2016) call for research exploring the impact of clinician-decision making on stroke recovery. There also is a lack of evidence relating specifically to the impact of cognitive impairment on decisions about rehabilitation potential, and how this knowledge of a patient’s cognition is used to inform treatment plans after stroke (Enderby et al., 2016; Burton et al., 2015). Therefore the objectives for this study are:

1. To explore how professionals in stroke services make decisions about whether a person has pre-existing cognitive impairment or dementia.
   
   What factors influence decision-making?

   What information do they use to inform decisions?

2. To explore professionals’ decision making about ongoing rehabilitation for people with pre-existing cognitive impairment or dementia in stroke services.

   What are the barriers or solutions to the decision making process?
**Design**

This study adopts a qualitative methodology, using semi-structured interviews to explore participant experiences and current practice. Qualitative research uses meaning and narrative rather than numbers and statistics to capture and interpret data and is ideal for research exploring experiences (Braun and Clarke, 2013). Semi-structured interviews use a list of questions as a guide but can deviate to allow unanticipated issues to be explored (Braun and Clarke, 2013). This approach will allow for flexibility within the interviews to ensure all areas relevant to the participant are discussed in detail.

**Sampling and recruitment**

*Participant identification:*

Participants (staff) will be recruited from the Hyper-acute Stroke Unit (HASU), inpatient rehabilitation, and Early Supported Discharge (ESD) teams in both Salford Royal Hospital and Fairfield General Hospital. Professionals in each stage of the pathway are likely to be involved in making decisions about patients’ cognition and ongoing rehabilitation. The key people within the Multi-Disciplinary Team (MDT) involved in assessing and making decisions around a patient’s cognition will be identified using knowledge of professional roles and informal discussions. The National Clinical Guidelines for Stroke (2012) recommend Occupational Therapists, Psychologists and Speech and Language Therapists are involved in cognitive interventions, however the guidelines also state the patient’s cognitive status should be taken into account by all members of the MDT (Royal College of Physicians, 2012). The researcher will meet with a member of each team in order to explain the research and gather information about team composition. The team will then be approached by the researcher who will briefly meet with them, explain the purpose of the research and supply contact details. Potential participants will contact the researcher via email or telephone with expressions of interest at their own will. The researcher will then contact the participant via email or post with an information sheet and consent form. On confirmation of a wish to participate, interviews will be arranged at a time and place convenient to the participant. The participant’s role in decision-making will be confirmed on approach for interview. A potential barrier to recruitment may be individuals not seeing themselves as decision-makers regarding patient cognition, therefore attempts will be made to explain the research to the wide MDT and if a
potential participant is unsure, their role will be discussed with the researcher using information from the National Clinical Guidelines for Stroke (2016). Each team will comprise of a mix of professional backgrounds and sampling will attempt to reflect this, however it is expected the majority of professionals interviewed will be Occupational Therapists, Psychologists and Speech and Language Therapists.

**Sample**

Purposive sampling will be used to select staff for the qualitative interviews. Purposive sampling is a method of selecting participants due to their knowledge or experience and is an efficient method of acquiring relevant experience and understanding, in this case of making decisions about patient’s cognition (Braun and Clarke, 2013). It is estimated around five interviews will be conducted in each of the six settings, or until data saturation is reached, giving a maximum total of around 30 participants. Data saturation is the point at which data is no longer generating new information therefore collection can end (Braun and Clarke, 2013). The teams have a range of around 8-15 staff members, most of whom may be suitable for participation however it is not expected all will be available or willing for consent or interview. The sample will be derived from members of the MDT who are available for interview (i.e. not on long term leave) and who play a key role in assessing cognition and making decisions about cognition-based interventions and rehabilitation.

The professional mix of each team will influence sampling, and information on staff mix in each team will be gathered prior to recruitment from a contact within the team. For example, at Salford Royal there is no Clinical Psychologist available on the HASU compared with three full time Occupational Therapists. It is expected there will be more Occupational Therapists within the team than Clinical Psychologists or Doctors across all settings therefore sampling will reflect this, for example, it is unlikely there will be a Clinical Psychologist available for interview in every setting. Occupational Therapists often have the role of assessing cognition in stroke settings (Intercollegiate Stroke Working Party, 2016), and therefore will be more highly represented in the sample. A mix of years of experience within professions would be of value in order to explore factors impacting on decision making in the interviews, therefore samples will aim to represent a range of experience if possible. If not possible, this should not affect data but will be acknowledged on analysis. There are a number of professionals in each setting who have been involved in consultation of this project, for example,
one out of the three Occupational Therapists working in the Salford DSC was involved in the study design. This will limit the amount of professionals available to participate in some settings.

**Eligibility criteria**

*Inclusion criteria for professionals:*

- Qualified healthcare professional (or unqualified assistant e.g. assistant psychologist) currently working in an inpatient or community stroke service as part of a multidisciplinary team (e.g. nurse, doctor, physiotherapist, occupational therapist, speech and language therapist, psychologist).
- Involved in assessing or making decisions about cognition-based interventions and rehabilitation.

*Exclusion criteria for professionals:*

- Not currently working in an inpatient stroke service.
- Not involved in assessing or decision-making about cognition-based interventions or rehabilitation.

**Consent**

Following ethics approval, participants will be identified as detailed previously. They will be approached for interview and provided with an information sheet at least 24 hours prior to the interview taking place to allow time for an informed decision. Written consent will be gained before all interviews by the researcher. Participants will receive a copy of the consent form and will be made aware they can withdraw at any time without reason and that all information will remain confidential.

**Data collection and analysis**

Consenting participants will be invited to participate in semi-structured interviews. Demographic (profession, age, sex, year qualified and years of experience in stroke services) and preferred contact information will be collected about all participants with their consent during the interview. The interviews will be conducted by the researcher. They will take place face-to-face, in a quiet room on the hospital site. If the participant is willing to participate but unable to attend an interview, the option for telephone interviewing will be offered. Telephone interviews can offer privacy, give access to
hard to reach participants and require less time to conduct and participate, however they can restrict development of rapport which is important when interviewing (Sturges and Hanrahan, 2004). Both types of interviews will be audio recorded with consent and transcribed by a University approved transcription service. At this point any identifying information (for examples names and places) will be removed.

Semi-structured interviews follow a list of questions but allow the interviewer to be flexible about the topics discussed (Braun and Clarke, 2013). This format also gives participants the opportunity to disclose information of importance to them relevant to the topic that may not be covered by the interview schedule (Braun and Clarke, 2013). These interviews use open questions in order to encourage participants to provide a detailed response (Braun and Clarke, 2013). Field notes will be taken directly after the interview in order to aid reflection.

Interviews were chosen rather than questionnaires or focus groups as they are most appropriate for exploration of experience, perceptions, and influence-type research (Braun and Clarke, 2013). This research aims to investigate personal experiences in detail and requires participates to have an in-depth involvement with the topic, which focus groups and questionnaires cannot always demonstrate (Braun and Clarke, 2013). Focus groups can be a logistical challenge for healthcare professionals due to the demands of their role, and can have issues with confidentiality and power within groups where participants work together or manage each other (Kitzinger, 2006).

Thematic analysis was chosen because it allows a flexible approach of data collection not linked to any theoretical framework; it provides an introduction to qualitative methods for those new to it; and it provides accessible results that can be directly disseminated to wide audiences, especially within healthcare settings (Peters, 2010; Braun and Clarke, 2006; Braun and Clarke, 2013). Thematic analysis also can be used with larger sample sizes than other methods such as Interpretive Phenomenological Analysis (Braun and Clarke, 2013). Thematic analysis follows a six stage, iterative process: data familiarisation; generation of initial codes; identification of themes; reviewing themes; definition of themes; and report production (Braun and Clarke, 2006).
A thematic analysis will be started following the first interviews and will guide when interview data have reached saturation point. The research team will undertake all stages of the analysis. Data will be anonymised, coded and then organised into themes. Data will be organised and managed using NVivo software. Themes and categories will be checked by the supervisory team. When initial analysis is complete, themes will be member checked with participants in order to ensure their views are accurately represented (Braun and Clarke, 2013).

**Ethical considerations**

The study has been approved by the University of Manchester ethics committee reference number 16438.

This study has minimal ethical issues; however consideration has been given to data protection, data storage, confidentiality and disclosure of information, and risk to participants as outlined in the following section.

**Project management**

**Data protection and storage**

Data will be stored on a password protected university network drive, and back-up data stored on an encrypted and password protected external hard drive, both accessible only to the research team. All paper documentation will be stored in a locked filing cabinet in a locked or code-accessible office. The Data Protection Act (1998) and NHS Code of Confidentiality (2003) will be followed, and participant data will be anonymised using codes. Participant identifiable data will be stored on an encrypted document. Audio recordings will be stored for the minimal length of time practical and deleted once transferred to a password-protected university computer. Audio files will be labelled with a non-identifying participant number the point of transfer to computer. Interviews will be transcribed as soon as possible after recording, either by the researcher or by a university approved transcription service. Audio files will be uploaded to the transcription service using a secure portal and a dedicated password protected account and transcriptions received via the same method. Audio files will be deleted following transcription. As soon as is practicable after receiving the transcribed electronic files, the documents will be reviewed and any names, locations or other identifiers in the transcript will be removed and replaced by pseudonyms. In
any reports, published material or communications about the study, participants will be referenced by an ID number or pseudonym. Care will be taken to ensure that the identity of individuals is not revealed through contextual information, for example, if there is only one member of a profession in the service and their statement could be potentially identifiable.

