Establishing the Content Validity of a Stroke Specific Patient Reported Outcome Measure (PROM) in People Living with Stroke: A Mixed Methods Content Validity Study

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Abstract

Introduction: A stroke-specific 15-item Patient Reported Outcome Measure (PROM) has been recommended by the International Consortium for Health Outcomes Measurement (ICHOM) to measure health-related quality of life (HRQoL) in people living with stroke, as part of a standard set of stroke outcome measures. The PROM-15 has not been validated in this population. This study aimed to establish the content validity of the PROM-15 in people living with stroke, using the evidence-based **CO**nsensus-based **S**tandards for the selection of health **M**easurement **IN**struments (COSMIN) methodology.

Method: A mixed-methods, convergent study design was employed. A purposive sample was recruited of six people living with stroke, two informal carers and eight Health Care Professionals (HCPs) specialising in stroke in South Wales. The HCPs completed an on-line survey to rate the relevance of the PROM-15's items to people living with stroke. Cognitive interviews were carried out with patients with stroke and their informal carers, to elicit their views on the comprehensibility, comprehensiveness and relevance of the PROM-15's items to HRQoL following a stroke. Analysis of the survey data employed the Content Validity Index (CVI) and thematic analysis was carried out on the interview data and survey free-text comments. The results were integrated for final analysis.

Results: The Scale CVI for the PROM-15 indicated excellent content validity (S- CVI/Ave=0.96/0.1). Deductive thematic analysis found that the PROM-15 met the COSMIN criteria for content validity. Integration of the findings indicated that the PROM-15 demonstrates content validity in this study sample, with complementarity across data sets.

Conclusion: This study provides supporting evidence that the PROM-15 has satisfactory content validity to measure HRQoL in people living with stroke. Results are limited to a small sample of patients with minimal post-stroke impairments, their informal carers and HCPs. Further psychometric testing of the PROM- 15 with a larger, more diverse sample is recommended.

Acknowledgements

Undertaking this research has been challenging alongside my work commitments and a particularly stressful time professionally and personally during the COVID-19 pandemic. The level of engagement from the participants in the study, especially those living with stroke and their relatives, was above my expectations and gave me the motivation to complete the study and this thesis. I'd also like to thank the HCPs who took the time to recruit participants and to complete the on-line survey at a particularly challenging time in the NHS.

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Finally, or perhaps firstly, I would like to thank the Nevill Hall Hospital Thrombosis and General Research Fund committee, as without their generous funding for my doctorate, none of this would have been possible.

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List of PROMs' abbreviations

EQ-5D ..... **EuroQuol-5 Dimension**

EQ-5D-3L ..... **EuroQuol-5 Dimensions-3 Levels**

EQ-5D-5L ..... **EuroQuol-5 Dimension-5 levels**

EQ-VAS ..... **EuroQol Visual Analog Scale**

GHQ-28 ..... **General Health Questionnaire-28 items**

HUI ..... **Health Utility Index**

HRQoLISP ..... **Health Related Quality of Life in Stroke Patients**

PROMIS-10….**Patient Reported Outcome Measures Information System10 items**

QOLIBRI-OS..... **Quality of Life after Brain Injury-Overall Scale**

SA-SIP ..... **Stroke Adapted Sickness Impact Scale**

SATIS-Stroke ..... **Satisfaction after Stroke**

SFHS ..... **Short Form Health Survey**

SF-12 ..... **Short Form-12 items**

SF-36 ..... **Short Form-36 items**

SF-SIS ..... **Short Form-Stroke Impact Scale**

SIS..... **Stroke Impact Scale**

SIS-16 ..... **Stroke Impact Scale-16 items**

SSQoLSStroke ..... **Specific Quality of Life Scale**

SSQoL-8 ..... **Stroke Specific Quality of Life Scale-8 items**

WHOQoL ..... **World Health Organisation Quality of Life**

CHAPTER ONE

Introduction to the thesis

This thesis presents a mixed methods study that aimed to establish the level of content validity in a stroke-specific patient reported outcome measure (PROM). The stimulus for this study evolved through my clinical practice with patients with stroke, participation in international and UK- based stroke research (Salinas et al. 2016; Hewitt et al. 2019; Hewitt et al. 2021), and the planned administration of the PROM in the strategy for quality improvement in stroke services across Wales. The rationale for the study was informed by the health measurement literature and a review of studies that assessed the psychometric properties of PROMs used in stroke, which identified a gap in the knowledge base. This confirmed the need to address an area of concern regarding the validity of the PROM, which could have implications for the planned stroke care improvement strategy in Wales.

1.1 Background to the study

Over the last two decades there has been growing recognition globally of the importance of placing the patient at the centre of their care and in the evaluation of healthcare services through co-production between patients, healthcare professionals and the public (Institute of Medicine 2001; Realpe and Wallace 2010; Department of Health 2011; Batalden et al. 2016; World Health Organisation 2015; Australian Commission 2017; Elwyn et al. 2020; NHS England 2022). This concept has been operationalised through PROMs, usually in the form of questionnaires, reported directly by patients regarding their health, functional status and quality of life in relation to a health condition and healthcare interventions (Weldring and Smith 2013; Churruca et al. 2021). The use of PROMs can be organised into three broad categories of healthcare: they can facilitate shared decision making and self-management at the individual level of the patient- clinician interaction (micro level); inform descriptive and analytical studies, such as comparisons of treatment

effectiveness, or variation among providers (meso level); and population surveillance and policy (macro level) (Al Sayah et al. 2021).These three categories are not mutually exclusive but interact and all can contribute to improvements in healthcare safety and quality. PROMs have become an integral part of the quality improvement agenda for healthcare services globally (Darzi 2008; Devlin and Appleby 2010; Black et al. 2013; World Health Organisation 2015; Australian Commission 2019; Withers et al. 2020). There is also increasing evidence of the use of PROMs to inform clinical practice (Boyce et al. 2014: Greenhalgh et al. 2018; Dammam et al. 2019; Field et al. 2019; Gibbons et al. 2021), and research (Ahmed et al. 2012; Calvert et al. 2013; Reeve et al. 2013).

The use of PROMs data to inform health care quality improvements in the NHS in Wales is advocated in the Prudent Health Framework (Ayelward et al. 2013; Welsh Government 2014), which promotes the ethos of co-production and equal partnership between the public, patients and healthcare professionals (HCPs) to achieve optimum health and well-being (Elwyn et al. 2020). This initiative is being operationalised by stroke services across Wales through the Welsh NHS Stroke Delivery Plan (Welsh Government 2017; Cross Party Group on Stroke 2020), led by the All-Wales Stroke Implementation Group. This strategy includes the use of PROMs to measure the health-related quality of life (HRQoL) of people living in Wales who have had a stroke, with the aim of informing the evaluation of stroke service delivery and future planning of services to meet the needs of this client group.

The multi-agency International Consortium for Healthcare Outcome Measures (ICHOM) has recommended a Standard Set of clinical and patient- reported outcomes for stroke, to enable comparable assessment of healthcare value in stroke care across different settings (Salinas et al. 2016). The Stroke Standard Set is increasingly being used by healthcare services globally, to evaluate the quality and effectiveness of stroke care provision (Rimmele et al. 2020; Philipp et al. 2021; Lebherz et al. 2022). It includes a 15-item PROM, which consists of the validated generic PROMIS-10 Global Health measure (Cella et al. 2010, Katzan and Lapin 2018), and five additional items taken from existing stroke registers, relating to functional activity after stroke (appendix i). The PROMIS-10 measure

includes items relating to physical and mental health domains, each consisting of four items, which are used to calculate *t* scores of the respective domains. The general population reference norm is 50 with a standard deviation of 10 and lower values reflect a poorer outcome. Two further items in the PROMIS-10 measure achievement of social participation and general health, with a rating from 1 (poor) to 5 (excellent). The five additional items relate to post-stroke function in mobility, dressing, toileting, feeding, and communication. The PROM is stroke-specific, evidence based and can be administered in various modes with little test burden, as it consists of 15 items (Salinas et al. 2016).
For the purposes of this thesis, the PROM will be referred to as the PROM-15.
The All-Wales Stroke Implementation Group has employed the PROM-15 in its stroke service quality improvement strategy and it has been used in Welsh Government funded randomised controlled trials (RCTs) in stroke (Hewitt et al. 2019; Hewitt et al. 2021; Corrigan et al. 2022), and other neurological conditions (Carter et al. 2021). Hewitt et al. (2019) acknowledged that the PROM-15 was not validated for use with people with stroke and assessment of its psychometric properties was recommended to establish its validity for use with this target population in Wales.
The health measurement literature emphasises the importance that a PROM accurately measures an identified construct, such as HRQoL, in a target population, to ensure that any action taken based on the analysis of the PROM data is effective and relevant to the target group (Streiner et al. 2015; Polit and Yang 2016; Bowling 2017).
Psychometric testing of a PROM is required to establish its validity, which entails assessment of the PROM's measurement properties (Streiner et al. 2015). The **CO**nsensus-based **S**tandards for the selection of health **M**easurement **In**struments (COSMIN) initiative, led by an international multidisciplinary team of researchers, has developed a taxonomy of measurement properties for health-related PROMs (Mokkink et al. 2010) to facilitate psychometric assessment. Three quality domains are distinguished - *reliability, validity*, and *responsiveness*, and each domain contains one or more measurement properties (Figure 1):

- *Reliability* refers to the degree to which a PROM is free from measurement error, and it contains the measurement properties internal consistency, reliability, and measurement error.

- *Validity* refers to the degree to which a PROM measures the construct it purports to measure and contains the measurement properties content validity (including face validity), construct validity (including structural validity, convergent and divergent validity, hypotheses testing, and cross-cultural validity/measurement invariance) and criterion validity.
- *Responsiveness* refers to the ability of a PROM to detect change over time in the construct to be measured.

All measurement properties included in the taxonomy are relevant and should be evaluated for any PROM used in any application to ensure its quality.

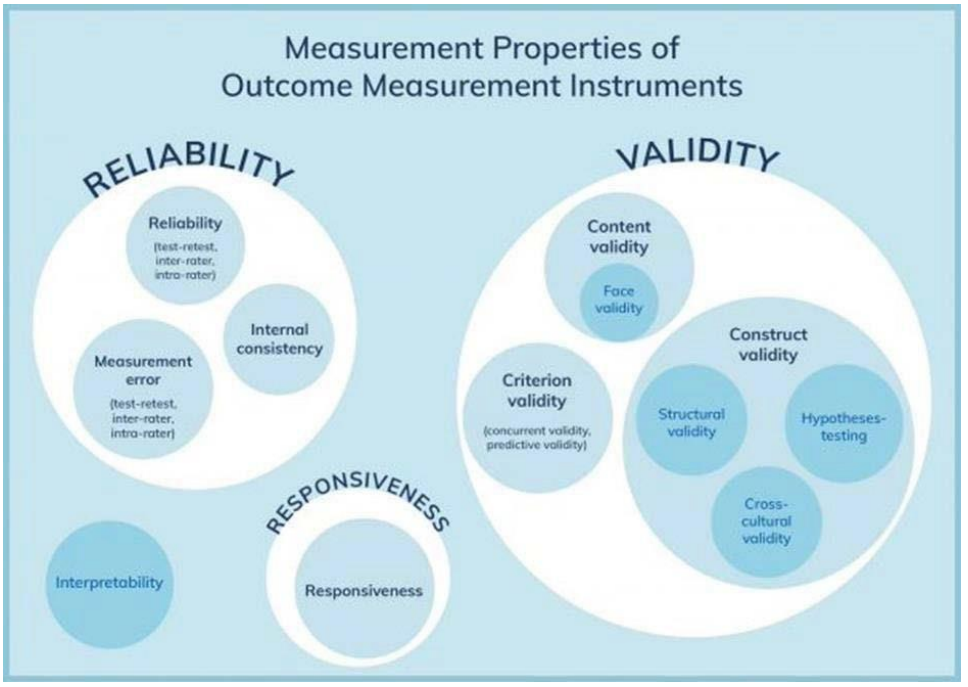


Figure 1.1 The COSMIN taxonomy of measurement properties of PROMS (Mokkink et al. 2010).

Content validity is considered the most important measurement property because it should firstly be established that all content of a PROM is *relevant, comprehensive,* and *comprehensible* with respect to the construct of interest and target population before further psychometric testing can be carried out (Mokkink et al. 2010; Terwee et al. 2018).

If adequate content validity is not established at the development stage of a

PROM, there is a risk of excluding elements that are important to respondents, or imprecise measurement of the construct, due to misinterpretation of items (Rothrock et al. 2011; Heiberg-Agerbeck et al. 2021). There may be over- or under-estimation when applying the results of the PROM, due to measurement invariance - the risk that the same construct is not measured equally, for example, among people with different cultures, languages, or genders.

Of specific relevance to this study, making changes to a PROM can reduce certainty that it still measures the construct the original PROM was designed to measure. Output from a modified PROM may not be able to be compared with output from other PROMs, nor reliably interpreted with reference to norms generated using the unmodified measures (Rothman et al. 2009; Australian Commission 2019). Consequently, the results of studies using modified PROMs that have not been validated might be questionable.

Although there is evidence of validation of the PROMIS-10 in people with stroke (Katzan and Lapin 2018; Lam and Kwa 2018; Philipp et al. 2021), the content validity of the PROM-15 has not been established in this target population, indicating a gap in current knowledge that needs to be addressed. There is a risk that the actions taken by the All-Wales Stroke Implementation Group based on the results of analysis of the PROM-15 data may be inaccurate, leading to incorrect use of healthcare resources and ineffective service provision for the people living with stroke in Wales.

This provides a clear rationale for conducting a study to assess the content validity of the PROM-15 in individuals with stroke.

1.2 Chapter summary

This chapter explained the motivation and rationale for this content validity study and contextualised it within the all-Wales strategy for evaluation and quality improvement of stroke care. The identified concern that the PROM-15 has not been validated needs to be addressed for the strategy to be effective in improving the HRQoL of people living with stroke, and the results of future research using the PROM-15 can be considered valid.

1.3 Guide to the thesis

This thesis is organised into eight chapters:

Chapter One presented the introduction to the thesis and explained the stimulus and rationale for this content validity study. It placed the study in the context of quality improvement in stroke care in Wales, UK, operationalised by using the condition-specific PROM-15 to measure HRQoL in people living with stroke.

Chapter Two explores the essential elements to this study - stroke and its impact on people living with stroke, including their HRQoL; evidence-based stroke care in the UK; evaluation of, and quality improvement in, stroke care in the UK; and the use of PROMs in stroke.

Chapter Three reviews existing studies that have assessed the psychometric properties of PROMs used to measure post-stroke HRQoL. The findings of the review confirm that the PROM-15 has not been validated, which supports the clinical rationale for this study. The aims and objectives of the study are outlined.

Chapter Four presents the philosophical stance and theoretical framework underpinning this study and discusses the rationale for the methodology employed to achieve the study's objectives. It outlines the selected mixed methods convergent study design, comprising of qualitative, quantitative and integrative study strands.

Chapter Five presents the qualitative strand of the study, including the setting and study sample; the use of cognitive interviewing as the data collection method; the use of deductive thematic analysis; and discussion of the study strand findings, with reference to current healthcare research literature.

Chapter Six presents the quantitative strand of the study, including the setting and study sample; the use of an on-line survey as the data collection method; use of the Content Validity Index (CVI) to analyse the data; and discusses the findings, with reference to current healthcare research literature.

Chapter Seven presents the integrative strand of the study, which includes interpretation of the results of the data analyses from the qualitative and quantitative study strands. The findings are presented in a visual joint display, along with a narrative interpretation, and discussed in relation to the aim of the study.

Chapter Eight presents a summary and discussion of the entire study, including the outcome, the strengths and limitations of the study, and contextualises the findings within the existing body of research evidence. Implications for the use of the PROM-15 and recommendations for clinical practice, research and quality improvements in stroke care are presented. The chapter concludes with a statement of contribution to knowledge.

CHAPTER TWO

Background to the study

2.1 Introduction

This chapter presents the central elements to this study, including stroke; the impact of stroke on the individual's physical and mental health, social participation and HRQoL; current evidence-based stroke care in the UK; quality improvement in stroke care; and the use of PROMs in stroke.

2.2 Definition of stroke

The World Health Organisation defines stroke as "rapidly developing clinical signs of focal (or global) disturbance of cerebral function, with symptoms lasting 24 hours or longer or leading to death, with no apparent cause other than vascular origin" (Aho et al.1980 p.114). More recent attempts have been made to update this definition based on advances in diagnostic technologies (Sacco et al. 2013), but the WHO's definition remains the most widely used (Coupland et al. 2017).

A stroke is caused by disruption of blood supply to the brain and can be classified into two major categories: ischaemic stroke (62% incidence) and haemorrhagic stroke (28% incidence) (Feigin et al. 2022). Ischaemic stroke occurs when the blood supply to an area of the brain is reduced, due to an embolism or thrombus (clot), resulting in tissue hypoperfusion. This causes a lack of oxygen in the brain cells, resulting in damage or death of brain tissue (necrosis). Haemorrhagic stroke (bleed), including sub-arachnoid haemorrhage, occurs when there is a rupture of a blood vessel or abnormal vascular structure within the brain. This results in an increase in intra-cranial pressure and inflammatory response, damaging surrounding tissue. The type of stroke is diagnosed by a CT scan or MRI scan, which is vital for the correct treatment to be administered to reduce the neurological damage due to the stroke and increase the potential for recovery.

The brain is divided into two hemispheres. The right hemisphere controls the left side of the body, and the left hemisphere controls the right side of the body. Each hemisphere of the brain is divided into six regions, or lobes, that control different functions (figure. 2.1).

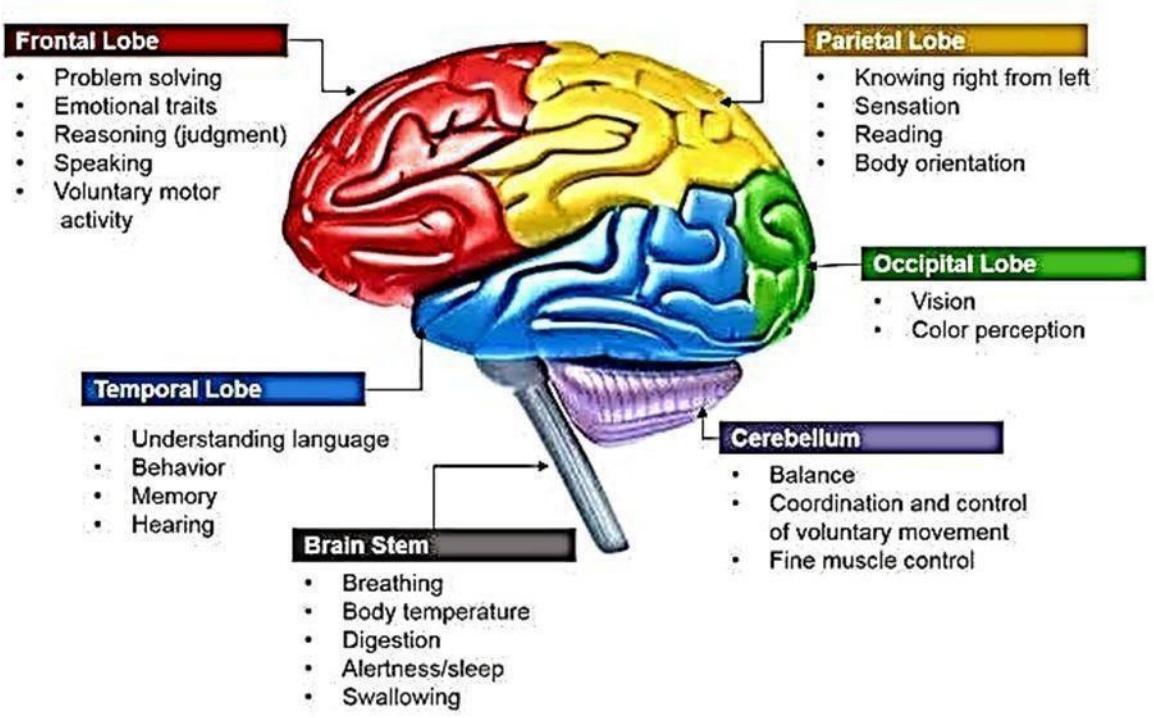


Figure 2.1. The lobes of the brain and their functions (anatomyinfo.com)

Reduced blood supply (hypoperfusion) or structural damage to any of these areas of the brain will result in impairment or complete loss of their related functions, presenting as clinical signs and symptoms in the individual having the stroke. These are outlined in section 2.4 of this chapter.

2.3 Stroke epidemiology

In the UK, where this study was carried out, there are more than 100,000 stroke admissions each year, which equates to one stroke every five minutes (Royal College of Physicians 2016) and the rate of first- time stroke admissions in people over 45 years of age is expected to rise by 60% by 2035 (Patel et al. 2020). Stroke is considered the fourth biggest killer in the UK, causing 7% of all deaths in men and 6% of all deaths in women, and over 1.3 million people (8% of the total population) are living with stroke (NICE 2023). As more people are surviving a stroke, due to improved technology and treatments to reduce the neurological effects of the stroke, the number of patients disabled by stroke discharged from in-patient care to the community is increasing (King et al. 2020;

Feigin et al. 2022). In 2020-2021,16% of patients discharged from hospitals in the UK had a modified Rankin Scale score of 4, indicating moderate to severe disability (van Swieten et al.1988; SSNAP 2022).

2.4 The impact of stroke on the individual

The impact of stroke on a person's functioning and participation in their usual activities can be defined using the International Classification of Functioning, Disability and Health (ICF) (WHO 2002). The ICF conceptualises a person's level of functioning as a dynamic interaction between their health condition and environmental and intra-personal factors. It is a biopsychosocial model, integrating social and medical models of disability, based on systems and complexity theory, and highlights the contribution of and interrelation between biological, psychological and social factors in determining health (Engel 1977). This approach is the basis of person-centred care (Kitson et al. 2013), which can improve patient health outcomes. It also underpins the goal-setting process widely used in neurorehabilitation (Wade 2015) and clinical practice in the healthcare professions, such as occupational therapy (Gentry et al. 2018).

The ICF model is multi-dimensional, encompassing *body functions and structures* (physiological and psychological functions of body systems); *activities and participation* (execution of a task by an individual and involvement in life situations); external *environmental factors* that affect these experiences (such as social attitudes, social support, legal and social structures, access to information, buildings and transport); and internal *personal factors* that influence how disability is experienced by the individual (including age, sex, social and educational background, coping styles, and past and current experiences) (World Health Organisation 2002) (figure 2.2).

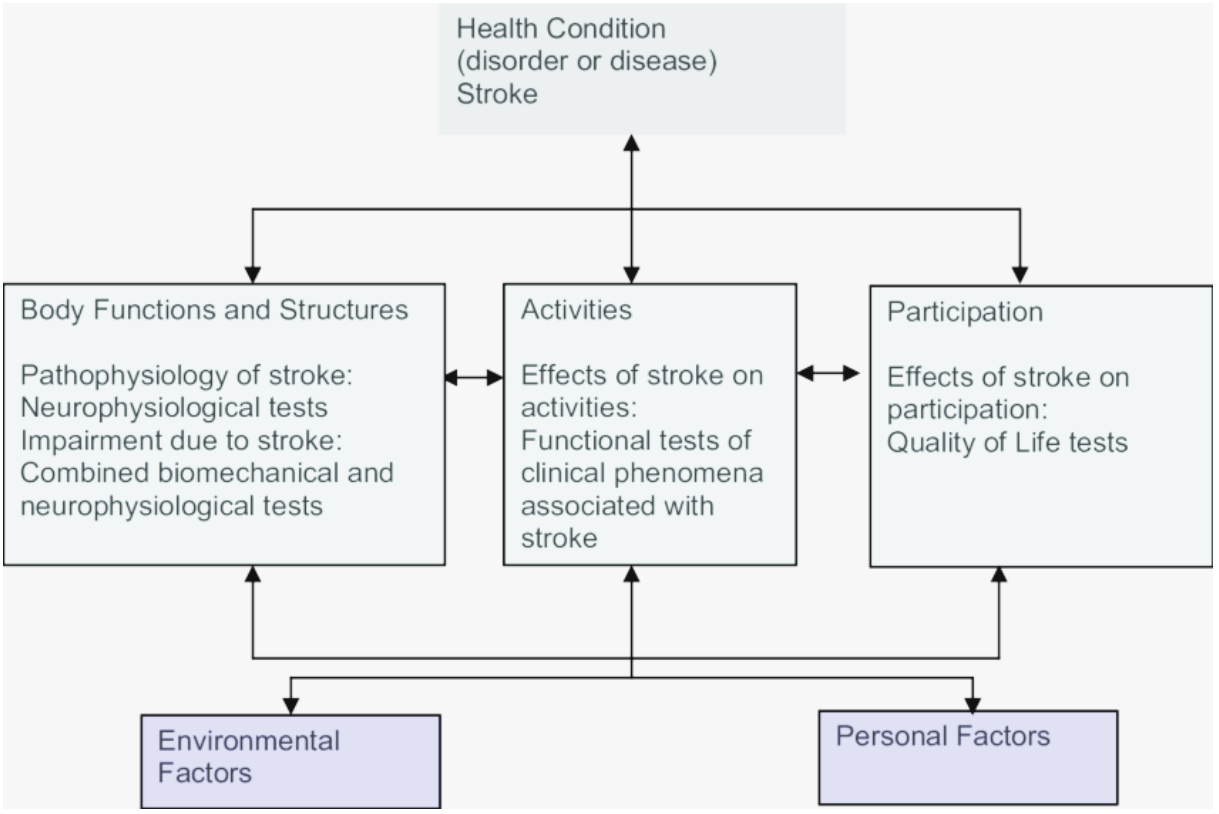


Figure 2.2 The ICF framework applied to stroke (Hughes 2009)

ICF Core Sets have been developed, which are a selection of ICF categories specifically chosen for various health conditions, condition groups, and settings. These Core Sets facilitate a systematic and comprehensive description of functioning, which can be used for various purposes, including clinical practice and research. They include the Comprehensive and Brief ICF Core Sets for Stroke (Geyh et al. 2004), which have been validated globally with people living with stroke and HCPs specialising in stroke (Karlsson and Gustafsson 2022). They have been utilized in the development of evidence-based stroke care guidelines (Royal College of Physicians 2016); and in stroke research (Sumathipala et al. 2012; Tempest et al. 2012; Ganesh et al. 2017; Ezekiel et al. 2019; Perin et al. 2020; dos Santos et al. 2022). For example, Perin et al. (2020) employed the ICF Core Set for Stroke to identify the rehabilitation needs of younger patients with stroke (<65 years) compared with older patients with stroke (>65 years). Patient information was obtained, including stroke severity, post-stroke disability and HRQoL, and the data were linked to ICF categories. Older patients reported more problems relating to activities of daily living and

basic needs, whilst younger participants identified problems with regaining social roles and social participation. The authors concluded that the ICF Core Set for Stroke was a useful tool to identify the needs of different groups of patients with stroke and could guide a more person-centred approach to rehabilitation.

2.4.1 The impact of stroke on body functions and structures

The most common impact on body structures and functions is contralateral hemiparesis (partial paralysis) or hemiplegia (total paralysis), which can involve one side of the face, trunk, upper and lower limbs (Teasell and Hussein 2013). There may be neurological and medical complications, for example cerebral oedema; incontinence; problems with swallow (dysphagia), which can lead to fatal infections (Popović et al. 2013). The stroke can also affect vision (hemianopia), sensation, perception, cognition and communication (aphasia, dysarthria), and can cause fatigue and changes in mood, such as anxiety, depression or emotional lability (Barrett 2009; Teasell and Hussein 2013; Shewangizaw et al. 2023). These effects can be temporary, lasting a few houor days, depending on the amount of damage to cerebral tissue and provision of treatment to recanalise the affected area, such as thrombolysis or thrombectomy for ischaemic strokes (Wardlaw et al. 2014; Wartenberg et al. 2020); or craniotomy to reduce the cerebral oedema caused by haemorrhagic strokes (Chen et al. 2014). Effects may improve or stabilise over several weeks as the inflammatory response within the surrounding cells diminishes; or worsen if further damage to the cortical cells occurs due to reinfarction or expansion of the haematoma (Chen et al. 2014; Bustamente et al. 2016).

2.4.2 The impact of stroke on activity and participation

Effective participation in an activity requires the integrated function of the whole central nervous system, and if one area of the brain is damaged, the rest of the system is affected by the loss of input from the injured part, resulting in reduced ability, if not inability, to carry out a task (Teasell and Hussein 2013). The impact on the person can range from mild impairment to life changing disability, affecting their participation in daily occupations such as self-care, work, leisure,

social participation and roles within the family and community. Katzan et al.'s (2018a and 2018b) large retrospective cohort study of 2,181 participants, who had completed PROMs as part of their routine clinical care, found that people living with all types of stroke reported similar effects across multiple health domains (Katzan et al. 2018a). The most negatively affected were shown to be physical and executive functions, and satisfaction with social roles (Katzan et al. 2018b).

2.4.3 The influence of environmental and personal factors on activity and participation after a stroke

This was explored by Sumathipala et al. (2012) in their study of the long- term needs of people living with stroke. Semi-structured interviews were conducted with 35 participants between one and 11 years after stroke and thematic analysis of the interview data was carried out using the ICF core set for stroke as a conceptual framework (Geyh et al. 2004). Participants identified a range of environmental factors that facilitated their participation in activities after stroke, including social support; access to assistive equipment and home adaptations; rehabilitation after the stroke and on return to the community and attendance at local stroke clubs. Barriers included lack of suitable transport to access the community; lack of information on allowances and financial support; attitudes of other people, such as over-protective relatives and perceived stigma from neighbours, which prevented them going out, for example, if they used a walking aid. Personal factors included participants' past experiences with ill health, which some found helped them to cope with having a stroke- some felt lucky when comparing the effects of their stroke with others. Social position and personal attitudes were facilitating factors. For example, previous knowledge of the health care system helped participants to access services and many reported a strong determination to recover. The authors asserted that the ICF framework was useful to investigate how contextual factors impacted on functioning and participation; and to identify long-term needs relevant to people living with stroke. They concluded that future developments in stroke services should consider the range of environmental and personal factors that can influence how needs are perceived by people living with stroke.

2.4.4 The impact of Stroke on HRQoL

HRQoL is defined by the International Society for Quality Of Life research (ISOQOL) as the functional effect of a medical condition and /or therapy on a patient. It is subjective and multidimensional, encompassing physical and psychological domains, occupational function, and social interaction (ISOQOL 2012). This definition was supported in Bakas et al.'s (2012) systematic review of HRQoL models, with the addition of social and spiritual factors. Karimi and Brazier (2016) argued that the term HRQoL is used in the literature interchangeably with the terms 'health status' and 'quality of life', leading to uncertainty of the definition of the concept, which hinders research (Costa et al. 2021). Several models have been developed to clarify how HRQoL should be defined and measured (Bakas et al. 2012). The most reported is the Wilson and Cleary's (1995) Model of HRQoL, which combines biomedical and social science approaches and includes five domains – biological and physiological factors, symptoms status, functioning, general health perceptions and overall HRQoL (figure 2.3). The model proposes specific causal links between these health factors and their influence on HRQoL, with the acknowledgement that there may be reciprocal relationships between factors.

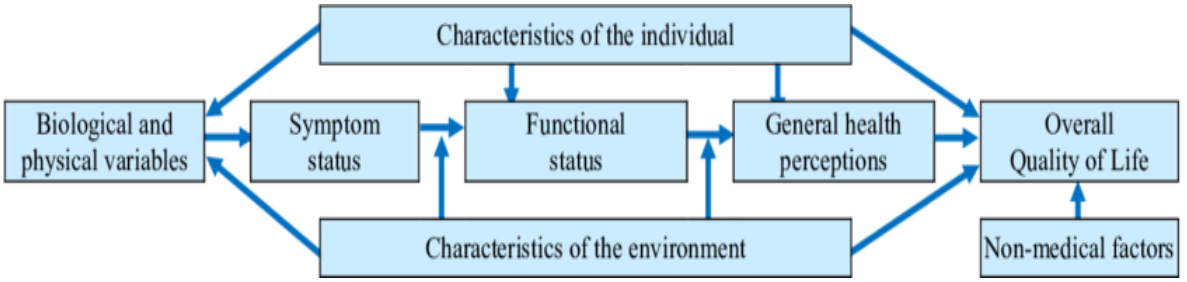


Figure 2.3. Wilson and Cleary HRQoL model (Robinson 2016)

Understanding the relationships among these factors can inform the design of effective clinical interventions (Ferrans et al. 2005) and help clinicians and policy makers to improve HRQoL outcomes in patients, for example, those living with long-term conditions such as stroke (Ojelabi et al. 2017). This model of HRQoL is particularly relevant to the inter-related, multi-dimensional effects of stroke on an individual and the impact on activities and participation as described by the ICF for stroke (Geyh et al. 2004) and an appropriate model to inform this study.

Post-stroke HRQoL can be defined as a holistic measure of a person's perceived physical, mental and social health following a stroke (Carod-Artal 2012), and encompasses subjective health status, life satisfaction and well-being (Donkor 2018). The impact of stroke on HRQoL over time has been explored by Alguren et al. (2012) in a study employing the ICF Core Set for Stroke and the generic EQ-5D PROM. It included a cohort of 99 patients from four stroke units based in Sweden, and their HRQoL was assessed during admission and at six weeks, three months, and one- year post-stroke, by self-completion of the EQ-5D Visual Analogue Scale (EQ-5D VAS). This is presented in a thermometer format, with 0 being the worst health state imaginable and 100 the best health state imaginable. At each time point, interviews were carried out with the patients by an HCP specialising in stroke, using an interview schedule based on the 155 categories of the ICF Core Set for Stroke (Geyh et al. 2004). Observations were also made by the HCP of any problems the interviewee had with, for example, mobility. The interview data and field notes were analysed and mapped to the ICF categories of Body Functions; Activities and Participation; and Environmental factors. Results showed that on admission, the respondents' mean EQ-5D VAS score was 50/100 and at one year post-stroke it had increased to 75/100, indicating an improvement in HRQoL. In the Body Functions category, impaired energy; sleep problems; balance problems; use of the affected limbs; and pain were rated by respondents as very important factors affecting HRQoL three months post-stroke. In the Activity and Participation category, limited capacity for learning; problems carrying out a task; difficulties with driving; and problems with participation in leisure activities were reported by respondents as central factors affecting HRQoL three months post-stroke. At one year post-stroke, HRQoL was reported to be less influenced by these categories, whilst elements in the Environmental Factors category were rated as more important. These included the provision of aids and equipment to facilitate mobility and activities of daily living and access to transport and healthcare services. Alguren et al. (2012) concluded that factors influencing HRQoL may vary over time after stroke and reflect changes in a person's standards, expectations and values, depending on their recovery.

The authors suggested that stroke rehabilitation should initially address elements in the Body Functions and Activities and Participation categories.

At a later stage in recovery, when the person has returned to living in the community, adjustment of elements in the Environmental Factors category can greatly contribute to improved HRQoL in the person living with stroke over the long- term.

These findings are consistent with studies of the neurological process of recovery through neuroplasticity that can be influenced by rehabilitation (Allred et al. 2014; Carey et al. 2019). However, it is reported that after three months spontaneous neurological recovery diminishes (Joy and Carmichael 2020) and potential for further motor and functional recovery declines. Clinically, a more compensatory approach may then be indicated to enable the person with stroke to manage the long-term effects of the stroke and optimise their HRQoL. Alguren et al.'s (2012) study is an example of how the use of a PROM can inform stroke service provision along the stroke care continuum.

2.5 The use of PROMs to assess post-stroke HRQoL

Post-stroke HRQoL can be measured using generic and stroke-specific PROMs, usually self-administered by the person living with stroke (Reeves et al. 2018), or by an advocate (Salinas et al. 2016; Lapin et al. 2021a,2021b). Generic PROMs, such as the EQ-5D, are useful for comparing patients' HRQoL across different health conditions to evaluate healthcare provision and equity of service delivery (Black 2013). Generic scales have some limitations in stroke, including a limited content validity because specific stroke impairments that are relevant to stroke patients may not be covered (hemiparesis, vision, language, concentration and memory), and limited value in assessing stroke interventions, owing to their lack of responsiveness to change in HRQoL (Carod-Artal and Egido 2009). Condition-specific PROMs capture elements of health relevant to a particular patient group or condition (Churruca et al. 2021), and changes in specific aspects of HRQoL can be better assessed using condition-specific PROMs, particularly when used at the patient-clinician level of healthcare (Al Sayah et al. 2021).

PROMs have been used in studies investigating post-stroke HRQoL across various countries and cultural perspectives worldwide, providing a global

representation of the concept (Ayis et al. 2015; Khalid et al. 2016; Wang and Langhammer 2018). Post-stroke HRQoL has also been investigated using PROMs in relation to types of stroke (Katzan et al. 2018a); stroke severity (Ramos-Lima et al. 2018); recovery after a stroke (Skoglund et al. 2019); and the long-term impact of stroke (Crichton et al. 2016; De Wit et al. 2017; Mandic et al. 2018).

Factors that influence or may predict post-stroke HRQoL have also been explored, such as clinical and sociodemographic factors (Tsalta-Mladenov et al. 2021); psychological factors (Van Mierlo et al. 2014), including anxiety (Tang et al. 2013) and depression (Oni et al. 2018; Gall et al. 2018); fatigue (Ramirez-Moreno et al. 2019; Aarnes et al. 2020); social factors, such as social participation (Chou et al. 2015); and treatment in the hyperacute phase post-stroke such as thrombolysis (Grabowska-Fudala et al. 2017) and thrombectomy (Deb-Chatterji et al. 2020).

Generic and stroke-specific PROMs have been used to compare the HRQoL in people living with stroke to people without stroke in cross-sectional studies (Haley et al. 2011; Pinkney et al. 2017). For example, Pinkney et al.'s (2017) study compared the HRQoL of people living with stroke and apparently healthy adults based in Jamaica. The sample included 50 adults living in the community between 16-28 months after a mild to severe stroke and 50 healthy adults of similar age (mean age 60 years), ethnicity, co-morbidities and socio-economic backgrounds. The 108 item Health-Related Quality of Life in Stroke Patients (HRQOLISP) PROM was administered to patients face-to-face or by phone. Analysis of the PROM data showed that the HRQoL in people living with stroke was markedly worse than that of the apparently healthy group, across physical, cognitive, psycho-emotional and social interaction domains.

2.5.1 Post-stroke HRQoL across socio-economic and cultural variations

PROMs have been used to compare HRQoL in people living with stroke across high income countries (HICs) in Europe (Ayis et al. 2015), and across low-and-middle income countries (LMICs) (Khalid et al. 2016). Ayis et al. (2015) used the generic Short-Form Health Survey (SFHS), to assess HRQoL in patients with stroke across five regions in Europe. They found wide variations in self-reported

HRQoL-for example, post-stroke HRQoL was much higher in Italy and lower in France as compared to England, whilst there was no difference between England and Poland. These variations could not be explained by stroke severity or socio-demographic factors, and the authors recommended further research to examine other factors that may influence stroke outcomes.

There are few studies of post-stroke HRQoL in people living with stroke in LMICs, which bear two thirds of the global stroke burden (Feigin et al. 2022). Khalid et al.'s (2016) sequential mixed methods study, based in Pakistan, explored the HRQoL in people living with stroke and their care givers. The HRQoL of 350 patients attending two out-patient stroke clinics in Karachi, Pakistan, was assessed using the validated Stroke Specific Quality of Life Scale (SSQoLS), which has a total score of 245, with a higher score indicating better HRQOL. Results showed that the patients reported a mean SSQoLS score of 164 out of a total score of 245. The authors compared their findings with those from studies in other LMICs, including Brazil (139/245) (Rangel et al. 2013); and S.E. Nigeria (156/245) (Akosile et al. 2013), which employed the same PROM. They concluded that, whilst the HRQoL in people living with stroke in Pakistan, was higher than in those living in other LMICs, it was still adversely affected.

Owolabi's (2013) study aimed to identify determinants of post-stroke HRQoL across diverse cultures. The Health-Related Quality of Life In Stroke Patients (HRQOLISP) PROM was used to measure the HRQoL in participants from two settings-Nigeria, a LMIC and Germany, a HIC. The study found that, regardless of socio-economic status or culture, the key predictors of post-stroke HRQoL were stroke severity, level of disability, emotional well-being and sense of purpose in life. Similar findings were reported in Wang and Langhammer's (2018) literature review of Chinese and Western studies of post-stroke HRQoL (n=43), which found that most of the factors that influenced HRQoL were the same in both cultures. For example, poor physical function, impaired cognitive function and depression/anxiety were negatively related to HRQoL after stroke in both Chinese and Western countries. Higher age, female gender, lower education level and lower socioeconomic status also tended to fit with poorer HRQoL. Those with better social support, social participation and positive self-perception were reported to have higher HRQoL, independent of culture.

These global studies demonstrate that, regardless of location, socio-economic status or culture, the negative impact of stroke on HRQoL is consistent. They also illustrate

how the use of PROMs can inform strategies for stroke care at a worldwide level, such as the World Stroke Organisation's global stroke guidelines and quality action plan (Lindsay et al. 2014).

2.5.2 Long-term impact of stroke on HRQoL

The long-term impact of stroke on HRQoL has been explored using PROMs in several studies ranging from 3-15 years post-stroke (Haley et al. 2011; Crichton et al. 2016; De Wit et al. 2017; Rudberg et al. 2018; Skoglund et al. 2019). Crichton et al. (2016) carried out a population-based cohort study using data collected from the South London Stroke Register, which follows up people admitted with a stroke on an annual basis. Outcome measures include the SF-12, a generic HRQoL measure, that has been validated in people living with stroke (Okonkwo et al. 2010). Information on HRQoL was extracted from the data for people admitted with stroke between1995-2003 (n=2626) who were still alive 10 years (n= 723) and 15 years (n=262) after their stroke. Analysis of the SF-12 scores showed that people living 15 years after their stroke reported poorer physical than mental aspects of HRQOL, with a mean SF-12 physical component score of 35/100 and mental component score of 44/100. Both scores were lower than the population norm mean score of 50/100, indicating a worse overall HRQoL than people of matched age and gender, who had not had a stroke. The authors advised that, as more people are surviving stroke, the focus of research and service improvement should include addressing the long-term problems faced by people living with stroke.

De Wit et al.'s (2017) study examined the HRQoL with a cohort of people living five years after a stroke in four European countries-Belgium, UK, Switzerland and Germany. Participants (n=532) were recruited on admission to four stroke rehabilitation units with first-ever stroke, aged between 40 and 85 years, with at least minimal motor impairment. The participants took part in a study of rehabilitation in stroke across Europe, the CERISE study (De Wit et al. 2007), which followed them up at five years after stroke to assess various outcomes. The primary outcome measure in the study was the generic EQ-5D, that includes a visual analogue scale (EQ-VAS). The mean EQ-VAS scores were compared against each country's population norm to ascertain the level of

HRQoL in people living with stroke, compared to those of matched age and gender without stroke. Results showed that participants reported a mean EQ-VAS score of 64/100 with large variability (SD=19). Interestingly, 8% of participants scored above the population norm, 52% scored on the norm and 40% scored below the norm for HRQoL. The authors suggested that the 8% who scored above the population norm may have adapted to their situation post-stroke, which the authors referred to as a "response shift" in their scoring of the PROM (De Wit et al. 2017 p1439). It was also suggested that perceived improvement in HRQoL could be ascribed to the disability paradox (Albrecht and Devlieger 1999), when people with severe disease may not rate their HRQoL as low as people with mild disease or in full health. The study found a large variability in the impact of stroke on HRQoL that could only be partially explained by factors such as anxiety and depression and functional impairment. Other studies have reported that self-reported HRQoL after a stroke can improve over time, although it is noted that the studies took place over a period of one month to a year, which is relatively short when compared to the studies referred to above. For example, Mandic et al.'s (2018) study used the generic SF-36 PROM to assess the HRQoL of 136 people living with stroke at one and six months after the event. Results showed a continual improvement in all HRQoL domains, from admission to one month, and at six months. A strong correlation was found between improved functional status and improved HRQoL, particularly in the physical functioning, emotional role, and mental and general health domains. Improvements in motor function and cognition were also significantly associated with improved HRQoL. Whether this was a result of rehabilitation cannot be determined, as it was reported that only 136 of the initial sample of 216 participants received in-patient rehabilitation, which could be considered a limitation of the study.

Correspondingly, Yeoh et al.'s (2019) study of post-stroke HRQoL over a twelve- month period, analysed EQ-5D PROM data collected in the nationwide Singapore Stroke Study. Data analysis showed that at three months post-stroke, there was a self-reported decrease in HRQoL of 30% compared to pre-stroke levels (this finding may have been confounded by participant recall bias and that the EQ-5D was not designed to be used in retrospect). This level rose to a comparative 10% decrease in HRQoL at 12 months. The participants reported a

lower HRQoL than the general Singapore population by 35% at three months but this improved to 19% at one year. Results indicated that, although lower than the populations norms, the perceived HRQoL of the people living with stroke did improve over time. Yeoh et al. (2019) suggested that the perceived improvement in post-stroke HRQoL could be due to the individual's adaptation to the impact of the stroke or changed expectations of quality of life after the stroke, which was also reported as response shift in De Wit et al.'s (2017) study.

2.5.3 Determinants of post-stroke HRQoL

Chou et al. (2015) carried out a cross- sectional study of HRQoL in 134 people living with stroke six months after the event, using the Stroke Impact Scale (SIS), to identify the determinants of post-stroke HRQoL. Five categories were explored, including clinical; sociodemographic; symptom severity; and physical, cognitive and psychosocial factors. Analysis of the PROM responses were mapped to these categories and results showed that the levels of HRQoL were significantly impacted by what the authors referred to as psycho-social factors, specifically social participation, followed by symptom severity and physical factors.

The influence of social participation was also identified in Vincent-Onabajo et al.'s (2015) study of 55 individuals living with stroke. Their HRQoL was measured at one month, three months, six months and at one year using the stroke-specific HRQOLISP PROM, and the results indicated that motor function, functional activity and participation influenced HRQoL. The type of stroke, sex or marital status had no significant association with HRQoL, whilst social participation was the most consistent correlating factor over the 12 months after stroke.

Van Mierlo et al.'s (2014) systematic review examined the relationship between psychological factors and HRQoL after stroke. Nine studies were found, all of which used PROMs to identify determinant factors including personality; coping; internal locus of control; self-esteem; hope; and optimism. Personality traits such as neuroticism and pessimism, were moderately associated with poorer HRQL (r = 0.26–0.49), whilst coping; internal locus of control; self-worth; hope and optimism were moderately positively associated with HRQoL (r = 0.026–0.81). The authors recommended that clinicians should consider the relationship

between psychological factors and HRQoL, as well as physical functioning, when planning interventions for people recovering from a stroke.

HRQoL can be negatively affected by post-stroke anxiety and depression (De Wit et al. 2017; Khalid et al. 2016, Gall et al. 2018). Tang et al. (2013) used the stroke -specific SSQOL scale to explore the impact of post-stroke anxiety on HRQOL in a cohort of 374 patients three months after their stroke. Anxiety was assessed using the Hospital Anxiety and Depression Scale (HADS) (Zigmond and Snaith 1983). The study found that 86 (23%) patients with stroke reported anxiety (a score of >8 on the HADS) and they rated a lower SSQOL score than those without anxiety. Multivariate regression analysis showed that the HADS score was negatively associated with the SSQOL total score (r = -0.154). The authors suggested that the severity of post-stroke anxiety is associated with poor HRQoL in the domains of personality, mood, energy, thinking and work performance, independent of depression, and cognitive or physical functioning. Kim et al. (2018) studied the longitudinal effects of post-stroke depression on HRQoL in a cohort of 423 patients 2 weeks after stroke, and 288 (68%) were followed up twelve months later. Depression was diagnosed according to Diagnostic and Statistical Manual of Mental Disorders-IV criteria, and HRQoL was assessed using the World Health Organization Quality of Life-Abbreviated form (WHOQOL-BREF). The longitudinal associations of post-stroke depression at baseline with HRQoL across two evaluation points were assessed using a repeated-measures analysis of variance. Results showed that the WHOQOL-BREF scores were significantly and persistently lower one year post-stroke in patients with depression, compared with those without depression at baseline, independent of demographic and clinical characteristics, including stroke severity. The authors concluded that depression in the acute phase of stroke is an independent predictor of HRQoL in both the acute and long-term phases after stroke, highlighting the importance of evaluating depression in the acute phase of stroke. Similar conclusions were reached in Khedr et al.'s (2020) study, which compared the frequency of depression, as measured by the Hamilton depression rating scale (Hamilton 1960), in a cohort of 103 people living with stroke with 50 matched healthy adults. The HRQoL in stroke patients with and without depression was then assessed using the generic WHOQOL-BREF scale. The study showed that

37% of the patients with stroke had depression, compared to 12% in the control group. Physical, psychological and social domains of HRQoL were significantly worse among stroke patients with depression than in stroke patients without depression. The authors suggested that comprehensive evaluation and management of post-stroke depression could improve the impact of stroke on HRQoL.

Post-stroke fatigue, often described in terms of extreme and persistent tiredness, weakness or exhaustion that is not traceable to previous experiences of fatigue, is another factor that influences HRQoL early in recovery and in the long-term after a stroke. Vincent-Onabajo et al.'s (2014) study used the Fatigue Severity Scale (Krupp 1988) and the stroke specific HRQOLISP-26 to identify the impact of fatigue on HRQoL in a sample of 100 patients 12 months post-stroke. Data analysis found that a higher level of post-stroke fatigue correlated with poorer HRQoL, regardless of a person's age, marital status, gender, pre-stroke employment status or whether they had a first-time or recurrent stroke. Similar results were found in Ramirez-Moreno et al.'s (2019) study, which used the EQ-5D-5L and the Fatigue Assessment Scale (FAS), to explore the short-term effects of fatigue on post-stroke HRQoL in 92 patients with TIA/minor stroke three months post-event. The FAS showed a strong negative correlation score with the EQ-5D-5L index ($r = -.480$; $P < 0.0001$), and higher levels of mental and physical fatigue were associated with lower EQ-5D-5L index ($r = -.376$; $P < .001$ and $r = -.497$; $P < .001$, respectively. The authors suggested that the results may be indicative of the profound impact of fatigue on HRQOL post-stroke and that addressing fatigue may lead to improving stroke patients' HRQoL.

The differences in post-stroke HRQoL between males and females were identified in Gall et al.'s (2018) systematic review of studies from 2007-2017 that investigated the sex differences in HRQoL after stroke. The review found 13 suitable studies, which all used generic or stroke specific PROMs to measure the HRQoL in people living at least one-year post-stroke. The studies showed that females reported poorer HRQoL than males, after accounting for a range of covariates, with associative factors of post-stroke depression, age, greater stroke severity and poorer health at the time of the stroke. Similar results were found in Phan et al.'s (2019) study, which aimed to quantify the sex differences

in HRQoL in people living up to five years post-stroke. The PROM data from four population-based studies carried out in different countries (n=4228) were analysed. Generally, females reported poorer HRQoL than males, specifically in the sub-domains of independent living, social relationships, physical functioning, vitality, mental health and psychological well-being. The main associative factors to poorer HRQoL included advanced age, stroke severity, pre-stroke functional limitations and post-stroke mood disorder.

HRQoL after stroke may be influenced by treatment provided in the hyperacute phase post-stroke, for example thrombolysis, an intervention that is known to have beneficial clinical post-stroke outcomes (Wardlaw et al. 2014). Grabowska-Fudala et al. (2017) used the SSQoLS, to measure the HRQoL 12 months post-stroke in 53 individuals who had received thrombolysis. On analysis, the SSQoLS mean score was high at 147 points along the theoretical range of the scale (49–245). The study found that 80% of participants reported an acceptable level of HRQoL, which, it was suggested, may be associated with the thrombolysis intervention. However, 20% reported a poor HRQoL, despite having good neurological and functional status, as assessed by the National Institutes of Health Stroke Scale (Brott et al.1989) and the Barthel Index (Mahoney and Barthel 1965). The authors suggested this could be due to the complex, individualistic nature of post-stroke recovery. They acknowledged that the small sample number was a limitation to the study, as was a lack of control group who had not received thrombolysis, so no association could be made between thrombolysis and the positive outcomes reported by 80% of the participants in the study.

In conclusion, the findings of these studies illustrate the complexity of post-stroke HRQoL and the myriad of factors that can influence it. They also demonstrate the use of PROMs to measure HRQoL in individuals with stroke and to provide valuable information for researchers, clinicians and stroke service providers.

2.6 Current provision of evidence-based stroke care in the UK

As this current study was carried out in Wales, UK, it was useful to ascertain the provision of evidence-based stroke care in this region, which is underpinned by the UK national clinical guideline for stroke (Royal College of Physicians 2016)

and measured by the Sentinel Stroke National Audit Programme (SSNAP). The annual SSNAP report for 2021-2022, when this study was conducted, provides statistical information on the attainment of performance targets in stroke services across the UK and recommendations for further improvement. Currently, 182 acute stroke services are included in the audit – 158 in England, 15 in Wales, 8 in Northern Ireland, and one in the Isle of Man. During 2021-2022, 89,000 patients were admitted to these services (SSNAP 2022). National attainment of SSNAP targets across the stroke care continuum is outlined as follows:

Pre-admission to hospital: Stroke is considered a medical emergency (Norrving et al. 2018) and early recognition of the signs of a stroke, using the public health campaign FAST test (Face, Arm, Speech, Time to call 999), has been widely publicised in the UK, with some success (Hickey et al. 2018). The median time from stroke onset to hospital admission is 3 hours and 53 minutes. Once the ambulance service has been called, the mean time to admission is 73 minutes. Some hospitals are now using pre-alert systems by phone (26%) or video (4%), to alert stroke teams of a potential stroke admission to reduce delays (SSNAP 2022).

Admission to hospital: The proportion of patients who receive urgent brain imaging within one hour of admission is 54.8%, which is necessary before a patient can receive reperfusion treatment (SSNAP 2022). Thrombolysis is an established intravenous treatment that needs to be carried out within 4 hours of stroke onset and requires a CT scan to establish that the stroke is ischaemic not haemorrhagic. Thrombolysis breaks down the clot and is shown to reduce the risk of death and dependency (Wardlaw et al. 2014). The proportion of patients who receive thrombolysis is 10.4% and the door to needle time is 53 minutes. Thrombectomy (mechanical clot retrieval) increases the chance of survival with a good functional outcome (Roaldsen et al. 2021) but is currently only carried out in 2.4% of patients (SSNAP 2022). There are 26 specialist centres that carry out this procedure-24 in England, one in Wales and one in NI and 50% of patients are referred from hyper-acute stroke units (SSNAP 2022).

Patients with haemorrhagic stroke receive emergency treatment to reduce bleeding and damage to the brain tissue caused by cerebral oedema. This can include surgical procedures such as a craniotomy to relieve intracerebral

pressure or coiling to plug the bleed. The mortality rate of hospitalized patients with haemorrhagic strokes has fallen from 33% in 2013 to 22% in 2022 (SSNAP 2022).

Admission to a specialist stroke unit: The proportion of patients admitted to a Hyperacute Stroke Unit (HASU) within four hours of stroke onset is 51.5%. (SSNAP 2022). Specialist assessments should be carried out by the stroke consultant, stroke specialist nurse and therapists within the first 24 hours. The median time of assessment by a stroke consultant is currently 9 hours and 53 minutes and the median time for a specialist nurse assessment is 48 minutes. Once medically stable, the patient is transferred to an acute stroke unit (ASU), which may be co-located with the HASU and staffed by the same multidisciplinary team (MDT) specialising in stroke. The team should include stroke specialists in medicine; nursing; occupational therapy; physiotherapy; speech and language therapy; clinical psychology; dietetics; orthoptics and access to a social work team (Royal College of Physicians 2016). Care provided in ASUs reduces mortality and improves clinical outcomes (Stroke Unit Triallists' Collaboration 2013). A Cochrane review (Langhorne et al. 2020) reported that people who received organised stroke unit care were more likely to be alive, living at home and independent in daily activities a year after their stroke. Currently, the proportion of patients who spend more than 90% of their admission on a stroke unit is 82.4% (SSNAP 2022).

In-patient rehabilitation: This is provided by a stroke specialist MDT in a co-located stroke unit or designated stroke units in hospitals within the stroke patient's locality. Rehabilitation aims to maximize neurological, motor, cognitive, and functional recovery to reduce impairments and, when necessary, teach the patient adaptive approaches to manage the disabling effects of the stroke on return to the community (Teasell and Hussein 2016). It also includes complex discharge planning involving the patient, family and community-based care services, depending on the patient's level of recovery and discharge destination. Rehabilitation should be carried out seven days a week and currently 42% of sites meet this standard (SSNAP 2022). The percentage of days patients receive OT is 60.6%; PT is 68.3%; SLT is 48%; and clinical psychology is 10.2%. The percentage of patients receiving the national clinical guideline for stroke standard of 45 minutes therapy by OT is 30.7%, PT is 28.7% and SLT is 16.3%. (SSNAP 2022).

These figures reflect the shortages in staffing provision, or lack of commissioning, in these services, which are consequently unable to meet the evidence-based practice standards (Gittins et al. 2020).

Community-based rehabilitation: Stroke rehabilitation is increasingly being provided in the person's home to enable earlier discharge from a stroke unit (Langhorne et al. 2017) and can be provided for up to 12 weeks post-discharge. These services are provided by stroke specialist teams and are particularly beneficial for patients with mild to moderate stroke (Fisher et al. 2016). Early supported discharge has been shown to reduce long-term dependency, admission to institutional care and can reduce the length of hospital stay by up to six days (Langhorne et al. 2017). The proportion of patients discharged to a Community Stroke Rehabilitation Service has increased to 60%, and 26% of teams now provide a seven-day service (SSNAP 2022). Vocational rehabilitation for people who wish to return to work after their stroke is recommended in clinical guidelines for stroke (RCP 2016). However, availability of services is inconsistent (Leary et al. 2020) and more evidence is required to confirm its effectiveness (Brouns et al. 2019).

Life After Stroke: The UK national clinical guideline for stroke (RCP 2016) recommends that people living with stroke should have a post-stroke review at six months of their physical and psychological condition, as well as their social environment, to identify whether further interventions are required. The proportion of patients with stroke having a review has increased from 20% in 2013 to 42% in 2022, with the majority of reviews being carried out by phone (72%) (SSNAP 2022).

The SSNAP report acknowledges a slight decrease in target attainment in 2021-2022 due to the negative impact of the COVID-19 pandemic on the workforce and emergency pressures on hospital beds and services. However, although stroke services have improved since the SSNAP began in 2013, they still fall short of the required standards of care and need to improve (Rudd et al. 2018).

2.7 Measurement and quality improvement of stroke care in the U.K.

The provision of stroke care is reported and measured in many countries worldwide, in population-based registers, such as the Swedish Riksstroke stroke register (Asplund et al. 2011), the American Heart Association's Get With The

Guidelines- Stroke Registry (Ormseth et al. 2017), the South London Stroke Register (Wolfe and Rudd 2014; Clery et al. 2020); and national audits, such as the National Stroke Audit in Australia; and the SSNAP and Scottish Stroke Care Audit in the UK. These tools provide a wealth of statistical information on the epidemiology of stroke; provision of care along the stroke care continuum; compliance to performance targets based on evidence based clinical guidelines, and regional variations of processes of care and clinical outcomes (Rudd et al. 2018). They can be used to benchmark services for quality improvement purposes; provide information on service improvements over time and identify aspects of care that need to be improved.

In the UK, the information provided by the SSNAP has underpinned quality improvement strategies, such as the NHS Long Term Plan for Stroke published in 2019 (NHS 2019). The plan includes a National Stroke Service Model implemented from 2021 by Integrated Stroke Delivery Networks across England. In Wales, the Quality Statement for Stroke was published in 2021(Welsh Government 2021) and a National Stroke Programme is being developed to optimise stroke care pathways in Wales.

The involvement of people living with stroke in the measurement and quality improvement of stroke care in the UK is still evolving. The national clinical guideline for stroke (Royal College of Physicians 2016) aimed to be more person-centred in its focus, and one of its key recommendations was that the views of people with stroke and their families should be sought when evaluating service quality and when planning service developments. The challenges in obtaining information on people's experiences and outcomes of stroke care was acknowledged and the guideline recommended that the use of validated PROMs would be a valuable method that needed to be invested in and tested (Rudd et al. 2018).

Recently, the SSNAP has acknowledged the importance of measuring the impact of stroke on people living with stroke in the longer term, to highlight the needs of patients and families, and to assess the effects of stroke care interventions on service users. In 2021, the SSNAP included the administration of the EQ-5D-5L, a generic PROM, at patients' six-month post-stroke clinical review, which is a move towards a more collaborative approach to service evaluation. However, only 38% of patients currently receive a review (SSNAP

2022), which may limit the generalisability of analysis findings of the PROM data to the whole stroke population.

2.8 The use of PROMs in stroke research, clinical practice and service improvement

As the number of people surviving stroke is increasing (Donkor 2018; Feigin et al. 2022; King et al. 2020), PROMs are being recognized as a valuable tool to complement clinician-reported patient outcomes of stroke interventions in stroke research, clinical practice and performance measurement in stroke care (Greenhalgh et al. 2017; Katzan et al. 2017; Reeves et al. 2018).

2.8.1 The use of PROMs in stroke research

As illustrated earlier in this chapter, the findings of studies using PROMs to measure HRQoL after stroke provide useful information for the provision of person-centred care, relevant rehabilitation, and tailored services to meet individuals' needs at different stages of stroke recovery (Alguren et al. 2011; Reeves et al. 2018). Stroke specific PROMs can provide more sensitive data of specific relevance to people living with stroke than clinician-reported measures, such as the ICF stroke core set, Barthel Scale or modified Rankin Scale (mRS), which measure post-stroke disability (Sangha et al. 2015; Katzan et al. 2017). Paanalahti et al.'s (2019) study compared the ICF core set for stroke with the patient-reported Stroke Impact Scale (SIS). The cross-sectional study of 242 participants with stroke examined whether the ICF core set included problems that were relevant to people living with stroke as reported using the SIS. The agreement between the perceived problems in the SIS items and problems in the categories of the ICF comprehensive core set for stroke were analysed using percentage of agreement and Kappa statistic. The study found moderate agreement between SIS and ICF ratings in problems with mobility (kappa = 0.27-0.48), activities of daily living (kappa = 0.26-0.59), hand function (kappa = 0.41-0.51) and strength (kappa = 0.45). There was small or medium agreement between the SIS and ICF ratings relating to emotion (kappa = 0.14-0.21) and communication (kappa = 0.33- 0.37). The study concluded that the use of the ICF core set by HCPs could identify the physical aspects of functioning after

stroke but was less effective at capturing the perceived importance of the impact of a stroke on emotional or social participation, which could be identified by using the SIS. This study highlights the value of using PROMs to complement clinician reported measures to give a deeper insight into the impact of stroke and guide person-centred stroke services.

A recent systematic review of the use of Patient Reported Outcome Measures Information System outcome measures (PROMIS) (Cella et al. 2010) in clinical stroke studies (Arwert et al. 2022), identified 27 studies, nine of which used the PROMIS-10, the main component of the PROMIS-15 being evaluated in this current study. The authors concluded that the recommendation from ICHOM to employ the PROMIS-10 in stroke research was supported and that future studies on stroke outcomes should follow international guidelines such as the ICHOM standard set for stroke (Salinas et al. 2016).

Due to the diverse impairments that can be caused by a stroke, condition - specific PROMs have been developed for use with people who have impairments that might impact on their ability to complete more generic self-reported measures (Patchick et al. 2016; Swinburn et al. 2019).
Patchick et al. (2016) developed and evaluated the psychometric properties of a PROM for people with a cognitive impairment, to evaluate the outcomes of cognitive rehabilitation. The PROM was developed in collaboration with patients with stroke, who had cognitive difficulties, and their informal carers. Psychometric analysis was carried out on the responses to the PROM from 159 (97%) patients and they were asked for their views on the coverage and acceptability of the PROM following completion. Results showed that the PROM showed good acceptability and reliability in the target group and was a valid tool to measure the perceived impact of cognitive problems on a person's skills, life, mood and sense of self.
Swinburn et al. (2019) developed and validated a PROM to measure the impact of aphasia (language impairment) on the HRQoL of individuals with this post-stroke impairment. The PROM was developed with people with aphasia using interviews with communication support, and validation of the prototype was carried out, including assessment of concurrent validity, internal consistency and responsiveness. The authors acknowledged limitations of the study, including the different participant samples used for the psychometric evaluation,

which caused complexity when analysing and reporting the results. They concluded that the PROM had potential to be one of a core set of aphasia tests for clinical and research use.

The feasibility of administering a set of PROMS to patients with stroke was evaluated by Groeneveld et al. (2019). Participants were recruited from an in-patient and out-patient rehabilitation facility in the Netherlands and six different PROMs were administered on admission, discharge, and at three, six and twelve months. Analysis of the responses to the PROMs showed clinical improvements over twelve months, except for two measures, which were then excluded from future use. The authors reasoned that the set of PROMs selected for the study corresponded in content to those recommended in the ICHOM standard set of stroke outcome measures (Salinas et al. 2016). However, one could suggest that, in comparison to the PROM-15 recommended in the standard set, the completion of four questionnaires may lead to a degree of cognitive overload for a person who has had a stroke, particularly in the early stages of recovery, or who has post-stroke impairments. This could result in respondent fatigue, affecting their responses to the PROMs and potentially distort the results of the study. Feasibility was assessed by participation, retention and response rates to the questionnaires, with reported moderate to good results. The study also identified that more than half of the participants preferred postal, rather than on-line, questionnaires.

Similar findings were reported in a study to identify the preferred mode of administration of the PROM-15 to people living with stroke in England and Wales (Hewitt et al. 2019). The PROM-15 was administered to a cohort of 2074 patients living in the community six months after a stroke, using four administration methods. These included face-to-face, phone, postal and on-line methods. The postal method had the most responses (22%), and the electronic method had the least (9%), regardless of age, stroke type or severity. The conclusion to the study was that the use of on-line assessments should be carefully considered and that a choice of alternative methods may be more effective to achieve a good response rate.

2.8.2 The use of PROMs in stroke clinical practice

Currently, there is little evidence of the use of PROMs with patients with stroke in the clinical setting. Katzan et al.'s (2017) large study with 3,283 patients with stroke attending out-patient clinics over a period of one year, determined the potential benefits of using PROMs, including the SIS-16, EQ-5D, PHQ-9, PROMIS Physical Function, and PROMIS fatigue measure, compared to only using clinician-reported measures, such as the mRS (van Swieten et al.1988). Patient-and clinician-reported scales were completed at the clinics as part of routine care. The information obtained from the PROMs and the clinician-reported measure was compared, and it was found that the use of a PROM provided valuable insight into stroke patients' HRQoL that was not captured by the clinical measure alone. Katzan et al. (2017) reasoned that, as the mRS is not self-reported, it may not accurately reflect the perspectives of people living with stroke. Furthermore, it does not assess domains such as pain or fatigue, which are known to be factors that impact on HRQoL after stroke and can be measured using PROMs. The authors concluded that PROMS could be a useful adjunct to clinician-reported measures to assess post-stroke recovery in clinical practice.

Katzan et al.'s study correlated with a more recent study by Lens et al. (2021), that collected PROM data using the PROMIS v2.1-Profile-57 questionnaire completed by a cohort of 102 patients with stroke attending an out-patient clinic, three months after their stroke. The PROM data was compared with the patients' mRS scores completed by the HCPs treating them, and the authors identified correlations between the mRS and PROMIS health domains. However, the strength of the correlations varied by domain, suggesting that not all health domains were fully captured by the mRS. The authors concluded that the PROM better reflected the overall health status of stroke patients beyond functional outcome measured by the mRS and should be used with patients to enable individualised care that covers all the health domains affected by stroke.

Lebherz et al.'s (2022) study aimed to evaluate the implementation of the ICHOM Standard Set for Stroke (ICHOM-SSS) (Salinas et al. 2016), which includes the PROM-15 under study in this thesis, into routine care of patients with stroke. The ICHOM-SSS was administered in a stroke unit during and after inpatient care. Semi-structured interviews with HCPs (n = 5) and patients or their

proxies (n=19) about their experiences of completing the measure were recorded and analysed using thematic analysis. Patients perceived the ICHOM-SSS to be relevant and feasible and the overall acceptance of using the PROM was high. The HCPs perceived the Standard Set to be appropriate but reported negative views on feasibility, sustainability and implementation. The authors concluded that implementation of PROMs in clinical practice requires IT support and additional clinical resources to be viable.

The limited evidence of the use of PROMs in stroke clinical practice indicates that this area of stroke care still needs to be developed (Reeves et al. 2018), particularly as there are reported benefits in promoting person-centred care, improving patient-clinician communication, and facilitating clinicians' decision-making (Boyce et al. 2014; Porter et al 2015; Nelson et al. 2015; Greenhalgh et al. 2018; Field et al. 2019).

2.8.3 The use of PROMs in the evaluation and quality improvement of stroke care

The use of PROMs to inform the evaluation of and quality improvement in stroke care at all levels is increasing (Salinas et al. 2016; Katzan et al. 2017; Reeves et al. 2018). Reeves et al.'s (2018) comprehensive review described the rationale for the development and implementation of PROMs in stroke care and research and discussed the application of stroke PROMs to clinical practice and improvements in the quality of stroke care. The authors provided an inventory of PROMs used with people living with stroke. It includes five generic measures- the EQ-5D; the GHQ-28; the SF-36; the NeuroQOL and the PROMIS10; and four stroke specific measures – the SSQOLS; the SIS; the SA-SIP30 and the SATIS-Stroke (see page ix of this thesis for a list of PROMs abbreviations). The inventory details the focus of the measure, the time taken to administer it and which aspects of HRQoL are assessed by each measure ie. physical; cognitive; social; role; depression; psychological; mental health; pain; fatigue and other domains. Reeves et al.'s (2018) review concluded that further information on the psychometric properties of PROMs used in stroke is needed, including assessments of reliability, validity and responsiveness. This will enable researchers and clinicians to select a PROM that is psychometrically sound and relevant to people living with stroke.

2.9 Chapter summary

This chapter presented the central elements of the study, including the definition of stroke; the impact of stroke on the individual, specifically post-stroke HRQOL; current provision of evidence-based stroke care services in the UK; and the use of PROMs in stroke. It highlighted the value of using PROMs to inform stroke clinical practice, stroke services quality improvement and research, and the importance for PROMs to have sound measurement properties to be valid and reliable.

The next chapter presents the literature review that was carried out at the commencement of this study to confirm the evidence gap in current knowledge and guide the study design.

CHAPTER THREE

Literature Review

3.1 Introduction

This chapter presents the narrative literature review that was carried out, using a systematic approach, at the commencement of this study.

3.2 Purpose of the review

The purpose of the review was to identify published studies that had assessed the psychometric properties of PROMs used to measure HRQOL after a stroke, to ascertain whether there was evidence that the PROM-15 had been validated in this target population. The review would also provide information on how psychometric properties of PROMs were assessed, to guide the research design for this current study once the gap in existing knowledge had been confirmed.

3.3 Method

3.3.1 Search strategy

Electronic searches were carried out in MEDLINE, CINAHL and PubMED in June 2019. Relevant keywords and medical sub-headings were selected by the researcher to define the scope of the search. Boolean connectors "**AND**"/ "**OR**" were used to expand or narrow the search:

Search terms used to identify relevant papers for review:

'Stroke' **OR** 'ischaemic stroke' **OR** 'haemorrhagic stroke' **OR** 'CVA' **OR** 'cerebro-vascular accident' **OR** 'intracerebral haemorrhage' **OR** 'ICH' **OR** 'subarachnoid haemorrhage' **OR** 'aSAH'

AND 'PROMs' **OR** 'patient reported outcome measures' **OR** 'self-reported quality of life'

AND 'HRQoL' **OR** 'health related quality of life' **OR** 'QOL' **OR** 'quality of life'

AND 'measurement properties' **OR** 'psychometric properties' **OR** 'psychometrics'

AND 'assessment' **OR** 'evaluation' **OR** 'measurement' **OR** 'validation' **OR** 'validity study

3.3.2 Identification and selection of papers

After removal of duplicates, papers were screened by the researcher by title and abstract and excluded if they did not meet the following inclusion criteria:

- The study aim was to assess one or more psychometric properties of a PROM or PROMs used to measure HRQOL after a stroke
- The study population comprised of adults diagnosed with either ischaemic or haemorrhagic stroke, at any stage of their recovery
- Full text articles published in English as original studies

The full texts of the remaining papers were read by the researcher to ensure they still met the inclusion criteria and citation chaining was carried out from the bibliographies in the retrieved articles to identify further potential sources of literature for screening (figure 3.1). The bibliographic software Zotero was used to store and manage the identified articles.