Participants will be made aware on the information sheet that all audio recorded and transcribed data will be kept confidential within the research team. Data will be read and analysed by the research team only. Data will be archived in accordance with the University of Manchester’s data archiving policy.

Confidentiality will only be breached in the event of a disclosure of information deemed to be a safeguarding or emergency issue. The project supervisor will be made aware and appropriate course of action taken, dependant on context. The participant will be made aware of a disclosure to a secure authority.

All research data will be stored in line with the University’s policy on the storage of research data is that it is kept for 5 years after the date of publication of the thesis upon which it is based.

**Patient and public involvement**

Stakeholders will be involved at different time points throughout the project and will be consulted during the development and dissemination stages. The stakeholders in this project are the clinicians working in stroke services. The idea for the project originated from clinicians working at one of the sites. Following initial development of the protocol, the researcher met with these clinicians in order to discuss the proposed ideas and also completed informal shadowing and observations. A summary of the proposed method was then presented to a meeting of clinicians at the Greater Manchester Stroke Operational Delivery Network Rehabilitation (ODN) sub-group in June 2016. Their feedback was used to develop the protocol further. Consultation was an appropriate level of involvement for this study due to the need for a range of views in order to refine the research question (INVOLVE, 2015).

Following the completion of the interviews and thematic analysis, the researcher will consult with clinicians working within stroke services who did not participate to check
the preliminary findings, similar to member checking, in order to ensure the findings are applicable to practice (Braun and Clarke, 2013). The findings will be presented to the ODN sub-group.

**Dissemination**

A written summary sheet will be provided to all participants involved in the study (who expressed a wish to receive a copy of the findings), with the option for the researcher to present findings to the teams involved in person. Findings will be presented at local stroke network meetings, for example at the ODN sub-group meeting. Poster and platform presentations will be produced for appropriate conferences, as well as a peer-reviewed journal paper.

**Potential risk to participants**

No risks have been identified for staff participating in interviews. Staff may be required to use an hour of their clinical time to participate in interviews, which will be negotiated on the initial approach for interview. Interviews may lead staff to reflect on missed opportunities to support a dual diagnosis for patients and so will be made aware of this in the information sheet. This study aims to provide knowledge in order to improve quality of the care for people with dementia after stroke and has negligible risk to participants.

**Benefits for participants**

The idea for this research project stemmed from an issue raised by some clinicians working at one of the sites regarding the need to improve the stroke care pathway for patients with suspected dementia. This study should provide an opportunity for professionals to talk about the difficulties and successes within their current practice, and to allow these to be disseminated to a wide audience.
Participant Information Sheet

Health professionals’ experience of diagnosing and managing stroke patients with cognitive impairment: a qualitative study

What is the purpose of the study?
Cognitive impairment is common after a stroke, and many patients may also have a pre-existing undiagnosed cognitive impairment prior to their stroke. Little is known about how professionals decide whether a patient has a pre-existing cognitive impairment, and if cognitive impairment impacts on their rehabilitation. We want to identify and describe current practice and the experience of professionals working with people with cognitive impairment in stroke services. This study forms part of a PhD.

Why have I been invited to take part?
You have been invited to take part in the study because you currently work with people with cognitive impairment after stroke.

Do I have to take part?
No, you can decide not to take part. Participation is voluntary. If you agree, you will be given a consent form to sign. You are free to withdraw at any time, without giving a reason.

What will happen to me if I take part?
You will be interviewed by a researcher in a place convenient to you within your workplace. You will be given the option for the interview to take place over the telephone if more convenient for you. The interview should take no more than one hour. You will be asked questions about how you work with people with cognitive impairment, your experience and feelings on this topic. The interview will be audio recorded and transcribed by the researcher or a University approved external transcription service.

What are the possible risks of taking part?
No risks have been identified. You will be required to use up to an hour of your clinical time to participate in interviews. Interviews may lead you to reflect on missed opportunities within your practice, in which case your usual supervision procedure should be followed. Patients and their care will not be affected by the study.

What are the possible benefits of taking part?
There are no direct benefits for you taking part. However this study aims to provide knowledge in order to improve quality of the care for people with cognitive impairment after stroke. It will give you an opportunity to talk about current difficulties and successes within your current practice and share these with other professionals.

What happens when the research study stops?
This study involves a single interview with each participant; therefore your participation ends after the interview. You can choose to be informed of the results of the study when they are available.

What will happen if I don’t want to carry on with the study?
You are free to withdraw at any time, even during the interview. You do not have to give a reason.

Will my taking part in the study be kept confidential?
All information collected about you will be kept strictly confidential. Your information will be stored securely in a locked filing cabinet or on a password-protected computer, accessible only to the research team. We will anonymise the interview transcripts, and will store them separately from personal data that could identify you. Audio recordings will be deleted following transcription. Information and data from the interviews will be stored for in line with University policy for 5 years and will be disposed of securely after this time. Individuals from the University of Manchester, NHS Trust or regulatory authorities may need to look at the data collected for this study to make sure the research is being carried out appropriately. Information collected from this study may be shared with authorised members of the research team and may be shared anonymously with other researchers. All individuals have a duty of confidentiality to you as a research participant. Your contact details will be stored in order to send you the study results. Confidentiality will only be breached in the event of a disclosure of information deemed to be a safeguarding or emergency issue. You will be made aware of a disclosure to a secure authority.

What will happen to the results of the study?
The data will be used as part of a PhD thesis. The results of this study will be written up with an aim to be published in peer-reviewed journal. These publications will not include any identifiable data. Your anonymous quotes may be used in the final report. You will be informed when the results become available, if you wish.

What if there is a problem?
Complaints:
If you have a concern about any aspect of the study, you should ask to speak to the researcher who will do their best to answer your questions:
Verity Longley
A3.14 Ellen Wilkinson Building
University of Manchester
Oxford Road
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If they are unable to resolve your concern or you wish to make a complaint regarding the study, please contact the Research Governance and Integrity Manager, Research Office, Christie Building, University of Manchester, Oxford Road, Manchester, M13 9PL, or by emailing: research.complaints@manchester.ac.uk or by telephoning 0161 275 2674 or 275 2046.

Who is organising and funding the research?
The research is being funded by the NIHR Collaboration for Leadership in Applied Health Research and Care (CLAHRC) Greater Manchester. The research is sponsored by the University of Manchester.

Who has reviewed the study?
The study has been reviewed by the University of Manchester ethics committee (reference 16438).

Further information and contact details
For further information about the research study, please contact the lead researcher:

Verity Longley verity.longley@postgrad.manchester.ac.uk

154
CONSENT FORM

Health professionals' experience of diagnosing and managing stroke patients with cognitive impairment: a qualitative study.

Researcher: Verity Longley
verity.longley@postgrad.manchester.ac.uk

1. I confirm that I have read the information sheet (version 1, 18/08/2016) for the above study.
   I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.

2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason.

3. I understand that the information collected from this study may be shared with authorised members of the research team and may be shared anonymously with other researchers. All these persons will have a duty of confidentiality. Confidentiality will only be breached in the event of a disclosure of information deemed to be a safeguarding or emergency issue.

4. I agree to the interviews being audio recorded

5. I agree to anonymous quotes being used in the final reports.

6. I agree to my contact details being stored so that the study findings can be sent to me.

7. I agree to take part in the above study.

__________________________________________  __________________________  __________________________
Name of Participant  Date  Signature

__________________________________________  __________________________  __________________________
Name of Researcher  Date  Signature

When completed: 1 copy for participant; 1 original for researcher site file.
Appendix 4
Interview topic guide

Project Title: Health professionals’ experience of diagnosing and managing stroke patients with cognitive impairment: a qualitative study

As the interview is being conducted on a semi-structured basis, the questions listed below will serve as prompts for the interviewer. The exact order, wording and number of the questions may change as the interview progresses, and some further questions may be asked in order to pursue emerging themes. The following interview schedule will act as a guide for the researcher whilst conducting the interview.

Before starting:
A. The purpose of this research is to explore the experiences of health professionals working with patients with cognitive impairment in stroke services.
B. By cognitive impairment, I mean all types of cognitive problems for example, apraxia, inattention or Alzheimer’s disease, but will focus of pre-existing difficulties and dementia.
C. I know cognitive impairment affects people after a stroke, and it impacts on rehabilitation. Every service works slightly differently, and we don’t know anything about what any of you do to adapt to these conditions. I’m trying to find a baseline of what you do in your service so this interview is about finding out how you work.
D. Everything you say in this interview will be anonymous and your confidentiality maintained
E. Please remember that it is OK to stop at any point, or refuse to answer any questions during this interview
F. Are you still OK for us to tape record this conversation?
G. There are four sections to this interview: your role, how you make decisions, rehabilitation potential, knowledge and training.
H. Provide the opportunity to ask questions before starting

General prompts to questions:
- Why? / Please tell me more about that? / Please expand on that? / What do you mean by that?

Section 1: Current role
1. Please can you describe your current role?

2. Are you involved in assessing cognition?
   - If so, can you tell me about it?
   - If not, go to question 4.

3. Do you use any specific assessments to assess cognition?
   (probe for specifics)

4. What happens if you identify a patient has cognitive impairment?

5. Who raises the suspicions of a cognitive impairment?

6. Where do you get information about a patient’s cognition? And where do you record it?
   - i.e. patient notes, liaison with family, through use of assessment
   - What do you do when no family to ask?

7. What’s the purpose/your motivation of identifying cognitive impairment?
8. Have you ever had a patient who you suspected had a pre-stroke cognitive impairment? (for example someone with no diagnosis but was struggling at home) Could you describe them? What did you do?

9. How do you differentiate between old and new impairments?

10. How prevalent do you think pre-stroke cognitive impairment is?

11. Is there anything you found difficult working with patients with pre-existing difficulties?
   - Other people have mentioned it can be frustrating, do you have any thoughts on that?

Section 2: Decision making
1. Are there any considerations you make when treating patients with pre-existing cognitive impairment?

2. Would cognitive impairment change the types of intervention you provide? (probe for example)

3. How do you explain cognitive difficulties to the patient or family?

Section 3: Rehabilitation potential
1. What is it that makes you think a patient will benefit from rehabilitation or not?

2. What do you think other people base decisions about rehab potential on?
   a. And what do you base your decisions on?

3. How do you judge willingness to engage?
   - Is it just if they consent to the session?

4. How do you facilitate motivating patient’s to engage?

5. Do you think a patient’s cognitive impairment affects length of hospital stay?

Section 4: Knowledge and training
We’ve talked about general cognitive impairment, now I want to ask about your experiences of dementia service availability.

1. Tell me about what, if any, training you have had to support patients with cognitive impairments? (Probe for how and by whom it was delivered, content of training, how (if it’s been used within clinical practice)

2. What dementia services are available to you and your patients within the hospital or externally?
   a. What experience have you had of them?
   b. How could they be improved?

3. Is there anything I haven’t asked you that you would like to say?
Appendix 5

Consolidated criteria for reporting qualitative studies (COREQ): 32-item checklist: What influences decisions about ongoing stroke rehabilitation for patients with pre-existing dementia or cognitive impairment? A qualitative study *(chapter four)*

<table>
<thead>
<tr>
<th>No.</th>
<th>Item</th>
<th>Guide questions/description</th>
<th>Reported in section</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td><strong>Domain 1: Research team and reflexivity</strong></td>
<td></td>
<td></td>
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<tr>
<td></td>
<td><strong>Personal Characteristics</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.</td>
<td>Interviewer/facilitator</td>
<td>Which author/s conducted the interview or focus group?</td>
<td>Methods</td>
</tr>
<tr>
<td>2.</td>
<td>Credentials</td>
<td>What were the researcher’s credentials? E.g. PhD, MD</td>
<td>VL – BSc Psychology, BSc Occupational Therapy, PhD candidate</td>
</tr>
<tr>
<td>3.</td>
<td>Occupation</td>
<td>What was their occupation at the time of the study?</td>
<td>PhD candidate</td>
</tr>
<tr>
<td>4.</td>
<td>Gender</td>
<td>Was the researcher male or female?</td>
<td>Female</td>
</tr>
<tr>
<td>5.</td>
<td>Experience and training</td>
<td>What experience or training did the researcher have?</td>
<td>Relevant clinical experience, university training in qualitative methods</td>
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<tr>
<td></td>
<td><strong>Relationship with participants</strong></td>
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<tr>
<td>6.</td>
<td>Relationship established</td>
<td>Was a relationship established prior to study commencement?</td>
<td>Methods</td>
</tr>
<tr>
<td>7.</td>
<td>Participant knowledge of the interviewer</td>
<td>What did the participants know about the researcher? e.g. personal goals, reasons for doing the research</td>
<td>Methods, Participant Information Sheet (appendix 2)</td>
</tr>
<tr>
<td>Domain 2: study design</td>
<td></td>
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<tr>
<td><strong>Theoretical framework</strong></td>
<td></td>
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<tr>
<td>9. Methodological orientation and Theory</td>
<td>What methodological orientation was stated to underpin the study? e.g. grounded theory, discourse analysis, ethnography, phenomenology, content analysis</td>
<td></td>
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<tr>
<td><strong>Participant selection</strong></td>
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<tr>
<td>10. Sampling</td>
<td>How were participants selected? e.g. purposive, convenience, consecutive, snowball</td>
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<tr>
<td>11. Method of approach</td>
<td>How were participants approached? e.g. face-to-face, telephone, mail, email</td>
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<tr>
<td>12. Sample size</td>
<td>How many participants were in the study?</td>
<td></td>
<td></td>
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<tr>
<td>13. Non-participation</td>
<td>How many people refused to participate or dropped out? Reasons?</td>
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<td></td>
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<tr>
<td><strong>Setting</strong></td>
<td></td>
<td></td>
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<tr>
<td>14. Setting of data collection</td>
<td>Where was the data collected? e.g. home, clinic, workplace</td>
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<tr>
<td>15. Presence of non-participants</td>
<td>Was anyone else present besides the participants and researchers?</td>
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<tr>
<td>16. Description of sample</td>
<td>What are the important characteristics of the sample? e.g. demographic data, date</td>
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<tr>
<td><strong>Data collection</strong></td>
<td></td>
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<tr>
<td>17. Interview guide</td>
<td>Were questions, prompts, guides provided by the authors? Was it pilot tested?</td>
<td></td>
<td></td>
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<tr>
<td>18. Repeat interviews</td>
<td>Were repeat interviews carried out? If yes, how many?</td>
<td></td>
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<tr>
<td>19. Audio/visual recording</td>
<td>Did the research use audio or visual recording to collect the data?</td>
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<tr>
<td></td>
<td>Question</td>
<td>Methods</td>
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<tr>
<td>20.</td>
<td>Field notes Were field notes made during and/or after the interview or focus group?</td>
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<tr>
<td>21.</td>
<td>Duration What was the duration of the interviews or focus group?</td>
<td>Results</td>
<td></td>
</tr>
<tr>
<td>22.</td>
<td>Data saturation Was data saturation discussed?</td>
<td>Methods</td>
<td></td>
</tr>
<tr>
<td>23.</td>
<td>Transcripts returned Were transcripts returned to participants for comment and/or correction?</td>
<td>No</td>
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**Domain 3: analysis and findings**

**Data analysis**

<table>
<thead>
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<th>Methods</th>
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</thead>
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<tr>
<td>24.</td>
<td>Number of data coders How many data coders coded the data?</td>
<td>Methods</td>
</tr>
<tr>
<td>25.</td>
<td>Description of the coding tree Did authors provide a description of the coding tree?</td>
<td>N/A</td>
</tr>
<tr>
<td>26.</td>
<td>Derivation of themes Were themes identified in advance or derived from the data?</td>
<td>Methods</td>
</tr>
<tr>
<td>27.</td>
<td>Software What software, if applicable, was used to manage the data?</td>
<td>Methods</td>
</tr>
<tr>
<td>28.</td>
<td>Participant checking Did participants provide feedback on the findings?</td>
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</tbody>
</table>

**Reporting**

<table>
<thead>
<tr>
<th></th>
<th>Question</th>
<th>Methods</th>
</tr>
</thead>
<tbody>
<tr>
<td>29.</td>
<td>Quotations presented Were participant quotations presented to illustrate the themes/findings?</td>
<td>Findings</td>
</tr>
<tr>
<td></td>
<td>Was each quotation identified? e.g. participant number</td>
<td></td>
</tr>
<tr>
<td>30.</td>
<td>Data and findings consistent Was there consistency between the data presented and the findings?</td>
<td>Yes, findings.</td>
</tr>
<tr>
<td>31.</td>
<td>Clarity of major themes Were major themes clearly presented in the findings?</td>
<td>Yes, findings and figure 4.1.</td>
</tr>
<tr>
<td>32.</td>
<td>Clarity of minor themes Is there a description of diverse cases or discussion of minor themes?</td>
<td>Yes, findings.</td>
</tr>
</tbody>
</table>
Study protocol: Examining process of care and experience of stroke-specific rehabilitation for people with pre-existing cognitive difficulties

Study team

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1.1 Rationale

Stroke and dementia are highly prevalent, and both are two of the leading causes of disability and death worldwide (World Health Organisation, 2017). The two conditions are also associated. Stroke more than doubles the risk of subsequently developing vascular dementia (Ivan et al., 2004), and a diagnosis of vascular dementia increases risk of ischaemic stroke (Imfeld et al., 2013). In addition, any type of dementia has been found to develop at twice the expected rate over 25 years following ischaemic stroke (Kokmen et al., 1996).

Age is the most significant risk factor for stroke and dementia, and incidence rates of both are expected to rise alongside increasing life expectancy (Seshadri et al., 2006; LSE, 2007). It is therefore likely that numbers of patients with both conditions will also increase (Saposnik et al., 2012). Current estimates suggest around 10% of patients have a diagnosis of dementia prior to first stroke, and one third of patients will develop
dementia after recurrent stroke (Pendlebury and Rothwell, 2009). Pre-existing dementia is associated with poorer functional outcome, higher rates of disability, increased likelihood of discharge to institutional care, and increased risk of death after stroke when compared with patients without diagnosis of pre-existing dementia (Tatemichi et al., 1994; Appelros et al., 2003; Saposnik et al., 2011).