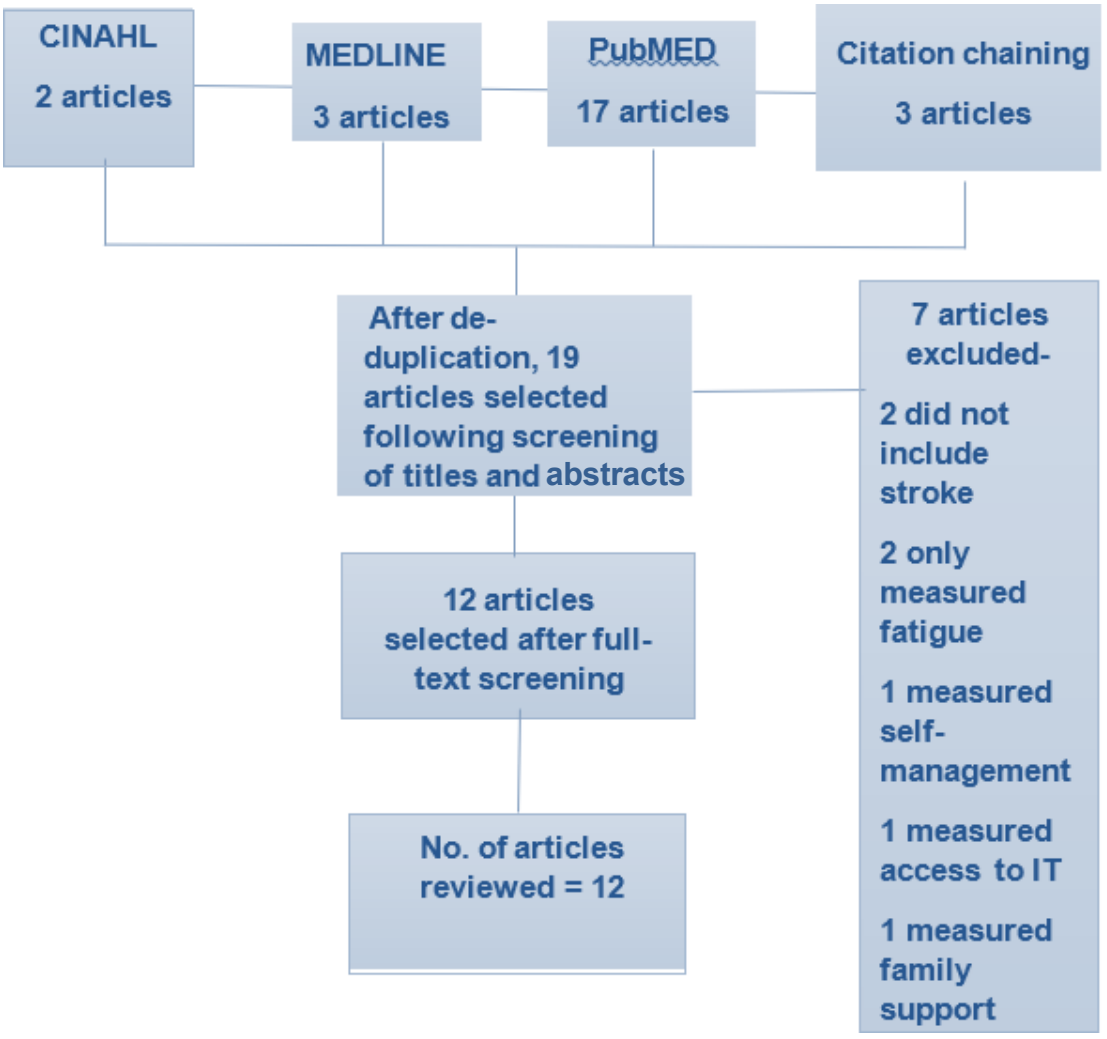


Figure 3.1. Flowchart of selection of PROMs' psychometric studies for appraisal

3.3.2 Data extraction

Each selected paper was read by the researcher and evidence of the assessment of any psychometric properties, namely reliability, validity and responsiveness of the PROM was tabulated (appendix ii). This provided a clear overview of the PROMs and psychometric properties that had been evaluated in each study. The COSMIN taxonomy of the measurement properties of PROMs (Mokkink et al. 2010) was used to guide the process.

3.4 Results

Twenty-five relevant articles were identified, of which, after de-duplication and screening of title and abstract and full texts against the inclusion criteria, twelve were included for appraisal.

Reasons for exclusion included studies that did not include stroke and studies that assessed measures of post-stroke fatigue, self-management after stroke, access to IT and family support after stroke.

The papers selected for review included three systematic reviews of studies that assessed the psychometric properties of commonly used PROMs in stroke (Jenkinson et al. 2009; Price-Haywood et al. 2019), including subarachnoid haemorrhage (Nobels-Janssen et al. 2019); four studies that evaluated the properties of modified PROMs (Jenkinson et al. 2013; MacIsaac et al. 2016; Richardson et al. 2016; Heiberg et al. 2018); and three studies that assessed the properties of translated PROMs (Chou et al. 2015; Vellone et al. 2015; Pedersen et al. 2018). Two studies evaluated the psychometric properties of the PROMIS-10 (Katzan and Lapin 2018; Lam and Kwa 2018), which is the main component of the PROM-15 evaluated in this current study.

The earliest systematic review of PROMs used in stroke was carried out by Jenkinson et al. (2009) for the UK Department of Health. This was an update of an earlier review of PROMs used in Long Term Conditions, including stroke (Fitzpatrick et al. 2006). Jenkinson et al.'s review identified published evidence of PROMs in stroke and assessed the psychometric properties of each PROM and the methodological quality of the studies. The review included 54 papers selected in the 2006 review and nine further papers published between 2006 and 2008. PROMs included the generic SF-36; SF-12; SF-6D; EQ-5D; and HUI; and stroke- specific SIS; SS-QOL; SIPSO; BOSS and SAQOL-39 (see page ix. of this thesis for the list of abbreviated PROMs). The review team carried out assessments of reliability, validity and responsiveness of each PROM. The studies were rated for quality of evidence as '*not reported*'; '*some limited evidence in favour*'; '*some good evidence in favour*'; '*good evidence in favour'* and '*evidence available does not meet criteria'*. Appraisal of the results by the team found that evidence for the psychometric properties varied across PROMs and studies. Construct validity was the most frequently assessed (all ten PROMs), with an evidence rating between '*some limited evidence in favour'* and '*some good evidence in favour*'. Content validity was the least assessed (in the SIS only) with an evidence rating of '*some limited evidence in favour'*. The review concluded that, based on available evidence, no single PROM could be recommended without reservation. Jenkinson et al.'s (2009) review was comprehensive but it is noted that the evidence criteria were set by the review team.

This could have been because at that time no evidence-based guidance, such as the COSMIN checklist for evaluating the methodological quality of studies on PROMs' measurement properties (Mokkink et al. 2010), was available. However, there is a risk of reviewer bias, which is a limitation of the review.

More recently, Price-Haywood et al. (2019) carried out a systematic review of PROMs used in stroke-related RCTs between 2002 and 2016. Of the 159 stroke RCTs included, 34 reported the use of PROMs, of which 26 were generic and five were stroke -specific. Seven PROMs measured post-stroke HRQoL, including the SIS versions 2.0 and 3.0; EQ-5D; SF12; SF36; GHQ and HUI. The authors reported on the psychometric properties of each PROM by reviewing evidence of available validation studies. The tabulated study results indicate that there was variation in the assessment of the elements of reliability and validity in the seven PROMs that measured HRQoL. It is also noted that, although the authors made reference to the ISOQOL minimum standards for PROMs (Reeve et al. 2013), they did not consider content validity in their reporting of the psychometric properties of the identified PROMs. This is a limitation of the study, as it is recognised that evidence of content validity is one of the minimum standards required for a PROM being used in patient-centred outcomes research or comparative effectiveness research (Reeve et al. 2013).

Nobels-Janssen et al. (2019) carried out a systematic review of studies which evaluated the psychometric properties of PROMs used for patients with aneurysmal subarachnoid haemorrhage (aSAH). Nine studies were identified that assessed the properties of seven different PROMs, of which only one was specific to aSAH. The reviewers used the COSMIN Risk of Bias checklist (Mokkink et al. 2017) to assess the methodological quality of the studies, including the evaluation of content validity, reliability and responsiveness of each PROM. The review found that some studies identified the measurement properties incorrectly; at least half of the measurement properties were not reported as being assessed; and in those that were, the level of evidence was rated as very low according to the COSMIN Risk of Bias checklist. As a consequence, the reviewers could not reach conclusions about the validity or reliability of any of the PROMs being used with patients with aSAH. They recommended that future research should focus on the assessment of content validity and measurement error to judge the suitability of a PROM for use in patient care. The review was a good example of how the COSMIN standards (Mokkink et al.

2017) can be employed to conduct a robust assessment of the measurement properties of PROMs.

The findings of these systematic reviews suggest that the methodological quality of studies assessing the psychometric properties of PROMs used in stroke was doubtful, indicating a need for further good quality validation studies.

Four studies assessed the psychometric properties of modified PROMs:
Jenkinson et al. (2013) validated the 59-item SIS version 3.0, a shortened version of the SIS which has 64 items, in people living with stroke in two areas of England. Postal surveys were sent to 418 patients with stroke listed on GP registers in the two localities. The surveys included the SISv3 and the EQ-5D and 151 patients responded (36% response rate). However, complete data were only available from 73 respondents (48% completion rate), which the authors suggested was due to the length of the SISv3. The internal consistency of some of the domains of the SISv3 was also very high (α = >0.95), indicating some item redundancy. The authors modified the PROM by taking the most highly correlated item in each of the eight domains to devise a shorter, eight-item PROM, the SF-SIS, which was piloted using the completed data. The SF-SIS index scores were strongly correlated with those gained from the SISv3 (ρ=0.98; *P*<0.001) and the correlation of the SISv3 index and SF-SIS index with the EQ-5D was identical (ρ=0.83; *P*<0.001). The authors concluded the SF-SIS could replicate scores from the SISv3, whilst greatly reducing respondent burden, particularly important for people with post-stroke impairments.
Richardson et al. (2016) assessed the SISv3 as part of a Canadian stroke service evaluation study with 164 patients receiving community- based rehabilitation after a stroke. The participants completed the SISv3 at three time points over a year and the authors were able to infer that the SISv3 was responsive to changes in HRQoL over time. They reported that the SISv3 showed excellent internal consistency, with Cronbach's alpha coefficients ranging between 0.81 and 0.97. Concurrent validity of the SISv3 score with the EQ5D-5L score was also high ($r > 0.67$). The authors asserted that the multidimensionality of the SISv3 could enable clinicians to track change in patient's HRQoL and tailor rehabilitation, thus providing a more effective, person-centred service.
It is noted that the objective of the study was to evaluate the full psychometric

properties of the SISv3. However, only internal consistency, concurrent validity and responsiveness were assessed, using data from the completed PROM scores. Content validity was not assessed, which is a limitation of the study.
MacIssac et al. (2016) built on the conclusions of Jenkinson et al.'s (2013) study and validated the SF-SIS using data from the Virtual International Stroke Trial Archive. The authors reported that validation of the new PROM demonstrated good agreement of the SF-SIS with the SISv3 and the SIS-16; and good correlation with validated outcome measures used in stroke ($\rho>0.70$, $P<0.001$). Face validity and acceptability were assessed by a focus group ($n=13$) including patients with stroke and HCPs, who agreed with the choice of items for the SF-SIS across seven of eight domains**.** The authors acknowledged that although a shorter version of a PROM should have less associated test burden, there was a risk of missing rich data that could be elicited in the original version, which had more items, a concern raised by Richardson et al. (2016). This issue was discussed by the focus group and the participants reached agreement on the final set of eight items as an acceptable compromise. MacIssac et al. (2016) concluded that the SF-SIS demonstrated robust properties, was acceptable to patients and provided a suitable alternative to the original 59-item SISv3.
It was not reported whether participants in the focus group were asked about their views on the comprehensibility, comprehensiveness or relevance of the SF-SIS, so it is unclear if content validity of the PROM was established, which is a limitation of the study. Holding a focus group with stakeholders to collect specific data relating to content validity would have increased the robustness of the validation process of the modified PROM (Terwee et al. 2018).
Heiburg et al.'s (2018) validation study, based in Norway, evaluated the 6-item QOLIBRI-OS, a PROM developed to measure HRQoL after traumatic brain injury, in patients with stroke. The COSMIN guidelines (Mokkink et al. 2010) were used to assess the reliability and validity of the PROM in a sample of 125 patients with stroke at three months and 12 months post-stroke. Results showed that the QOLIBRI-OS demonstrated excellent internal consistency ($\alpha=0.93$), and the strong correlations between the PROM's sum score and those of selected outcome measures used in stroke, such as the SS-QOL, which also measures post -stroke HRQoL, supported its construct validity ($\rho = 0.71$). The study concluded that the QOLIBRI-OS is a valid and reliable PROM for use with patients living with stroke in clinical settings and in research.

Although the authors referred to the COSMIN taxonomy for measurement properties of a PROM (Mokkink et al. 2010), they did not assess content validity in the target population. As this psychometric property is considered to be essential in a PROM (Mokkink et al. 2010), this is considered a limitation of the study.

Two studies were found that translated and validated PROMs to enable their wider implementation to measure HRQoL in people living with stroke from diverse cultural backgrounds. Poorly translated PROMs may not be conceptually equivalent to the original or relevant to the new target population (Wild et al. 2005). Translating a PROM can alter the meaning of items and undermine its psychometric properties (Krogsgaard et al. 2021), so needs to be re-validated in its adapted form (Wild et al. 2005).

Vellone et al. (2015) translated the SISv3 into Italian and evaluated the psychometric properties of the PROM in a cross-sectional design study based in16 stroke rehabilitation centres across Italy, with 392 patients with stroke. Participants were asked to complete the translated PROM, along with other measures relating to stroke, so that construct validity could be evaluated. The participants completed the PROM 15 days later so that test-retest reliability could be assessed. Results showed that internal consistency was high across all domains (α ranged from 0.89-0.98). Correlations with the other scales were almost all significant, ranging from 0.27-0.69, confirming construct validity. Test-retest reliability was also high (ICC's ranged between 0.79 and 0.93). Acknowledged limitations were that the sample only included hospitalized patients with stroke and that patients with severe neurological conditions and co-morbidities were not included. The participants were given help by research assistants to complete the PROMs if they were unable to, which may have biased the responses. The authors concluded that the SIS 3.0 Italian version showed sufficient validity and reliability to evaluate HRQoL in patients undergoing stroke rehabilitation, recommending that further validation studies should be carried out in more diverse populations. However, content validity of the PROM was not established and, whilst acknowledging this may have been difficult, due to the characteristics of the study sample and setting, it is considered a necessary psychometric property to assess when a PROM is translated (Patrick et al. 2011).

Pedersen et al. (2018) translated and validated the Norwegian version of the SS-QOLS in a study based in Tromso, Norway. A total of 125 people living with stroke were prospectively recruited and postal questionnaires, including the SS-QOLS,

were administered three months post-stroke. A sub-group of 40 participants received the same questionnaires 12 months post stroke so that test-retest reliability of the translated PROM could be assessed. Results of the psychometric assessments showed that the internal consistency values of the PROM's domains were high (α= 0.79–0.93). The item-to-subscale correlation coefficients supported convergent validity (α = 0.48–0.87). Test–retest reliability indicated stability in most domains, with Spearman's rho = 0.67–0.94 (all $P < 0.001$). Hypothesis testing supported the construct validity of the scale. The authors concluded that the Norwegian version of the SS-QOLS was a reliable and valid instrument with good psychometric properties. They recommended its use in health research and individual assessments of people with stroke. Content validity was not assessed, which was acknowledged by the authors, who reported that it had been established in the development and pilot of the original SS-QOLS (Williams et al.1999). However, as the original PROM was in English, the content validity of the translated version should have been assessed to ensure it remained valid and reliable in a different target population (Rothman et al. 2009; Reeve et al. 2013).

Chou et al. (2015) compared the psychometric properties of Chinese versions of four stroke specific PROMs - the SS-QOLS; the modified 8-domain SSQOLS; the SISv3.0, and modified SIS-16. The study was based in stroke units and clinics across Taiwan and recruited a total of 263 patients in the first administration of the PROMs and 121 in the second, an average of two weeks later. Psychometric analysis indicated that the four translated PROMs generally showed good reliability; good convergent and discriminant validity; acceptable floor effects and strong ceiling effects. Acknowledged limitations of the study included the lack of severely impaired patients with stroke in the sample and the single geographical location. The authors suggested that all four PROMs had acceptable psychometric properties in the target population and that the 8- domain SSQOLS and SIS 3.0 were feasible PROMs to monitor the HRQoL of people living with stroke in clinical practice. However, content validity was not assessed in any of the four PROMs, which could affect the trustworthiness of the study's conclusions and recommendations.

These studies on modified PROMs all included large samples of patients with stroke (n=125-5881), at various stages of recovery, which adds to the generalizability of the findings to the general stroke population. Psychometric analysis was carried out on the PROMs with the aim of validating them in the

stated target group. However, although certain measurement properties were assessed, such as construct validity and reliability, content validity was not considered, despite its importance in establishing the validity of a PROM when it has been modified (Rothman et al. 2009).

Of particular relevance to this current study, two studies were identified that assessed the psychometric properties of the PROMIS-10, which is the main component of the PROM-15 (Salinas et al. 2016).
A large validation study of the PROMIS-10 was carried out by Katzan and Lapin (2018). The study included 1102 patients with stroke, who attended an out- patient stroke clinic in the US over a period of two years. The participants' average age was 60 years and the majority (65%) had a mild disability as measured by the modified Rankin scale (mRS) (van Swieten et al.1988). Each participant completed the PROMIS-10 and a total of 1062 (96%) of participants completed all items, indicating a high level of acceptability of the scale. There was moderate internal consistency (ordinal α= 0.82–0.88) and marginal model fit for the 2- factor solution for component scores (root mean square error of approximation= 0.11). There was excellent discrimination for all PROMIS-10 items and component scores across mRS levels. Good responsiveness (effect size >0.5) was demonstrated for 8 of the 10 PROMIS-10 items. Reliability and validity remained consistent across stroke subtype and disability level (mRS <2 versus ≥2). Test-retest reliability was mostly high and the study demonstrated good convergent validity. The authors reported that a limitation of the study was the overall mild degree of disability of participants (mRS<2). They also acknowledged that the cohort consisted of patients with stroke who attended a single centre in an urban setting in the US, so may not be representative of all people living with stroke. The authors concluded that the PROMIS-10 showed acceptable performance in people iving with stroke and supported the recommendation by ICHOM to include it in the standard set of outcome measures for stroke (Salinas et al. 2016). This was a large study that used robust methods to assess the measurement properties of the PROMIS-10. However, it did not include assessment of content validity, which is acknowledged to be the first step in the validation process and necessary to establish before assessing other measurement properties of a PROM (Terwee et al. 2018). This impacts on the reported

findings that the PROMIS-10 has validity in the stroke population.
Lam and Kwa (2018) validated the Dutch version of the PROMIS-10 with a cohort of 75 patients with minor stroke and Transient Ischaemic Attack (TIA). Participants completed the PROM 12 months post-stroke either by phone or on paper. The scores were compared with the SF-36, an established, generic PROM (Hays and Morales 2001) and results indicated a strong correlation between the two measures. The PROMIS-10 and SF-36 Physical Health and Mental Health domain scores correlated significantly (r=0.81, 95% BCa CI 0.69 to 0.88, *P*<0.001; and r=0.76, 95% BCa CI 0.64 to 0.85, *P*<0.001, respectively), indicating construct validity of the PROMIS-10. The PROMIS-10 demonstrated high reliability for both Physical Health (α=0.79), and Mental Health domains (α=0.83), indicating internal consistency. The authors concluded that the study provided evidence of the usefulness of the PROMIS-10 in patients with minor stroke or TIA. However, although it was reported as a validity study, only construct validity and some elements of reliability of the PROMIS-10 were assessed. Test-retest reliability and content validity were not evaluated, suggesting the study lacked methodological quality, according to the COSMIN standards for evaluating the measurement properties of PROMs (Mokkink et al. 2019).

3.5 Narrative synthesis

All of the reviewed single studies assessed at least one psychometric property of a PROM or PROMs used in stroke (appendix ii). However, no studies evaluated all of the COSMIN recommended psychometric properties, namely validity, reliability and responsiveness (Mokkink et al. 2010). One systematic review reported that some psychometric studies incorrectly identified the property being assessed (Nobels-Janssen et al. 2019). The quality of evidence of the assessments of the PROMs' psychometric properties was poor (Jenkinson et al. 2009; Lam and Kwa 2018; Nobels-Janssen et al. 2019), when rated by the reviewer against the COSMIN standards for studies assessing the measurement properties of a PROM (Mokkink et al. 2019). Three studies (Heiburg et al. 2018; Nobels-Janssen et al. 2019; Price-Haywood et al. 2019) employed or made reference to the Professional Society for Health Economics and Outcomes Research standards for PROMs

(Reeve et al. 2013) and the COSMIN guidelines for assessing psychometric properties of PROMs (Mokkink et al. 2010; Mokkink et al. 2019). As these guidelines have been available for a decade, the more recent studies could have made use of them to ensure robust methodology and valid findings. This may have been due to constraints on research resources, or the availability of PROMs data for psychometric analysis. Content validity was not assessed in any of the single studies, despite the acknowledged importance that this is the initial and necessary step before evaluating the other psychometric properties of a PROM (Mokkink et al. 2010; Terwee et al. 2018; Almanasreh et al. 2019). Evaluation of content validity is a complex process, involving representatives of the target population the PROM is intended for, such as patients, carers and HCPs (Terwee et al. 2018). As six of the single studies did not carry out participant-facing data collection, content validity could not be assessed (Jenkinson et al. 2016; Richardson et al. 2016; Heiberg et al. 2018; Katzan and Lapin 2018; Lam and Kwa 2018; Pedersen et al. 2018), However, three studies had face-to-face contact with participants during data collection (Chou et al. 2015; Vellone et al. 2015; MacIsaac et al. 2016), which could have provided the opportunity to assess content validity, perhaps with a subgroup of participants from the large samples recruited. No evidence could be found of studies that assessed the psychometric properties of the PROM-15. This confirmed the knowledge gap identified in a previous study that used the PROM-15 to measure HRQoL in people living with stroke (Hewitt et al. 2019).

3.6 Conclusion

Validation studies of PROMs used in stroke indicate an increasing awareness ofthe importance of assessing the psychometric properties of PROMs to ensure they are sound and fit for purpose to measure the HRQoL in people living with stroke. However, critical appraisal of the small number of available papers found discrepancies between studies in what constitutes the required criteria for the properties of a PROM, as recommended by expert bodies such as the COSMIN (Mokkink et al. 2010). It also highlighted the inconsistencies in evaluation of the psychometric qualities of PROMs used in stroke, which presents a challenge for the research community regarding the selection of valid PROMs to measure HRQoL in people living with stroke (Reeves et al. 2018).

Content validity is well documented to be the first and essential psychometric property that should be assessed in a PROM (Mokkink et al. 2010; Reeve et al. 2013; Terwee et al 2018; Mokkink et al. 2019). As there was no evidence found in the literature of the assessment of the PROM-15, the decision was made to conduct a study to evaluate the content validity of the PROM-15.
The literature review did not provide the researcher with guidance on the design of this study. However, reference was made in some of the articles to the COSMIN standards for psychometric properties of PROMs (Mokkink et al. 2010) and for the evaluation of these properties, including content validity (Terwee et al. 2018; Mokkink et al. 2019), These standards are based on the principles of measurement theory (de Vet et al. 2011) and provided a clear, systematic approach for this study design to address the research question and guide the study objectives:

3.6.1 Research Question:

- What is the level of content validity in the PROM-15 in people living with stroke?

3.6.2 Study objectives:

- To determine the views of people living with stroke in the community six months after their stroke, and their informal carers, on the relevance, comprehensibility and comprehensiveness of the PROM-15
- To determine the views of HCPs specialising in stroke on the relevance of the PROM-15
- To synthesise the information to determine the level of content validity of the PROM-15

3.7 Chapter summary

This chapter presented the narrative literature review that was carried out at the commencement of the study. Twelve papers were reviewed, including systematic reviews and single studies that assessed the psychometric properties of PROMs employed in stroke. No evidence was found of the assessment of the PROM-15,

which established the rationale to conduct this study. There was evidence of the use of the COSMIN standards for assessing the psychometric properties of PROMs (Terwee et al. 2018; Mokkink et al. 2019), which informed the design of this study. The next chapter presents the philosophical stance and theoretical framework underpinning the study and discusses the rationale for the methodology employed to achieve the study's objectives.

CHAPTER FOUR

Methodology

4.1 Introduction

This chapter describes and discusses the philosophical and theoretical underpinnings of this study which aimed to establish the level of content validity of the PROM-15 in people living with stroke. It details the use of the COSMIN standards for designing a study on measurement properties of existing PROMS, specifically content validity (Mokkink et al. 2019) and explains the rationale for using a mixed methods approach, as recommended in the COSMIN standards. The selected mixed methods convergent design is outlined, including the questions set for the qualitative, quantitative and integration strands of the study and the methods of data collection and analysis. These will be presented in more detail in chapters 5, 6 and 7 of this thesis. Finally, an overview of the study procedure and ethical and research governance considerations is provided.

4.2 Study design process

Crotty (1998) and Cresswell (2013) have conceptualised how research philosophy links with research methodology to underpin and guide the choice of a study design. This includes the paradigmatic worldview of the researcher, also referred to as ontology and epistemology; the interpretive or theoretical perspective underpinning a study; the methodological approach informed by these assumptions which in turn informs the choice of methods. These elements are related to each other, with each level informing the next, to provide a sound research study design (Crotty 1998). Crotty (1998), perhaps taking a pragmatic stance, explains the process from the research question to the methods needed to best answer the question, to the methodology informing the choice of methods, which in turn is linked to the epistemological stance of the researcher. Cresswell (2013) however, asserts that the researcher's worldview is the main influence on the choices made when

designing a study and needs to be made explicit at the start.

4.2.1 Paradigmatic worldview

All researchers bring their own worldview, or a set of philosophical assumptions, to their studies, whether they acknowledge them or not (Cresswell 2013). Also known as paradigms, these beliefs relate to what the individual considers to be the nature of reality (ontology) (Greene and Hall 2015); and what can be known (epistemology) (Biesta 2015).

Ontology- There are two distinctive ontological perspectives - a realist ontology relates to the existence of one single reality which can be studied and understood as a 'truth'; a real world exists independent of human experience. Alternatively, relativist or constructivist ontology assumes that reality is constructed within the human mind. Reality is relative to how individuals experience it at any given time and place (Moon and Blackman 2014).

I believe that physical entities exist with or without our knowledge of them, as acknowledged when new, or extinct, forms of life or phenomena are reported to be discovered. However, *reality,* to me, is constructed and interpreted by the individual through interactions with those entities or the environment. My ontological stance is thus a mixture of both realist and constructivist positions, which lends itself to a critical realist stance (Bhaskar 2008; Deforge and Shaw 2012; Denzin and Lincoln 2017). This is exemplified in my clinical practice as an occupational therapist working with people who have had a stroke- the effects of a stroke exist but how they impact on the person is constructed by that individual, who is coming to terms with a new, changed reality, depending on their own life experiences, values and social circumstances. As a critical realist, I can empathise with them and help them to adjust to their new reality.

Epistemology - Philosophically, there are two very different views about knowledge and how it can be obtained through research. The positivist, or objectivist view holds that it is possible to gain knowledge about the world independently from the knower; whilst the interpretivist, or subjectivist view asserts that knowledge contains a subjective element at least, if not entirely, produced by the knower (Biesta 2015, Bryman 2016). Historically, these two

stances have been considered incompatible in the arena of social research (Howe 1988) although more recently the dichotomy between them has been questioned (Bryman 2016).

My own view is that either approach can be reasoned, depending on the type of knowledge required to answer the research question or issue being addressed. This view resonates with *pragmatism,* which rejects the ontological issues of truth and reality, accepts that there are singular and multiple realities that are open to inquiry and orients itself toward solving practical problems in the real world (Feilzer 2010).

Pragmatism as a research paradigm places an emphasis on actionable knowledge, acknowledges the interlink between experience, knowing and acting, and views social inquiry as an experiential process (Kelly and Cordeiro 2020). A process-based approach is advocated (Cresswell 2013), which uses a range of methodologies and methods that best meet the research purpose (Hesse-Biber 2015). Pragmatic inquiry is anchored in participants' experiences to produce knowledge that has practical consequences (Feilzer 2010; Biesta 2015; Kelly and Cordeiro 2020).

In keeping with my ontological position of a critical realist, I considered the use of a critical realist approach to this study. It has similarities to the pragmatic approach in that it considers the understanding of the world as constructed by the individual. It suggests the use of both qualitative and quantitative approaches to research, to accommodate the strengths of both, whilst avoiding their weaknesses (Maxwell and Mitapalli 2010). However, the focus of critical realism as an approach to social inquiry is to explore and understand the structures and mechanisms that cause, or influence, what is seen or experienced by the individual (McEvoy and Richards 2006; Bhaskar 2008). As the focus of this study was to elicit the views of an expert panel on the content of a stroke-specific PROM, rather than to gain an understanding of the structures that influence the HRQoL of people living with stroke, a critical realism approach was rejected.

The pragmatist approach reflects the rationale for carrying out this study, which was to address the concern that the PROM-15 was not validated, thus the actions taken based on the analysis of aggregated responses to the PROM may be erroneous. This approach also values the knowledge that can

be gained from individuals based on their experiences and perceptions, which I was aiming to do by asking participants their views on the content of the PROM-15. Therefore, a pragmatist approach was selected to underpin the design of this study.

4.2.2 Theoretical perspective

Measurement theory is employed in the development and validation of health measures, such as PROMs (Polit and Yang 2016; Streiner et al. 2015), thus an appropriate theoretical framework to inform this study. Measurement theory relates to how the scores generated by items in a scale, such as a PROM, represent the construct being measured, specifically non-observable constructs such as HRQoL (de Vet et al. 2011; Polit and Yang 2016). The quality of a PROM can be assessed in terms of its psychometric properties, including *validity*, *reliability* and *responsiveness* (Streiner et al. 2015; Polit and Yang 2016; Bowling 2017; Mokkink et al. 2010).The validity of a measurement scale needs to be established, to inform the user whether it accurately measures the concept of interest, thus the inferences made from the outcomes of the scale are likely to be accurate. If elements of the concept are missing in the scale, this could lead to inaccurate, therefore invalid, inferences being made (Streiner et al. 2015).

One component of validity is ***content validity***. This is the degree to which the content of an instrument adequately *reflects* the construct being measured, for example, HRQoL, with a particular group of people in a specific context (Streiner et al. 2015; Polit and Yang 2016; Bowling 2017; Mokkink et al. 2019). According to the US Food and Drugs Agency PRO guidance, which provides principles for evaluating PROMs (Rothman et al. 2009), establishing the content validity of a PROM is a vital first step and the basis for testing other psychometric properties of a measure. This view is supported by the COSMIN initiative, which asserts that content validity is the most important psychometric property of a PROM (Terwee et al. 2018).

Content validity can be assessed by seeking the opinions of experts, for example patients and healthcare professionals , who are representative of the target population (Davis 1992; Grant and Davis 1997), on the relevance of a PROM's items to the construct being measured; whether any important aspects are missing and

whether there are any items in the scale that do not measure the construct (Rothman et al. 2009; de Vet et al. 2011; Streiner et al. 2015; Polit and Yang 2016; Terwee et al. 2018). This can be achieved using qualitative methods such as interviews or focus groups (Brod et al. 2009; Rothman et al. 2009; Bredart et al. 2014; Streiner et al. 2015; Polit and Yang 2016); quantitative methods such as the Content Validity Index (CVI) (Lynn 1986; Polit et al 2007; Wilson et al. 2012; Streiner et al. 2015; Almanasreh et al. 2019); or a combination of both (Luyt 2012; Newman et al. 2013; Polit and Yang 2016; Terwee et al. 2018; Aber et al. 2019). Polit and Yang (2016) asserted that the more evidence that can be generated regarding content validity, the greater confidence in the measure and advocated a mixed methods approach.

4.2.3 Methodology

The COSMIN initiative, led by an international group of experts in health measurement has developed standards for evaluating the content validity of PROMs (Terwee et al. 2018). Criteria were developed relating to the three main elements of content validity- *comprehensibility* - respondents' level of understanding of the questions in a PROM; *comprehensiveness* - whether the content covers all aspects of the construct being measured; and *relevance* - whether the PROM is considered relevant to the respondent's experience of the construct. These criteria are presented as a checklist of questions to guide the evaluation process (Terwee et al. 2018 p.7) (table 4.1).

Table 4.1. Criteria for good content validity (Terwee et al. 2018 p.7)

Ten criteria for good content validity
Relevance
• Are the included items relevant for the construct of interest?
• Are the included items relevant for the target population of interest?
• Are the included items relevant for the context of use of interest?
• Are the response options appropriate?
• Is the recall period appropriate?
Comprehensiveness
• Are no key concepts missing?
Comprehensibility

• Are the PROM instructions understood by the population of interest as intended?
• Are the PROM items and response options understood by the population of interest as intended?
• Are the PROM items appropriately worded?
• Do the response options match the question?

These questions can be addressed through appraisal of the evidence for the PROM's development and content validity studies on existing PROMs, and by evaluating the PROM itself to establish the content validity in the population of interest.

The literature review carried out at the commencement of this study (see chapter 3 of this thesis) identified a lack of evidence of studies on the development and assessment of content validity of the PROM-15. This supported the rationale to carry out this content validity study using the COSMIN criteria outlined in table 4.1 (Terwee et al. 2018) to guide the study objectives.

The COSMIN has also developed standards for designing and conducting a study to evaluate the measurement properties of existing PROMs, such as the PROM-15 (Mokkink et al. 2019). These standards include the evaluation of content validity and are presented as a study design checklist (appendix xiv). This was used to guide the design of the study and as a benchmarking tool to ensure it met evidence based, theoretically sound standards for methodological quality. The checklist advises that content validity should be assessed by employing both qualitative and quantitative methods of data collection and analysis. This guidance supported the use of a mixed methods approach to evaluate the content validity of the PROM-15.

Mixed methods research (MMR) is defined as an approach which combines qualitative and quantitative research methods to address research problems (Johnson et al. 2007; Cresswell 2015; Thierbach et al. 2020). MMR is considered to have its philosophical foundation in pragmatism (Teddlie and Tashakkori 2009; Feilzer 2010; Morgan 2014; Biesta 2015), which resonates

with my own philosophical stance. The core characteristics of MMR include the use of a specific MMR design for the collection and analysis of qualitative and quantitative data; the integration of the data analyses and interpretation of the findings to answer the research question (Cresswell 2015). Integration is regarded as the defining feature of MMR, threading through the processes of study design, data collection and analysis, ensuring methodological rigour of the study (Guetterman et al. 2020). Advocates of this approach emphasise the importance of the researcher having knowledge and skills in both qualitative and quantitative research methods to ensure methodological quality of the study (Cresswell 2015; Polit and Yang 2016).

Mixed methods study design

A mixed methods study consists of quantitative, qualitative and integrative strands, each with a specific research question to be addressed, relating to the aim of the study. The following questions were set so that each component of the convergent design was carried out with equal rigour to ensure the validity and trustworthiness of the study (Cresswell 2015):

- ***Qualitative strand question:*** *What are the views of people living with stroke, their informal carers and HCPs specialising in stroke, on the relevance, comprehensibility and comprehensiveness of the content of the PROM-15?*
- ***Quantitative strand question:*** *What is the level of content validity of the PROM-15 as assessed by an expert group of HCPs working with people living with stroke?*
- ***Integration strand question:*** *What is the outcome of integrating the findings of the qualitative and quantitative data analyses in establishing the level of content validity of the PROM-15 to measure the HRQoL of people living with stroke?*

A number of mixed methods study designs have been developed, including three core designs (Cresswell 2015; Creswell and Plano Clark 2017) -

- The *explanatory* design involves using quantitative methods of data collection and analysis and then using qualitative methods to further explain the quantitative results.

- The *exploratory* design involves using qualitative methods to explore an issue, then using the findings to develop a quantitative phase, such as designing an intervention which is then used in a quantitative data collection and analysis phase.
- The *convergent* design is employed when the intent of the study is to collect and analyse qualitative and quantitative data simultaneously, then merge the results so that the research area of concern can be viewed from multiple perspectives. The integrated results can then be discussed in relation to the research questions and aim of the study. Both sets of data are regarded as being of equal value and their combination leads to more understanding than using one approach alone (Cresswell 2015).

The *convergent design* was selected for this study, to ensure that the datasets from the qualitative and quantitative strands were equally considered in the integration strand to address the research question.

4.2.4 Methods

As recommended in the COSMIN study design checklist (Mokkink et al. 2019), qualitative and quantitative methods of data collection and analysis were employed, which are presented in detail in Chapters 5 and 6 of this thesis.

Data collection:

Qualitative cognitive interviews with the patients with stroke and their informal carers were carried out to elicit their views on the relevance, comprehensiveness and comprehensibility of the PROM-15. Cognitive interviews were chosen as they would evaluate the participants' cognitive processing whilst completing the PROM, to address the comprehensibility element of content validity.

An on-line survey was administered to HCPs specialising in stroke to gain quantitative data relating to their views on the content of the PROM-15. This method was selected as the HCPs would not be completing the PROM-15 in practice, therefore evidence of their understanding of the PROM's items, instructions and response options was not necessary. However, the survey included space for free-text comments on the content of the PROM-15, which were added to the cognitive

interview data for more in-depth qualitative analysis. The study was conducted during the COVID-19 pandemic and the use of an on-line survey was considered to be the most effective way to obtain data at a time of increased clinical pressures on the HCPs (Gemine et al. 2021; Ness et al. 2021).

Data analysis:

Qualitative thematic analysis (Braun and Clarke 2006) was carried out on the cognitive interviews and survey free-text data, and quantitative analysis of the on-line survey data employed the Content Validity Index (Lynn 1986: Polit and Beck 2006).

The results of the data analyses were then merged and interpreted in relation to the content validity of the PROM (see chapter 6 of this thesis).