It is unclear however whether poorer outcomes for patients with pre-existing dementia are linked to rehabilitation or care received in the hospital phase. There are limited data on how to manage these patients, with some studies reporting patients with pre-existing dementia being less likely to be referred for rehabilitation and having perceived limited potential to improve (Hakkennes et al., 2013; Burton et al., 2015). Mizrahi et al. (2016) compared short-term functional outcomes in a case-control study of 919 stroke patients with and without pre-existing dementia and found lower functional scores (measured using the Functional Independence Measure (FIM)) on admission, discharge, and increase in score for patients with pre-existing dementia. They noted daily gains in FIM score were similar in both patient groups, concluding that patients with pre-existing dementia were able to benefit from rehabilitation but were starting at lower functional baseline than patients without pre-existing dementia (Mizrahi et al., 2016).

Whilst Mizrahi et al. ’s (2016) suggests that patients with pre-existing dementia are able to benefit from rehabilitation, clinical data were analysed retrospectively using FIM score as the sole outcome, which only measures change in independence. Dementia diagnosis was taken from a disease register. The current study will build on these findings by examining process of care as well as outcomes (specifically therapies received, referrals and discharge destination) for patients with pre-existing dementia after stroke in order to determine rehabilitation pathways for these patients compared with patients without diagnosis of pre-existing dementia.

Furthermore, a stroke may cause a sudden or gradual decline in cognition for someone with underlying undetected cognitive impairment or small vessel disease, due to the stepped progression of vascular dementia (Román, 2003). Not all patients who present with a pre-existing cognitive impairment may have a formal diagnosis of dementia, and hospital admission provides an opportunity for referral to appropriate services (Kane and Terry, 2015). It is estimated only around 61% of people living with dementia ever
have a formal diagnosis (Kane and Terry, 2015). This study will also gather data on patients who clinicians suspect may have pre-existing cognitive impairments or undiagnosed dementia in order to examine their rehabilitation pathways. This will be compared to those with formal diagnosis as well, which has not been investigated in previous studies (Saposnik et al., 2012; Mizrahi et al., 2016).

In addition, gathering service user perspectives is important when conducting research within healthcare. Patient experience serves a vital role in facilitating service design (Mockford et al., 2012), and qualitative research can explore a problem from the perspective of those experiencing it (Clarke, 2003). Patients with cognitive impairments or dementia are often excluded from research due to their cognitive or associated language impairments (Dewing, 2007), but will have unique experiences of care processes that would add to the understanding of the experience of stroke (Clarke, 2009). There currently appears to be no literature on stroke rehabilitation from the perspective of patients with pre-existing cognitive impairment or dementia. Gathering this would provide insight into positive or negative aspects of current rehabilitation pathways and in particular, how pre-existing cognitive impairments can impact on these care processes.

1.2 Aim

To examine whether pre-existing cognitive impairment or dementia affects stroke-specific rehabilitation care processes and to understand service users’ experiences.

Objectives:

1. To examine relationships between three cohorts of patients (no dementia diagnosis/undiagnosed cognitive impairment, documented dementia diagnosis, and undiagnosed cognitive impairment) in terms of:
   a. Primary outcome: number of therapy sessions (physiotherapy and occupational therapy) received during time period.
   b. Secondary outcomes: process of care such as type of therapy received, amount of therapy received during inpatient phase, and outcomes such as discharge destination, modified Rankin Score (mRS) on discharge from rehabilitation.
2. To explore self-reported experience of a) how cognitive difficulties were explained, and b) positive or negative aspects of stroke rehabilitation received, from the perspective of patients with pre-existing cognitive impairment or dementia.

1.3 Design

This is a mixed methods study with two phases: a prospective cohort study and a nested qualitative study. During the first phase routinely collected clinical data will be gathered from patient notes in order to meet objective one.

For the second phase, a sample of participants who have pre-existing cognitive impairment or dementia will be selected to take part in qualitative interviews. Semi-structured interviews will be used to explore participant experiences of stroke rehabilitation in order to meet objective two.

The Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) (von Elm et al., 2008) and Consolidated criteria for reporting qualitative research (COREQ) (Tong et al., 2007) checklists have been used in developing this protocol.
2 Phase one – cohort study

2.1 Setting

Acute stroke services in Greater Manchester were centralised in 2010 and reconfigured again in 2015 (Turner et al., 2016). All patients who present with a recent stroke are admitted to one of three Hyper Acute Stroke Units (HASUs) dependent on residence: Salford Royal Hospital in Salford, Fairfield General Hospital in Bury and Stepping Hill Hospital in Stockport. Salford Royal Hospital is the region’s main HASU and open 24/7 seven days a week for residents within the catchment area. Fairfield General Hospital and Stepping Hill Hospital serve as a Primary Stroke Centres (PSCs), providing hyper acute care from 06.45am to 22.45pm seven days a week for residents within their catchment areas. Outside of these hours, patients are admitted to Salford. If well enough, patients normally remain in the HASU for up to 3 days and are either discharged with community services directly, or transferred to their local District Stroke Centre (DSC) for ongoing rehabilitation. All three PSCs have a DSC on site providing rehabilitation for local residents. Some patients are discharged into the community from the DSC with Early Supported Discharge (ESD) specialist stroke support or general community neurological rehabilitation/stroke services (CNRT/CST).

The DSC rehabilitation units are located at Salford Royal Hospital, Fairfield General Hospital, Stepping Hill Hospital, University Hospital of South Manchester, Manchester Royal Infirmary, Trafford General Hospital, Tameside General Hospital, Royal Bolton Hospital and Royal Albert Edward Infirmary. As many DSCs as possible will be recruited as research sites, with participants identified in these hospitals whilst inpatient on the rehabilitation wards.

2.2 Eligibility criteria

*Inclusion criteria:*

- Admitted to rehabilitation hospital with a clinically confirmed stroke and under the care of the stroke team.
- Individuals capable of giving informed consent, or those having an individual available to act in the capacity of a personal consultee.
- Identified as having rehabilitation needs, as evidenced by being admitted to a stroke rehabilitation unit.
Exclusion criteria:

- Patients without a clinically confirmed stroke, or with clinically confirmed stroke under care of neurosurgical team.
- Individuals unable to give informed consent, and do not have an individual available to act in the capacity of a personal consultee.
- Patients in the last days of life.
- Patients discharged from a HASU without any need for further rehabilitation.

2.3 Participant identification

All people admitted with acute stroke meeting the eligibility criteria (section 2.2) will be approached by local research practitioners (local Clinical Research Network staff) to receive information about the study before they are discharged from inpatient care. Verbal consent will be requested for the researcher (VL) or research practitioners to contact them. Following consent to contact, the researcher or research practitioner will visit the potential participant, provide information about the study and gather written consent to participate (section 2.4).

2.4 Sample

Consecutive sampling will continue until as many participants as possible are recruited within the pragmatic timeframe, at least three months but will be extended to six if required. Nine sites are proposed, with a mean number of 60 patients admitted to each site every three months (SSNAP data, 2016). This gives approximately 540 patients available for recruitment within a three month period. With a conservative 50% consent rate this gives around 270 participants, which is suitable for the planned analysis; typical rule of thumb for a linear regression states 10 participants per confounding variable (Wilson VanVoorhis and Morgan, 2007). Literature suggests around 10% of patients have a dementia diagnosis prior to first stroke (Pendlebury and Rothwell, 2009) although clinical experts report a much higher frequency, therefore potentially 27 patients with dementia should be recruited. Completeness of the sample will be reported (i.e. loss to follow up, drop out, missing data).
2.5 Consent

Phase one (cohort study) is a low risk study that does not require data collection directly from participants (see section 3 regarding consent for nested qualitative study). Consent is required to access patient notes, containing personal information. Participants will be approached on the ward by research practitioners as soon as medically appropriate to give verbal consent to receive information about the study. The researcher or a research practitioner will then visit the potential participant to explain the research and provide an information sheet. At least 24 hours to consider the Participant Information Sheet (PIS) will be suggested. Due to the low risk nature of the study, if a potential participant is due to be discharged within 24 hours of approach and therefore unable to take time to consider the information sheet, they will be able
to provide consent when they feel ready to do so. An accessible format information sheet and consent form will be provided for patients with communication, visual or specific cognitive difficulties, identified by the clinical team, and the consent procedure will be witnessed by a member of clinical or research team, or by a carer/family member of the patient. Both written and verbal information will be provided to the patient, and adapted to suit the needs of the patient (Dewing, 2007).

Some participants will have either known or suspected dementia (or cognitive impairment) however this does not necessarily mean that they will lack capacity to provide informed consent. In line with the Mental Capacity Act (2005), patients will be deemed to have capacity to consent unless a clinician involved in their care determines otherwise. The researcher or research practitioner taking consent will liaise with the referring team in order to ascertain whether they may not have capacity to consent. If there are doubts as to whether a participant has capacity to consent to the study, the Assessing Capacity form will be used by the person taking consent.