The application of the convergent design to this study is presented in figure 4 below:

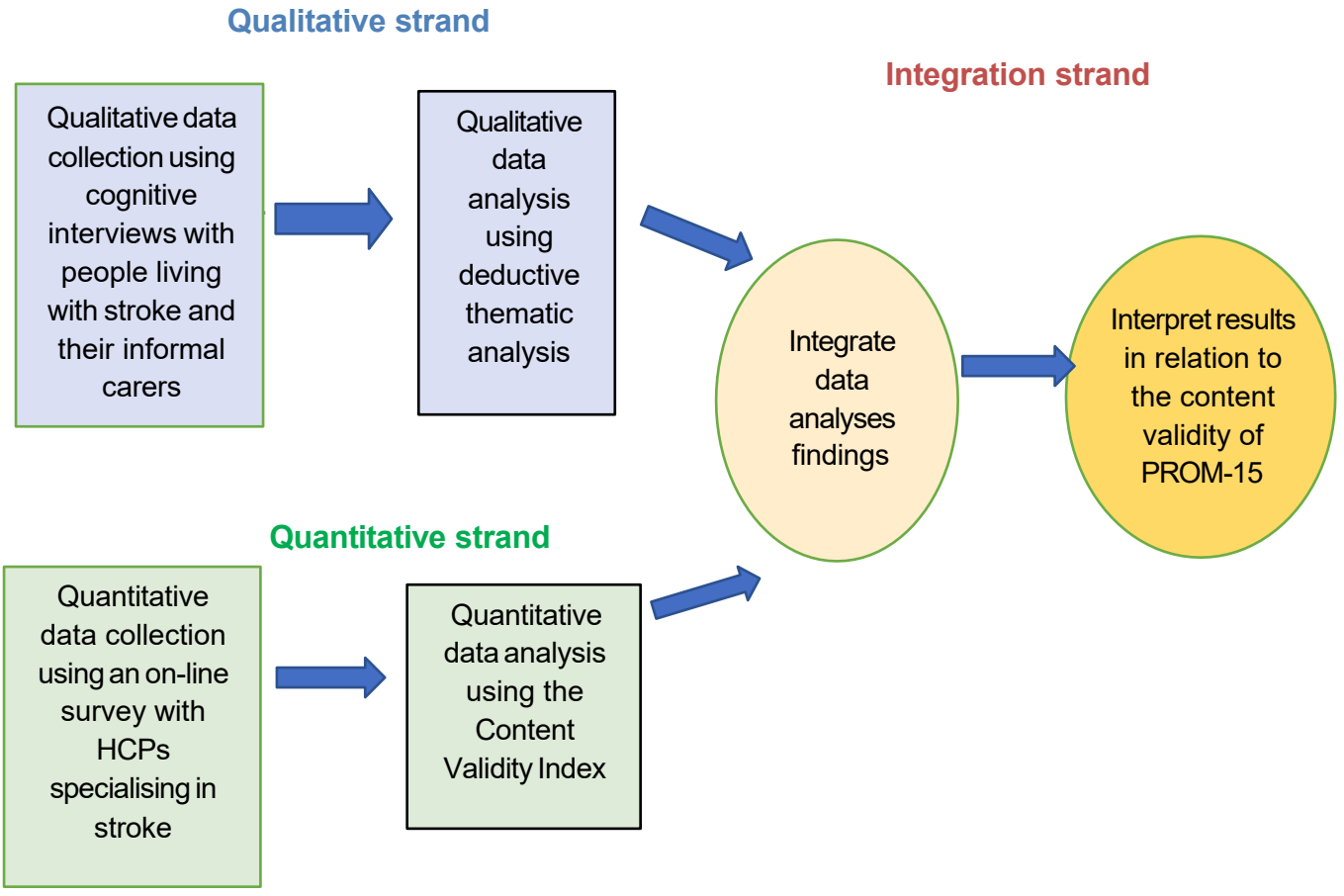


Figure 4.1. Application of the convergent design to this study (Cresswell 2015)

4.3 Study procedure overview

This study was conducted between February 2021 to December 2021, and, in keeping with the mixed methods convergent study design (Cresswell 2015), the qualitative and quantitative strands of the study were carried out over the same period.

4.3.1 Research ethics and governance

This study was conducted in accordance with the UK Policy for Health and Social Care Research (2017) and the Cardiff University Research Integrity and Governance Code of Practice, which emphasises that any concerns relating to the dignity, rights, safety and well-being of all involved in research must be addressed. Ethics approval was obtained from the Cardiff University School of Healthcare Sciences Ethics Committee and the Health Research Authority's Integrated Research Application System (IRAS) (ID. 276885). Copies of the approval letters are found in appendix (iii) of this thesis.

All participant personal data were anonymised and stored in an encrypted database with the password known only to the researcher or, if in paper form, in a locked filing cabinet at the research site, which could only be accessed by the researcher. No identifiable personal data were used when reporting the results of the study. Direct quotes from participants were anonymised and not attributed to individual participants. Data will be securely stored for 15 years after the study has been completed, in line with Cardiff University Research Integrity and Governance Code of Practice.

Monitoring and audit of the conduct of the research was carried out by the Chief Investigator on behalf of the sponsor, Cardiff University, which has operating procedures in place to monitor studies for which it is sponsor.

4.4 Chapter Summary

This chapter presented the philosophical stance and theoretical framework underpinning this study and explained the rationale for the choice of MMR methodology and the convergent study design. It provided an overview of the study procedure and the ethical and governance considerations required by the Cardiff University Research Integrity and Governance Code of Practice and IRAS.

The methods of data collection, data analysis and discussion of the findings of each study strand are presented in the following chapters:

- Chapter Five: The qualitative strand
- Chapter Six: The quantitative strand
- Chapter Seven: The integration strand

The next chapter presents the qualitative strand of the study, including the methods used for data collection and analysis, and discussion of the findings.

CHAPTER FIVE

Qualitative strand of the study

5.1 Introduction

This chapter presents the qualitative strand of the study, including the sample, the setting, the use of cognitive interviews as a data collection tool and thematic analysis of the data. The findings are then discussed in relation to the content validity of the PROM-15. The study strand is informed by and benchmarked against the COSMIN study design standards for evaluating the content validity of a PROM (Mokkink et al. 2019) (appendix xiv).

This study strand aimed to answer the following qualitative research question:

What are the views of people living with stroke, their informal carers and HCPs specialising in stroke, on the comprehensibility, comprehensiveness and relevance of the content of the PROM-15?

5.2 Participants

A convenience sample of adults with stroke living in their own home, who had attended their six-month clinical review during the time period of the study, and their informal carers. The sample was selected to represent patients who may complete the PROM-15 as part of their clinical review or for research purposes. The sample also included informal carers to represent carers who may be asked to complete the PROM-15 as proxy responders, on behalf of those stroke patients unable to complete the PROM due to post-stroke impairments. Studies report that this can affect up to 25% of patients with stroke (Barrett 2009; Lapin et al.2019), therefore gaining carers' views on the content of the PROM was considered valid. The planned sample size of 10 participants was informed by the COSMIN standards of a sample of seven or more participants for a "very good" content validity study (Mokkink et al. 2019 p7). Additionally, research literature relating to cognitive interviewing as a data collection method, suggests a sample size of 5-15 interviewees (Willis 2005; Beatty and Willis 2007; Blair and Conrad 2011; Peterson et al. 2017).

Inclusion and exclusion criteria for the sample were set to ensure the participants were representative of the target population of people living with stroke and their informal carers, who may be asked to complete the PROM-15 as proxy-responders; able to complete the PROM-15; and engage in cognitive interviews (table 5.1).

Table 5.1. Study inclusion and exclusion criteria

Inclusion criteria
• Patients over 18 years of age living in their own home within the locality of the study, six months after a stroke with varying levels of post-stroke disability, as indicated by their modified Rankin Scale (mRS) score (van Swieten et al. 1988) on discharge from a stroke rehabilitation unit (1= no symptoms or disability; 2 = slight disability; 3 = moderate disability; 4 = moderate severe disability; 5 = severe disability) • Informal carers of stroke patients living in the locality of the study, who can be proxy-responders to the PROM-15 on behalf of patients unable to complete it due to post-stroke impairments. • Patients with stroke or their informal carers who can communicate in English and have no physical, cognitive or communication impairments affecting their ability to read, understand and respond to the PROM's items and can use a telephone to participate in a cognitive interview
Exclusion criteria
• Patients whose primary condition is not stroke ie. have multiple co-morbidities, which may influence their views on the content of the PROM-15 • Informal carers of patients with stroke who are under the age of 18 years • Informal carers who are not able to complete the PROM-15 on behalf of their dependents with stroke, due to their own health-related impairments

5.3 Setting

Data collection was planned to take place in community locations, such as participants' homes, or health care settings within a Health board in Wales. However, due to constraints on face-to-face research during the COVID-19 pandemic at the time of the study, this was amended to carrying out the data collection by phone.

5.4 Recruitment

Prior to the recruitment phase, the stroke clinical nurse specialist, who conducted the six-month clinical review of patients with stroke in the locality, was contacted by the researcher. The aims of the study were explained, and she agreed to act as recruiter for patients and informal carers. She was provided with copies of the participant information sheets and the inclusion/exclusion criteria to facilitate recruitment.
During the patients' clinical reviews, carried out over the phone due to COVID-19 restrictions, the specialist nurse identified the patients who met the inclusion criteria based on their healthcare records. She provided them with information about the study and asked if they would be interested in taking part. The names and patient identification numbers of the interested patients were sent with their consent to the researcher via password protected e-mails. The researcher reviewed the patients' healthcare records held on the health board's clinical work-station to ensure they met the inclusion criteria, and non-randomised, purposive sampling was used to select potential participants. This was done with the aim of recruiting participants with differing severity of stroke and consequent impairments, who would be representative of the target population.
If informal carers participated in the phone clinical reviews alongside the patients, and met the inclusion criteria, as judged by the specialist nurse according to their verbal engagement in the clinical review, they were asked if they would be interested in participating in the study. The contact details of those who stated an interest were e-mailed to the researcher with their consent.
Once a sample of ten participants had been recruited, the researcher contacted them by phone. If they still expressed an interest and met the inclusion criteria, confirmed by the researcher based on their responses during the phone-call, they were sent a participant information sheet (appendices iv and v), an informed consent form to

participate in the study (appendices vi and vii), and a copy of the PROM-15 to complete at the time of the cognitive interview (appendix i). A stamped-addressed envelope was enclosed for them to return their informed consent form and on receipt of this, the researcher phoned the participant to arrange a convenient time for the phone interview.

5.5 Ethical considerations

5.5.1 Informed consent

The participant information sheets (appendices iv and v) sent to potential participants included information about the researcher; the purpose, methods and intended uses of the research; what participation entailed; and any risks or benefits anticipated from participation. They were requested to take a minimum of 24 hours to consider participation in the study before returning the informed consent forms (appendices vi and vii), and were made aware of their right to withdraw at any time from the study without reason, without it affecting any future clinical intervention.

5.5.2 Confidentiality and data protection

Management of participants' confidentiality was explained in the participant information sheet and included in the participant informed consent form. The study was carried out in compliance with the safeguards outlined in the Good Clinical Practice Guidelines (2018) and Data Protection Act (2018). No breach of confidentiality was expected in the process of identifying potential participants, as patients and carers were recruited by a member of the immediate care team, and they gave verbal consent to be contacted by the researcher before their personal details were provided. Participants were given a study participant identifier known only to the researcher, ensuring confidentiality. The researcher required access to the stroke patients' personal data, for example healthcare records, to confirm that the participant met the inclusion criteria for the study, their home address and contact number. This was done via the health board's clinical work-station to which the researcher had password protected access as an employed clinician.

Participants were known only by an ID number and all interview quotes and on-line survey free-text comments included in the thesis were anonymised.

5.5.3 Risk assessment

There were no physical risks inherent in this study as it did not involve medical, surgical or pharmacological interventions. However, potential risks to the participants' well-being, and to the researcher, were considered. Completing the PROM-15 and answering questions about its content in relation to the person's own experiences of living with stroke, or being an informal carer, may cause distress. As an experienced clinician working with stroke patients and their informal carers in hospital and the community, the researcher had sufficient skills to discuss the participants' concerns with them at the end of the interview, or if necessary, cut the interview short. If appropriate, the researcher would advise the participant to contact their stroke clinician or GP for further support. They were also provided with the website address of the UK Stroke Association and contact details of their local Stroke Association Family Support Coordinator.

The researcher was supported by experienced co-researchers, and if any clinical or professional concerns were identified by the researcher, they would be discussed with a nominated responsible, independent stroke clinician.

5.6 Qualitative data collection method

The COSMIN study design standards recommend that qualitative interviews should be used as a data collection tool to evaluate the content validity of a PROM (Mokkink et al. 2019) and they have been used in validity studies of PROMs for various conditions (Frost et al. 2007; Rothman et al 2009; Lasch et al. 2010; Aber et al. 2020). The recommended qualitative interview methods were considered for this study:

Individual interviews can be structured or semi-structured and can provide in-depth data, as the interviewer is able to clarify or explore the information the participant gives, with further questions during the interview (Kvale and Brinkmann 2009). However, individual interviews can be lengthy and intensive, which may lead to respondent burden for the participants in this study living with post-stroke impairments.

Focus groups are carried out with participants by a skilled moderator to gain their views on a research topic. Advantages of focus groups include the benefits of the interactions between members commenting on eachothers'

points of view, with the discussion reminding participants of additional issues (Kitzinger 1994). However, the discussion may be dominated by a small number of participants (Brod et al. 2009; Bryman 2016). This may be particularly relevant to people living with stroke, as those with communication or cognitive impairments may feel less able to engage than those who are not impaired. Participants may also be reluctant to admit to others that they have difficulty understanding something (Willis 2005). The topic of HRQoL after a stroke could be regarded as sensitive by some participants and may cause undue distress, which would be difficult to address in a group situation. For these reasons, focus groups were not considered appropriate to use in this study.

Cognitive Interviewing: This qualitative interview method is widely recommended in the health measurement literature as a method of evaluating the content validity of PROMs (Rothman et al. 2009; Patrick et al. 2011; Streiner et al. 2016; Haywood et al. 2017; Peterson et al. 2017; Polit and Yang 2018; Terwee et al. 2018; Mokkink et al. 2019; Wright et al. 2021). There are also several reports of studies that have used this method to validate PROMs for various conditions (Schildmann et al. 2016; Van Leuwwen et al. 2016; Tsangaris et al. 2017; Krohe et al. 2019; Esfandiary et al. 2020; Rausch-Koster et al. 2021; Chhina et al. 2022; Gabes et al. 2022; Penton et al. 2022), although there are no reports of studies relating to stroke.

Cognitive interviews are carried out with a target population of interest, also referred to as an expert panel, to elicit their views on the content of a PROM at the development stage (Kelly et al. 2016); for evaluation of an existing PROM (Safikhani et al. 2013); or if it is going to be administered to a different target population or translated (Wild et al. 2005; Solorio et al. 2016). The method is based on the cognitive theory of information processing that an individual uses when responding to survey questions (Tourangeau 1984; Drennan 2003; Gubrium et al. 2012). This cognitive process involves *comprehension* of the question; *recall* of the necessary information to answer the question; *judgement* about the information required to answer the question and make a *response*.

Cognitive interviewing is used to assess respondents' understanding of a PROM and its items in relation to their intended meaning; and to identify if

there are items of importance to the respondent that are missing (Bredart et al. 2014). Respondents are asked to complete the PROM and may either express their thoughts as they answer each item (think aloud) (Padilla and Leighton 2017), answer pre-set questions after they have responded to the item (concurrent verbal probing) or at the end of the PROM (retrospective verbal probing) (Willis 2005; Beattie and Willis 2007; Gray 2015; Polit and Yang 2016). Some interviewers use a combination of both approaches (Priede and Farrell 2011; D'Ardenne and Collins 2015; Willis 2015). The interviews are transcribed verbatim or summarised as a text summary and the interviewer may also use fieldnotes to enhance the data provided by the respondent (Willis 2015). Data collated from the cognitive interview transcriptions or summaries are analysed using thematic or framework analysis methods and, depending on the findings, items may be retained, modified or removed (Knafl et al. 2007; Kelly et al. 2016; Bristowe et al. 2020).

Guided by the health measurement literature, and considering the aim of this study and the characteristics of the sample, cognitive interviewing was selected as the most appropriate method to use in the qualitative data collection phase.

5.7 Pilot study

A pilot study was carried out before interviewing participants to gain feedback on the researcher's interview technique and the questions in the interview schedule (appendix vii). The pilot was carried out over the phone with a healthy individual not associated with the study, during which the interviewee completed the paper-based PROM-15 and answered the questions about its content. The pre-designed interview schedule was used to guide the interview, which took approximately 40 minutes. As the interviewee was carrying out two tasks at once - completing the PROM-15 and answering the interview questions, she was not rushed for her responses. The feedback was that the interview was easy to participate in over the phone at the same time as completing the PROM-15. The questions asked after each item were repetitive but straightforward and related well to the PROM-15. This feedback was kept in mind when the cognitive interviews were carried out with the study participants.

5.8 Data collection procedure

The cognitive interviews were carried out with the participants over the phone and were relatively short, between 25 and 45 minutes in duration, which was an important consideration for the participants living with stroke, as post-stroke physical and mental fatigue is common (Crosby et al. 2012; Drummond et al. 2017).

5.8.1 Interview guide:

The COSMIN study design standards recommend that interviews should be based on an interview guide (Mokkink et al. 2019 p 7). As the aim was to elicit participants' views on the content of the PROM-15, rather than exploring their experiences of living with stroke, a pre-set interview guide was employed (appendix ix) to keep the interview focused (Meadows 2021). The guide design and content were informed by literature on carrying out cognitive interviews (Willis 2005; Miller et al. 2014), and evidence of the use of interview guides in other PROM validity studies (Brod et al. 2009; Castillo-Diaz et al. 2013; Izumi et al. 2013). Use of the guide aimed to ensure standardisation of data collected across interviews, which would enable robust across-case data analysis at a later stage. The guide was used for all interviews, with slight amendments to the questions for the carers. For example, the carers were asked if they thought the PROM-15's items were relevant to someone living with stroke rather than to themselves. The guide included 13 questions about each PROM-15 item, based on the elements of cognitive processing outlined earlier in this chapter (Tourangeau 1984). In keeping with the COSMIN study design checklist (Mokkink et al. 2019) (appendix xiv), the guide included questions seeking participants' opinions about the PROM-15's content, including their level of understanding of the items (*comprehensibility*); whether the content covered all aspects of HRQoL (*comprehensiveness*) and whether it adequately reflected the impact of having a stroke on HRQoL (*relevance*).The participants were also asked for suggestions of additional items they felt were relevant to HRQoL after a stroke (Brod et al. 2009). Concurrent verbal probing was used after the participant answered each item, so that their responses to the interview questions linked directly to that item and allowed them to complete each item of the PROM-15 in their own time,

with no distractions (Brod et al. 2009). This was particularly important for the participants with stroke, who may have mild, unreported cognitive impairments following the stroke, for example in sustained attention or memory, which could affect their responses to the interview questions, if rushed or distracted (Barrett 2009; Patchick et al. 2016).

After each interview, field notes were written on how the participant responded to the interview questions and whether many probes were needed to elicit information. As recommended in the COSMIN study design standards (Mokkink et al. 2019), the interviews were recorded and professionally transcribed verbatim for analysis. The anonymised transcripts and participant demographical data, including participant ID, sex, age and mRS disability score on discharge, were stored in the qualitative data analysis software package NVivo12, which enabled data cleaning and coding for analysis by the researcher.

5.9 Analysis of cognitive interview data

The COSMIN study design standards recommend that a widely used or well-justified approach should be used to analyse the qualitative data (Mokkink et al. 2019 p 8). This analysis included coding of the interview data using well-justified methods (Willis 2015), followed by thematic analysis using a well-established approach (Braun and Clarke 2006).

5.9.1 Coding of data

Cognitive interview data analysis entails coding of the data followed by qualitative analysis (Willis 2015), to identify patterns of problems with the items or recurrent themes emerging from participants' responses to the PROM (Blair and Brick 2010; Garcia 2011). Historically, there has been concern among survey researchers that cognitive interviews are not reliably interpreted (Conrad and Blair 2009) and that problem item identification may be inconsistent (Beatty and Willis 2007). The variation in data coding and analysis approaches hampers the comparison of studies for research purposes and has led to concern about the merit of cognitive interviewing as an effective method for survey research (Buers et al. 2014). To address this

issue, Willis (2015) provided five models to guide the analysis of cognitive interview data-

- *text summary* (description of dominant themes, conclusions and problems arising from the interviews)
- *cognitive coding* (application of codes associated with the respondent's cognitive processing to answer the items)
- *question feature coding* (assignment of codes relating to design features of the questions)
- *theme coding* (development of discrete labels which are applied to segments of the interview data); and
- *pattern coding* (searching for patterns in the data).

When planning the analysis of the interview data in this current study, the qualitative strand question was considered, and it was reasoned that the *cognitive coding* model would identify data regarding the comprehensibility of the PROM items. *Theme coding* would label data according to the pre-set themes of comprehensibility, comprehensiveness and relevance of the PROM-15. Both models were therefore used to code the data for qualitative analysis.

5.9.2 Deductive thematic analysis

A deductive thematic analysis approach (Braun and Clarke 2006) was employed, which entailed mapping the coded data to the pre-set themes relating to the required criteria for content validity (Terwee et al. 2018).

Within-interview analysis aimed to establish whether individual interviewees understood and could respond to the PROM-15's items, based on the cognitive processing model (Tourangeau 1984); and whether they considered the content of the PROM-15 to be comprehensive and relevant to their experiences of HRQoL after a stroke (Terwee et al. 2018).

Across-interview analysis aimed to identify similarities and differences across participants within the cohort, in their views of the PROM-15's content. This would provide robust evidence to establish the level of content validity of the PROM-15 in people living with stroke.

The free-text comments from the HCP's on-line survey (appendix xii) were

also coded and included in the deductive analysis to add depth to the findings.

5.9.3 Inductive thematic analysis

During the theme coding process, patterns in the data were identified that did not map to the predetermined themes relating to content validity. These data were collated and coded using NVivo12 and analysed using an inductive approach (Braun and Clarke 2006) to ensure no findings were missed.

5.10 Qualitative strand data analysis results

Ten people returned the consent forms to take part in the cognitive interviews and two people then withdrew, giving ill health as a reason. A total of eight people therefore participated in the interviews, including six patients living with stroke and two informal carers. Participants included five males and one female, with an average age of 73 years. Their mRS scores ranged from 1 (no disability) to 3 (moderate disability) (table 5.2).

Table 5.2 Participants with stroke

Participants with stroke (n=6)		n	%
Age (years)			
Mean	73		
Range- min/max	58-84		
Sex			
Female		1	17
Male		5	83
mRS score on hospital discharge			
1 No disability		2	33
2 Slight disability		3	50
3 Moderate disability		1	17

The two informal carers were females, and their relatives, one male and one female with stroke, had an average age of 80 years, with mRS scores of 2 (slight disability) and 3 (moderate disability) (table 5.3).

Table 5.3. Informal carers

Informal carers (n=2)		n	%
Sex			
Female		2	100
Age of relative with stroke (years)			
Mean	80		
Range- min/max	74-86		
mRS score of relative with stroke			
2 Slight disability		1	50
3 Moderate disability		1	50

All interviewees completed the PROM-15 and answered all of the cognitive interview questions that were asked by the researcher. Examples of the interview transcripts are included in this thesis to illustrate the depth of qualitative data collected for analysis (appendices x and xi).

The HCPs' on-line survey comments relating to the content of the PROM-15 (appendix xii) were also collated for inclusion in the analysis.

The PROM-15's items are presented in table 5.4 to provide context for the analysed responses.

Table 5.4 PROM-15's items

PROM-15's items
1. In general would you say your health is….?
2. In general would you say your quality of life is…?
3. In general, how would you rate your physical health?
4. In general how would you rate your mental health, including your mood and ability to think?
5. In general how would you rate your satisfaction with your social activities and relationships?
6. In general please rate how well you carry out your usual social activities and roles?
7. To what extent are you able to carry out your everyday physical activities?
8. In the past 7 days How often have you been bothered by emotional problems such as feeling anxious, depressed or irritable?
9. In the past 7 days How would you rate your fatigue on average?
10. In the past 7 days How would you rate your pain on average?
11. Are you able to walk?
12. Do you need help from anybody to go to the toilet?
13. Do you need help with dressing/undressing?
14. Do you need a tube for feeding?
15. Do you have problems with communication or understanding?

5.10.1 Results of deductive thematic analysis of the data

The findings of the deductive thematic analysis of the data collated from the cognitive interviews are presented in relation to the pre-determined themes of *comprehensibility*, *comprehensiveness,* and *relevance* (Terwee et al. 2018), with illustrative quotes from the participants. The findings of analysis of the survey comments from the HCPs are tabulated (appendix xii) and included in the discussion section of this chapter.

Comprehensibility of the PROM-15's instructions, items and response options

The majority of interviewees reported that the PROM-15's instructions, items and response options were comprehensible. This finding was supported in the analysis of their interview responses using the cognitive processing model, which comprises of *comprehension, recall, judgement* and *response* (Tourangeau 1984, Willis 2015).

- ***PROM-15's instructions:***

  One participant with stroke pointed out that items 11-15 did not have instructions on how to answer them:

  > *'It doesn't actually say what to do, it just asks the question. With the box, it doesn't say tick it or, well, how to answer it'* (PA03-male participant with stroke).

  This is important to note, as a lack of instructions may make the response choices open to interpretation by the respondent, affecting the validity of the PROM's scores.

- ***PROM-15's items:***

  Most interviewees stated they understood all the items and, with further probing, were able to explain what they thought each item was about and how it related to living with stroke, as follows:

  A participant with stroke explained item number 2, which asks about quality of life:

  > *'Whether you still like doing the things you used to do, whether you can do the things you used to do, or whether you're just existing, you know, that sort of thing'* (PA02-male participant with stroke).

  An informal carer explained item number 4, which asks about mental health and mood:

  > *'How she's feeling with her mental health and her mood and everything…Being able to do things for herself, thinking for herself and coping'* (PB02-daughter of female participant with stroke).

  Another informal carer explained item number 5, which asks about carrying out social activities and roles, and extended this to include his relationships with others:

  > '*Does he want to, well, does he want to do any activities yet? And what's his relationship with other people and the children and us, you know?'* (PB01-wife of male participant with stroke).

  Another participant with stroke explained item number 5, focusing on his roles rather than social activities:

  > *'Well, it's asking me if I can continue with my responsibilities, do*

I feel I can't do it as well as I used to' (PA04-male participant with stroke).

A participant with stroke explained item number 8, which asks about emotional problems:

> *'It's asking me if I'm anxious…depressed or irritable because that then, depending on how you answer, it's telling you what my state of mind is'* (PA02-male participant with stroke)

and item number 9 which asks about fatigue:

> *'Well, it's asking me how I feel, do I get tired quickly, easily and all that sort of thing'* (PA02- male participant with stroke).

Some items elicited mixed responses. For example, one participant with stroke found the phrase "general health" in item number 1 ambiguous and, with further probing, explained that the item did not specify whether it was relating to her health as a result of her stroke, or in general:

> *'The first one I didn't quite understand, "would you say your health is..?" because that could apply to anything that anybody has ever had, not just stroke'* (PA06-female participant with stroke).

Item number 7, which asks about carrying out everyday physical activities, also prompted varying comments:

> '*Well, it's self- explanatory really, are you able to carry out your everyday physical activities such as walking?'* (PB01-wife of male participant with stroke).

> *'The person might not have been able to do this before the stroke, so how would they answer the question?'* (PA06-female participant with stroke).

Item number 15, which asks about problems with communication or understanding was viewed as problematic:

> '*What I'm wondering is, with those people, would they be able to have filled this in anyway? Somebody else would probably have had to fill this questionnaire in'* (PA02-male participant with stroke)

- ***Item response options:***

  Interviewees considered the recall period of seven days as realistic and the response choices straightforward and clear.

  A participant with stroke reported difficulty judging how to respond to item number 10, which asks the respondent to score average pain levels over the last seven days. When asked what the difficulty was, he explained that his pain was due to arthritis, not his stroke, so was unsure how to score his response:

  > *'Well, I get a lot of pain in my one leg but that's nothing to do with my stroke. You know so, what would I put down for that? I mean it's not really relevant to my, to having a stroke, totally different entity'* (PA04-male participant with stroke).

  Two HCPs also commented in the on-line survey that the item does not specify if the pain is due to the stroke, which could make it difficult for the respondent to give a rating (appendix xii).

Comprehensiveness of the PROM-15:

- The interviewees all reported that the PROM-15 covered all the aspects of HRQoL domains of physical and mental health, social activities and functional ability they considered important following a stroke:

  > *'How are you going to find out how a stroke patient reacts or feels if you don't ask the right questions?'* (PA04-male participant with stroke)

- None of the participants suggested additional items or domains not already included in the PROM-15. No comments regarding the comprehensiveness of the PROM-15 were made by the HCPs in the free-text sections of the on-line survey.

Relevance of the PROM-15:

- All participants with stroke considered all items in the PROM-15 relevant to their perceptions and experiences of the impact of having a stroke on their HRQoL:

  > *'Yes, I would say it is relevant, yes, because it's giving you an insight into how I feel as a patient'* (PA03- male participant with

stroke)

'Well, yes I would think so because if somebody answered that [fatigue] *as severe or very severe well then you know, you obviously need to get them to see a doctor or whatever'* (PA03-male participant with stroke)

'I would say so, yes because you know, if these questions are not asked, how are you going to find out?' (PA05-male participant with stroke).

- One informal carer reported uncertainty about the relevance of item number 14, which asks whether the respondent needs a tube for feeding:

  'Obviously, the food, the feeding one wasn't really relevant to my mum. But some people would have to have had that, I would have thought, depending on how severe their stroke was' (PB02-daughter of female participant with stroke).

Participants with stroke and informal carers reported completing the PROM-15 as a positive experience, from a personal perspective:

'You know, if you're suffering with mental health the best way is to talk. Well, that's what this form is doing in a way, it's asking me and it's getting me to talk about how I feel' (PA03-male participant living with stroke).

And as a way of helping others:

'She'd like to think that she'd put her contribution in to help other victims, sorry not victims, other patients, not victims' (PB02-daughter of a female participant with stroke).

5.10.2 Secondary findings from the analysis of the cognitive interview data

As participants with stroke completed the PROM-15 during their cognitive interviews, they expressed their feelings about having a stroke and the impact it had on them, their ability to carry out daily activities and social participation. They were generally positive about their experiences of living with stroke, although some expressed fears of having another stroke, frustration with the impact of the stroke on their lives and the perceived lack of formal support after discharge. Carers also described the impact of the stroke on their relatives, including fatigue and cognitive impairment.

Following the principles of inductive thematic analysis (Braun and Clarke 2006, Braun and Clarke 2022), patterns in the transcript data were coded using NVivo12 and the codes were conceptualised as an overarching theme of *'Life after stroke'* with sub-themes of *'the impact of stroke on the person'; 'coping with the effects of stroke'*; *'support following a stroke'*; and *'looking to the future'*. These findings are presented with illustrative quotes from the interviewees:

Life after stroke

- ***The impact of stroke on the person***

  It was evident that the impact of having a stroke affected all domains of HRQoL including physical and mental health, activity and participation.

  Participants with stroke described the negative impact of the stroke on their physical health and their ability to do things, often comparing it to how they were before the stroke-

  > *'Well, I can't do the things I used to do and I struggle, I've only got one good limb now and that's my right arm'* (PA05-male participant with stroke).
  >
  > *'I have been taught to climb the stairs now [but] I can't go out and walk, I've got sticks; I've got two Zimmers. So, yes you know, to me I think that's poor, for what I'm used to, yes'* (PA01-male participant with stroke).

  Post-stroke fatigue was reported as being a problem by participants with stroke-

  > *'I sleep more than I ever did. Yes, I get tired very easily, too easily'* (PA04- male participant with stroke).

  and commented on by their informal carers-

  > *'I mean he gets very, very tired that's all we can say you know; he does things but he feels fatigued afterwards'* (PB01- wife of male participant with stroke).

  Participants with stroke described the emotional effects of having a stroke and the impact on their mental health-

  > *'When I first had the stroke, my moods were slightly different. But when I came home, I was quite down you know, would be the words. And yes, I was quite moody but I knew it myself. And you know, I'd be a bit snappy*

and that but lucky enough that's gone' (PA06- female participant with stroke).

Post-stroke cognitive impairments were noticed by the informal carers-

'You know, he really has to think of things a lot more. For instance, when he came home, I mean he couldn't remember codes for the computer or phone or anything and he was very frustrated with that. Because he's always been really good on that sort of aspect of things' (PB01-wife of male participant with stroke).

Some participants expressed the fear of having another stroke -

'*At first, I was scared to shut my eyes in case I didn't wake up the next morning, so that was why it was important for me to find out from the stroke doctor are there any warning signs that tell me when it's coming on? But there's nothing, no, that's it, I mean I could go out in the car one day, I could have one… that's the end of that'* (PA03- male participant with stroke).

One participant with stroke expressed his feeling of being overwhelmed when he started going out into the community again-

'You walk through the doors and well, there's a million things to look at you know. I was out the house and there's just a hundred things going on. And you know on your computer when the timer goes around and around and it's overloaded? It can get like that. There's too much to process' (PA02-male participant with stroke).

Usually an outgoing person, this participant also experienced problems coping with family gatherings-

'You know when you get a group of people together and they start talking and it gets louder and louder. I found that difficult to deal with, it just got too loud you know. Yes, she's got three sisters and they were all just laughing and joking. Just too bloody loud. I'm getting better but I found out the other day that I'm still a little bit, I still don't like it as much as I used to. It didn't used to bloody bother me; I was out and about and that was it' (PA02-male participant with stroke).

One participant expressed how he felt people with stroke (including himself) may be viewed negatively by others-

'*Like all illnesses it can carry a certain stigma. Some people can feel that*

they're different now they've had a stroke or people will see them differently because they've had a stroke. Well, it doesn't bother me, I mean I speak to people, complete strangers sometimes when I'm fishing on the bank and we get talking and I just say, "Oh, I had a stroke in November." You know, I'm quite open about it because it's nothing that anybody can catch off me, it's not like it's some sort of disease where you can pass it on. It just happens to certain people at a certain age and with a certain lifestyle' (PA04-male participant with stroke).

On a more positive note, one participant reported that having a stroke and being unable to work had an unexpected positive impact on his family relationships-

'My daughter has said to me we spend more time talking on the phone than we ever did. I mean she used to ring but I would say, "Yes, your mum is here, I'll just pass the phone over." But now because I'm not actually working at the moment, if she phones up, I bend her ear a bit [laughs] and then she said she's probably never spoken to me so much than she has since I've had the stroke [laughs]' (PA02 male participant with stroke).

The same participant went through his PROM-15 item scores with his wife and found her response quite illuminating-

'To be honest, I went through this and read it and I sat down with her because I thought 'this would be good, I'm thinking about starting back to work at some time. I thought let's just see where I am'. And I went through it with her and she actually [laughs] scored me bloody lower than I thought she would. But anyway, her thinking was slightly different to mine, so, I said like if you've got something to say let's be honest and open. And we did, we had a bloody good laugh about it after as well, but you know, because there were things she was saying and I thought, yes, she's right [laughs]' (PA02- male participant with stroke).

Although this was said in a light-hearted way, it was clear their discussion gave this participant an insight into how his wife perceived the impact of the stroke on him, which may not have been otherwise talked about.

❖ ***Coping with the effects of stroke***

Participants with stroke voiced their frustrations at not being able to do things as before and how they were trying to cope-

> *'It's driving me up the wall not being able to go out and not being able to do things Yes, the stroke is a blooming nuisance putting it mildly, but it will come'* (PA01-male participant with stroke).

> *'This stroke occurred in my sleep so of course, that left me feeling, not depressed, but feeling a little concerned and a little worried that I could go to sleep and that could be the last time I'd wake up you know. Now I've got more used to it and I don't think about it now, I just take each day at a time'* (PA04- male participant with stroke).

An informal carer reported how her husband was coping with post-stroke cognitive impairment-

> *'He was looking at the car the other day- put oil and water in. And he said to me, "I don't know where to put the oil," and I said, "There's no good asking me to put it in." [Laughs] but he stayed out a little while, I said, "Look, I'll get the book, we'll have a look at the car book." And then by the time I came back he said, "It's okay, I've got it, I remember it now". And those sorts of things he's worked on and in all fairness, he'll stick to it until he does it, you know'* (PB01- wife of male participant with stroke).

❖ ***Support after stroke***

Participants with stroke reported mixed experiences of informal and formal support after their stroke-

> *'Well, I am fortunate, I've got family and friends and if I didn't have those I don't know what I'd do. What kept me going was your team down in [the hospital] when I was down there. You got me back on my feet'* (PA05-male participant with stroke).

One participant expressed his disappointment with formal follow-up after discharge and the negative impact this had on his well-being-

> *'You've been told what you've had, you've been told that there's no*

warnings or symptoms that you can look out for. You know, and then sort of that's it, off you go. And then okay, I had numbers I could ring if there was anything I was concerned about or worried about. But you know, I suppose the hardest thing was no follow up from my own GP. For a while I felt, when I first came out of hospital for the first few months, nobody was bothering with me. Nobody was trying to find out how I was feeling, following up, all that sort of thing. And I did feel like, hang on a minute, they've kicked me out of hospital, so they've forgotten about me….' (PA03 male participant with stroke).

- ***Looking to the future***

Participants were generally positive about life after stroke, including getting back to their hobbies-

'Well, I was just thinking of compared to a lot of people I've got a pretty good quality of life. I'm going on holiday again in June and out fishing most days. Or you know, generally I'm doing what I intended to do when I retired last year' (PA04-male participant with stroke).

and doing things with their families again-

'I think my relationship with my grandson who's only four, that's getting better now over the last couple of weeks as I'm getting stronger. You know, a four year old will wear you out at the best of the times but that's no good when you're already tired. We can start getting back together, get on with having more fun together' (PA02-male participant with stroke).

An informal carer reported her mum's determination to get back to normal life-

'Oh, yes she wanted to get back walking and you know, to doing things, couldn't wait to get back on the hoover [laughs]' (PB02-daughter of female participant with stroke).

These findings were unexpected and, although based on the analysis of a small dataset, provided insight into the lives of people living with stroke and their informal carers. This illustrates the potential of using the PROM-15 to gain valuable qualitative data on post-stroke HRQoL for clinicians and researchers.

5.11 Discussion

The findings of the deductive thematic analysis of the data provided evidence that the PROM-15 has acceptable content validity in this cohort.

Within-interview and across-interview data analysis data found consensus between interviewees that the PROM-15 was easy to understand (comprehensibility) and covered all aspects of physical, mental and social domains of HRQoL (comprehensiveness) relevant to people living with stroke (relevance). However, across-case analysis found mixed views between the interviewees and HCPs about the comprehensibility of some of the PROM-15's content. Two of the eight interviewees expressed problems with understanding three items, the lack of response instructions for five items and the judgement of how to answer one item. Six out of the eight HCPs expressed concerns with ten of the fifteen items, including clarity of the item or judgement for item response (appendix xii). The HCPs' views may have been influenced by their clinical knowledge and experiences of treating people living with stroke; and their professional engagement with designing, administering, critiquing or completing questionnaires, such as a PROM.

The item that was considered to be the least relevant by all interviewees and HCPs was item number 14, which asks if the individual requires tube feeding. This response may be a reflection of the reported low incidence of tube feeding in the longer-term post-stroke, reported by Sutcliffe et al.(2020) to be approximately 2% in the UK, and not experienced by this cohort.

These findings illustrate the importance of including patients and HCPs in the evaluation of a PROM, as recommended in the COSMIN standards (Mokkink et al. 2019), particularly in the PROM development phase.

Cognitive interviewing methodology has been used in several content validity studies of PROMs for various conditions, as detailed earlier in this chapter. However, there are no reported studies in stroke, which suggests this study is novel in using this approach. The positive engagement of the participants in the interviews and robust data analysis findings in this study indicate this is an effective method to use in future content validity studies of stroke-specific PROMs.

Whilst completing the PROM-15, several participants talked unprompted about their experiences of living with stroke, or having a relative with stroke, and their perceptions of stroke service provision on return to the community. The information

gained provided valuable insight into the impact of stroke on HRQoL, particularly on return to the community and, in some cases, the lack of available formal support. It is suggested that using the PROM-15 with stroke patients during clinical interventions could facilitate a more person-centred approach, such as collaborative goal setting in the rehabilitation phase, and to identify individual needs at post-stroke clinical reviews. This use of PROMs has been implemented in various other clinical fields, such as oncology, rheumatology and heart failure (Nelson et al. 2015; Kane et al. 2018; Graupner et al. 2021). For example, Graupner et al. (2021) conducted a systematic review of studies that used PROMs in daily cancer care. The review included 22 studies,15 of which compared the use of a PROM versus not using a PROM. Results showed that in the majority of studies, the use of a PROM improved patient outcomes in symptoms, HRQoL, patient satisfaction and patient-clinician communication. There is some evidence of the effective use of PROMs in clinical practice in stroke, as discussed in section 2.7.2 of this thesis (Katzan et al.2017; Lebherz et al. 2022), and further research and implementation is indicated (Reeves et al. 2018).

5.12 Strengths and limitations

Strengths: This qualitative strand achieved six of the nine COSMIN standards for assessing the content validity of a PROM outlined in the study design checklist for PROMs (Mokkink et al. 2019) (appendix xiv).
The first two standards recommend that content validity should be assessed from the perspectives of patients and HCPs. This was achieved through the purposive sampling of people with stroke and HCPs specializing in stroke.
The sample size of 16 participants rated ‘very good’ for the COSMIN standard of evaluating each PROM item with a minimum of seven participants in a qualitative study (Terwee et al 2018). The average age of the participants with stroke was 73 years, which is representative of the UK stroke population average age of 72 years for males and 78 years for females.
The purposive sampling of informal carers, who completed the PROM-15 as proxy respondents for their relative who was living with stroke, and participated in the cognitive interviews, was an informed decision based on the understanding that the PROM-15 can be self-administered or completed

by an advocate, such as a relative or carer (Salinas et al. 2016). The use of proxy-respondents to complete PROMs on behalf of patients with stroke has been reported in the literature to show mixed levels of agreement on HRQoL (Kozlowski et al. 2015; Lapin et al. 2021a; Lapin et al. 2021b). However, as it is reported that as many as 25% of patients with stroke are unable to self-complete PROMs due to post-stroke impairments (Lapin et al. 2019), seeking the views of informal carers, representing people who might act as proxy-respondents, on the content of the PROM-15 was a strength of this study. It also reflected the value of engaging patients and carers in research advocated by the Patient Centred Outcomes Research Institute and supported in the health research literature (Crocker et al. 2016; Harrington et al. 2020; Staley et al. 2021).

The study rated 'very good' for the COSMIN standards recommending the use of well justified and established qualitative methods for data collection; 'very good' for the use of an interview guide; and 'very good' for recording and transcribing the interviews (Mokkink et al. 2019 pp 7-8).

The use of both cognitive interviews and free-text survey comments as data collection methods provided a range of qualitative data for analysis. This triangulation of methods (Denzin 2012), contributed to the quality of the analysis and credibility of the findings.

The cognitive coding model (Willis 2015) facilitated the analysis of data relating to the aspects of comprehensibility of the PROM-15. Deductive thematic analysis of the data (Braun and Clarke 2022) was an effective method of ascertaining the level of content validity of the PROM-15 as perceived by the participants. By setting predetermined themes based on the elements of content validity, stipulated by COSMIN (Terwee et al. 2018), the data analysis was focused and specific to the qualitative strand question. The use of well-justified, widely recognized approaches for analysing the data (Willis 2015; Braun and Clarke 2006) rated 'very good' against the COSMIN standards.

Limitations include the small size and the demographic and clinical characteristics of the participant sample, which limits representativeness of the whole stroke population. The sample size of eight participants with stroke and informal carers, who were interviewed, may be considered too small to

generate meaningful interview data to reach the point of saturation, when no new codes or themes emerge (Guest et al. 2006; Hennink et al. 2017). However, there is no fixed rule on the number of interviews needed to achieve data saturation in content validity studies (Rothman et al. 2009). Furthermore, Cresswell (2015) asserts that if interview data begin to repeat and no new knowledge is being heard, data saturation has been reached and the sample size is sufficient. This is supported by experts in the fields of cognitive interviewing (Willis 2015) and content validity assessment of PROMs (Polit and Yang 2015). The across-interview analysis findings in this study showed consensus among all interviewees that the PROM-15 demonstrates content validity, thus it is suggested that data saturation was achieved.

The interviewees all lived in one locality in South Wales and spoke English as their first language, which limits the generalisability of the study findings to the stroke population. Future research is recommended to include patients with stroke from diverse cultures and socio-economic backgrounds to be more representative of this clinical group.

The inclusion criteria of this study required the participants with stroke to have no reported cognitive impairments or problems communicating, so they could complete the PROM-15 and respond to the interview questions about its content validity. This meant that a proportion of the stroke population was not represented. Population-based studies of people with stroke indicate that between a quarter and a third have impairments that could challenge or prevent them from completing a PROM, which is an area of concern to researchers (Reeves et al. 2018). Future research is recommended to explore alternative methods for collecting PROM data, such as computer-assisted or pictorial versions of PROMs, so that studies can be more inclusive and representative of the wider stroke population.

The HCPs who provided written comments in the on-line survey worked in the same health board and, despite attempts to recruit HCPs from all relevant disciplines, as recommended by the COSMIN (Mokkink et al. 2019), only therapists, clinical psychologists and stroke family support coordinators completed the survey. This rated ‘inadequate’ in the COSMIN checklist. Future research should aim to recruit larger numbers of a variety of HCPs practising in a wider range of stroke settings, to be more representative of HCPs working in stroke.

5.13 Reflexivity

Two of the participants with stroke were known to me, as they had been patients in the stroke unit where I work a few months before the study took place. This could have presented a risk of researcher bias in how I interviewed them and potentially influenced the data they provided. This risk was minimised by using an interview guide, which standardised the interviews with all of the participants. There was also a risk of response bias, as they may have provided responses that they thought would please me. However, on listening to the interviews and reading through the interview transcripts, although the language used was arguably more informal, their responses did not differ overall to the other participants.

5.14 Conclusion

This qualitative strand of the study aimed to address the following question: *What are the views of people living with stroke, their informal carers and HCPs specialising in stroke on the comprehensibility, comprehensiveness and relevance of the content of the PROM-15?*

Methodological rigour was achieved by employing the COSMIN standards for assessing the content validity of a PROM (Terwee et al. 2018; Mokkink et al. 2019) and extensively cited texts on the practice of cognitive interviewing (Boeje and Willis 2013; Collins 2015; Willis 2015), to guide the sampling of participants, data collection and analysis to answer the research question. The study rated 'very good' for the majority of the COSMIN standards for the study design (Mokkink et al. 2019).

The findings provide supporting evidence that the PROM-15 has acceptable content validity for use with people living with stroke and their informal carers.

These findings are integrated with the results of the quantitative strand for interpretation in the final phase of this mixed methods content validity study (chapter 7 of this thesis).

5.15 Chapter summary

This chapter presented the qualitative strand of the study, including the use of cognitive interviews and free-text survey comments for data collection and thematic

analysis of the coded data. It discussed the findings and concluded that the PROM-15 has acceptable content validity in this cohort.

The next chapter presents the quantitative strand of the study, including the methods used for data collection and analysis, and discussion of the findings.

CHAPTER SIX

Quantitative strand of the study

6.1 Introduction

This chapter presents the quantitative strand of the study including the sample, the setting, ethical considerations, the design and use of an on-line survey for data collection, and the use of the content validity index (CVI) for the data analysis. The findings are then discussed in relation to the content validity of the PROM-15. The study strand is informed by and benchmarked against the COSMIN study design standards for evaluating the content validity of a PROM (Mokkink et al. 2019). This study strand aimed to answer the following research question: *What is the level of content validity of the PROM-15 as assessed by an expert group of HCPs working with people living with stroke?*

6.2 Participants

Non-randomised, purposive sampling was used to recruit HCPs specialising in stroke, who represented clinicians most likely be involved in the administration of the PROM-15 or be working with respondents to the PROM. The planned sample size of ten participants matched that of the qualitative strand of the study, as recommended in mixed methods studies (Creswell 2015). Additionally, the content validity literature suggests a sample of between eight to 12 experts (Lynn 1986; Polit and Beck 2006).
The sample consisted of a cohort of HCPs working with people living in the community with stroke and their informal carers. The aim was to include clinical nurse specialists, clinical psychologists, doctors, occupational therapists, physiotherapists, speech and language therapists and Stroke Association Family Support Co-ordinators.

Table 6.1 Inclusion criteria

Inclusion criteria
• HCPs based in a health board's Community Neuro-Rehabilitation Service (CNRS) • HCPs carrying out six- month clinic reviews with patients with stroke living in the community within the health board locality • Stroke Association Family Support Co-ordinators working with people living with stroke in the local community • HCPs able to communicate in English and with access to the internet

6.3 Setting

Hospital and community clinical settings in a health board in Wales.

6.4 Recruitment

The researcher contacted the clinical lead for the local CNRS and discussed the aims of the study and the use of an on-line survey as the data collection method.
The clinical lead agreed to act as recruiter and was provided with written information on the inclusion criteria to aid recruitment. She sent e-mail invitations to potential participants, which included a participant information sheet (appendix viii) and a link to the questionnaire (PROM Survey for HCPs in Stroke) held on the password protected survey platform *onlinesurveys.ac.uk* (see appendix xv).

6.5 Ethical considerations

6.5.1 Informed consent

The participant information sheet included information about the researcher; the purpose, methods and intended uses of the research; what participation entailed; and any risks or benefits anticipated from participation. The on-line survey included an informed consent form, which the participant had to complete before they could access the survey questionnaire (appendix xiii).

6.5.1 Confidentiality

The study was carried out in compliance with the safeguards outlined in the Good Clinical Practice Guidelines (2018) and Data Protection Act (2018).
Management of participants' confidentiality was explained in the participant information sheet and included in the participant informed consent section of the on-line survey.
The survey was anonymous and only requested information on the participant's sex, profession, grade, and years of experience in stroke to provide demographical information on the study sample. Participants were given a study participant identifier known only to the researcher and all survey free-text comments included in this thesis were anonymised.

6.5.2 Risk assessment

There were no physical risks inherent in this study, as it did not involve medical, surgical or pharmacological interventions. However, potential risks to the HCP's well-being, and to the researcher, were considered. The HCPs taking part in the study may have found aspects of the survey process unsettling, or raise issues relating to their practice. The participant information sheet advised them to discuss any concerns with their clinical lead, who had agreed to provide support.
The researcher was supported by experienced co-researchers, and if any clinical or professional concerns were identified by the researcher, they were discussed with a nominated responsible, independent stroke clinician.

6.6 Quantitative data collection method

The COSMIN study design standards recommend the use of a survey to elicit the opinions of professionals on the content validity of a PROM (Mokkink et al. 2019). Traditional methods for administering surveys include telephone interviewing, postal questionnaires, and face-to-face interviewing. More recent methods include e-mail and on-line surveys, and each administration method

has advantages and disadvantages (Sue and Ritter 2012). It was decided to use an on-line survey as it was low-cost to administer, easily accessible by the HCPs and could be completed at any time, which was important during the period of increased work pressures in the National Health Service due to the COVID-19 pandemic.

The 'on-line surveys' tool (available at https://www.onlinesurveys.ac.uk) was selected, as it is password protected, GDPR compliant and enables researchers to create, distribute and analyse on-line surveys.

The survey was designed by the researcher and included a participant information page about the aims of the study, and an informed consent form, which the respondent had to complete to access the PROM-15 content validity questionnaire.

The questionnaire asked participants to rate the *relevance* of each PROM-15 item to the HRQoL of people living with stroke, using a 4- point ordinal scale based on the content validity index (Lynn 1986), which was used to analyse the questionnaire responses. Each question had space for additional comments, for example on the wording of the item or response options (figure.6.1).

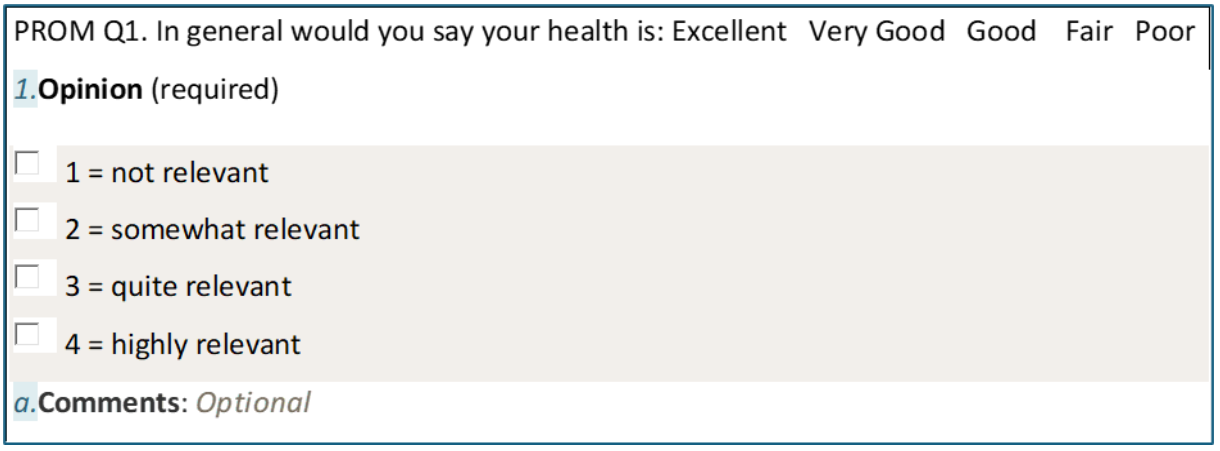


Figure 6.1 Exemplar of HCPs survey question and response options

6.7 Pilot study

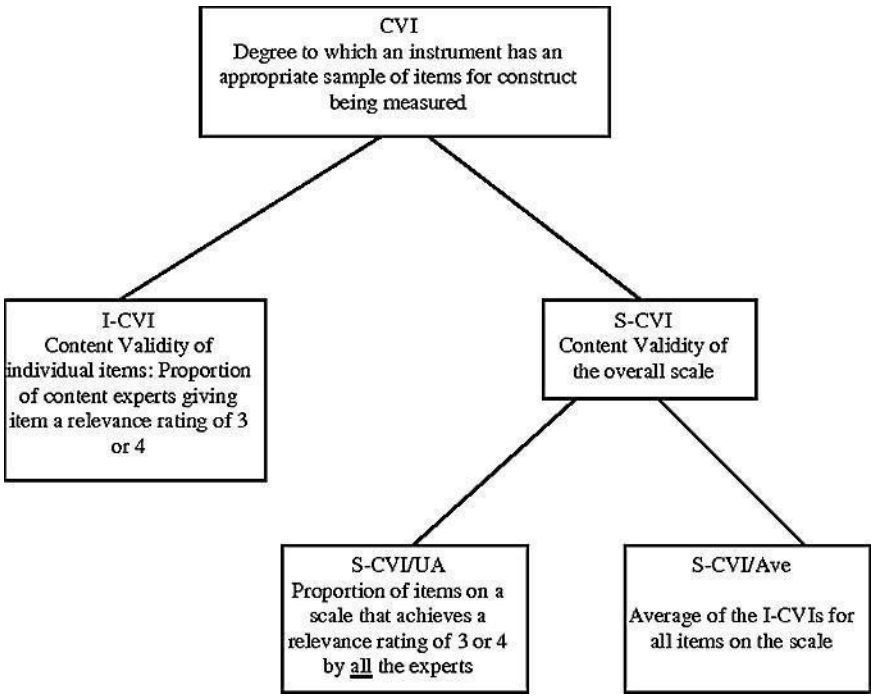
As the on-line survey was designed specifically for this study, it was first piloted with two members of the stroke team where the researcher worked- a physiotherapist and an occupational therapist. This was carried out to ensure

ease of access to the survey website; that the survey instructions and informed consent pages were clear; and that the survey questions and response options were easy to understand. The therapists were provided with the link to the on-line survey and they completed each section with no guidance from the researcher. Following their feedback, the wording of the introduction page to the survey was amended but no changes needed to be made to the informed consent form or the questionnaire itself. Both therapists reported that the questionnaire was easy to follow and did not take long to complete (approximately 30 minutes). The survey data they provided were removed from the dataset so as not to confound the survey analysis results.

6.8 Content validity assessment tool

The COSMIN study design standards recommend that a widely recognized method for evaluating content validity is employed (Mokkink et al. 2019). The Content Validity Index (CVI), an evidence based, established content validity assessment tool (Lynn 1986; Polit and Beck 2006; Polit et al. 2007), was used in the data collection and analysis phases of this study strand, to ensure rigour in the PROM-15 content evaluation process and trustworthiness of the data analysis results. Lynn's (1986) CVI is the method most widely cited by healthcare researchers (Rubio et al. 2003; Polit and Beck 2006; Polit et al. 2007; Kovacic 2018). It is considered preferable to other methods as it provides assessment of data at item and scale levels, is easy to use and captures agreement in one direction (Polit and Beck 2006). This means that it only takes agreement about the *relevancy* of items into account, which is considered essential to establish content validity (Polit and Yang 2016). Lynn (1986) advocated two stages of content validity evaluation- at the development stage of a PROM and at the judgement/quantification stage of an existing PROM. The second stage incorporates two steps, which entail the judgement of a panel of experts on a PROM's items (I-CVI) and on the whole scale (S-CVI) (figure 6.2)

Figure 6.2 Definitions of CVI terms (Polit and Beck 2006 p.493)



Key: I-CVI= item-level content validity index; S-CVI= scale-level content validity index; S-CVI/ UA= scale-level content validity index, universal agreement calculation method; S-CVI/Ave= scale-level content validity index, averaging calculation method.

Assessment of I-CVI: The experts are provided with the PROM and asked to complete a content validity questionnaire. A 4- point rating scale is used to avoid a neutral mid-point score (Lynn 1986). A score of 1= not relevant; 2= somewhat relevant; 3= quite relevant; and 4= highly relevant (Lynn 1986; Davis 1992). The scores are then dichotomised so that the I-CVI is computed as the number of experts scoring 3 or 4 (*relevant*) divided by the total number of experts. The scores of 1 or 2 are discounted as *irrelevant*. For example, an item rated as 3 or 4 by five out of five experts would have an I- CVI of 1.00. An item rated 3 or 4 by four out of five experts would score 0.80 (Polit and Beck 2006).

Some have raised concerns that the CVI expresses the proportion of inter-rater agreement, which can be affected by chance factors (Wynd et al. 2003; Polit and Beck 2006). Polit et al. (2007) acknowledged this and formulated a method for adjusting each I-CVI using a modified kappa statistic, so name because it calculates the agreement of a certain type i.e. agreement on the

relevance of the item to the construct being measured. The authors have formulated a table showing the evaluation of I-CVIs with different numbers of experts and agreement, which was employed in the data analysis stage of this study strand.

Assessment of S-CVI: This is computed by the number of items that achieve a rating of 3 or 4 by *all* experts on the panel (S-CVI/UA) or by the number of items rated as 3 or 4 divided by the number of experts (S-CVI/Ave) (Polit et al. 2007). It is generally accepted among researchers that the acceptable level for S-CVI/Ave is 0.80 or above (Davis 1992).

Polit et al. (2007) recommend that for a scale to be classified as having excellent content validity, it should have I-CVI modified kappa values of at least 0.78 and an S-CVI/Ave modified kappa value of at least 0.90. Lower scores may indicate a problem with the items and the scale may need revision.

These criteria were used as a guide when analysing the on-line survey data in this current study.

6.9 Quantitative data collection procedure

The on-line survey was open for a period of 12 weeks from February 2021 to allow time for the recruiter to send out the study invitation e-mails and for the HCPs to access and respond to the survey. During that time two reminder e- mails were sent from the recruiter to the potential participants, to maximise the unit response rate (Sue and Ritter 2012).

6.9.1 Data cleaning and transformation

The responses to the on-line survey questionnaires were exported to SPSS v28 for data cleaning before analysis. This process enables identification and correction of errors in the data, such as incomplete data or answers out of the possible range for example, age recorded as 149 years instead of 49 years old (Sue and Ritter 2012). Data transformation was then carried out to ensure that missing values were coded in the same way (i.e., coded as 99) and that all response options were consistent (Sue and Ritter 2012).

The textual comments in the questionnaires (appendix xii) were added to the

qualitative data collected from the cognitive interviews in the qualitative strand of the study (see chapter 5 of this thesis) for deductive thematic analysis (Braun and Clarke 2006).

6.10 Quantitative data analysis

Descriptive analysis was carried out on the demographic data provided in the on-line survey to describe the features of the participant sample, such as sex, profession, grade of expertise and years of experience in stroke.
Frequency distributions were calculated for responses to each question across the sample, reported as a median score, to give an overview of the participants' opinions of the relevance of the PROM-15's items.
Further data analysis was carried out using Polit et al.'s (2007) adaptation of Lynn's CVI (Lynn 1986), which included the modified kappa statistic, to establish the level of interrater agreement on the content validity of the PROM-15's I-CVI and S-CVI/Ave.
Each I-CVI was calculated by dividing the total number of HCPs giving a rating of 3 or 4 by the total number of HCPs in the group (n=8) and the resulting score was tallied with the I-CVI rating table (Polit et al. 2007)
The S-CVI/Ave was calculated by adding the items scored as "relevant" divided by the total number of items in the PROM-15 (n=15). The resulting score was tallied with the S-CVI/Ave values (Polit and Beck 2006; Polit et al. 2007).
The CVI results were tabulated and held in SPSS 28 for merging with the results of the qualitative data analysis, in keeping with the mixed methods integration phase of this study (Cresswell 2015).

6.11 Quantitative data analysis results

A total of eight HCPs responded to the survey, resulting in a 50% response rate, including a combination of therapists and family support coordinators (table 6.2). The respondents were all female with an average of 12 years of experience working in stroke. They reported various levels of expertise, from specialist to highly advanced specialist, as demonstrated by their

NHS banding (the two family support coordinators were employed by local authorities, thus were not banded).

Table 6.2 Demographic characteristics of study sample

HCPs (n=8)		n	%
Sex			
Female		8	100
Male		0	0
Profession			
Clinical Psychologist		1	12.5
Occupational Therapist		2	25
Physiotherapist		2	25
Speech and Language Therapist		1	12.5
Stroke Association Family Support Coordinator		2	25
NHS Banding			
8		1	12.5
7		2	25
6		3	37.5
N/A		2	25
Experience in stroke (years)			
Mean	12		
Range- min/max	5-30		

All of the HCPs rated all of the PROM-15's items, resulting in a 100% completion rate. As illustrated in the table below, their relevance ratings ranged from *2* ('*somewhat relevant'*), to *4* ('*highly relevant'*); with an average rating of *3,('quite relevant'*) for four items and *4* ('*highly relevant'*) for eleven items (table 6.3).

Table 6.3 PROM-15's items relevance ratings from HCPs (n=8)

PROM-15 item	Relevance rating distribution 1	2	3	4	Relevance rating median	Relevance Rating range
1. In general would you say your health is….?			6	2	3	3-4
2. In general would you say your quality of life is…			1	7	4	3-4
3. In general, how would you rate your physical health?		1	3	4	3	2-4
4. In general how would you rate your mental health, including your mood and ability to think?			1	7	4	3-4
5. In general how would you rate your satisfaction with your social activities and relationships?				8	4	-
6. In general, please rate how well you carry out your usual social activities and roles?				8	4	-
7. To what extent are you able to carry out your everyday physical activities?			1	7	3	3-4
8. In the past 7 days: How often have you been bothered by emotional problems such as feeling anxious, depressed or irritable?				8	4	-
9. In the past 7 days: How would you rate your fatigue on average?			1	7	4	3-4
10. In the past 7 days: How would you rate your pain on average?			4	4	4	3-4
11. Are you able to walk?			1	7	4	1-4
12. Do you need help from anybody to go to the toilet?			2	6	4	3-4
13. Do you need help with dressing/undressing?			1	7	4	3-4
14. Do you need a tube for feeding?		2	5	1	3	2-4
15. Do you have problems with communication or understanding?				8	4	–

6.11.1 Content Validity Index for the PROM-15's items (I-CVI) and whole PROM (S-CVI/Ave and S-CVI/UA)

The I-CVI ratings indicate that the PROM-15 has *good* to *excellent* content validity (Table 6.4). Twelve out of fifteen items scored an I-CVI of 1.00 (*excellent*); two items scored an I-CVI of 0.88 (*excellent*); and one item scored an I-CVI of 0.72 (*good*). Overall, 93% of items were rated as having *excellent* content validity according to the CVI.

The S-CVI/Ave score of 0.96 and S-CVI/UA score of 0.80 indicated that the level of content validity of the whole PROM-15 is *excellent*. The modified kappa statistic (*k**) for every item demonstrated *good* to *excellent* inter-rater agreement (0.72-1.00) across all items, and *excellent* agreement across the whole PROM-15 (S-CVI/Ave 0.96) (table 6.4).

Table 6.4 Summary Content Validity Index for the PROM-15

Key: I-CVI= Item Content Validity Index; S-CVI/Ave= Scale Content Validity Index/Average; S-CVI/UA= Scale Content Validity Index/Universal Agreement

Item	No. of experts agreeing	Item-UA (I-UA)	Item-CVI (I-CVI)	Modified kappa *k** value	Evaluation of Content Validity
1	8	1	1.00	1.00	Excellent
2	8	1	1.00	1.00	Excellent
3	7	0	0.88	0.88	Excellent
4	8	1	1.00	1.00	Excellent
5	8	1	1.00	1.00	Excellent
6	8	1	1.00	1.00	Excellent
7	8	1	1.00	1.00	Excellent
8	8	1	1.00	1.00	Excellent
9	8	1	1.00	1.00	Excellent
10	7	0	0.88	0.88	Excellent
11	8	1	1.00	1.00	Excellent
12	8	1	1.00	1.00	Excellent
13	8	1	1.00	1.00	Excellent
14	6	0	0.75	0.72	Good
15	8	1	1.00	1.00	Excellent
S-CVI/Ave		-	0.96	0.96	Excellent
S-CVI/UA		0.80	-	-	Acceptable

Modified *k**=kappa designating agreement on relevance; Evaluation criteria for kappa from Cicchetti and Sparrow (1981) and Fleiss (1981) - Fair=*k* of 0.40-0.59; Good =*k* of 0.60-0.74; and Excellent=*k* of >0.74.

6.12 Discussion

The analysis of the on-line survey data using the CVI demonstrated that the PROM-15 has an overall excellent level of content validity to measure the HRQoL of people living with stroke, as assessed by an expert group of HCPs practising with this target population.

The I-CVI scores ranged between 0.72 and 1.00 with 14 of the 15 items scoring > 0.88, which is above the benchmark score of 0.74 for an excellent I-CVI (Cicchetti and Sparrow1981). The item that was rated by the HCPs as the least relevant was item number 14, which asks if the individual requires tube feeding. The relevance rating score of 0.72 for this item was also below Lynn's (1986) criteria for an acceptable I-CVI of 0.78. Studies have reported that tube feeding in the long-term post-stroke is uncommon (Calvo et al. 2019), relating to only 2.0% (mean) of the stroke population in the UK (Sutcliffe et al. 2020). This may have been experienced by the HCPs in their practice with patients with stroke and influenced their views on the relevance of this item.

Interestingly, item number 11, which asked about levels of mobility, was rated both *1* (not relevant) and *4* (highly relevant). As seven out of eight HCPs gave the item a rating of *4*, it was evaluated as 'excellent' in the I-CVI. This indicates that the I-CVI scores are not impacted by anomalies in the range of relevance ratings. However, it is suggested that discordance between raters should be acknowledged for transparency and including provision for textual comments in a survey can clarify the reasons for variances in ratings by respondents.

The PROM-15's S-CVI/Ave score of 0.96 exceeded the recommended content validity benchmark of 0.90 (Polit et al. 2007). The modified kappa statistic (*k**) showed excellent agreement between raters after correcting for chance agreement, indicating a high consensus among the expert group of HCPs that the PROM-15 has acceptable content validity for assessing the HRQoL in people living with stroke.

There is a paucity of published studies that have used the CVI to assess the content validity of PROMs that measure HRQoL in people with health conditions. Three studies were found that used a quantitative approach to evaluate the content validity of a PROM, of which one related to stroke (Luo et

al. 2015; Engstrom et al. 2018; Bobos et al. 2020). Luo et al. (2015) used the CVI method in the development and validation of a PROM (Stroke-PROM) to measure HRQoL in people with stroke. The content validity of the PROM was assessed by a small sample of four physicians and five people with stroke based in an area of North China. Results showed that the I-CVIs of seven of the 62 items rated as 'fair', one item as 'good' and the other items as 'excellent'. The PROM was revised, the seven 'fair' items were modified or deleted, and the final PROM was considered to have satisfactory validity in the target population. The authors acknowledged the small sample of participants in the content validity phase of the study (n=9), and that they were from one location, which could limit the generalisability of findings. There is a lack of information on the characteristics of the participant sample or how the data was collected for the CVI analysis, which are considered limitations of the study.

The identified lack of evidence in the healthcare literature indicates that this current study is novel in the use of a quantitative approach, such as the CVI, to assess the content validity of a PROM, particularly in stroke.

6.13 Strengths and limitations

***Strengths**:* The purposive sampling of HCPs specializing in stroke meets the COSMIN study design recommendation to include professionals, as well as patients, when assessing content validity of a PROM (Mokkink et al. 2019). The variation in the HCPs' clinical roles, ranges of experience and levels of expertise in stroke (table 6.2) enabled the provision of high-quality, relevant data, which enhances the credibility of the data analysis results.

The use of an on-line survey meets the COSMIN recommendation to employ this method to assess content validity (Mokkink et al. 2019). It ensured that the questionnaire was administered in an unbiased, standardised manner to the participants and allowed them to give their opinions on the PROM-15 anonymously. This is a known benefit of using on-line surveys (Sue and Ritter 2012), and useful in this study, as some participants may have known the researcher professionally.

The response rate to the on-line survey was 50% of potential participants,

which is higher than the reported average 44.1% survey response rate in research (Wu et al. 2022). The completion rate of the survey questionnaire was 100%, thus there was no missing data due to item non-response (Sue and Ritter 2012), that could have skewed the analysis results and lessened the validity of the findings.

The pilot study carried out before the data collection commenced ensured that the survey was easily accessible, straightforward and not time-consuming, which are all factors that influence survey response rates (Polit and Beck 2008). This was particularly important, as the survey was carried out during the COVID-19 pandemic which caused increased stress and workload demands on all NHS staff (Gemine et al. 2021; Ness et al. 2021).

The use of the CVI enabled transparent, robust data collection and analysis of the data to provide objective results that were relevant to the aim of the study. The data analysis method rated '*very good'* in the COSMIN study design standards for using a quantitative approach to assess the content validity study of a PROM (Mokkink et al. 2019).

Limitations: The small size (n=8) and the demographic characteristics of the participant sample limit generalisability of the findings. The sample size of eight participants is small by survey research standards - the COSMIN standards for assessing the content validity of a PROM recommend a survey sample size of at least 30 participants (Mokkink et al. 2019). This was not possible due to study resource limitations. However, the sample size is in keeping with recommendations by leading researchers in the use of the CVI, that an expert group of between three and 20 members is sufficient for a content validity study using this method (Davis 1992; Lynn 1986; Polit and Yang 2016).

The COSMIN study design standard of including all relevant HCPs was only partially met (Mokkink et al. 2019). Although attempts were made to recruit a wider range of relevant HCPs, including stroke physicians and stroke specialist nurses, those who responded to the on-line survey only included one clinical psychotherapist, two occupational therapists, two physiotherapists, one speech and language therapist, and two Stroke Association family support coordinators. This may have been due to the increased work demands and changed priorities for HCPs during the COVID-19 pandemic (Ness et al.

2021). For pragmatic reasons, the sample was recruited from one health board in Wales and the therapists all worked in the same community neuro-rehabilitation team, which may have skewed the results. Future studies should aim to recruit a wider range of HCPs working in a variety of stroke care settings to achieve a more representative sample.

6.14 Conclusion

This quantitative strand of the study aimed to address the following question: *What is the level of content validity of the PROM-15 as assessed by an expert group of HCPs working with people living with stroke?*

The procedures for sampling, data collection and analysis were guided by the COSMIN standards for assessing the content validity of a PROM (Mokkink et al. 2019), and literature on the use of the CVI (Lynn 1986: Polit et al. 2007; Polit and Yang 2016). The CVI showed positive results, thus providing robust, quantifying evidence that the PRIM-15 has acceptable content validity in this sample.

6.15 Chapter summary

This chapter presented the quantitative strand of the study, including the employment of an on-line survey for data collection and the CVI for data analysis. It discussed the results and concluded that the PROM-15 has acceptable content validity, according to an expert group of HCPs.

The next chapter will present the integrative strand of the study, which merged the qualitative and quantitative strands' findings for interpretation in relation to the aim of the study.

CHAPTER SEVEN

Integration strand of the study

7.1 Introduction

This chapter presents the integration of the results from the qualitative and quantitative study strands. It describes the methodology employed, the procedure for merging the data analyses findings, and interpretation of the results in relation to this study strand question: *What is the outcome of integrating the findings of the qualitative and quantitative data analyses in establishing the level of content validity of the PROM-15?*

7.2 Integration strand methodology

Integration is the process of bringing qualitative and quantitative data together in one study to address a research problem (Cresswell 2015) and is considered the hallmark of mixed methods research (O'Cathain et al. 2007; Fetters and Freshwater 2015). Integration can lead to new insights beyond the separate findings of quantitative and qualitative data analyses (Fetters et al. 2013; Cresswell 2015). Fetters and Freshwater (2015 page 116) expressed this as *"1+1=3. That is, qualitative + quantitative = more than the individual components"*. The outcome is improved knowledge or understanding of an issue (O'Cathain et al. 2007). Barriers to carrying out mixed methods analysis have been reported, due to a lack of guidance for integrating and analysing data (Bryman 2007; O'Cathain et al. 2007; Guetterman et al. 2015). Consequently, Moseholm and Fetters (2017) developed a typology of analytical frameworks for merging data during integration, based on three dimensions of data integration analytics (table 7.1).

Table 7.1 Three dimensions of data merging analytics

(Moseholm and Fetters 2017 p4)

Relational dimension	• Separative • Iterative
Methodological dimension	• Qualitatively driven • Quantitatively driven • Equivalently driven
Directional dimension	• Unidirectional • Bidirectional

The ***relational dimension*** of data merging refers to how the collection and analyses of the data in the quantitative and qualitative strands interface: in the *separative* approach, the data collection and analyses are conducted independently of each other, then merged to inform discussion of the integrated findings. The *iterative* approach involves 'cross-talk' during the data collection and analyses (Moseholm and Fetters 2017 p4), so that one dataset interacts with the other to inform subsequent phases of a mixed methods study.

This current study adopted the separative approach, as the qualitative cognitive interview data and quantitative survey data were collected and analysed separately, in accordance with the design of the study. The findings were then integrated and interpreted in relation to the content validity of the PROM-15.