Capacity to consent will be assessed by using the following principles:

- Does the person have a general understanding of what decision they need to make and why they need to make it?
- Does the person have a general understanding of the likely consequences of making, or not making, this decision?
- Is the person able to understand, use and weigh up the information relevant to this decision?
- Can the person communicate their decision (by talking, using sign language or any other means)?

(Office of the Public Guardian 2007)

If a person is able to retain information relevant to a decision for a short period only this does not prevent them from being able to make the decision (HM Government, 2005), which is especially pertinent when assessing capacity in people with memory problems or dementia. For potential participants who are deemed not to have capacity, the British Psychological Society approach will be taken (Dobson 2008), adopting the following steps:
5. Identify a family member / friend who knows the person, who will act in the
capacity of personal consultee. If no family or friends are willing or able to be
consulted, a nominated professional consultee will be sought (a person with
whom the potential participant has a professional relationship who is not
involved in the research, for example a member of staff in a care home in
which the person lives).
6. Present the consultee information sheet to the consultee, giving the opportunity
to ask questions.
7. If the consultee is satisfied, they will be asked to sign a declaration form.
8. Following successful completion of the declaration form, the researcher will
include data from the person who lacks capacity as a participant in the cohort
study. Should the declaration form not be signed, no further steps will be
taken.

The consultee will give their advice on whether the participant would wish to
participate in the research, or whether they would be likely to decline had they the
capacity (Dobson, 2008). Consultees unavailable during normal working hours will be
given the option to receive the information sheet via email or post via the consent to
contact form, with a postal consent form for return in a ready stamped and addressed
envelope.

2.6 Data collection

Recruitment to the cohort study will ideally be completed with a three month period at
each site. However due to potential delays in site set up and recruitment, a ‘worst
case’ six month study period is planned to factor in delays and difficulties.

Routinely collected data will be extracted for the eight week period post-stroke for
each participant. Admission data will be collected after consent, and outcome data at
the eight week time point. Eight weeks was chosen to allow reasonable time for
patients to receive rehabilitation services. Participants will typically be recruited whilst
inpatient in rehabilitation units, however data will be available on HASU admission
details. Patients admitted to Salford Royal have a mean length of stay of 16 days
(median 5.7) (mean 20 days at Fairfield General, mean 13 days at Stepping Hill)
(SSNAP data, 2016) and ESD services are limited for six weeks; therefore eight weeks
captures a reasonable and practical amount of time following stroke onset to explore the process of care in those referred for post-HASU rehabilitation.

Clinical notes will be reviewed on NHS sites using electronic or paper based records. Clinical notes from hospital admission (and community teams if available) will be accessed and reviewed manually by the researcher (or research practitioners if possible), recorded on a paper Case Report Form (CRF) and input into a database by the researcher. The data collection process will be piloted initially in order to ensure all the appropriate data can be collected.

Participants will be assigned to one of three cohorts based on routinely collected data regarding their pre-stroke cognitive functioning. Some of this information will only come to light post-admission therefore this data will be collected at the eight week time point. Data about cognition will be categorised, with a yes/no answer for documentation about cognition, detail of who recorded it and brief detail of reason. For example if an occupational therapist suspects a patient had pre-existing memory problems due to a relative stating the patient was struggling to remember appointments, this would be categorised as ‘Clinician documentation: yes; Clinician: OT; Detail: relative report, social history’. Categorisation of data will be checked for interrater reliability using a small (around 10%) sample of records.

2.7 Analysis

CONSORT style (Schulz et al., 2010) data will be presented on baseline data:

- Number of admissions at each site
- Number of patients screened for eligibility, number of eligible and ineligible patients and reason (as per exclusion criteria).
- Unidentifiable eligible patients who decline to participate (nominal and ordinal variables will be presented in order to examine external validity e.g. sex, stroke severity (NIHSS (Brott et al., 1989), pre-stroke functioning (modified Rankin Score (mRS) (Bonita and Beaglehole, 1988)).

Following data collection, three cohorts will be created if sufficient data are available: Cohort 1: no documented dementia diagnosis and no documented pre-stroke cognitive impairment.
Cohort 2: anyone categorised as ‘yes’ to clinician documentation of pre-existing cognitive impairment in the absence of documented dementia diagnosis.
Cohort 3: documented dementia diagnosis at admission.

Cohort assignment will be tested during the pilot phase to ensure adequate data is being collected to allow creation of the cohorts. Around 20 participants will be desired in each cohort for analysis, however cohorts are likely to be of unequal size. If the cohorts are too small to carry out planned analysis only two cohorts will be created, combining cohorts two and three.

Demographic and clinical descriptive baseline characteristics of participants in each cohort will be presented and visually examined. Primary outcome of number of therapy sessions will be calculated by combining number of physiotherapy and occupational therapy (OT) sessions offered during the eight week data capture period (eight weeks post-stroke). This is because all patients on a rehabilitation ward will receive these two therapies, whereas not all will receive speech and language therapy or psychology. Profession-specific sessions will be analysed separately in secondary analysis, with distinctions between direct, indirect and joint therapy sessions, as will referral to relevant services e.g. memory clinics, dementia services if data available.

For the primary outcome a linear regression will be used to compare the cohorts using number of therapy sessions during the eight week period as a continuous outcome variable, adjusting for the possible confounders of age, pre-stroke mRS and stroke severity (NIHSS). Data will be graphed and examined to clarify the distribution and quality of the data to ensure they warrant a linear regression. If the data are not adequate to support a linear regression then a logistic regression analysis will be considered dichotomising the primary outcome variable. Some participants may receive more than eight weeks of therapy so our inferential analyses will need to take into consideration the possibility and implications of censored data.
3 Phase two – nested qualitative study

3.1 Participant identification

A sub-sample of participants from the phase one cohort study will be approached to participate in interviews by the researcher. Approximately 15-20 participants will be recruited (see section 3.2). These participants will be identified as having a pre-stroke cognitive impairment or dementia, experience of receiving inpatient rehabilitation, and the capacity to consent to interview. Expressions of interest to participate in the interview study and contact details will be gathered during recruitment for phase one; the consent form includes a section on consent to be approached again for a possible interview. Participants will be approached whilst inpatient in the DSCs, as close to discharge as is feasible.

3.2 Sample

Purposive sampling will be used to select participants for the qualitative study. The purpose of the interviews is to gather data on experience of stroke services from the perspective of patients with pre-stroke cognitive impairment or dementia, therefore this will be taken into consideration. Demographic and clinical information will be collected during phase one and used to inform sampling. Using the current data on estimated dementia prevalence pre-stroke (Pendlebury and Rothwell, 2009), around 10% of patients have a diagnosis of dementia pre-stroke and one third will have dementia after recurrent stroke. Sampling will take place over about two months whilst gathering data for phase one, therefore it is expected around 6 participants may be suitable to approached for interview at each site (using data on average number of admissions at each site), however some of these participants may not meet the inclusion criteria for the nested study. Participants will also be sampled from those without a formal diagnosis of dementia but with a suspected cognitive impairment as identified in phase one. Interviews will be conducted until data saturation is reached, estimated at around 15-20 participants, allowing for those who decline to participate within the eligible sample. The sample size indicated is based on typical numbers required for a qualitative piece of work to ensure saturation of responses (Braun and Clarke, 2013). Factors such as willingness to participate and capacity to consent have been considered. Type of cognitive impairment or dementia documented in the clinical notes if applicable (for example, mild cognitive impairment or Alzheimer’s disease) will be recorded but participants with any type of diagnosis will be recruited.
3.3 Eligibility criteria

Inclusion criteria:

- Individuals capable of giving informed consent.
- Admitted to hospital with a clinically confirmed stroke and under the care of the stroke team.
- Diagnosis of a pre-stroke cognitive impairment or dementia as documented in the clinical notes.
- Identified as having rehabilitation needs, as evidenced by being admitted to a stroke rehabilitation unit.

Exclusion criteria:

- Individuals unable to give informed consent.
- Patients without a clinically confirmed stroke, or with clinically confirmed stroke under the care of neurosurgical team.
- No experience of cognitive impairment or dementia.
- No rehabilitation needs identified.
- Non-English language speaker.
- Patients in the last days of life.

Only participants with capacity to give informed consent will be recruited for the interview study. This part of the study is addressing a complex concept about past experiences, and some patients may struggle with recall, increasing the potential risk of distress. Participants may have communication impairments due to stroke in addition to cognitive difficulties therefore in order to minimise risk of distress only those with capacity to give informed consent will be recruited for interview. Open ended questions will be used as these have been found to be less distressing for people with dementia than specific questions requiring accurate recall (Aggarwal et al., 2003). A distress protocol is included.

Only English language speaking participants will be recruited for phase two due to the complications of interviewing people with cognitive impairment or dementia as well as potential post-stroke communication difficulties. This will be identified during the screening process for phase one. This is a PhD project therefore resources are limited,
however numbers of patients excluded for consideration due to being unable to communicate in the English language will be recorded and reported.

3.4 Consent

Following identification and expression of interest to participate, the researcher or research practitioner will first review data collected in phase one to confirm the participant is alive and not in the last days of life. They will then contact the participant via telephone to arrange a visit for consent and interview (or in hospital if still inpatient). Information sheets will be mailed to the participant in advance of the visit if the patient has been discharged at this point. The researcher will visit the participant in their post-hospital place of residence (if they have been discharged at this time point) and address any questions arising from the information sheet. Capacity to consent will be assessed by the researcher using the Assessing Capacity form if appropriate and written informed consent will be gained if the participant is deemed to have capacity. If not, the visit will be ended at this point. All participants will be made aware they can withdraw at any time without reason and all information will remain confidential. The capacity to consent process will reassessed during the interview if required.

This study will require awareness of verbal and non-verbal behaviour that may indicate lack of consent to participate from those who have communication impairments. For example, if a participant chooses not to answer questions or appears disengaged, the interview will be terminated if the participant no longer consents to participate (Slaughter et al., 2007). The principle of the consent process as outlined in section 2.5 will be followed.

3.5 Data collection

Around 15-20 participants will be recruited as detailed and invited to participate in semi-structured interviews. The interviews will be conducted by the researcher. Face to face interviews will take place in a location convenient to the participant, most likely their post-hospital place of residence. Interviews will be audio recorded (with consent) and transcribed by the researcher or another person within the University of Manchester stroke research team, or by a University approved transcription service. At this point any identifying information (e.g. names and places) will be removed. Audio recordings will be deleted following checking the transcription. Aphasia-friendly
interviews will be conducted where appropriate, using pictures, prompt cards or visual analogue scales to represent opinions (Young et al., 2013). Semi-structured interviews with open questions and closed structured prompts have been found to be an effective method of gathering experiential data from participants with cognitive impairment (Patchick et al., 2015; Dalemans et al., 2009). This format also gives participants the opportunity to disclose information of importance to them relevant to the topic that may not be covered by the interview schedule (Braun and Clarke, 2013).

Participants may have communication impairments due to their stroke which has been highlighted as a barrier when including participants with cognitive impairment in qualitative research (Lloyd et al., 2006). This will be considered when designing the interview schedule; questions will be concise, clear and attempt to avoid complex concepts (Lloyd et al., 2006). Methods will be as inclusive as possible and appropriate training will be sought in order to facilitate aphasia-friendly interviews. The purpose of this study is to explore how cognitive impairment impacted on patient’s receipt of services, which may prove too complex for those with severe communication and cognitive impairments. Participants’ ability to participate will be gauged during the consent visit and methods will be adapted accordingly.

Interviews will focus on patients’ experience of health professionals’ communication about cognitive difficulties, and positive or negative experiences of rehabilitation. Field notes will be taken directly after the interview in order to aid reflection and eliminate potential interviewer bias.

3.6 Analysis

A thematic analysis will be started following the first interviews and will guide when interview data have reached saturation point. Thematic analysis follows a six stage, iterative process: data familiarisation; generation of initial codes; identification of themes; reviewing themes; definition of themes; and report production (Braun and Clarke, 2006). The researcher will undertake all stages of the analysis guided by the supervisory team. Data will be anonymised, coded and then organised into themes. Data will be organised and managed using NVivo software. Themes and categories will be checked by the supervisory team. When initial analysis is complete, themes will be member checked with participants in order to ensure their views are accurately represented if they wish (Braun and Clarke, 2013).
4 Project management

4.1 Ethical considerations

The study has been approved by the North West - Haydock Research Ethics Committee [17/NW/0427].

Consideration has been given to capacity, lone working, data protection, data storage, confidentiality and disclosure of information, and risk to participants as outlined in the following section. Training on electronic patient records has been completed.

4.1.1 Capacity

This study involves participants with and without capacity. Appropriate procedures have been put in place (see sections 4.1.2 – 4.1.4) to support participants who may not have capacity. The consent process has been described in section 2.4 and is a recognised way of working in the dementia research field. The researcher has experience of working with people living with dementia (with and without capacity) and has the necessary capacity training exposure to conduct the work.

4.1.2 Participant distress

Whilst the potential for distress is minimised in this project, a Distress Protocol is in place and will be followed should the situation necessitate.

4.1.3 Disclosure of abuse

Should any disclosure of abuse be made, the Abuse Protocol will be actioned and reported to the academic supervisor (Prof Audrey Bowen) immediately for further guidance.

4.1.4 Incident reporting

Should any incident with the potential to cause physical or psychological distress or harm occur during the project, the Incident Report Form will be actioned.

4.2 Data protection and storage

Data will be stored on a password protected university network drive accessible only to the research team. All paper documentation will be stored in a locked filing cabinet in a
locked or code-accessible office. The Data Protection Act (1998) and NHS Code of Confidentiality (2003) will be followed, and participant data will be anonymised using codes. University data protection training has been completed by the researcher. Participant identifiable data will be stored on an encrypted document separate to study data. Data will be input into a database and stored on a university-owned encrypted laptop or password protected university computer. Audio recordings will be stored for the minimal length of time practical and deleted once transferred to a password-protected university computer. Audio files will be labelled with a non-identifying participant number the point of transfer to computer. Interviews will be transcribed as soon as possible after recording, either by the researcher or by a university approved transcription service. Audio files will be uploaded to the transcription service using a secure portal and a dedicated password protected account and transcriptions received via the same method. Audio files will be deleted following transcription. As soon as is practicable after receiving the transcribed electronic files, the documents will be reviewed and any names, locations or other identifiers in the transcript will be removed and replaced by pseudonyms. In any reports, published material or communications about the study, participants will be referenced by an ID number or pseudonym. Care will be taken to ensure that the identity of individuals is not revealed through contextual information.

Participants will be made aware on the information sheet that all audio recorded and transcribed data will be kept confidential within the research team. Confidentiality will only be breached in the event of a disclosure of information deemed to be a safeguarding or emergency issue, as detailed in section 4.1. Data will be read and analysed by the researcher, with the support of the supervisory team only. Data will be archived in accordance with the University of Manchester’s data archiving policy.

All research data will be stored in line with the University’s policy on the storage of research data is that it is kept for 5 years after the date of publication of the thesis upon which it is based.

4.3 Patient and public involvement

Patient and public involvement (PPI) groups have been consulted during the design and will be consulted during the dissemination stage of the study. Consultation in PPI is a method of using public views to inform decision when carrying out research
INVOLVE, 2015). PPI has been found to be particular value when designing experience-type qualitative research (Staley, 2009). The study was presented to the Salford Royal Hospital Cardiovascular PPI group for consultation on the overall topic of the study and to ensure all logistical aspects of the protocol have been considered, for example methods of contacting participants and the personal consultee process. The patient information sheets, consent forms and dissemination plans were presented for feedback also. Proposed interview schedules were discussed with the PPI groups to ensure questions were worded appropriately, relevant to participants, and well-timed (Brett et al., 2014). The impact of the consultation on the research design will be fed back to the groups when presenting the findings. Following analysis, preliminary findings will be presented to the PPI groups and they will be consulted on the patient dissemination summary sheet.

4.4 Dissemination

Participants will be given the option to provide contact details for dissemination when giving consent and an accessible summary sheet will be sent to those who provide this information. Findings will be presented at the PPI groups used for consultation and at local stroke network meetings with clinicians. Poster and platform presentations will be produced for appropriate conferences, alongside at least one peer-reviewed journal paper.

4.5 Potential risk to participants

Participants will be informed they are able to withdraw at any time without reason and all data will remain confidential. Patient care will not be affected by the study. Participants selected for interview will be asked to reflect on the hospital experience, which may cause distress. The distress protocol will be followed and consent to participate will be reviewed.

4.6 Benefits for participants

Whilst this research will have no direct benefit for participants, the project aims to identify potential areas for service developments, thus facilitating future benefits for patients. Furthermore, patients may find the interviews a valuable opportunity to discuss positive and negative aspects of care they have received.
4.7 Risks for researchers

This study will involve lone working in patient’s places of residence therefore the university’s lone working policy will be followed. The researcher (Verity Longley) has experience of both clinical and research lone working in the community.
Examining the process of care and experience of pre-existing cognitive impairment on stroke-specific rehabilitation

What is the purpose of the study?
Many patients experience difficulty with thinking after a stroke, for example difficulty remembering, or slowed thinking. This is called cognitive impairment. Many patients may have started to have difficulties with thinking before their stroke also. We do not know whether these problems affect the rehabilitation patients receive after a stroke. We want to find out what rehabilitation patients have had in hospital and look at whether having a cognitive impairment changes the rehabilitation people have.

Why have I been invited to take part?
You have been invited to take part in the study because you are being treated for a stroke.

Do I have to take part?
No, you can decide not to take part. Participation is voluntary. If you agree, you will be given a consent form to sign. You are free to withdraw at any time, without giving a reason.

What will happen to me if I take part?
You do not need to do anything. The researcher will access your notes and look at information that has been recorded about you. This information will include your past medical history and what has happened during your current admission. Your notes will be looked at eight weeks after your stroke, which might be after your discharge from hospital.

What are the possible risks of taking part?
No risks have been identified. You do not need to do anything to be a participant in the study. You will be giving the research team permission to look at your medical notes.

What are the possible benefits of taking part?
There are no direct benefits for you taking part. However this study aims to provide knowledge in order to improve quality of the care for people after stroke.

What will happen if I don’t want to carry on with the study?
You are free to withdraw at any time. You do not have to give a reason.