The ***methodological dimension*** defines how the quantitative and qualitative strands are weighted relative to merging analytics. *Quantitatively driven* data integration occurs when the quantitative data predominates the qualitative data (QUAN+qual); *qualitatively driven* data integration occurs when the qualitatative data predominates the quantitative data (QUAL+quan) (Johnson et al. 2007). The third approach, referred to as *equivalently driven* data integration by Moseholm and Fetters (2017), and as *equal status* data (QUAL+QUAN) by Johnson et al. (2007), regards both datasets as having equal weighting in the integration strand. In keeping with the convergent design of this study (Cresswell 2015), both qualitative and quantitative datasets were considered to have equal status in addressing the study question (see chapter 5 of this thesis). Therefore, the equivalently driven data integration approach (QUAL+QUANT) was selected.

The ***directional dimension*** refers to whether the merging analytics occur using a *unidirectional approach*, or a *bidirectional approach*. In the unidirectional approach, the lens of the analysis of one type of data frames the merging of the two types of data. In the bidirectional approach, the analytics of both the quantitative and qualitative strands are used to frame merging.
The five different frameworks for integration in mixed-methods studies are presented below (table. 7.2).

Table 7.2 Typology of data integration via merging for convergent mixed-methods integration (Moseholm and Fetters 2017 p7)

Typology	*Explanatory unidirectional*	*Exploratory unidirectional*	***Simultaneous bidirectional***	*Explanatory bidirectional*	*Exploratory bidirectional*
Definition	Quantitatively framed approach, enhanced with qualitative findings for the final interpretation	Qualitatively framed approach, enhanced with quantitative findings for the final interpretation	**Simultaneous quantitatively and qualitatively framed approach drives the final interpretation**	Initial quantitatively framed approach is followed by a qualitatively framed approach before reaching the final interpretation	Initial qualitatively framed approach followed by a quantitatively framed approach before reaching the final interpretation

Moseholm and Fetters (2017) advocated that in a mixed methods convergent design, such as this study, a simultaneous, bi-directional framework should be used, where the analyses of both qualitative and quantitative datasets are merged to frame the integration and interpretation of the results in relation to the aim of the study. This current study employed this framework to ensure that the analysis of the merged datasets simultaneously and equally addressed the integration strand question.
Triangulation is an established technique used in mixed methods studies to synthesize merged data analyses (O'Cathain et al. 2010; Curry and Nunez-Smith 2015) and was employed in this study to ensure robust integration of the qualitative and quantitative datasets. The triangulation process sorts the data according to pre-set or identified themes, then uses a convergence coding scheme to compare the findings. This identifies where the findings from

each dataset analysis agree (*convergence)*; offer complementary information on the same theme (*complementarity*); appear to contradict each other (*divergence* or *dissonance*); or there is *silence* (one set of results relates to a theme, whereas the other set of results provides no information) (O'Cathain et al. 2010; Curry and Nunez-Smith 2017).

Interpretation of the merged findings can be represented using a visual joint display (Cresswell 2015; Guetterman et al. 2015; Haynes-Brown and Fetters 2021); and in narrative form (Fetters et al. 2013). Advocates of joint displays consider them a powerful analytical tool to aid the interpretation of the integrated results (Guetterman et al. 2015; Johnson et al. 2019; Fetters 2019; Fetters and Guetterman 2021). The process of developing a joint display helps the researcher to gain a more comprehensive understanding of the data and provide more balanced and complete results (Haynes-Brown and Fetters 2021). It can improve the transparency of the analytic and integration process and how the findings relate to the research questions and aim of a study (Creamer 2018). A joint display table was formulated in this study to illustrate the findings of the integrated data analysis in relation to the theme of content validity of the PROM-15 (table 7.3).

The narrative approach presents the interpretation of the merged data analysis using either of three approaches (Fetters et al. 2013). The *contiguous* approach presents the findings within a single report but in separate sections; the *staged* approach is used in a multi-stage study to report findings at each stage of the study; and the *weaving* approach involves reporting both findings together. The weaving approach was used in this study, as the results were merged thematically, that is, the quantitative CVI results and qualitative thematic analysis findings were combined in relation to the theme of content validity of the PROM-15.

7.3 Integration strand procedure

In keeping with the mixed methods triangulation protocol (O'Cathain et al. 2010), the qualitative and quantitative data analyses results were sorted by the researcher in relation to the pre-determined theme of content validity and sub-themes of comprehensibility, comprehensiveness, and relevance of the PROM-15 (Terwee et al. 2018). The separate findings were then merged using

a convergent coding scheme for comparison and interpreted regarding their *convergence, complementarity* and *divergence* to each other, to inform the outcome regarding the content validity of the PROM-15 in this target group.

7.4 Results of data integration

The findings are presented as a convergence coding matrix (table 7.3) and in narrative form:

Table 7.3 Convergence coding matrix

Themes and sub-themes	Qualitative data analysis findings	Quantitative data analysis results	Interpretation of merged findings
Theme: ***Content validity of the PROM-15***	High consensus within- and across-cases that the PROM-15 has content validity in this target sample	I-VI, S-CVI/Ave and S-CVI/UA exceed established acceptable levels and rated the PROM-15 as having *good* to *excellent* content validity	*Convergence* and *complementarity* between merged dataset analysis findings
Sub-theme 1: ***Comprehensibility***	Most of the patients with stroke and informal carers reported understanding the items, instructions and response options of the PROM-15	N/A - COSMIN standards state that comprehensibility should only be assessed by patients (Terwee et al. 2018).	*Convergence, complementarity* and *divergence* within- and across-case qualitative data analysis findings *Silent* finding in the quantitative data analysis
Sub-theme 2: ***Comprehensiveness***	All patients with stroke and informal carers reported that the PROM-15's items covered all aspects of HRQoL following a stroke in the domains of physical and mental health and social functioning	HCPs commented that the PROM-15 covered all aspects of post-stroke HRQoL	*Convergence* and *complementarity* between merged dataset analysis findings

Sub-theme 3: *Relevance*	Patients with stroke and informal carers reported that all of the PROM-15's items were relevant to their experiences of living with stroke or caring for someone with stroke	HCPs' relevance ratings of the PROM-15's items ranged from *2* ('somewhat relevant'), to *4* ('highly relevant') The median relevance score per item was *3* ('quite relevant') for 4 items; and *4* ('highly relevant') for 11 items	*Convergence* and *complementarity* between merged dataset analysis findings

7.4.1 Narrative interpretation and discussion

Interpretation of the integrated data analysis is presented in relation to the overarching theme and subthemes relating to the content validity of the PROM-15:

- ***Theme: Content validity of the PROM-15.***

The *convergence* and *complementarity* between the merged data-set analysis findings suggest that, within this sample, the PROM-15 has acceptable content validity in people living with stroke. The PROM-15's items and whole scale content validity index (Lynn 1986, Polit et al. 2007), indicated an excellent level of content validity, which was congruent with the findings of the thematic analysis (Braun and Clark 2022) of the cognitive interview responses and textual comments from the on-line HCPs survey.

- ***Subtheme 1: Comprehensibility of the PROM-15 items.***

In keeping with COSMIN standards regarding the assessment of the content validity of a PROM (Terwee et al. 2018), the HCPs' on-line survey did not include questions on this element. However, free-text comments were made by some HCPs, which were collated and analysed with the cognitive interview data in the qualitative strand of the study.

Integrated results showed *convergence, complementarity* and *divergence* across the qualitative dataset, regarding the comprehensibility of several of the PROM-15's items. Convergence and complementarity were seen in the cognitive interview data from the patients with stroke and informal carers, most

of whom reported they understood the PROM-15's instructions, items and response choices.

However, there was *divergence* between some of the HCPs' and other participants' views regarding the wording or meaning of several items of the PROM. This finding could be attributed to differences in participants' experiences of completing, or administering, measures such as a PROM. The patients with stroke and informal carers may have taken the PROM's items at face value, whilst the HCPs may have based their comments on their clinical experiences with patients with stroke, and using other outcome measures. These findings illustrate the value of including a variety of experts in assessing content validity of a PROM, particularly at the development stage, when decisions are made about the wording of the PROM's items, instructions and response options.

- ***Subtheme 2: Comprehensiveness of the PROM.***

  The merged findings showed convergence and complementarity within and between the datasets regarding the comprehensiveness of the PROM-15. This indicates that the PROM-15 meets this criterion of content validity, from the perspectives of the patients with stroke, their informal carers and the HCPs.

Subtheme 3: Relevance of the PROM-15

The *convergence* and *complementarity* between the merged data-set analysis findings indicate that the PROM-15's items are relevant to HRQoL in people living with stroke. The least relevant item according to both dataset analyses was the item that asked if the person required tube feeding (item number 14). This finding is not unexpected, as it is known that only a minority of individuals living with stroke require enteral feeding in the long-term (Ojo and Brooke 2016; Calvo et al. 2019; Sutcliffe et al. 2020).This was illustrated in Corrigan et al.'s (2022) study that used the PROM-15 with a cohort of patients with stroke (n=549), which found that the number of participants who responded that they required tube feeding was very low (5.6%), compared to those who reported they did not require tube feeding (85.4%)

7.5 Interpretation of integrated findings

The interpretation of the merged findings showed a high level of convergence and little divergence between the findings of the qualitative and quantitative data analyses relating to the pre-determined theme of content validity and the sub-themes of comprehensibility, comprehensiveness and relevance of the PROM-15. This outcome indicates that the PROM-15 has acceptable content validity to measure HRQoL following stroke, from the perspectives of this selected sample.

As there are no published mixed methods content validity studies on stroke-specific PROMs, the findings of this study strand could not be compared with other studies. However, similar outcomes have been reported in studies that used mixed methods to assess the content validity of PROMs for people with other conditions, including epilepsy (Michaelis et al. 2019); cancer (Goswami et al. 2020); and orthodontics (Tassi et al. 2021). Michaelis et al. (2019) assessed content validity in the development stage of a PROM for people with seizures, to measure change following psychotherapeutic interventions. They administered a PROM item rating questionnaire to an expert group of patients and clinicians (n=8) and held cognitive interviews on the content of the PROM, with 14 patients attending a psychotherapy clinic. Content analysis was carried out on the interview data and the CVI was used to analyse the questionnaire data. The PROM was amended, based on the results of the analyses, and a second item relevance questionnaire was then administered to a group of eight clinicians and analysed using the CVI. The results scored an excellent CVI rating for the PROM, indicating that it had content validity in patients with seizures.

Goswami et al. (2020) examined the content validity of a newly developed PROM for patients with a haematological malignancy. Cognitive interviews were held with a sample of eight patients and an item-rating questionnaire was administered to an expert group of patients, clinicians and PROM researchers (n=22). Thematic analysis was carried out on the interview data and the CVI was used to analyse the questionnaire data. The results were discussed with the participants at a content validity meeting and consensus was reached on the final PROM items.

The final version was evaluated in cognitive interviews with 26 patients and the findings indicated that the PROM exhibited satisfactory content validity to identify the impact of the condition and its treatment on patients' HRQoL.
Tassi et al. (2021) assessed the content validity of a sub-set of the FACE-Q Craniofacial Module for children and young adults, which measures outcomes for patients aged 8 to 29 years with facial conditions. Feedback was sought on the relevance, comprehensibility and comprehensiveness of the PROM via an on-line survey administered to a sample of clinical experts in orthodontics (n= 21). Cognitive interviews were carried out with 15 patients, aged between 8 and 29 years. attending orthodontic clinics. The feedback resulted in amendments to the five sub-set scales and the authors concluded that the sub-set demonstrated content validity for inclusion in the Craniofacial module. However, the methods of data analysis for both sets of data are not clearly reported, which could be considered a limitation of the study.

Although these mixed methods studies demonstrated positive outcomes, the authors did not provide clear information on how the integration of the qualitative and quantitative data analysis findings was achieved. This may have been due to the limitations on publication content (Curry and Nunez-Smith 2015) but could suggest that this important step was not adequately considered. This has long been an area of concern to mixed methods researchers (O'Cathain et al. 2007; Johnson et al. 2019), and guidance on how to integrate, interpret and present the findings of mixed methods studies is provided by experts in the field (O'Cathain et al. 2010; Fetters et al. 2013; Cresswell 2015; Moseholm and Fetters 2017; Bazeley 2018).
These resources were used in this current study to ensure robust integration of the datasets, transparent interpretation of the findings and clear presentation of the results, to enhance the methodological quality of this study strand.

7.6 Strengths and limitations

This integrative study strand encompasses the strengths of the qualitative and quantitative strands (see sections 5.12 and 6.13 of this thesis). Both study strands followed established, evidence-based standards for evaluating the content validity of a PROM (Terwee et al. 2018; Mokkink et al. 2019) and

achieved most of those standards. The procedures for merging the datasets, interpreting and presenting the integrated findings of this study strand followed expert guidance (O'Cathain et al. 2010; Fetters et al. 2013; Moseholm and Fetters 2017), which adds to the credibility and validity of the findings.
The main limitation is that the findings are based on the merged analysis of data collected from a small, purposive sample of experts (n=16), living or working in the same health board locality, which limits the generalisability of the findings to the wider stroke population.

7.7 Conclusion

This study strand aimed to answer the question *What is the outcome of integrating the findings of the qualitative and quantitative data analyses in establishing the level of content validity of the PROM-15?*
The outcome of the integration of the datasets analyses complements and confirms the results of the qualitative and quantitative strands of the study, which both concluded that the PROM-15 has acceptable content validity, as evaluated by this study sample. The triangulation of methods of data collection and analysis, and interpretation of the integrated findings provides robust, supporting evidence that the PROM-15 has sufficient content validity to measure the HRQoL in people living with stroke.

7.8 Chapter summary

This chapter presented the integration strand of the study, which merged the results of the quantitative and qualitative study strands and interpreted the findings in relation to the content validity of the PROM-15. It concluded that the PROM-15 demonstrates acceptable content validity to measure post-stroke HRQoL.

The next, concluding chapter presents a summary of this thesis, discusses the overall study findings in relation to the purpose of the study and provides recommendations for clinical practice, quality improvement of stroke care and research in stroke.

CHAPTER EIGHT

Conclusion to the study

8.1 Introduction

This chapter presents a summary of the study and reviews its strengths and limitations. It discusses the findings in the context of current HRQoL measurement literature and the implications for the use of the PROM-15.
Recommendations are made for clinical practice, service quality improvements and research in stroke. The chapter concludes with a statement of the study's contribution to knowledge.

8.2 Summary of the study

This study aimed to establish the content validity of a stroke-specific PROM (the PROM-15) recommended for the measurement of HRQoL in people living with stroke (Salinas et al. 2016).
The study was conducted to address an identified concern that the PROM-15, which was being employed in the Welsh stroke services quality improvement strategy, did not possess the necessary psychometric properties, specifically content validity (Mokkink et al. 2010; Streiner et al. 2016; Terwee et al. 2018). There was a risk that decisions made based on the information provided by the PROM-15 could be erroneous and lead to incorrect use of healthcare resources and ineffective service provision for the people living with stroke in Wales.
The literature review carried out at the commencement of this study (see chapter 3 of this thesis) confirmed that there was no evidence of assessment of content validity of the PROM-15, indicating a gap in existing knowledge, which this study has addressed.
This study is an example of the application of theory to a real-world practical issue, by employing measurement theory (de Vet et al. 2011; Streiner et al. 2016) and the COSMIN methodology for evaluating the content validity of a PROM (Terwee et al. 2018; Mokkink et al. 2019) (see chapter 4 of this thesis). It highlights the importance of underpinning a study with a theoretical framework to guide the study design,

choice of data collection and analysis methods, and add to the credibility of the study findings.

The findings of this study suggest that the PROM-15 has sufficient content validity to measure HRQoL in people living with stroke and is a suitable tool to inform clinical practice, research and the improvement of stroke care services (see chapter 7 of this thesis).

An unexpected finding of the study was the depth of qualitative data elicited from the cognitive interviews with the patients with stroke and their informal carers (see chapter 5 of this thesis). Whilst completing the PROM-15, several participants talked unprompted about their experiences of living with stroke or having a relative with stroke. They were generally positive about their experiences of living with stroke, although some expressed frustration with the impact of the stroke on their lives, including their ability to carry out daily activities and social participation, and the perceived lack of formal support after discharge. Carers also described the impact of the stroke on their relatives, including fatigue and cognitive impairment.

Inductive thematic analysis of the cognitive interview data (Braun and Clarke 2006) provided valuable insight into their lives after stroke. The data analysis identified an overarching theme of *'life after stroke'* with sub-themes of '*the impact of stroke on the person'*; *'coping with the effects of stroke'; 'support following a stroke'*; and *'looking to the future'*.

It is suggested that the use of the PROM-15 with people living with stroke can provide quantitative information on their HRQoL but also act as a vehicle to gain valuable qualitative insights into their experiences of living with stroke to inform clinical practice, quality improvement of stroke care and research.

8.3 Strengths of the study

The application of measurement theory using the COSMIN Study Design checklist for PROM instruments (Mokkink et al. 2019) (appendix xiv), and a mixed methods convergent design ensured a robust, transparent approach to the study process.

The study achieved most of the evidence-based COSMIN standards for assessing the content validity of a PROM (Terwee et al. 2018; Mokkink et al. 2019).

These standards recommend that content validity of an existing PROM should be assessed by patients and professionals. This standard was met through the purposive sampling of patients with stroke and HCPs specialising in stroke.

The sample size of eight participants, who engaged in the cognitive interviews, scored ‘very good’ for the COSMIN standard of seven or more participants for a qualitative study. It also met the recommendations from experts in the field of cognitive interviewing of holding 5-15 interviews (Willis 2004; Blair and Conrad 2011).

The inclusion of informal carers was important, as they represented proxy respondents to the PROM, recommended by ICHOM (Salinas et al. 2016), for patients who are not able to complete the PROM due to post- stroke impairments. This also reflected the person-centred approach to the study, acknowledging the value of engaging patients and carers in the research process, advocated by the Patient Centred Outcomes Research Institute. However, a larger sample of patients with stroke and informal carers may have resulted in different findings to the study.

The use of cognitive interviews and an on-line survey, which are established qualitative and quantitative data collection methods, rated ‘very good’ in the COSMIN study design checklist (Mokkink et al. 2019) and increased the rigour of this phase of the study The qualitative study strand scored ‘very good’ for using an interview guide and recording and transcribing the cognitive interviews.

The response rate to the on-line survey in the quantitative strand was 50% of potential participants, which is higher than the reported average 44.1% survey response rate in research (Wu et al. 2021). The completion rate of the survey questionnaire was 100%, which meant there were no missing data due to item non-response (Sue and Ritter 2012) that could have skewed the analysis results and reduced the validity of the findings.

The study rated ‘very good’ for the COSMIN standards for analysing data using widely recognised or well justified approaches: the quantitative CVI used to analyse the on-line survey data has been widely employed in healthcare and social research for some time (Lynn 1986; Rubio et al. 2003; Polit and Beck 2006; Polit et al. 2007; Almanasreh et al. 2019; Yusoff 2019). The qualitative cognitive interview data and free-text survey comments underwent thematic analysis, which is an established qualitative method developed by Braun and Clarke (2006) that continues to evolve and inform the research community (Braun and Clarke 2022). Using established qualitative and quantitative methods of data analyses ensured that the results of both study strands were credible and equally informed the integration phase of the study (Tashakorri and Teddlie 2021).

In keeping with the mixed methods convergent study design, the quantitative and qualitative strands of the study addressed the identified research question for each strand, providing breadth and depth of data analyses for integration, which could not have been achieved by using one approach alone (Cresswell 2015). The integration and interpretation strand of the study was guided by experts in the field of mixed methods research (O'Cathain et al. 2010; Guetterman et al. 2015; Fetters et al. 2013), which enhances the credibility of the findings and the overall validity of the study.

8.4 Limitations of the study

The recruitment of participants was carried out by members of the care team- the lead clinician of the CNRS recruited the HCPs and the stroke specialist nurse recruited the patients with stroke and their informal carers. The study protocol was discussed with both clinicians and they were provided with the participant inclusion and exclusion criteria to assist recruitment. However, the risk of recruiter bias is possible, as they may have only provided information to people they felt could engage favourably with the on-line survey and cognitive interviews. They may have had concerns about how the study could affect the well-being of some participants, particularly those with stroke, which may have influenced their selection of potential participants. This potential limitation of the study was considered less of a risk than the researcher carrying out the recruitment, which could have posed the risk of researcher bias.

The decision to recruit a sample size of 16 HCPs for the quantitative strand was influenced by constraints on time and resources available to the researcher. The sample size did not meet the COSMIN standard of at least 30 participants for survey studies (Mokkink et al. 2019) and therefore the results should be viewed with caution. However, the sample size did meet the recommendations from developers of the Content Validity Index that an expert group of between three and 20 members is sufficient for a study using this method (Lynn 1986; Davis 1992; Polit and Yang 2016).

The participants with stroke and informal carers all lived within the same rural/urban location and spoke English as their first language, so may not be representative of the stroke population in Wales or the UK. The participants with stroke had mild to moderate stroke impairments, as defined by the mRS scale of post-stroke disability (van Swieten 1986), and, due to the aim and objectives of the study, people with

cognitive and communication impairments were excluded, as they may not have been able to complete the PROM-15 or engage in the cognitive interviews. This resulted in a skewed sample that did not reflect the variations and severity of post-stroke impairments and may have influenced the findings of the qualitative strand of the study. This is an acknowledged issue in stroke research (Patchick et al. 2015; Swinburn et al. 2018), as studies report that up to a third of people living with stroke have impairments that make the completion of PROMs a challenge (Barrett 2009; Reeves et al. 2018; Lapin et al. 2019). It is recommended that future research should aim to recruit a more diverse range of patients with stroke so that the sample is more representative of the target group and results can be better generalized to the stroke population.

Whilst attempts were made to recruit a range of HCPs specialising in stroke via the e-mail invitation, one clinical psychologist, two occupational therapists, two physiotherapists, one speech and language therapist and two family support coordinators completed the on-line survey. The invited doctors and stroke specialist nurses did not respond, which limits the generalisability of findings due to the small, homogenous sample. The study was carried out during the COVID-19 pandemic, which placed unprecedented strain on NHS staff, and may have been a factor in the lack of HCPs' engagement in the survey. Recruitment of a larger number of HCPs specializing in stroke from other healthcare locations could have resulted in a more diverse sample that was more representative of this target group.

These limitations to the study have been acknowledged so that they can be improved upon to ensure the methodological quality of further psychometric studies of the PROM-15.

8.5 Implications of the study findings for the PROM-15 and recommendations for service quality improvement, clinical practice and research in stroke

The findings of this study provide evidence that, overall, the PROM-15 meets the COSMIN criteria for having acceptable content validity to measure the HRQoL in people living with stroke (Terwee et al. 2018; Mokkink et al. 2019). However, qualitative analysis of the cognitive interview data and free-text comments from the on-line survey indicated that some elements of the PROM were problematic. Some items were considered to be repetitive or ambiguous and there was uncertainty about the relevance of one item, which related to tube feeding. This suggests that

the PROM-15 needs further testing, possibly modifying and revalidating in people living with stroke.

The PROM-15 consists of the PROMIS-10, a generic measure of HRQoL, validated in the stroke population (Katzan and Lapin 2018), plus five additional items relating to functional ability following stroke (Salinas et al. 2016). The participants who completed the PROM-15 considered all items relevant and comprehensive, which suggests that the additional five items do not detract from the overall purpose of the PROM. This finding is supported in a recent study of the psychometric properties of the German version of the PROMIS-10 and three of the five functional ability items in the PROM-15 with a cohort of patients with stroke (Philipp et al. 2021). The study demonstrated that the translated PROMIS-10 had validity in the target population and the other three items were considered an informative addition.

As far as the researcher is aware, the PROM-15 has not been translated into other languages. The PROMIS-10 and some of the PROM-15's five additional items have been translated and employed in two recent stroke studies set in the Netherlands (Lens et al. 2021) and Spain (Sanchez-Gavilan et al. 2022). EXPAND However, the use of the full PROM-15 is currently limited to English speaking patients living with stroke.

Recommendation: Further translation and cross-cultural adaptation of the PROM-15, followed by psychometric testing, including content validity, is indicated (Wild et al. 2005; Streiner et al. 2015), so that it can be used in the wider stroke population.

8.5.1 Implications for the use of the PROM-15 in quality improvement in stroke care

The PROM-15 was recommended by the ICHOM as part of an international minimum data set for stroke outcomes, with the aim of improving the quality of stroke care globally (Salinas 2016). It was acknowledged that work was required to further assess the Stroke Standard Set against robust evaluation criteria. This current study supports this work by evaluating the PROM-15's content validity against recognised evidence-based standards, such as the COSMIN methodology for assessing the content validity of PROMs (Terwee et al. 2018) and the Study Design checklist for assessing the measurement properties of PROM instruments (Mokkink et al. 2019).
Whilst completing the PROM-15, some of the participants with stroke voiced positive

and negative views of healthcare services after their stroke (section 5.10.2 of this thesis).This suggests that the use of the PROM-15 in an interview setting can provide useful feedback on stroke care provision from the perspectives of patients with stroke. This finding is supported in healthcare research literature and health system policies on the use of PROMs at micro (patient-clinician); meso (service provision); and macro (policy) levels to inform and improve healthcare (Devlin and Appleby 2010; WHO 2015; Greenhalgh et al. 2018; Al Sayah et al. 2021; NHS England 2022).

In 2021, the SSNAP included collection of PROM data at patients' six-month post-stroke clinical reviews. The EQ-5D-5L, a well validated, generic PROM (Herdman et al. 2011) was selected to provide information on the impact for patients of various stroke interventions and models of care. The EQ-5D-5L includes five questions relating to mobility; usual activities; self-care; pain/discomfort and anxiety/depression with 5 response options. It also includes a visual analogue scale presented in a thermometer format with 0 representing the worst health imaginable and 100 representing the best health imaginable. A systematic review of studies that had evaluated the psychometric properties of the EQ-5D-5L was carried out by Feng et al. (2021). The review identified 99 studies, which assessed validity, including convergent validity; reliability including correlation with other health measures; and responsiveness (sensitivity to change). Results demonstrated that validity and responsiveness were fully established, and reliability of the PROM was acceptable in various conditions and settings.

Two of the reviewed studies validated the EQ-5D-5L in stroke:

Golicki et al.'s (2015) validation study administered the Polish version of the EQ-5D-5L and the EQ-5D-3L to a cohort of 408 patients with stroke in a hospital setting. The 5L and 3L versions were compared in terms of feasibility, ceiling effect and discriminatory power. Construct validity was assessed in terms of known- groups validity, and convergent validity of the EQ-5D-5L dimensions with other stroke outcome measures (the Barthel Scale and the mRS) and between themselves, using Spearman's rank correlation coefficient. Results indicated that the EQ-5D-5L demonstrated acceptable feasibility, a small reduction in ceiling effect and sufficient discriminatory power. Known group validity was similar for both PROMs and convergent validity was confirmed by the moderate to strong correlations with the other stroke outcome measures. The study concluded that the EQ-5D-5L was a valid generic PROM in patients with acute stroke and demonstrated some psychometric advantages in comparison with the EQ-5D-3L.

Different outcomes were found in Chen et al's (2016) study which examined the criterion validity, responsiveness, and minimal clinically important difference (MCID) of the EQ-5D-5L in people receiving rehabilitation after stroke. The EQ-5D-5L, along with four other outcome measures for comparison, including the SIS, was administered to 65 patients with stroke before and after 3 to 4 weeks of out-patient stroke rehabilitation. Criterion validity was estimated using the Spearman correlation coefficient. Responsiveness was analyzed by the effect size, standardised response mean and criterion responsiveness. The MCID was determined by anchor-based and distribution-based approaches. Results confirmed the concurrent validity of the EQ-5D-5L and indicated that it had better power for predicting the rehabilitation outcome in activities of daily living than other motor- related outcome measures. The EQ-5D-5L was moderately responsive to change (SRM = 0.63). The authors reported that these results were more limited than those of Golicki et al.'s (2015) study. They suggested this was due to the different timings of the data collection, as their participants were in the sub-acute to long- term stages of post stroke recovery, rather than in the acute phase. The study concluded that the EQ-5D-5L demonstrated reasonable concurrent validity, limited predictive validity, and acceptable responsiveness for detecting the HRQoL in stroke patients undergoing rehabilitation.

The EQ-5D-5L and the PROMIS-10 were compared by de Graaf et al. (2021) for the evaluation of HRQoL three months after stroke. The PROMs were administered to 360 patients with stroke by a stroke specialist nurse over the phone. Results showed that the PROMIS-10 showed higher internal consistency (α=0.90) compared to the EQ-5D-5L (α=0.75). Both the EQ-5D-5L and the PROMIS-10 were strongly correlated with the mRS (r=0.62 and 0.60 respectively). A ceiling effect and a non- normal left skewed distribution were observed in the EQ-5D-5L. The PROMIS-10 showed better discriminant ability in individuals with minimal post- stroke impairment (mRS=0-2), whereas the EQ-5D-5L showed slightly better discriminant ability in individuals more affected by their stroke (mRS=3-5). The authors concluded that both PROMs were valid instruments to evaluate HRQoL in patients living at home three months after stroke and the selection of which one to use may depend on the aims of the study and the levels of post-stroke impairment in the participant sample.

As the EQ-5D-5L has fewer items than the PROM-15, it may be easier and less time consuming for HCPs to administer, and for patients with stroke to complete. However, the PROM-15 is stroke specific and, as shown by the detailed responses made by the participants in this current study to the PROM-15 (see chapter 5 of this thesis), it is

suggested that it covers more domains of HRQoL that are relevant to people living with stroke and can provide more in-depth data to inform quality improvement in stroke care services.

Recommendation: The PROM-15 can be used as part of a strategy to elicit patients' views in an interview setting to inform stroke care quality improvement activities.

8.5.2 Implications for the use of the PROM-15 in person-centred clinical practice in stroke

The process of completing the PROM-15 gave participants the opportunity to talk about their experiences of life after stroke. These included positive and negative consequences of the stroke on their daily activities and social participation and how they were coping (see 5.10.2 of this thesis). Greenhalgh et al. (2018) advised that completing a PROM can help a patient to reflect on their condition and gives them a framework to discuss their experiences and concerns with clinicians. Furthermore, clinicians can gain a deeper understanding of the impact of a long-term condition, such as stroke, on their patients (Boyce et al. 2014). Participants in this present study were keen to express their feelings as they responded to the PROM-15's items, which not only served to support their response choices, but highlighted the potential value of using the PROM-15 to guide person-centred stroke reviews with HCPs, to identify and discuss their needs and be signposted to appropriate agencies.

The practical challenges of administering PROMs in clinical stroke care have been acknowledged (Reeves et al. 2018), including the time required to collect PROM data. The cognitive interviews carried out in this current study, which included the administration of the PROM-15 over the phone and completed by participants on paper, as well as answering the interview questions, took between 25 to 45 minutes. The PROMIS-10 takes five minutes to administer (Reeves et al. 2018) and even with the five extra items, could realistically be administered as part of the clinical encounter to guide patient/clinician communication. If able, the patient could complete the PROM-15 before their clinic appointment and discuss their responses with the stroke clinician. PROMs have been used with patients in various clinical settings, including stroke (Katzan et al. 2017; Lebherz et al. 2022) with positive findings from the perspectives of patients and HCPs.

Recommendation: The PROM-15 can be used by HCPs to provide effective, person-centered interventions with patients with stroke, such as collaborative goal setting and the six-month post-stroke clinical review recommended in the National Clinical Guideline for Stroke (Royal College of Physicians 2016). The International Society for Quality of Life Research has provided a User's Guide on implementing PROMs in clinical practice to facilitate the process (Aaronson et al. 2015; Chan et al. 2019).

8.5.3 Implications for the use of the PROM-15 in stroke research

A review of the literature at the commencement of this study identified that there is no current evidence that the psychometric properties of the PROM-15 have been assessed, although there was some evidence of assessment of the PROMIS-10 (Katzan and Lapin 2018; Lam and Kwa 2018).

Since this study was conducted, further psychometric studies of the PROMIS-10 have been carried out. The measurement properties of the Dutch-Flemish version of the PROMIS-10 were assessed in 4370 individuals from the Dutch general population (Pellicari et al. 2021). Results indicated that internal consistency, measurement invariance, structural validity and cross-cultural validity were all sufficient. Content validity could not be assessed, as the sample was taken from the general Dutch population, rather than a condition-specific cohort. The authors recommended that further evaluation of the PROMIS-10 should be carried out in clinical populations and other countries.

Oosterveer et al.'s (2022) systematic review of studies that assessed the psychometric properties of PROMIS measures used in stroke included the PROMIS-10. Ten studies were identified, in which the PROMIS-10 was the most studied measure. Psychometric assessments of the PROMIS-10 demonstrated sufficient structural validity and reliability, (content validity was not assessed in any of the studies), with high quality evidence as evaluated using a modified Gradings of Recommendations, Assessment, Development and Evaluation approach (Schunemann et al. 2013). The reviewers concluded that further research was needed on content validity, structural validity and measurement invariance of the PROMIS measures in patients with stroke.

Recommendation: Further research is needed to evaluate other psychometric properties of the PROM-15, such as construct validity, reliability and responsiveness (Mokkink et al. 2010). This will ensure that the PROM-15 is a valid tool to measure HRQoL in individuals with stroke to inform research consistently. The use of evidence-based standards, such as the study design checklist developed by COSMIN (Mokkink et al. 2019) employed in this study, is recommended to facilitate the assessment of other measurement properties of the PROM-15.

The PROMIS-10 component of the PROM-15 can be scored for physical and mental health domains, and both sum scores convert into t-scores (standardized to have a population mean of 50 and a population standard deviation of 10 points) (ICHOM 2015). This is useful for comparative studies or for organisational benchmarking purposes (Appleby et al. 2015; Cella et al. 2015). However, this current study has identified that the PROM-15 cannot, in its current form, be scored, therefore has limited value in providing a quantitative measure of HRQoL in people with stroke for comparative research purposes.

Recommendations*:* Further work is indicated to amend the PROM-15 so that all items can be scored, to provide quantitative data on HRQoL in individuals living with stroke, to inform research.

Researchers need to clearly state whether they are using the whole PROM-15 scale or the PROMIS-10 component in their study, so as not to confound comparisons with findings in other studies.

8.6 Dissemination of study findings

The findings of this study will be presented as a report to the Welsh Stroke Implementation Group to inform future evaluation and quality improvement in stroke care across Wales.

An abstract/ poster presentation of the study will be submitted to relevant conferences such as the annual Welsh Stroke Conference; the UK Stroke Forum Conference; and ICHOM Conference.

The study will be reported and submitted for peer review to relevant international journals, including Stroke; Patient Related Outcome Measures;

and the Journal of Patient Outcomes.
A report will be presented to the Nevill Hall Hospital Thrombosis and Research Fund committee who funded my doctorate and copies sent to those participants who requested it when they consented to the study.

8.7 Conclusion

This thesis has presented a mixed methods content validity study that determined that, from the perspectives of a small, purposive study sample, the PROM-15 has sufficient content validity to measure the HRQoL of people living with stroke.
The outcome of this study needs to be tempered by the limitations of the study sample characteristics but provides supporting evidence for the use of the PROM-15 in person-centred clinical practice, service quality improvement strategies, and research in stroke.

Figure 8.1 Statement of contribution to knowledge

Statement of contribution to knowledge
What is already known? ~ ❖ PROMs provide information on HRQoL from the viewpoint of a person with a health condition, such as stroke ❖ PROMs are increasingly being used in stroke research, clinical practice and quality improvement in stroke care ❖ A PROM needs to have content validity to ensure it has an acceptable level of comprehensibility, comprehensiveness and relevance with respect to the construct of interest and the target population. ❖ A stroke-specific 15-item PROM has been recommended by ICHOM to measure the HRQoL in people living with stroke as part of a stroke standard set of outcomes
The knowledge gap ~ ❖ There is no reported evidence in the healthcare research literature that the content validity of the PROM-15 has been established.
What this study adds ~ ❖ This study provides supporting evidence that the PROM-15 has sufficient content validity, in a small purposive sample, to measure HRQoL in people living with stroke, to inform person- centred clinical practice, quality improvement of care, and research in stroke.

References

Aarnes, R., Stubberud, J., & Lerdal, A. 2020. A literature review of factors associated with fatigue after stroke and a proposal for a framework for clinical utility. *Neuropsychological rehabilitation*, *30*(8), 1449–1476. https://doi.org/10.1080/09602011.2019.1589530

Aaronson, N. et al. 2015. User's guide to implementing patient-reported outcomes assessment in clinical practice. *International Society for Quality of Life Research*, *2*, pp.1-47.

Aber, A. et al. 2020. Mixed methods study to develop the content validity and the conceptual framework of the electronic patient-reported outcome measure for vascular conditions. *BMJ Open* 10(8), p. 034154. doi: 10.1136/bmjopen-2019- 034154.

Ahmed, S. et al. 2012. The Use of Patient-reported Outcomes (PRO) Within Comparative Effectiveness Research: Implications for Clinical Practice and Health Care Policy. *Medical Care*, *50*(12), 1060–1070. http://www.jstor.org/stable/41714633

Aho, K., Harmsen, P., Hatano, S., Marquardsen, J., Smirnov, V.E. and Strasser, T. 1980. Cerebrovascular disease in the community: results of a WHO collaborative study. *Bulletin of the World Health Organization*, *58*(1), p.113.

Akosile, C.O. et al. 2013. Quality of life and sex-differences in a South-Eastern Nigerian stroke sample. *African Journal of Neurological Sciences* 32(1), pp. 19–25. doi: 10.4314/ajns.v32i1.