Will my taking part in the study be kept confidential?
All information collected about you will be kept strictly confidential. Your information will be stored securely in a locked filing cabinet or on a password-protected computer on
Trust property during the data collection period and University premises after this. It will be accessible only to the research team.

Information and data will be stored for in line with University policy for 15 years and will be disposed of securely after this time. Individuals from the University of Manchester, NHS Trust or regulatory authorities may need to look at the data collected for this study to make sure the research is being carried out appropriately. Information collected from this study may be shared with authorised members of the research team and may be shared anonymously with other researchers. All individuals have a duty of confidentiality to you as a research participant.

The data collected during this study could be used to support research in the future. We may use the data in future studies or share it with other researchers working on other studies. All of the data will be anonymised before it is shared or used for future research so no-one will be able to identify you.

Your contact details will be stored in order to send you the study results. Confidentiality will only be breached in the event of a disclosure of information deemed to be a safeguarding or emergency issue. You will be made aware of a disclosure to a secure authority.

What will happen to the results of the study?
The data will be used as part of a PhD thesis. The results of this study will be written up with an aim to be published in peer-reviewed journal. These publications will not include any identifiable data. You will be informed when the results become available, if you wish.

What happens when the research study stops?
You can choose to be informed of the results of the study when they are available.

If you are interested, the researcher might like to talk to you about what you thought about your hospital stay. Please let the research team know if you would be happy to be considered for an interview.

What if there is a problem?
Complaints:
If you have a concern about any aspect of the study, you should ask to speak to the researcher or academic supervisor who will do their best to answer your questions:
Verity Longley, A3.14 Ellen Wilkinson Building
University of Manchester
Oxford Road
Manchester M13 9PL
Verity.longley@postgrad.manchester.ac.uk
Supervisor: Professor Audrey Bowen: Audrey.bowen@manchester.ac.uk

If they are unable to resolve your concern or you wish to make a complaint regarding the study, please contact the Research Governance and Integrity Manager, Research Office, Christie Building, University of Manchester, Oxford Road, Manchester, M13
9PL, or by emailing: research.complaints@manchester.ac.uk or by telephoning 0161 275 2674 or 275 2046.

**Who is organising and funding the research?**
The research is being funded by the Stroke Association. The research is sponsored by the University of Manchester.

**Who has reviewed the study?**
The study has been reviewed by the North West - Haydock Research Ethics Committee [17/NW/0427].

**Further information and contact details**
For further information about the research study, please contact the lead researcher:

**Verity Longley**  verity.longley@postgrad.manchester.ac.uk
Participant Identification Number:

CONSENT FORM

Examining the process of care and experience of pre-existing cognitive impairment on stroke-specific rehabilitation

Researcher: Verity Longley
verity.longley@postgrad.manchester.ac.uk

1. I confirm that I have read the information sheet (version [1], [08/05/2017]) for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.

2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason.

3. I understand that the information collected from this study may be shared with authorised members of the research team and may be shared anonymously with other researchers. All these persons will have a duty of confidentiality. Confidentiality will only be breached in the event of a disclosure of information deemed to be a safeguarding or emergency issue.

4. I understand that relevant sections of my medical notes and data collected during the study may be looked at by individuals from the University of Manchester, from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records.

5. I understand that the information collected about me will be used to support other research in the future, and may be shared anonymously with other researchers.

6. OPTIONAL: I would like a summary of the main study findings. I agree to my contact details being stored so that the study findings can be sent to me.

7. I agree to take part in the above study.

8. OPTIONAL: I agree to being approached for interview in next part of the study.
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<thead>
<tr>
<th>Name of Participant</th>
<th>Date</th>
<th>Signature</th>
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<tr>
<th>Name of Researcher</th>
<th>Date</th>
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<tr>
<th>Name of Witness if required</th>
<th>Date</th>
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When completed: 1 copy for participant; 1 original for researcher site file.
What is the research?

We are looking at **difficulty thinking** after a stroke.

These difficulties might **affect** the **rehabilitation** people have after a stroke.

We would like to look at your **medical notes** find out about what rehabilitation you have had.

Invitation to participate in this research is **not a diagnosis of any difficulties**.

Why is the research happening?

**Difficulty thinking** after a stroke can be problems with your memory, attention, or slowed thinking.

Some people have these difficulties **before** their stroke also.

We want to find out whether it affects the rehabilitation people get after a stroke.
Why me?

You are being treated for a stroke.

Do I have to take part?

No – it is your decision.

It will not affect any current or future care you receive.

What will I have to do?

You do not have to do anything.

The researcher will look at your medical notes and record what happened to you during your hospital stay.
### What might be good about taking part?

| ![Thumbs Up] | You will help us learn about **how to help** people who have had a stroke in the future. |

### What might be difficult about taking part?

| ![Thumbs Down] | The research does not require you to do anything.  
There are no risks from being involved.  
You have the right to **withdraw** from the study at any point. |

### Who will see the information about me?

| ![Locked Cabinet] | We will keep the **information** about you in locked cabinets and specially protected computers at the University of Manchester.  
We will only share your information in the event of a safeguarding or emergency issue.  
**Coded names** will be used for you. |
### What will happen to the results?

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<tr>
<td>We will share the <strong>results</strong> with <strong>other people</strong>.</td>
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<tr>
<td>The results will <strong>not use your name</strong>.</td>
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<tr>
<td>You will not be able to be identified from any report arising out of the study.</td>
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### What next?

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<tr>
<td><strong>Ask</strong> us if you have any <strong>questions</strong>. If it would help, you can <strong>meet with a researcher</strong> before deciding to take part in the study.</td>
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<tr>
<td>If you decide to take part you will need to <strong>sign a form</strong> saying that you <strong>understand</strong> the research and you <strong>agree</strong> to take part.</td>
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</tr>
<tr>
<td>You are entitled to <strong>withdraw</strong> from the study at any time.</td>
<td></td>
</tr>
</tbody>
</table>
Contact details

If you have any questions about the research, or would like to take part in the study, please contact:

Verity Longley
Room A3.14, Ellen Wilkinson Building
University of Manchester, Oxford Road
Manchester, M13 9PL
Tel: 0161 2753507
verity.longley@postgrad.manchester.ac.uk

What if something goes wrong?

If there are any issues regarding this research that you would prefer not to discuss with members of the research team, please contact:

The research supervisor Professor Audrey Bowen:
Audrey.bowen@manchester.ac.uk

Or The Research Governance and Integrity Manager
Research Office, Christie Building
The University of Manchester, Oxford Road
Manchester, M13 9PL
Tel: 0161 275 2674 or 275 2046
Research.Complaints@manchester.ac.uk
### CONSENT FORM – COHORT STUDY (ACCESSIBLE)

**Version 1**

Please indicate yes or no by using thumbs up or down or marking each of the statements below.

<table>
<thead>
<tr>
<th>Statement</th>
<th>Yes</th>
<th>No</th>
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<tbody>
<tr>
<td>I have been given <strong>information</strong> to keep about taking part in the study.</td>
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<td>This information has been <strong>explained</strong> to me.</td>
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<td>I have <strong>understood</strong> the information.</td>
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<td>I have been given the chance to <strong>ask questions</strong> about taking part in the study.</td>
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<tr>
<td>I understand that I can <strong>stop</strong> the study at any time.</td>
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<tr>
<td>I <strong>do not</strong> have to give a reason.</td>
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<td>This will <strong>not</strong> affect the care I get from the NHS.</td>
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<tr>
<td>I <strong>agree</strong> to <strong>take part</strong> in the study.</td>
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<tr>
<td>Optional: I agree to be <strong>contacted again</strong> about an interview for the next part of the study.</td>
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</tbody>
</table>
Name of **Participant**

______________________________  ______________________
Signature                      Date

______________________________
Name of **Researcher**

______________________________  ______________________
Signature                      Date

______________________________
Name of **Witness** if required and relationship to participant

______________________________  ______________________
Signature                      Date

*When completed: 1 copy for participant; 1 original for researcher site file.*
Consultee Information Sheet
Examining the process of care and experience of pre-existing cognitive impairment on stroke-specific rehabilitation

Your relative/friend/person that you professionally care for is being invited to take part in a research study. We would like to ask your opinion as to whether or not you think they would be interested in being asked to take part. Before you decide, it is important that you understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Please consider any previous wishes and feelings that they may have had regarding involvement in this project. These should take precedence. Please feel free to ask if there is anything that is not clear or if you would like more information.

What is the purpose of the study?
Many patients experience difficulty with thinking after a stroke, for example difficulty remembering, or feeling slowed down. This is called cognitive impairment. Many patients may have started to have difficulties with thinking before their stroke also, or have a diagnosis of dementia. We do not know whether these problems affect the rehabilitation patients receive after a stroke. We want to find out what rehabilitation patients have had in hospital and compare it for people with and without cognitive impairment or dementia.

Why has my relative/friend been chosen?
They have been invited to take part in the study because they are being treated for a stroke.

Does my relative/friend have to take part?
- No. We are asking you to decide whether or not you are happy for your relative/friend/person you care for to take part in this project.
- You should only agree for your relative/friend to participate if you think they would not have refused to take part.
- If you are happy for us to include your relative/friend in the study, we will ask you to read and sign a consultee declaration form.
- If you decide that your friend/relative would not wish to be involved, it will not affect the standard of care they receive in any way.
- **If you agree for them to take part, but for any reason they do not wish to take part at a later date, we will not continue.**
- If you do not want your relative/friend to take part, or you want them to withdraw at any time this will not affect the medical care that they receive in any way.
- You do not have to give any reason for not wanting them to take part.

**What will happen to my relative/friend if they take part?**
The researcher will access their medical notes and look at information that has been recorded about them. This information will include their past medical history and what has happened during their current admission. Their notes will be looked at eight weeks after their stroke, which may be after their discharge from hospital. This information will be gathered for many patients and compared.

**Are there any risks to my relative/friend taking part?**
No risks have been identified. They do not need to do anything to be a participant in the study. You will be giving the research team permission to look at their medical notes. This will not affect their care in any way.

**Are there any benefits to my relative/friend taking part?**
There are no direct benefits for them taking part. However this study aims to provide knowledge in order to improve quality of the care for people after stroke.

**What happens when the research study stops?**
You and your relative/friend can choose to be informed of the results of the study when they are available.

**What will happen if I don’t want my relative/friend to carry on with the study?**
You are free to withdraw them at any time. You do not have to give a reason.
Will my relative/friend’s information be kept confidential?
All information collected about them will be kept strictly confidential. Their information will be stored securely in a locked filing cabinet or on a password-protected computer, on Trust property during the data collection period and University premises after this. It will be accessible only to the research team. Information and data will be stored for in line with University policy for 15 years and will be disposed of securely after this time.

Individuals from the University of Manchester, NHS Trust or regulatory authorities may need to look at the data collected for this study to make sure the research is being carried out appropriately. Information collected from this study may be shared with authorised members of the research team and may be shared anonymously with other researchers. All individuals have a duty of confidentiality to them as a research participant. Your contact details will be stored in order to send you the study results if you wish.

The data collected during this study could be used to support research in the future. We may use the data in future studies or share it with other researchers working on other studies. All of the data will be anonymised before it is shared or used for future research so no-one will be able to identify participants.

Confidentiality will only be breached in the event of a disclosure of information deemed to be a safeguarding or emergency issue. If anyone taking part indicates (either publicly or privately) that someone is at risk of harm, we would discuss this with the individual before telling anyone else.

What will happen to the results of the study?
The data will be used as part of a PhD thesis. The results of this study will be written up with an aim to be published in peer-reviewed journal. These publications will not include any identifiable data. You will be informed when the results become available, if you wish.
What if there is a problem?

Complaints:
If you have a concern about any aspect of the study, you should ask to speak to the researcher or research supervisor who will do their best to answer your questions:
Verity Longley
A3.14 Ellen Wilkinson Building
University of Manchester
Oxford Road
Manchester M13 9PL
Verity.longley@postgrad.manchester.ac.uk
Supervisor: Professor Audrey Bowen: Audrey.bowen@manchester.ac.uk

If they are unable to resolve your concern or you wish to make a complaint regarding the study, please contact the Research Governance and Integrity Manager, Research Office, Christie Building, University of Manchester, Oxford Road, Manchester, M13 9PL, or by emailing: research.complaints@manchester.ac.uk or by telephoning 0161 275 2674 or 275 2046.

Who is organising and funding the research?
The research is being funded by the Stroke Association. The research is sponsored by the University of Manchester.

Who has reviewed the study?
The study has been reviewed by the North West - Haydock Research Ethics Committee [17/NW/0427].

Further information and contact details
For further information about the research study, please contact the lead researcher:

Verity Longley
verity.longley@postgrad.manchester.ac.uk
Participant Identification Number:

CONSULTEE DECLARATION FORM

Examining the process of care and experience of pre-existing cognitive impairment on stroke-specific rehabilitation

Researcher: Verity Longley
verity.longley@postgrad.manchester.ac.uk

Please initial box

Please Initial Boxes

1. I confirm that I have read and understand the information sheet (version [1] [12/06/17]) for the above named study and I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.

2. In my opinion, the person I care for, when they had capacity, would have agreed to take part in the proposed study. By signing this form, I am agreeing for my relative / friend / person I care for to take part.

3. I understand that the participation of the person I care for is voluntary and that they are free to withdraw at any time. If they do decide to withdraw, or if I decide their withdrawal is in their best interests, they / I do not have to give a reason and our medical care and legal rights will not be affected.

4. I believe that the person I care for would, when they had capacity, have agreed for the information collected as part of the study to be shared anonymously.

5. In my opinion, the person I care for would have no objection to taking part in the study.
Name of Consultee:
...............................................................................................................................................
Date .................... Signature .................................................................................................

Name of the person I care for:
...............................................................................................................................................

Name of Researcher:
...............................................................................................................................................
Date ................. Signature..................................................................................................
### STROBE Statement—Checklist of items that should be included in reports of cohort studies: Differences in stroke rehabilitation for people with pre-existing cognitive impairment: an observational cohort study *(chapter five)*

<table>
<thead>
<tr>
<th>Item No</th>
<th>Recommendation</th>
<th>Page Number included</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Title and abstract</strong></td>
<td></td>
<td><strong>Page Number included</strong></td>
</tr>
<tr>
<td>1</td>
<td><em>(a)</em> Indicate the study's design with a commonly used term in the title or the abstract <em>(b)</em> Provide in the abstract an informative and balanced summary of what was done and what was found</td>
<td>96 97</td>
</tr>
<tr>
<td><strong>Introduction</strong></td>
<td></td>
<td><strong>Page Number included</strong></td>
</tr>
<tr>
<td>2</td>
<td>Explain the scientific background and rationale for the investigation being reported</td>
<td>98</td>
</tr>
<tr>
<td><strong>Objectives</strong></td>
<td></td>
<td><strong>Page Number included</strong></td>
</tr>
<tr>
<td>3</td>
<td>State specific objectives, including any prespecified hypotheses</td>
<td>99</td>
</tr>
<tr>
<td><strong>Methods</strong></td>
<td></td>
<td><strong>Page Number included</strong></td>
</tr>
<tr>
<td>4</td>
<td>Present key elements of study design early in the paper</td>
<td>99</td>
</tr>
<tr>
<td>5</td>
<td>Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection</td>
<td>99</td>
</tr>
<tr>
<td>6</td>
<td><em>(a)</em> Give the eligibility criteria, and the sources and methods of selection of participants. Describe methods of follow-up <em>(b)</em> For matched studies, give matching criteria and number of exposed and unexposed</td>
<td>99</td>
</tr>
<tr>
<td>7</td>
<td>Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable</td>
<td>101</td>
</tr>
<tr>
<td>8*</td>
<td>For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group</td>
<td>100</td>
</tr>
<tr>
<td>9</td>
<td>Describe any efforts to address potential sources of bias</td>
<td>101</td>
</tr>
<tr>
<td>10</td>
<td>Explain how the study size was arrived at</td>
<td>99 – consecutive sample within timeframe, no</td>
</tr>
<tr>
<td></td>
<td>11</td>
<td>Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why</td>
</tr>
<tr>
<td>-------------------------</td>
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<td>------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Quantitative variables</td>
<td></td>
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</tr>
</tbody>
</table>

|                         | 12 | (a) Describe all statistical methods, including those used to control for confounding                                      | 101                    |
| Statistical methods     |    | (b) Describe any methods used to examine subgroups and interactions                                                   | 101                    |
|                         |    | (c) Explain how missing data were addressed                                                                           | 101                    |
|                         |    | (d) If applicable, explain how loss to follow-up was addressed                                                        | n/a                    |
|                         |    | (e) Describe any sensitivity analyses                                                                                  | 101                    |

### Results

|                         | 13* | (a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed | 104                    |
| Participants            |    | (b) Give reasons for non-participation at each stage                                                                     | 104                    |
|                         |    | (c) Consider use of a flow diagram                                                                                     | 104                    |

|                         | 14* | (a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders | 102                    |
| Descriptive data        |    | (b) Indicate number of participants with missing data for each variable of interest                                       | 106                    |
|                         |    | (c) Summarise follow-up time (eg, average and total amount)                                                             | n/a                    |

|                         | 15* | Report numbers of outcome events or summary measures over time                                                          | 105                    |
| Outcome data            |    |                                                                                                                                 |                        |

<p>|                         | 16  | (a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included | 105                    |
| Main results            |    | (b) Report category boundaries when continuous variables were categorized                                               | 103                    |
|                         |    | (c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time                 | n/a                    |</p>
<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Other analyses</td>
<td>17</td>
<td>Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses</td>
</tr>
<tr>
<td><strong>Discussion</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Key results</td>
<td>18</td>
<td>Summarise key results with reference to study objectives</td>
</tr>
<tr>
<td>Limitations</td>
<td>19</td>
<td>Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias</td>
</tr>
<tr>
<td>Interpretation</td>
<td>20</td>
<td>Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence</td>
</tr>
<tr>
<td>Generalisability</td>
<td>21</td>
<td>Discuss the generalisability (external validity) of the study results</td>
</tr>
<tr>
<td><strong>Other information</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Funding</td>
<td>22</td>
<td>Give the source of funding and the role of the funders for the present study and, if applicable, for the original study on which the present article is based</td>
</tr>
</tbody>
</table>