Al Sayah, F., Lahtinen, M., Bonsel, G. J., Ohinmaa, A. and Johnson, J. A. 2021. A multi-level approach for the use of routinely collected patient-reported outcome measures (PROMs) data in healthcare systems. *Journal of patient-reported outcomes*, *5* (Suppl 2), 98. https://doi.org/10.1186/s41687-021-00375-1

Albrecht, G.L. and Devlieger, P. J. 1999. The disability paradox: high quality of life against all odds. *Social Science & Medicine*, *48*(8), pp.977-988. https://doi.org/10.1016/s0277-9536(98)00411-0

Algurén, B. 2012. Factors Associated with Health-Related Quality of Life After Stroke: A 1-Year Prospective Cohort Study. *Neurorehabilitation & Neural Repair* 26(3), pp. 266–274. doi: 10.1177/1545968311414204.

Allred, R.P., Kim, S.Y. and Jones, T.A. 2014. Use it and/or lose it—experience effects on brain remodelling across time after stroke. *Frontiers in Human Neuroscience* 8, p. 379. doi: 10.3389/fnhum.2014.00379.

Almanasreh, E., Moles, R. and Chen, T.F. 2019. Evaluation of methods used for estimating content validity. *Research in Social and Administrative Pharmacy* 15(2), pp. 214–221. doi: 10.1016/j.sapharm.2018.03.066.

Anatomyinfo.com.(no date). Image of the lobes of the brain and their functions. Available at www.anatomyinfo.com. Accessed 04/04/25.

Appleby, J., Devlin, N. and Parkin, D. 2015. *Using patient reported outcomes to improve health care*. John Wiley & Sons.

Arwert, H.J., Oosterveer, D.M., Schoones, J.W., Terwee, C.B. and Vliet Vlieland, T.P. 2022. Use of Patient-Reported Outcomes Measurement Information System Measures in Clinical Research in Patients with Stroke: A Systematic Literature Review. *Archives of Rehabilitation Research and Clinical Translation* 4(2), p. 100191. doi: 10.1016/j.arrct.2022.100191.

Asplund, K. et al. 2011. The Riks-Stroke story: building a sustainable national register for quality assessment of stroke care. *International journal of stroke: official journal of the International Stroke Society* 6(2), pp. 99–108. doi: 10.1111/j.1747- 4949.2010.00557.x.

Australian Commission on Safety and Quality in Health Care. 2019. *About PROMs.* Available at: https://www.safetyandquality.gov.au/our-work/indicators- measurement-and-reporting/patient-reported-outcomes/about-proms#what-is-the- commission%E2%80%99s-role-in-the-use-of-proms? Accessed 08/03/2023

Ayis, S., Wellwood, I., Rudd, A. G., McKevitt, C., Parkin, D., and Wolfe, C. D. 2015. Variations in Health-Related Quality of Life (HRQoL) and survival 1 year after stroke: five European population-based registers. *BMJ open*, *5*(6), e007101. https://doi.org/10.1136/bmjopen-2014-007101

Ayelward, M., Phillips, C. and Howson, H. 2013. *Simply Prudent Healthcare–achieving better care and value for money in Wales–discussion paper.* Cardiff. The Bevan Commission.

Bakas, T. et al. 2012. Systematic review of health-related quality of life models. *Health and quality of life outcomes*, *10*, 134. https://doi.org/10.1186/1477- 7525-10-134

Barbosa, P.M., Ferreira, L.N., Cruz, V.T., Silva, A. and Szrek, H. 2022. Healthcare, Clinical Factors and Rehabilitation Predicting Quality of Life in First-time Stroke Patients: A 12-month Longitudinal Study. *Journal of Stroke and Cerebrovascular Diseases* 31(4), p. 106300. doi: 10.1016/j.jstrokecerebrovasdis.2021.106300.

Barrett, A.M. 2009. Rose-coloured answers: Neuropsychological deficits and patient- reported outcomes after stroke. *Behavioural Neurology* 22(1–2), pp. 17–23. doi: 10.3233/BEN-2009-0250.

Batalden, M., Batalden, P., Margolis, P., Seid, M., Armstrong, G., Opipari-Arrigan, L. and Hartung, H. 2016. Coproduction of healthcare service. *BMJ Quality & Safety* 25(7), pp. 509–517. doi: 10.1136/bmjqs-2015-004315.

Bazeley, P. 2018. Integrating Analyses in Mixed Methods Research. Available at: https://dx.doi.org/10.4135/9781526417190. Accessed 01/09/2022.

Beatty, P., and Willis, G. 2007. Research Synthesis: The Practice of Cognitive Interviewing. *Public Opinion Quarterly* 71, pp. 287–311. https://doi.org/10.1093/poq/nfm006

Bhaskar, R. (2008). A Realist Theory of Science (1st ed.). Routledge. https://doi.org/10.4324/9780203090732

Biesta, G. 2015. Pragmatism and the Philosophical Foundations of Mixed Methods Research. In: *SAGE Handbook of Mixed Methods in Social & Behavioural Research*. 2nd ed. Thousand Oaks, CA: SAGE Publications, Inc, pp. 95–118. Available at: http://www.doi.org/10.4135/9781506335193. Accessed 02/11/2021

Black, N. 2013. Patient- reported outcome measures could help transform healthcare. *BMJ* 346. doi: 10.1136/bmj.f167.

Blair, J. and Brick, P.D. 2010. *Methods for the analysis of cognitive interviews.* In: Proceedings of the section on survey research methods. Washington: American Statistical Association, pp. 3739–3748.

Blair, J. and Conrad, F. 2011. Sample Size for Cognitive Interview Pretesting. *The Public Opinion Quarterly* 75, pp. 636–658. doi: 10.2307/41288411.

Bobos, P., MacDermid, J.C., Boutsikari, E.C., Lalone, E.A., Ferreira, L. and Grewal,

R. 2020. Evaluation of the content validity index of the Australian/Canadian osteoarthritis hand index, the patient-rated wrist/hand evaluation and the thumb disability exam in people with hand arthritis. *Health and Quality of Life Outcomes* 18(1), p. 302. doi: 10.1186/s12955-020-01556-0.

Boeije, H. and Willis, G. 2013. The Cognitive Interviewing Reporting Framework (CIRF): Towards the harmonization of cognitive testing reports. *Methodology: European Journal of Research Methods for the Behavioural and Social Sciences* 9(3), pp. 87–95. doi: 10.1027/1614-2241/a000075.

Bowling, A. 2017. *Measuring Health: a review of subjective health, well- being and quality of life measurement scales* (4thed.). Maidenhead. Open University Press.

Boyce, M.B., Browne, J.P. and Greenhalgh, J. 2014. The experiences of professionals with using information from patient-reported outcome measures to improve the quality of healthcare: a systematic review of qualitative research. *BMJ Qual* Saf.;23(6):508-518. doi: 10.1136/bmjqs-2013-002524.

Braun, V., and Clarke, V. 2006. Using Thematic Analysis in Psychology. *Qualitative research In Psychology* 3, pp. 77–101. doi: 10.1191/1478088706qp063oa.

Braun, V., and Clarke, V. 2022. *Thematic analysis: A practical guide*. Sage Publications Ltd.

Brédart, A., Marrel, A., Abetz-Webb, L., Lasch, K. and Acquadro, C. 2014. Interviewing to develop patient-reported outcome (PRO) measures for clinical research: Eliciting patients' experience. *Health and Quality of Life Outcomes* 12(1), p. 15. doi: 10.1186/1477-7525-12-15.

Bristowe, K. et al. 2020. The development and cognitive testing of the positive outcomes HIV PROM: a brief novel patient-reported outcome measure for

adults living with HIV. *Health and Quality of Life Outcomes* 18(1), pp. 1–10.

Brod, M., Tesler, L.E. and Christensen, T.L. 2009. Qualitative research and content validity: developing best practices based on science and experience. *Qual Life Res* (v;18(9):1263-78). doi: 10.1007/s11136-009-9540-9.

Brott, T.G. et al.1989. Measurements of acute cerebral infarction: A clinical examination scale. *Stroke; a journal of cerebral circulation.* 20. 864-70. 10.1161/01.STR.20.7.864.

Brouns, R., Espinoza, A.V., Goudman, L., Moens, M. and Verlooy, J. 2019. Interventions to promote work participation after ischaemic stroke: A systematic review. *Clinical Neurology and Neurosurgery*, *185*, p.105458. https://doi.org/10.1016/j.clineuro.2019.105458

Brown, M., Levack, W., McPherson, K.M., Dean, S.G., Reed, K., Weatherall, M. and Taylor, W.J. 2014. Survival, momentum, and things that make me "me": patients' perceptions of goal setting after stroke. *Disability and Rehabilitation* 36(12), pp.1020–1026. doi: 10.3109/09638288.2013.825653.

Bryman, A. 2007. Barriers to integrating quantitative and qualitative research. *Journal of Mixed Methods Research* 1(1), pp. 8–22. doi: 10.1177/2345678906290531.

Bryman, A. 2016. *Social Research Methods*. Oxford University Press.

Buers, C., Triemstra, M., Bloemendal, E., Zwijnenberg, N.C., Hendriks, M. and Delnoij, D.M. 2014. The value of cognitive interviewing for optimizing a patient experience survey. *International Journal of Social Research Methodology* 17(4), pp. 325–340. https://dx.doi.org/10.1080/13645579.2012.750830

Busetto, L. et al. 2020. Patient-centredness in acute stroke care - a qualitative study from the perspectives of patients, relatives and staff. *European Journal of Neurology* 27(8), pp. 1638–1646. doi: 10.1111/ene.14283.

Bustamante, A., Garcia-Berrocoso, T., Rodriguez, N., Llombart, V., Ribo, M., Molina, C. and Montaner, J., 2016. Ischemic stroke outcome: A review of the influence of post-stroke complications within the different scenarios of stroke care. *European journal of internal medicine*, *29*, pp.9-21.

Calvo, I. et al. 2019. Predictors of Oral Feeding Resumption after Stroke in a

Rehabilitation Hospital: A Retrospective Study. *Journal of Stroke and Cerebrovascular Diseases* 28(7), pp. 1958–1970. doi: 10.1016/j.jstrokecerebrovasdis.2019.03.040.

Cameron, L.J. et al. 2022. Self-reported quality of life following stroke: a systematic review of instruments with a focus on their psychometric properties. *Quality of Life Research* 31(2), pp. 329–342. doi: 10.1007/s11136-021-02944-9.

Cano, D. et al. 2022. Patient-reported outcome measures after thrombectomy in patients with acute stroke: fine-tuning the modified Rankin Scale. *Journal of NeuroInterventional Surgery*. doi: 10.1136/neurintsurg-2022-018840.

Carey, L. et al. 2019. Finding the Intersection of Neuroplasticity, Stroke Recovery, and Learning: Scope and Contributions to Stroke Rehabilitation. *Neural Plasticity* 2019, p. e5232374. doi: 10.1155/2019/5232374.

Carod-Artal, F.J. and Egido, J.A., 2009. Quality of life after stroke: the importance of a good recovery. *Cerebrovascular diseases*, *27*(Suppl. 1), pp.204-214.

Carod-Artal, F.J. 2012. Determining quality of life in stroke survivors. *Expert Review of Pharmacoeconomics & Outcomes Research; London* 12(2), pp. 199–211. doi: 10.1586/erp.11.104.

Carter B, Hayes C, Smith A, Pennington A, Price M, Pearson O, et al. (2021) A single patient reported outcome measure for acquired brain injury, multiple sclerosis & Parkinson's disease. *PLoS ONE* 16(6): e0251484. https://doi.org/10.1371/journal.pone.0251484

Castillo-Díaz, M. and Padilla, J.L. 2013. How cognitive interviewing can provide validity evidence of the response processes to scale items. *Social indicators research*, *114*, pp.963-975. doi:10.1007/s11205-012-0184-8.

Cella, D., Hahn, E.A., Jensen, S.E., Butt, Z., Nowinski, C.J., Rothrock, N. and Lohr,K.N. 2015. *Patient-reported outcomes in performance measurement*. Research Triangle Institute Press.

Cella, D., Riley, W. and Stone, A. 2010. The patient outcomes measurement information system (PROMIS) developed and tested its first wave of adult self-

reported health outcome item banks: 2005-2008. *Journal of Clinical Epidemiology* 63(11), pp. 1179–1194. doi: 10.1016/jclinepi.2010.04.011.

Chan, E. K. H., Edwards, T. C., Haywood, K., Mikles, S. P., & Newton, L. (2019). Implementing patient-reported outcome measures in clinical practice: a companion guide to the ISOQOL user's guide. *Quality of Life Research: an international journal of quality of life aspects of treatment, care and rehabilitation*, *28*(3), 621–627. https://doi.org/10.1007/s11136-018-2048-4

Chen, P., Lin, K.-C., Liing, R.-J., Wu, C.-Y., Chen, C.-L. and Chang, K.-C. 2016. Validity, responsiveness, and minimal clinically important difference of EQ-5D-5L in stroke patients undergoing rehabilitation. *Quality of Life Research* 25(6), pp. 1585– 1596. doi: 10.1007/s11136-015-1196-z.

Chen, S., Zeng, L. & Hu, Z. Progressing haemorrhagic stroke: categories, causes, mechanisms and managements. *J Neurol* **261**, 2061–2078 (2014). https://doi.org/10.1007/s00415-014-7291-1

Chhina, H., Klassen, A., Bade, D., Kopec, J. and Cooper, A. 2022. Establishing content validity of LIMB-Q Kids: a new patient-reported outcome measure for lower limb deformities. *Quality of Life Research* 31(9), pp. 2805–2818. doi: 10.1007/s11136-022-03140-z.

Chou, C.Y. 2015. Determinants of the health-related quality of life for stroke survivors. *Journal of Stroke and Cerebrovascular Diseases*, *24*(3), pp.655-662. https://doi.org/10.1016/j.jstrokecerebrovasdis.2014.10.022

Chou, C.Y., Ou, Y.C. and Chiang, T.R. 2015. Psychometric comparisons of four disease-specific health-related quality of life measures for stroke survivors. *Clinical Rehabilitation* 29(8), pp. 816–829. doi: 10.1177/0269215514555137.

Churruca K, Pomare C, Ellis LA, Long JC, Henderson SB, Murphy LED, Leahy CJ, Braithwaite J. 2021. Patient-reported outcome measures (PROMs): A review of generic and condition-specific measures and a discussion of trends and issues. *Health Expect.* 2021 Aug;24(4):1015-1024. doi: 10.1111/hex.13254. Epub 2021 May 5. PMID: 33949755; PMCID: PMC8369118.

Cicchetti, D. V., and Sparrow, S. A.1981. Developing criteria for establishing interrater reliability of specific items: applications to assessment of adaptive behaviour. *American Journal of Mental Deficiency*, *86*(2), 127–137.

Clery, A., Bhalla, A., Rudd, A.G., Wolfe, C.D. and Wang, Y. 2020. Trends in prevalence of acute stroke impairments: A population-based cohort study using the South London Stroke Register. *PLoS Medicine*, *17*(10), p.e1003366.

Collins, D. 2015. Cognitive Interviewing Practice. Available at: https://dx.doi.org/10.4135/9781473910102. Accessed 12/02/2020

Conrad, F.G. and Blair, J. 2009. Sources of Error in Cognitive Interviews. *Public Opinion Quarterly* 73, pp. 32–55. doi: 10.1093/poq/nfp013.

Corrigan, A.E., Carter, B., Smith, A., Pennington, A. and Hewitt, J. 2022. MORe PREcISE: a multicentre prospective study of patient reported outcome measures in stroke morbidity: a cross sectional study. *BMC Neurology* 22(1), p. 145. doi: 10.1186/s12883-022-02634-0.

Costa, D.S., Mercieca-Bebber, R., Rutherford, C., Tait, M.A. and King, M.T. 2021. How is quality of life defined and assessed in published research? *Quality of Life Research*, *30*, pp.2109-2121. https://doi.org/10.1007/s11136-021-02826-0

Coupland, A. P., Thapar, A., Qureshi, M. I., Jenkins, H., & Davies, A. H. 2017. The definition of stroke. *Journal of the Royal Society of Medicine*, *110*(1), 9–12. https://doi.org/10.1177/0141076816680121

Creamer, E.G. 2018. *An introduction to fully integrated mixed methods research*. Sage.

Creswell, J. W. 2013. *Qualitative Inquiry & Research Design: Choosing Among Five Approaches*. (3rd ed.). Thousand Oaks, CA: SAGE Publications.

Cresswell, J.W. 2015. *A concise introduction to mixed methods research*. SAGE Publications.

Cresswell, J.W. and Plano Clark, V.L. 2017. *Designing and conducting mixed methods research* (3rd edition). Sage Publications Inc.

Crichton, S.L. 2016. Patient outcomes up to 15 years after stroke: survival,

disability, quality of life, cognition and mental health. *Journal of Neurology, Neurosurgery, and Psychiatry* 87(10), pp. 1091–1098. doi: 10.1136/jnnp-2016-313361.

Crocker, J. C., Boylan, A. M., Bostock, J., & Locock, L. 2017. Is it worth it? Patient and public views on the impact of their involvement in health research and its assessment: a UK-based qualitative interview study. *Health expectations: an international journal of public participation in health care and health policy*, *20*(3), 519–528. https://doi.org/10.1111/hex.1247

Crosby, G.A., Munshi, S., Karat, A.S., Worthington, E. and Lincoln, N.B. 2012. Fatigue after stroke: frequency and effect on daily life. *Disability and Rehabilitation* 34(8), pp. 633–637. doi: 10.3109/09638288.2011.613517.

Cross Party Group on Stroke. 2020. The Future of Stroke Care in Wales. Available at https://business.sennedd.wales. Accessed 03/02/2021

Crotty, M. 1998.*The foundations of social research: Meaning and perspective in the research process.* London: Sage Publication, Inc.

Curry, L. and Nunez-Smith, M. 2015. *Mixed methods in health sciences research*. SAGE Publications, Inc. doi: 10.4135/9781483390659.

Dabrowska-Bender, M., Milewska, M., Gołąbek, A., Duda-Zalewska, A. and Staniszewska, A. 2017. The Impact of Ischemic Cerebral Stroke on the Quality of Life of Patients Based on Clinical, Social, and Psycho-emotional Factors. *Journal of Stroke and Cerebrovascular Diseases* 26(1), pp. 101–107. doi: 10.1016/j.jstrokecerebrovasdis.2016.08.036.

Damman, O. C., Verbiest, M. E. A., Vonk, S. I., Berendse, H. W., Bloem, B. R., de Bruijne, M. C., & Faber, M. J. 2019. Using PROMs during routine medical consultations: The perspectives of people with Parkinson's disease and their health professionals. *Health Expectations: an international journal of public participation in health care and health policy*, *22*(5), 939–951. https://doi-org.abc.cardiff.ac.uk/10.1111/hex.12899

D' Ardenne, J. and Collins, D. 2015. *Developing Interview Protocols In: Cognitive Interviewing Practice*. London: Sage Publications Ltd.

Darzi, A. 2008. *Our NHS Our Future: High Quality Care for All: NHS Next*

Stage Review Final Report. London: Department of Health.

Davis, L. 1992. *Instrument Review: Getting the most from your panel of experts*. Applied Nursing Research,5,194-197. https://doi.org/10.1016/S0897-1897(05)80008- 4

DeForge, R. and Shaw, J. 2012. Back-and fore-grounding ontology: exploring the linkages between critical realism, pragmatism, and methodologies in health & rehabilitation sciences. *Nursing Inquiry*,*19*(1), pp.83-95. https://doi.org/10.1111/j.1440-1800.2011.00550.x

de Graaf, J.A. et al. 2021. Comparison between EQ-5D-5L and PROMIS-10 to evaluate health-related quality of life 3 months after stroke: a cross-sectional multicenter study. *European Journal of Physical and Rehabilitation Medicine* 57(3),pp. 337–346. doi: 10.23736/S1973-9087.21.06335-8.
de Vet, HC, Terwee, CB, Mokkink, LB and Knol, DL 2011, *Measurement in Medicine - A practical guide*. U.S.A., New York. Cambridge University Press.

De Wit L. et al. 2007. Motor and functional recovery after stroke: a comparison of 4 European rehabilitation centers. *Stroke*.;38(7):2101-2107. doi:10.1161/STROKEAHA.107.482869

De Wit, L. et al. 2017. Long-term impact of stroke on patients' health-related quality of life. *Disability and Rehabilitation* 39(14), pp. 1435–1440. doi: 10.1080/09638288.2016.1200676

Deb-Chatterji, M. 2020. Patient-reported health-related quality of life after strokethrombectomy in clinical practice. *Neurology*. doi10.1212/WNL.0000000000010356.

Denham, A.M. et al. 2019. "This is our life now. Our new normal": A qualitative study of the unmet needs of carers of stroke survivors. *PloS one*, *14*(5), p.e0216682.

Denzin, N. K. 2012. Triangulation 2.0. Journal of Mixed Methods Research, 6(2), 80–88. https://doi.org/10.1177/1558689812437186

Denzin, N. K., & Lincoln, Y. S. (Eds.). 2017. *The SAGE Handbook of Qualitative Research* (5th ed.). SAGE Publications, Inc

Department of Health. 2011.The NHS Outcomes Framework 2011/2012. Available at: https://www.gov.uk/government/publications/nhs-outcomes-framework-2011-to-2012. Accessed 27/06/2016

Devlin, N. and Appleby, J. 2010 Getting the Most out of PROMs: Putting Health Outcomes at the Heart of NHS Decision-Making. OHE Monograph. Available at https://www.ohe.org/publications/getting- most-out-proms-putting-health-outcomes-heart-nhs-decision-making/ Accessed 27/06/2016

Donkor E. S. 2018. Stroke in the 21st Century: A Snapshot of the Burden, Epidemiology, and Quality of Life. *Stroke research and treatment*, *2018*, 3238165. https://doi.org/10.1155/2018/3238165

Drennan, J. 2003. Cognitive Interviewing: verbal data in the design and pretesting of questionnaires. *Journal of Advanced Nursing* 42(1), pp. 57-63 10 1046 1365-26482003 02579.1.

Drummond A. et al. 2017. The Nottingham Fatigue after Stroke (NotFAST) study: factors associated with severity of fatigue in stroke patients without depression. *Clinical Rehabilitation*;31(10):1406-1415.

doi:10.1177/0269215517695857

Eklund, J.H., Holmström, I.K., Kumlin, T., Kaminsky, E., Skoglund, K. and Höglander, J. 2019. Same or Different?" A Review of Reviews of Person-Centered and Patient-Centred Care. *Patient Education and Counselling* 102, pp. 3–11. https://doi.org/10.1016/j.pec.2018.08.029

Elwyn, G., Nelson, E., Hager, A., Price. A. 2020. Coproduction: when users define quality. *BMJ Quality & Safety* 2020; 29:711-716. doi:10.1136/bmjqs-2019-009830

Engel, L.G. 1977. The need for a new medical model: a challenge for biomedicine. Science. 196(4286). doi: 10.1126/science.847460.

Engström, M.S., Leksell, J., Johansson, U.B., Eeg-Olofsson, K., Borg, S., Palaszewski, B. and Gudbjörnsdottir, S., 2018. A disease-specific questionnaire for measuring patient-reported outcomes and experiences in the Swedish National Diabetes Register: development and evaluation of content validity, face validity, and

test-retest reliability. *Patient education and counseling*, *101*(1), pp.139-146.

Esfandiary, T. et al. 2020. Assessing the content validity of patient-reported outcome measures in adult myositis: A report from the OMERACT myositis working group. *Seminars in Arthritis and Rheumatism* 50(5), pp. 943–948. doi: 10.1016/j.semarthrit.2020.06.006.

Ezekiel, L., Collett, J., Mayo, N.E., Pang, L., Field, L. and Dawes, H. 2019. Factors Associated With Participation in Life Situations for Adults With Stroke: A Systematic Review. *Archives of Physical Medicine and Rehabilitation* 100(5), pp. 945–955. doi: 10.1016/j.apmr.2018.06.017.

Feigin, V. L., Brainin, M., Norrving, B., Martins, S., Sacco, R. L., Hacke, W., Fisher, M., Pandian, J., & Lindsay, P. 2022. World Stroke Organization (WSO): Global Stroke Fact Sheet 2022. *International Journal of Stroke:17*(1), 18–29. https://doi.org/10.1177/17474930211065917

Feilzer, M. 2010. Doing Mixed Methods Research Pragmatically: Implications for the Rediscovery of Pragmatism as a Research Paradigm. *Journal of Mixed Methods Research* 4(1), pp. 6–16. doi: 10.1177/1558689809349691.

Feng, Y.S., Kohlmann, T., Janssen, M.F. and Buchholz, I., 2021. Psychometric properties of the EQ-5D-5L: a systematic review of the literature. *Quality of Life Research*, *30*, pp.647-673.

Ferrans, C.E., Zerwic, J.J., Wilbur, J.E. and Larson, J.L. 2005. Conceptual Model of Health-Related Quality of Life. *Journal of Nursing Scholarship* 37, pp. 336–342. doi: 10.1111/j.1547-5069.2005.00058.x.

Fetters, M.D., 2019. *The Mixed Methods Research Workbook: Activities for Designing, Implementing, and Publishing Projects*. SAGE Publications.

Fetters, M., Curry, L. and Creswell, J. 2013. Achieving integration in mixed methods designs— Principles and practices. *Health Services Research* 48(6 Pt. 2), pp. 2134– 2156. doi: https://doi.org/10.1111/ 1475-6773.12117.

Fetters, M. and Freshwater, F. 2015. Editorial: The 1 + 1 = 3 integration challenge. *Journal of Mixed Methods Research* 9(2), pp. 115–117. doi: 10.1177/1558689815581222.

Fetters, M.D. and Guetterman, T.C. 2021. Development of a joint display as a mixed

analysis. *The Routledge Reviewer's Guide to Mixed Methods Analysis* (pp. 259-276). Routledge.

Field J., Holmes MM., Newell D., 2019. PROMs data: can it be used to make decisions for individual patients? A narrative review. *Patient Related Outcome Measures*.;10:233-24. https://doi.org/10.2147/PROM.S156291

Fisher, R.J. et al. 2016. Is Stroke Early Supported Discharge still effective in practice? A prospective comparative study. *Clinical rehabilitation* 30(3), pp. 268–276. doi: 10.1177/0269215515578697.

Fleiss, J., 1981. *Statistical methods for rates and proportions* (2nd ed.). New York: John Wiley.

Frank, L. et al. 2015. Conceptual and practical foundations of patient engagement in research at the patient-centered outcomes research institute. *Quality of life research: an international journal of quality of life aspects of treatment, care and rehabilitation*, *24*(5), 1033–1041. https://doi-org.abc.cardiff.ac.uk/10.1007/s11136-014-0893-3

Frost, M. H., Reeve, B. B., Liepa, A. M., Stauffer, J. W., Hays, R. D., and Mayo/FDA Patient-Reported Outcomes Consensus Meeting Group. 2007. What is sufficient evidence for the reliability and validity of patient-reported outcome measures? *Value in Health: the journal of the International Society for Pharmacoeconomics and Outcomes Research*, *10 Suppl 2*, S94–S105. https://doi.org/10.1111/j.1524- 4733.2007.00272.x

Gabes, M. et al. 2022. Content validity of the Recap of atopic eczema (RECAP) instrument in Dutch, English and German to measure eczema control in young people with atopic eczema: a cognitive interview study. *British Journal of Dermatology* 187(6), pp. 919–926. doi: 10.1111/bjd.21767.

Gall, S., Phan, H., Madsen, T.E., Reeves, M., Rist, P., Jimenez, M., Lichtman, J., Dong, L. and Lisabeth, L.D., 2018. Focused update of sex differences in patient reported outcome measures after stroke. *Stroke*, *49*(3), pp.531-535.

Ganesh, S., Mohapatra, S., Mohanty, P., Pattnaik, M. and Mishra, C. 2017. Identification of the components associated with functioning using the international classification of functioning, disability and health comprehensive core set for stroke in Indian stroke survivors. *Topics in Stroke Rehabilitation*,

24(7), pp.517-526.

García, A. 2011. Cognitive interviews to test and refine questionnaires. *Public Health Nursing* 28(5), pp. 444–450. https://doi.org/10.1111/j.1525-1446.2010.00938.x

Gemine, R., Davies, G.R., Tarrant, S., Davies, R.M., James, M. and Lewis, K., 2021. Factors associated with work-related burnout in NHS staff during COVID-19: a cross-sectional mixed methods study. *BMJ open*, *11*(1), p.e042591.

Gentry, K., Snyder, K., Barstow, B., & Hamson-Utley, J. 2018. The Biopsychosocial Model: Application to Occupational Therapy Practice. *The Open Journal of Occupational Therapy, 6*(4). https://doi.org/10.15453/2168-6408.1412

Geyh, S. et al. 2004. ICF Core Sets for stroke. *Journal of Rehabilitation Medicine*, *36*(0), pp.135-141.https://doi.org/10.1080/16501960410016776.

Gibbons, C. et al. 2021. Routine provision of feedback from patient-reported outcome measurements to healthcare providers and patients in clinical practice. *The Cochrane Database of Systematic Reviews* 10(10), p. CD011589. doi: 10.1002/14651858.CD011589.pub2.

Gittins, M., Vail, A., Bowen, A., Lugo-Palacios, D., Paley, L., Bray, B., Gannon, B., & Tyson, S., 2020. Factors influencing the amount of therapy received during inpatient stroke care: an analysis of data from the UK Sentinel Stroke National Audit Programme. *Clinical rehabilitation*, *34*(7), 981–991. https://doi-10.1177/0269215520927454

Golicki, D., Niewada, M., Buczek, J., Karlińska, A., Kobayashi, A., Janssen, M. F., & Pickard, A. S. 2015. Validity of EQ-5D-5L in stroke. *Quality of Life Research: an international journal of quality of life aspects of treatment, care and rehabilitation*, *24*(4), 845–850. https://doi.org/10.1007/s11136-014-0834-1

Goswami, P. et al. 2020. Development of a Novel Hematological Malignancy Specific Patient-Reported Outcome Measure (HM-PRO): Content Validity. *Frontiers in pharmacology*, *11*, 209. https://doi-10.3389/fphar.2020.00209

de Graaf J.A. et al. 2021. Comparison between EQ-5D-5L and PROMIS-10 to evaluate health-related quality of life 3 months after stroke: a cross-sectional multicenter study. *European journal of physical and rehabilitation medicine*.

Grabowska-Fudala, B. 2017. Clinical recovery and health-related quality of life in ischaemic stroke survivors receiving thrombolytic treatment: a 1-year follow-up study. *Journal of Thrombosis and Thrombolysis* 43(1), pp. 91–97. doi: 10.1007/s11239-016-1419-3.

Grant, J., and Davies, L. 1997. Selection and use of content experts in instrumental development. *Research in Nursing and Health* 20, pp. 269–274. doi: 10.1002/(SICI)1098-240X(199706)20:3.

Graupner, C., Kimman, M.L., Mul, S., Slok, A.H., Claessens, D., Kleijnen, J., Dirksen, C.D. and Breukink, S.O., 2021. Patient outcomes, patient experiences and process indicators associated with the routine use of patient-reported outcome measures (PROMs) in cancer care: a systematic review. *Supportive Care in Cancer*, *29*, pp.573-593.

Gray, M. 2015. Conducting Cognitive Interviews. In: *Cognitive Interviewing Practice*. London: Sage Publications Ltd

Greene, J. and Hall, J. 2015. Dialectics and Pragmatism: Being of Consequence. In: *SAGE Hand of Mixed Methods in Social & Behavioural Research*. Thousand Oaks: SAGE Publications Inc.

Greenhalgh, J., Dalkin, S., Gooding, K., Gibbons, E., Wright, J. and Meads, D. 2017. Functionality and feedback: A realist synthesis of the collation, interpretation and utilisation of patient-reported outcome measures data to improve patient care. *NIHR J Health Serv Del Res* 5(2), pp. 1-279 25.

Greenhalgh, J., Gooding, K., Gibbons, E., Dalkin, S., Wright, J., Valderas, J. and Black, N. 2018. How do patient reported outcome measures (PROMs) support clinician-patient communication and patient care? A realist synthesis. *Journal of Patient-Reported Outcomes* 2(1), p. 42. doi: 10.1186/s41687-018-0061-6.

Groeneveld, I. 2019. Value-Based Stroke Rehabilitation: Feasibility and Results of Patient-Reported Outcome Measures in the First Year After Stroke.

Journal of Stroke & Cerebrovascular Diseases 28(2), pp. 499–512. doi: 10.1016/j.jstrokecerebrovasdis.2018.10.033.

Gubrium, J., Holstein, J., Marvasti, A, and McKinney K. 2012. *The SAGE handbook of interview research: The complexity of the craft*. Sage Publications.

Guest, G., Bunce, A. and Johnson, L. 2006. How Many Interviews Are Enough? An Experiment with Data Saturation and Variability. *Field Methods* 18(1), pp. 59–82. doi: 10.1177/1525822X05279903.

Guetterman, T.C., Fetters, M.D. and Creswell, J.W. 2015. Integrating quantitative and qualitative results in health science mixed methods research through joint displays. *Annals of Family Medicine* 13(6), pp. 554–561. doi: 10.1370/afm.1865.

Guetterman, T.C., Molina-Azorin, J.F. and Fetters, M.D. 2020. Virtual special issue on integration in mixed methods research. *Journal of Mixed Methods Research* 14(4), pp. 430–435. doi: 10.1177/1558689820956401.

Haley W. et al. 2011. Quality of life after stroke: a prospective longitudinal study. *Quality of Life Research* 20(6), pp. 799–806. doi: 10.1007/s11136-010-9810-6.

Hamilton M. 1960. A rating scale for depression. *J Neurol Neurosurg Psychiatry.* 1960 Feb;23:56–62.

Harrington, Rachel L. et al. 2020. “Defining Patient Engagement in Research: Results of a Systematic Review and Analysis: Report of the ISPOR Patient-Centered Special Interest Group.” *Value in health: the journal of the International Society for Pharmacoeconomics and Outcomes Research* vol. 23,6, 677-688. doi:10.1016/j.jval.2020.01.019

Harrison, M. and Palmer, R. 2015. Exploring patient and public involvement in stroke research: A qualitative study. *Disability and rehabilitation* 37, pp. 1–10. doi: 10.3109/09638288.2014.1001525.

Haynes-Brown, T.K. and Fetters, M.D. 2021. Using Joint Display as an Analytic Process: An Illustration Using Bar Graphs Joint Displays from a Mixed Methods Study of How Beliefs Shape Secondary School Teachers’ Use of

Technology'. *International Journal of Qualitative Methods*. doi: 10.1177/1609406921993286.

Hays, R.D. and Morales, L.S. 2001. The RAND-36 measure of health-related quality of life. *Annals of medicine* 33(5), pp. 350–357. doi: 10.3109/07853890109002089.

Haywood, K.L., Wit, M., Staniszewska, S., Morel, T. and Salek, S. 2017. Developing patient-reported and relevant outcome measures. In: *Patient involvement in health technology assessment*. Singapore: Adis, pp. 103–120.

Heiberg, G. et al. 2018. Can the health- related quality of life measure QOLIBRI- overall scale (OS) be of use after stroke? A validation study. *BMC neurology*, *18*, pp.1-10. https://doi.org/10.1186/s12883-018-1101-9

Heiberg-Agerbeck, A., Martiny, FHJ., Jauernik, CP. et al. 2021. Validity of Current Assessment Tools Aiming to Measure the Affective Component of Pain: A Systematic Review. *Patient Related Outcome Measures*. 12:213-226. DOI: 10.2147/proms304950. PMID: 34262380; PMCID: PMC8274708.

Hennink, M.M., Kaiser, B.N. and Marconi, V.C. 2017. Code Saturation Versus Meaning Saturation: How Many Interviews Are Enough? *Qualitative health research* 27(4), pp. 591–608. doi: 10.1177/1049732316665344.

Herdman,M. et al. 2011. Development and preliminary testing of the new five-level version of EQ-5D (EQ-5D-5L). *Quality of life research: an international journal of quality of life aspects of treatment, care and rehabilitation*, *20*(10), 1727–1736. https://doi: 10.1007/s11136-011-9903-x

Hesse-Biber, S. 2015. Mixed Methods Research: The "Thing-ness" Problem. *Qualitative Health Research* 25(6), pp. 775–788. doi:

Hewitt, J., Bains, N., Wallis, K., Gething, S., Pennington, A. and Carter, B. 2021. The Use of Patient Reported Outcome Measures (PROMs) 6 Months Post-Stroke and Their Association with the National Institute of Health Stroke Scale (NIHSS) on Admission to Hospital. *Geriatrics* 6(3), p. 88. doi: 10.3390/geriatrics6030088.

Hewitt, J., Pennington, A., Smith. A., Gething, S., Price, M. 2019. A multi-centre, UK- based, non-inferiority randomised controlled trial of 4 follow-up

assessment methods in stroke survivors. *BMC medicine* 17(1), pp. 1–8. doi: 10.1186/s12916-019-1350-5

Hickey, A., Mellon, L., Williams, D., Shelley, E. and Conroy, R.M. 2018. Does stroke health promotion increase awareness of appropriate behavioural response? Impact of the face, arm, speech and time (FAST) campaign on population knowledge of stroke risk factors, warning signs and emergency response. *European stroke journal* 3(2), pp. 117–125. doi: 10.1177/2396987317753453.

Howe, K.1988. Against the Quantitative-Qualitative Incompatibility Thesis or Dogmas Die Hard. *Educational Researcher* 17(8), pp. 10–16. doi: 10.3102/0013189X017008010.

Hughes, A. 2009. *The Re-Education of Upper Limb Movement Post Stroke using Iterative Learning Control mediated by Electrical Stimulation.* University of Southampton Research Repository.

Hurford, R., Charidimou, A., Fox, Z., Cipolotti, L., and Werring, D. J. 2013. Domain- specific trends in cognitive impairment after acute ischaemic stroke. *Journal of neurology*, *260*(1), 237–241. https://doi.org/10.1007/s00415-012-6625-0.

ICHOM. 2015. ICHOM Standard set for stroke. Available at: www.ichom.org./medicalconditions/stroke. Accessed 14/07/2019

Institute of Medicine. 2001. *Crossing The Quality Chasm: A New Health System for the 21st Century*. Washington DC: National Academy Press.

ISOQOL. 2012. *What is health-related quality of life?* Available

at:http://www.isoqol.org/about-isoqol/what-is-health-related-quality-of-life

research. Accessed 14/07/2019

Izumi, S., Vandermause, R. and Benavides-Vaello, S. 2013. Adapting cognitive interviewing for nursing research. *Research in nursing & health*, *36*(6), 623–633. https://doi.org/10.1002/nur.21567

Jang, M.K., Kim, S., Collins, E.G., Quinn, L.T., Park, C.G. and Ferrans, C.E. 2020. Enriching the quality of cross-cultural instrument development through cognitive interviewing: Implications for nursing research. *Japan journal of*

nursing science: JJNS 17(2), p. 12301. doi: 10.1111/jjns.12301.

Jenkinson, C., Fitzpatrick, R., Crocker, H. and Peters, M. 2013. The Stroke Impact Scale: validation in a UK setting and development of a SIS short form and SIS index. *Stroke*, *44*(9), 2532–2535. https://doi.org/10.1161/STROKEAHA.113.001847

Jenkinson, C., Gibbons, E., Fitzpatrick, R. 2009. *A Structured Review of Patient-Reported Outcome Measures (PROMs) for Stroke.* Patient-Reported Outcome Measurement Group, University of Oxford.

Johnson, R., Grove, A.L, and A, Clarke, A. 2019. Pillar Integration Process: A Joint Display Technique to Integrate Data in Mixed Methods Research'. *Journal of Mixed Methods Research* 13(3), pp. 301–320. doi: 10.1177/1558689817743108.

Johnson, R., Onwuegbuzie. A., and Turner, L. 2007. Toward a Definition of Mixed Methods Research. *Journal of Mixed Methods Research* 1(2), pp. 112–133. doi: 10.1177/1558689806298224.

Jokinen, H., Melkas, S., Ylikoski, R., Pohjasvaara, T., Kaste, M., Erkinjuntti, T. and Hietanen, M. 2015. Post-stroke cognitive impairment is common even after successful clinical recovery. *European Journal of Neurology* 22(9), pp. 1288–1294. doi: 10.1111/ene.12743.

Joy, M. and Carmichael, S. 2021. Encouraging an excitable brain state: mechanisms of brain repair in stroke. *Nature Reviews Neuroscience* 22(1), pp. 38–53. doi: 10.1038/s41583-020-00396-7.

Kainz, A., Meisinger, C., Linseisen, J., Kirchberger, I., Zickler, P., Naumann, M. and Ertl, M. 2021. Changes of Health-Related Quality of Life Within the 1st Year After Stroke–Results from a Prospective Stroke Cohort Study. *Frontiers in Neurology* 12,p. 715313. doi: 10.3389/fneur.2021.715313.

Kane, P.M. et al. 2018. Understanding how a palliative-specific patient-reported outcome intervention works to facilitate patient-centred care in advanced heart failure: a qualitative study. *Palliative medicine*, *32*(1), pp.143-155.

Karimi, M. and Brazier, J.H. 2016. Health-Related Quality of Life, and Quality of Life: What is the Difference? *PharmacoEconomics* 34, pp. 645–649. doi: 10.1007/s40273- 016-0389-9.

Karlsson, E. and Gustafsson, J. 2022. Validation of the international classification of functioning, disability and health (ICF) core sets from 2001 to 2019–a scoping review. *Disability and rehabilitation*, *44*(14), pp.3736-3748. https://doi.org/10.1080/09638288.2021.1878562

Katona, M., Schmidt, R., Schupp, W. and Graessel, E. 2015. Predictors of health- related quality of life in stroke patients after neurological inpatient rehabilitation: a prospective study. *Health and Quality of Life Outcomes* 13(1), p. 58. doi: 10.1186/s12955-015-0258-9.

Katzan, I.L., and Lapin, B. 2018. PROMIS -GH (Patient-Reported Outcomes Measurement Information System Global Health) Scale in Stroke: A Validation Study. *Stroke*, *49*(1), 147–154. https://doi.org/10.1161/STROKEAHA.117.018766

Katzan, I. L., Schuster, A., Newey, C., Uchino, K., & Lapin, B. 2018a. Patient- reported outcomes across cerebrovascular event types: More similar than different. *Neurology*, *91*(23), e2182–e2191. https://doi.org/10.1212/WNL.0000000000006626

Katzan, I. L., Thompson, N. and Uchino, K. 2016. Innovations in Stroke: The Use of PROMIS and NeuroQoL Scales in Clinical Stroke Trials. *Stroke*, *47*(2), e27–e30. https://doi.org/10.1161/STROKEAHA.115.011377

Katzan, I.L., Thompson, N.R., Lapin, B. and Uchino, K. 2017. Added Value of Patient-Reported Outcome Measures in Stroke Clinical Practice. *Journal of the American Heart Association* 6(7), p. e005356. doi: 10.1161/JAHA.116.005356.

Katzan, I.L., Thompson, N.R., Uchino, K. and Lapin, B. 2018b. The most affected health domains after ischemic stroke. *Neurology* 90(16), pp. e1364–e1371. doi: 10.1212/WNL.0000000000005327.

Kelly, L. M. and Cordeiro, M. 2020. Three principles of pragmatism for research on organizational processes. *Methodological Innovations*, *13*(2). doi:10.1177/2059799120937242

Kelly, L., Potter, C. M., Hunter, C., Gibbons, E., Fitzpatrick, R., Jenkinson, C., & Peters, M. 2016. Refinement of the Long-Term Conditions Questionnaire (LTCQ): patient and expert stakeholder opinion. *Patient related outcome*

measures, *7*, 183–193. https://doi.org/10.2147/PROM.S116987

Khalid, W. 2016. Quality of life after stroke in Pakistan. *BMC Neurology* 16, pp. 1–12. doi: 10.1186/s12883-016-0774-1.

Khedr, E.M., Abdelrahman, A.A. and Desoky, T. 2020. Post-stroke depression: frequency, risk factors, and impact on quality of life among 103 stroke patients— hospital-based study. *Egypt J Neurol Psychiatry Neurosurg* 56, p. 66. doi: 10.1186/s41983-020-00199-8.

Kim, E.S., Kim, J.W., Kang, H.J., Bae, K.Y., Kim, S.W., Kim, J.T., Park, M.S., Cho, K.H. and Kim, J.M., 2018. Longitudinal impact of depression on quality of life in stroke patients. *Psychiatry Investigation*, *15*(2), p.141.

King, D., Wittenberg, R., Patel, A., Quayyum, Z., Berdunov, V. and Knapp, M. 2020. The future incidence, prevalence and costs of stroke in the UK. *Age and ageing*, *49*(2), 277–282. https://doi.org/10.1093/ageing/afz163.

Kitzinger, J.1994. The methodology of focus groups: the importance of interaction between research participants. *Sociology of Health & Illness* 16(1), pp.103–121. http://dx.doi.org/10.1111/1467-9566.ep11347023

Kitson, A., Marshall, A., Bassett, K. and Zeitz, K. 2013. What are the core elements of patient-centred care? A narrative review and synthesis of the literature from health policy, medicine and nursing. *Journal of Advanced Nursing*, *69*(1), 4–15. https://doi.org/10.1111/j.1365-2648.2012.06064.x

Knafl, K., Deatrick, J. and A, G. 2007. The analysis and interpretation of cognitive interviews for instrument development. *Res Nurs Health* Apr;30(2):224-34. doi: 10.1002/nur.20195.

Kovacic, D. 2018. Using the Content Validity Index to Determine Content Validity of an Instrument Assessing Health Care Providers' General Knowledge of Human Trafficking. *Journal of Human Trafficking* 4(4), pp. 327–335. doi: 10.1080/23322705.2017.1364905.

Kozlowski, A. et al. 2015. Agreement between responses from community-dwelling persons with stroke and their proxies on the NIH neurological quality of life (neuro- QoL) short forms. *Archives of Physical Medicine and Rehabilitation*.96(11):1986– 1992). https://doi.org/10.1016/j.apmr.2015.07.005

Krogsgaard, M., Brodersen, J., Christensen, K., Siersma, V., Jensen, J., Hansen, C., Engebretsen, L., Visnes, H., Forssblad, M. and Comins, J. 2021. How to translate and locally adapt a PROM. Assessment of cross-cultural differential item functioning. *Scandinavian journal of medicine & science in sports*, *31*(5), pp.999-1008.

Krohe, M., Tang, D.H., Klooster, B., Revicki, D., Galipeau, N. and Cella, D. 2019. Content validity of the National Comprehensive Cancer Network – Functional Assessment of Cancer Therapy – Breast Cancer Symptom Index (NFBSI-16) and Patient-Reported Outcomes Measurement Information System (PROMIS) Physical Function Short Form with advanced breast cancer patients. *Health and Quality of Life Outcomes* 17(1), p. 92. doi: 10.1186/s12955-019-1162-5.

Krupp LB, Alvarez LA, LaRocca NG, Scheinberg LC. 1988. Fatigue in Multiple Sclerosis. *Arch Neurol.* ;45(4):435–437. doi:10.1001/archneur.1988.00520280085020

Kvale, S. and Brinkman, S. 2009. *Interviews: Learning the craft of qualitative research interviewing*. Sage.

Lam, K. and Kwa, V. 2018. Validity of the PROMIS-10 Global Health assessed by telephone and on paper in minor stroke and transient ischaemic attack in the Netherlands. *BMJ Open* 8(7), p. e019919. doi: 10.1136/bmjopen-2017-019919.

Langhorne, P., Baylan, S. and Early Supported Discharge Trialists. 2017. Early supported discharge services for people with acute stroke. *The Cochrane Database of Systematic Reviews* 7(7), p. CD000443. doi: 10.1002/14651858.CD000443.pub4.

Langhorne, P., Ramachandra, S. and Stroke Unit Trialists' Collaboration. 2020. Organized inpatient (stroke unit) care for stroke: Network meta-analysis. *Stroke*, *51*(12), pp. e349-e350. https://doi.org/10.1002/14651858.CD000197.pub3

Lapin, B.R., Thompson, N.R., Schuster, A. and Katzan I. 2019. Patient versus proxy response on global health scales: no meaningful DIFference. *Qual Life*

Res **28**, 1585–1594. https://doi.org/10.1007/s11136-019-02130-y

Lapin, B., Thompson, N., Schuster, A. and Katzan, I. 2020. Magnitude and variability of stroke patient-proxy disagreement across multiple health domains. *Archives of Physical Medicine and Rehabilitation*.102(3):440–447). doi: 10.1016/j.apmr.2020.09.378.

Lapin, B., Thompson, N., Schuster, A., Honomichl, R. and Katzan, I. 2021a. The validity of proxy responses on patient-reported outcome measures: Are proxies a reliable alternative to stroke patients' self-report? *Quality of Life Research* 30(6), pp. 1735–1745. doi: 10.1007/s11136-021-02758-9.

Lapin, B., Thompson, N., Schuster, A. and Katzan, I. 2021b. Patient-proxy agreement on change in acute stroke patient-reported outcome measures: a prospective study. *J Patient Rep Outcomes* 5(1). doi: 10.1186/s41687-021-00329-7.

Lasch, K.E. et al. 2010. PRO development: rigorous qualitative research as the crucial foundation. *Qual Life Res* Oct;19. doi: 10.1007/s11136-010-9677-6.

Leary, S., Herford, J., Shanahan, N. 2020. *An expert opinion: Vocational Rehabilitation after Stroke*. Available at: https://acnr.co.uk/articles/vocational- rehabilitation-after-stroke. Accessed 09/01/2023

Lebherz, L. et al. 2022. Implementability of collecting patient-reported outcome data in stroke unit care – a qualitative study. *BMC Health Services Research* 22(1), p.346. doi: 10.1186/s12913-022-07722-y.

van Leeuwen, K., Jansen, A., Muntinga, M., Bosmans, J., Westerman, M., van Tulder, M. and van der Horst, H. 2015. Exploration of the content validity and feasibility of the EQ-5D-3L, ICECAP-O and ASCOT in older adults. *BMC Health Services Research* 15(1), p. 201. doi: 10.1186/s12913-015-0862-8.

Lens, C., Demeestere, J., Vanhaecht, K. and Lemmens, R. 2021. Patient Reported Outcomes Measurements Information System in Stroke Patients in Full and Shortened Format. *Frontiers in Neurology* 11, p. 630850. doi: 10.3389/fneur.2020.630850.

Lindsay, P., Furie, K.L., Davis, S.M., Donnan, G.A. and Norrving, B. 2014. World Stroke Organization global stroke services guidelines and action plan. *International journal of stroke: official journal of the International Stroke Society* 9 Suppl A100, pp. 4–13. doi: 10.1111/ijs.12371.

Luo, Y., Yang, J. and Zhang, Y. 2015. Development and validation of a patient- reported outcome measure for stroke patients. *Health and Quality of Life Outcomes* 13(1), p. 53. doi: 10.1186/s12955-015-0246-0.

Luyt, R. 2012. A Framework for Mixing Methods in Quantitative Measurement Development, Validation, and Revision: A Case Study. *Journal of Mixed Methods Research* 6, pp. 294–216. doi: 10.1177/1558689811427912.*32*(9), pp.751-761. doi:10.1177/1545968318777844

Lynn, M. 1986. Determination and Quantification of Content Validity. *Nursing Research* 35(6), p. 382.

McEvoy, P. and Richards, D. 2006. A critical realist rationale for using a combination of quantitative and qualitative methods. *Journal of Research in Nursing* 11(1), pp.66–78. doi: 10.1177/1744987106060192.

MacIsaac, R. et al. 2016. Derivation and validation of a modified short form of the stroke impact scale. *Journal of the American Heart Association*, *5*(5), p.e003108.

Mahoney, F. I., & Barthel, D. W. 1965. Functional Evaluation: The Barthel Index. *Maryland State Medical Journal*, *14*, 61–65.

Mandić, M., Aranđelović, M., Nikolić, M. and Rančić, N., 2018. Assessment of health- related quality of life of post-stroke survivors. *Acta Medica Medianae*, *57*(1), pp.80- 88.

Maxwell, J.A. and Mittapalli, K. 2010. *Realism as a stance for mixed method research*. Meadows, K. ed. Clinical Nursing Research. Sage.

Mead, N., & Bower, P. (2000). Patient-centredness: a conceptual framework and review of the empirical literature. *Social science & medicine, 51 7*, 1087-110.

Meadows, K. 2021. Cognitive Interviewing Methodologies. *Clinical Nursing Research* 30(4), pp. 375–379. doi: 10.1177/10547738211014099.

Michaelis, R., Meyer, S., Reuber, M., Schöne, C. 2019. Development of a patient-reported outcome measure for psychotherapeutic interventions in people with

seizures: a mixed methods study. *Epilepsy & Behaviour*, *99*, p.106464.

Miller, K., Chepp, V., Willson, S., Padilla, J.-L. 2014. *Cognitive Interviewing Methodology*. John Wiley & Sons.

Mokkink, L., Prinsen, C., Patrick, D., Alonso, J., Bouter, L., de Vet, H., Terwee, C. 2019. *COSMIN Study Design checklist for patient-reported outcome measurement instruments.* Available at: https://www.cosmin.nl. Accessed 01/02/2021

Mokkink, L., Terwee, C., Patrick, D., Alonso, J., Stratford, P., Knol, D. 2010. COSMIN study reached international consensus on taxonomy, terminology, and definitions of measurement properties for health-related patient-reported outcomes. *Journal of Clinical Epidemiology*.63(7):737–745. doi: 10.1016/j.jclinepi.2010.02.006.

Moon, K., and Blackman, D. (2014). A Guide to Understanding Social Science Research for Natural Scientists. *Conservation Biology*, **28**: 1167-1177. Online:http://onlinelibrary.wiley.com/doi/10.1111/cobi.12326/full . Accessed on 03/12/2023

Morgan, D. 2014. Pragmatism as a Paradigm for Social Research. *Qualitative Inquiry* 20(8), pp. 1045–1053. doi: 10.1177/1077800413513733.

Moseholm, E. and Fetters, M.D. 2017. Conceptual models to guide integration during analysis in convergent mixed methods studies. *Methodological Innovations* 10(2). doi: 10.1177/2059799117703118..

Nelson, E., Eftimovska, E., Lind, C., Hager, A., Wasson, J.H. and Lindblad, S. 2015. Patient reported outcome measures in practice. *BMJ* 350, p. g7818. doi: 10.1136/bmj.g7818.

Ness, M. M., Saylor, J., Di Fusco, L. A., & Evans, K. 2021. Healthcare providers' challenges during the coronavirus disease (COVID-19) pandemic: A qualitative approach. *Nursing & health sciences*, *23*(2), 389–397. https://doi-10.1111/nhs.12820

Newman, I., Lim, J. and Pineda, F. 2013. Content Validity Using a Mixed Methods Approach: Its Application and Development Through the Use of Table of Specifications Methodology. *Journal of Mixed Methods Research* 7(3), pp. 243–260. doi: 10.1177/1558689813476922.

NHS. 2019. *Long term Plan for Stroke*. Available at: https:// www.longtermplan.nhs.uk/areas- of-work/stroke. Accessed 05/06/2023

NHS England. 2020 Patient reported outcome measures (PROMs). https://digital.nhs.uk/data-and-information/data-tools-and-services/data-services/patient-reported-outcome-measures-proms. Accessed 06/11/2023

NHS England. 2022. Working in Partnership with People and Communities. Statutory Guidance. NHS. England.

Nobels-Janssen, E., van der Wees, P.J., Verhagen, W.I., Westert, G.P., Bartels, R.H. and Boogaarts, J.D., 2019. Patient-reported outcome measures in subarachnoid hemorrhage: a systematic review. *Neurology*, *92*(23), pp.1096-1112.

Norrving, B. et al. 2018. Action plan for stroke in Europe 2018–2030. *European stroke journal*, *3*(4), pp.309-336. https://doi.org/10.1177/2396987318808719

O'Cathain, A., Murphy, E. and Nicholl, J., 2007. Integration and publications as indicators of" yield" from mixed methods studies. *Journal of mixed methods research*, *1*(2), pp.147-163.

O'Cathain, A., Murphy, E. and Nicholl, J. 2010. Three techniques for integrating data in mixed methods studies. *BMJ (Clinical research ed* 341, p. 4587. doi: 10.1136/bmj.c4587.

Ojelabi, A.O., Graham, Y., Haighton, C. and Ling, J. 2017. A systematic review of the application of Wilson and Cleary health-related quality of life model in chronic diseases. *Health and Quality of Life Outcomes*, *15*(1), pp.1-15. https://doi.org/10.1186/s12955-017-0818-2

Ojo, O. and Brooke, J. 2016. The Use of Enteral Nutrition in the Management of Stroke. *Nutrients* 8(12), p. 827. doi: 10.3390/nu8120827.

Okonkwo, O.C., Roth, D.L., Pulley, L. and Howard, G., 2010. Confirmatory factor analysis of the validity of the SF-12 for persons with and without a history of stroke. *Quality of Life Research*, *19*, pp.1323-1331.

Oni, O.D., Olagunju, A.T., Olisah, V.O., Aina, O.F. and Ojini, F.I. 2018. Post-

stroke depression: Prevalence, associated factors and impact on quality of life among outpatients in a Nigerian hospital. *South African Journal of Psychiatry*, *24*. https://doi.org/10.4102/sajpsychiatry.v24i0.1058

Oosterveer, D.M., Arwert, H., Terwee, C.B., Schoones, J.W. and Vlieland, T. 2022. Measurement properties and interpretability of the PROMIS item banks in stroke patients: a systematic review. *Quality of Life Research* 31(12), pp. 3305–3315. doi: 10.1007/s11136-022-03149-4.

Oosterveer, D.M., van Meijeren-Pont, W., van Markus-Doornbosch, F. et al. 2023. Translation and cross-cultural adaptation of the ICHOM standard set for stroke: the Dutch version. *J Patient Rep Outcomes* **7**, 91 https://doi.org/10.1186/s41687-023-00630-7

Ormseth, C.H., Sheth, K.N., Saver, J.L., Fonarow, G.C. and Schwamm, L.H. 2017. The American Heart Association's Get With the Guidelines (GWTG)-Stroke development and impact on stroke care. *Stroke and Vascular Neurology*, *2*(2).

Owolabi, M.O., 2013. Consistent determinants of post-stroke health-related quality of life across diverse cultures: B erlin–I badan study. *Acta Neurologica Scandinavica*, *128*(5), pp.311-320.

Paanalahti, M., Berzina, G., Lundgren-Nilsson, Å., Arndt, T. and Sunnerhagen, K.S. 2019. Examination of the relevance of the ICF cores set for stroke by comparing with the Stroke Impact Scale. *Disability and Rehabilitation* 41(5), pp. 508–513. doi: 10.1080/09638288.2017.1396368.

Padilla, J.-L. and Leighton, J.P. 2017. Cognitive Interviewing and Think Aloud Methods. In: Zumbo, B. D. and Hubley, A. M. eds. *Understanding and Investigating Response Processes in Validation Research*. Social Indicators Research Series. Cham: Springer International Publishing, pp. 211–228. https://doi.org/10.1007/978-3- 319-56129-5_12.

Patchick, E., Vail, A., Wood, A. and Bowen, A. 2016. PRECiS (Patient Reported Evaluation of Cognitive State): psychometric evaluation of a new patient reported outcome measure of the impact of stroke. *Clinical Rehabilitation* 30(12), pp. 1229– 1241. doi: 10.1177/0269215515624480.

Patel, A., Berdunov, V., Quayyum, Z., King, D., Knapp, M., and Wittenberg, R. 2020. Estimated societal costs of stroke in the UK based on a discrete event simulation. *Age and ageing*, *49*(2), 270–276. https://doi.org/10.1093/ageing/afz162

Patrick, D.L. et al. 2011. Content Validity- Establishing and Reporting the Evidence in Newly Developed Patient-Reported Outcomes (PRO) Instruments for Medical Product Evaluation: ISPOR PRO Good Research Practices Task Force Report: Part 2-Assessing Respondent Understanding. *Value in Health* 14(8), pp. 978–988. doi: 10.1016/j.jval.2011.06.013.

Pedersen, S. G. et al. 2020. Stroke-specific quality of life one-year post-stroke in two Scandinavian country-regions with different organisation of rehabilitation services: a prospective study, *Disability and Rehabilitation*, 43(26), pp. 3810–3820. doi: 10.1080/09638288.2020.1753830.

Pellicciari, L., Chiarotto, A., Giusti, E., Crins, M.H.P., Roorda, L.D. and Terwee, C.B. 2021. Psychometric properties of the patient-reported outcomes measurement information system scale v1.2: global health (PROMIS-GH) in a Dutch general population. *Health and Quality of Life Outcomes* 19, p. 226. doi: 10.1186/s12955- 021-01855-0.

Penton, H., Dayson, C., Hulme, C. and Young, T. 2022. A Qualitative Investigation of Older Adults' Conceptualization of Quality of Life and a Think-Aloud Content Validation of the EQ-5D-5L, SF-12v2, Warwick Edinburgh Mental Well-Being Scale, and Office of National Statistics-4. *Value in Health* 25(12), pp. 2017–2027. doi: 10.1016/j.jval.2022.04.1735

Perin, C. et al. 2020. Differences in Rehabilitation Needs after Stroke: Similarity Analysis on the ICF Core Set for Stroke. *International Journal of Environmental Research and Public Health* 17(12), p. 4291. doi: 10.3390/ijerph17124291.

Peterson, C.H., Peterson, N.A. and Powell, K.G. 2017. Cognitive interviewing for item development: Validity evidence based on content and response processes. *Measurement and Evaluation in Counselling and Development* 50(4), pp. 217–223.

Phan, H.T. et al. 2019. Sex differences in long-term quality of life among survivors after stroke in the INSTRUCT. *Stroke*, *50*(9), pp.2299-2306.

Philipp, R., Lebherz, L., Thomalla, G., Härter, M., Appelbohm, H., Frese, M. and Kriston, L. 2021. Psychometric properties of a patient-reported outcome set in acute stroke patients. *Brain and Behaviour* 11, p. 2249. doi: 10.1002/brb3.2249.

Pindus DM, Mullis R, Lim L, Wellwood I, Rundell AV, Abd Aziz NA, et al. (2018) Stroke survivors' and informal caregivers' experiences of primary care and community healthcare services – A systematic review and meta-ethnography. PLoS ONE 13(2): e0192533. https://doi.org/10.1371/journal.pone.0192533

Pinkney, J., Gayle, F., K, M.-F. and Mullings, J. 2017. Health-Related Quality of Life in Stroke Survivors at the University Hospital of the West Indies. *Journal of Neurology Research* 7, pp. 46–58. doi: 10.14740/jnr422w.

Polit, D. and Beck, P. 2006. The content validity index: Are you sure you know what's being reported? Critique and recommendations. *Research in Nursing & Health* 29, pp. 489–497. doi: 10.1002/nur.20147.

Polit, D.F., Beck, C.T. and Owen, S.V. 2007. Is the CVI an acceptable indicator of content validity? Appraisal and recommendations. *Research in Nursing & Health* 30(4), pp. 459–467. doi: 10.1002/nur.20199.

Polit, D. and Yang, F. 2016. *Measurement and the Measurement of Change*. PA: Wolters Kluwer.

Popović, N. et al. 2013. The Frequency of Poststroke Infections and Their Impact on Early Stroke Outcome. *Journal of Stroke and Cerebrovascular Diseases* 22(4), pp. 424–429. doi: 10.1016/j.jstrokecerebrovasdis.2013.03.003.

Porter, M. E., Larsson, S. and Lee, T. H. 2016. Standardizing Patient Outcomes Measurement. *The New England journal of medicine*, *374*(6), 504–506. https://doi.org/10.1056/NEJMp1511701

Price-Haywood, E.G., Harden-Barrios, J., Carr, C., Reddy, L., Bazzano, L.A. and van Driel, M.L. 2019. Patient-reported outcomes in stroke clinical trials 2002–2016: a systematic review. *Quality of Life Research* 28(5), pp. 1119–1128. doi: 10.1007/s11136-018-2053-7.

Priede, C. and Farral, S. 2011. Comparing results from different styles of cognitive interviewing: 'Verbal probing' vs. 'thinking aloud'. *International Journal of Social Research Methodology, 14*, 271–287.

Ramírez-Moreno, J.M., Muñoz-Vega, P., Alberca, S.B. and Peral-Pacheco, D. 2019. Health-related quality of life and fatigue after transient ischemic attack and minor stroke. *Journal of Stroke and Cerebrovascular Diseases*, *28*(2), pp.276-284. doi: 10.1016/j.jstrokecerebrovasdis.2018.09.046. PMID: 30612638.

Ramos-Lima, M. J. M., Brasileiro, I. C., Lima, T. L. and Braga-Neto, P. 2018. Quality of life after stroke: impact of clinical and sociodemographic factors. *Clinics (Sao Paulo, Brazil)*, *73*, e418. https://doi.org/10.6061/clinics/2017/e418

Rangel, E.S.S., Belasco, A.G.S. and Diccini, S. 2013. Quality of life of patients with stroke rehabilitation. *Acta Paulista de Enfermagem*, *26*, pp.205-212. 10.1590/S0103- 21002013000200016.

Rausch – Koster, T.P., van der Ham, A.J., Terwee, C.B., Verbraak, F.D., van Rens, G., and van Nispen, R.M. 2021. Translation and content validity of the Dutch Impact of Vision Impairment questionnaire assessed by Three-Step Test-Interviewing. *Journal of Patient-Reported Outcomes* 5(1), p.1. doi: 10.1186/s41687-020-00272-z.

Realpe, A. and Wallace, L. 2010. *What is coproduction?* The Health Foundation, London.

Reeve, B. et al. 2013. ISOQOL recommends minimum standards for patient-reported outcome measures used in patient-centred outcomes and comparative effectiveness research. *Quality of life research; an international journal of quality of life aspects of treatment, care and rehabilitation*, *22*(8), 1889–1905. https://doi.org/10.1007/s11136- 012-0344-y

Reeves, M., Lisabeth, L., Williams, L., Katzan, I., Kapral, M., Deutsch, A., and Prvu- Bettger, J. 2018. Patient-Reported Outcome Measures (PROMs) for Acute Stroke: Rationale, Methods and Future Directions. *Stroke*, *49*(6), 1549–1556. https://doi.org/10.1161/STROKEAHA.117.018912

Richardson, M., Campbell, N., Allen, L., Meyer, M., and Teasell, R. 2016. The stroke impact scale: performance as a quality of life measure in a community-

based stroke rehabilitation setting. *Disability and Rehabilitation*, *38*(14), 1425–1430. https://doi.org/10.3109/09638288.2015.1102337

Ridgeway, J.L., Beebe, T.J., Chute, C.G., Eton, D.T., Hart, L.A. and Frost, M.H. 2013. A Brief Patient-Reported Outcomes Quality of Life (PROQOL) Instrument to Improve Patient Care. *PLoS Med* 10(11), p. 1001548. doi: 10.1371/journal.pmed.1001548.

Rimmele, D.L. et al. 2020. Health-related quality of life 90 days after stroke assessed by the International Consortium for Health Outcome Measurement standard set. *European Journal of Neurology* 27(12), pp. 2508–2516. doi: 10.1111/ene.14479.

Roaldsen, M. B., Lindekleiv, H., Mathiesen, E. B. 2021. Intravenous thrombolytic treatment and endovascular thrombectomy for ischaemic wake-up stroke. *The Cochrane database of systematic reviews*, *12*(12), CD010995. https://doi.org/10.1002/14651858.CD010995.pub3

Rothman, M., Burke, L., Erickson, P., Leidy, N.K., Patrick, D.L. and Petrie, C.D. 2009. Use of existing patient-reported outcome (PRO) instruments and their modification: the ISPOR Good Research Practices for Evaluating and Documenting Content Validity for the Use of Existing Instruments and Their Modification PRO Task Force Report. *Value in health: the journal of the International Society for Pharmacoeconomics and Outcomes Research* 12(8), pp. 1075–1083. doi: 10.1111/j.1524-4733.2009.00603.x.

Rothrock, N. E., Kaiser, K. A. and Cella, D. 2011. Developing a valid patient-reported outcome measure. *Clinical pharmacology and therapeutics*, *90*(5), 737–742. https://doi.org/10.1038/clpt.2011.195

Royal College of Physicians 2016. Intercollegiate Stroke Working Party. *National clinical guideline for stroke,* 5th. ed. London.

Rubio, D. M., Berg-Weger, M., Tebb, S. S., Lee, E. S. and Rauch, S. 2003. Objectifying content validity: Conducting a content validity study in social work research. *Social Work Research, 27*(2), 94–104. https://doi.org/10.1093/swr/27.2.94

Rudberg A-S, Berge E, Gustavsson A, Näsman, P. and Lundström E. 2018. Long- term health-related quality of life, survival and costs by different levels of functional outcome six months after stroke. *European Stroke Journal* 3(2):157-164. doi:10.1177/2396987317753444

Rudd, A.G., Hoffman, A., Paley, L. and Bray, B. 2018. 20 years of researching stroke through audit. *Clinical Rehabilitation* 32(8), pp. 997–1006. doi: 10.1177/0269215518784645.

Sacco, R.L. et al. 2013. An updated definition of stroke for the 21st century: a statement for healthcare professionals from the American Heart Association/American Stroke Association. *Stroke*, *44*(7), pp.2064-2089. https://doi.org/10.1161/STR.0b013e318296aeca

Safikhani, S., Sundaram, M., Bao, Y., Mulani, P., & Revicki, D. A. 2013. Qualitative assessment of the content validity of the Dermatology Life Quality Index in patients with moderate to severe psoriasis. *The Journal of dermatological treatment*, *24*(1), 50–59. https://doi.org/10.3109/09546634.2011.631980

Salinas, J. et al. 2016. An International Standard Set of Patient-Centred Outcome Measures After Stroke. *Stroke*, *47*(1), 180–186. https://doi.org/10.1161/STROKEAHA.115.010898

Sanchez-Gavilan, E. et al. 2022. Added value of patient-reported outcome measures (PROMs) after an acute stroke and early predictors of 90 days PROMs. *Journal of patient-reported outcomes* 6(1), p. 66. doi: 10.1186/s41687-022-00472-9. 1.

Sangha, R.S. et al. 2015. Quality of life in patients with TIA and minor ischemic stroke. *Neurology* 85(22), pp. 1957–1963. doi: 10.1212/WNL.0000000000002164.

dos Santos, H.M., de Oliveira, L.C., Bonifácio, S.R., Brandão, T.C.P., Silva, W.P., Pereira, G.S. and Silva, S.M. 2022. Use of the International Classification of Functioning, Disability and Health (ICF) to expand and standardize the assessment of quality-of-life following a stroke: proposal for the use of codes and qualifiers. *Disability and Rehabilitation* 44(24), pp. 7449–7454. doi: 10.1080/09638288.2021.1995055.

Schildmann, E.K. et al. 2016. Discovering the hidden benefits of cognitive interviewing in two languages: The first phase of a validation study of the Integrated Palliative care Outcome Scale. *Palliative Medicine* 30(6), pp. 599–610. doi: 10.1177/0269216315608348.

Schünemann, H., Brozek, J., & Oxman, A. 2013. GRADE handbook for grading quality of evidence and strength of recommendations.

Shannon-Baker, P. 2016. Making Paradigms Meaningful in Mixed Methods Research. *Journal of Mixed Methods Research* 10(4), pp. 319–334. doi: 10.1177/1558689815575861.

Shewangizaw, S., Fekadu, W., Gebregzihabhier, Y., Mihretu, A., Sackley, C., & Alem, A. (2023). Impact of depression on stroke outcomes among stroke survivors: Systematic review and meta-analysis. *PloS one*, *18*(12), e0294668. https://doi-org.abc.cardiff.ac.uk/10.1371/journal.pone.0294668

Skoglund, E., Westerlind, E., Persson, H.C. and Sunnerhagen, K.S. 2019. Self- perceived impact of stroke: A longitudinal comparison between one and five years post-stroke. *Journal of rehabilitation medicine* 51(9), pp. 660–664. doi: 10.2340/16501977-2595.

Solorio, R., Ayala, N. C., Paez, E., Skalicky, A. M. and Morales, L. S. 2016. Use of Cognitive Interviews to Adapt PROMIS Measurement Items for Spanish Speakers Living with HIV. *AIDS research and treatment*, *2016*, 8340863. https://doi.org/10.1155/2016/8340863

SSNAP 2022. The Road to Recovery: The Ninth SSNAP Annual Report. Ref.-374- SSNAP-Annual-Report-2022-FINAL.pdf (hqip.org.uk)

Staley, K., Elliott, J., Stewart, D. and Wilson, R., 2021. Who should I involve in my research and why? Patients, carers or the public? *Research Involvement and Engagement*, *7*(1), p.41.

Streiner, D., Norman, G. and Cairney, J. 2015. *Health Measurement Scales: a practical guide to their development and use*. 5th ed. Oxford. Open University Press.

Sue, V.M. and Ritter, L.A. 2012. *Conducting online surveys*. 2nd ed. SAGE Publications Inc. doi: 10.4135/9781506335186.

Sumathipala, K., Radcliffe, E., Sadler, E., Wolfe, C. D., & McKevitt, C. (2012). Identifying the long-term needs of stroke survivors using the International Classification of Functioning, Disability and Health. *Chronic illness*, *8*(1), 31–44. https://doi.org/10.1177/1742395311423848

Sutcliffe, L., Flynn, D. and Price, C.I. 2020. Percutaneous Endoscopic Gastrostomy and Mortality After Stroke in England from 2007 to 2018: A Retrospective Cohort Study. *Stroke* 51(12), pp. 3658–3663. doi: 10.1161/STROKEAHA.120.030502.

Swinburn, K. 2019. A concise patient reported outcome measure for people with aphasia: the aphasia impact questionnaire 21. *Aphasiology* 33(9), pp.1035–1060. doi: 10.1080/02687038.2018.1517406.

Tang, W.K., Lau, C.G., Mok, V., Ungvari, G.S. and Wong, K.S. 2013. Impact of anxiety on health-related quality of life after stroke: a cross-sectional study. *Archives of physical medicine and rehabilitation*, *94*(12), pp.2535-2541. https://doi.org/10.1016/j.apmr.2013.07.012.

Tashakkori, A. and Teddlie, C. eds., 2010. *Sage Handbook of Mixed Methods in Social & Behavioral Research*. Sage.

Tassi, A., Tan, J., Piplani, B., Longmire, N., Wong Riff, K.W. and Klassen, A.F., 2021. Establishing content validity of an orthodontic subset of the FACE-Q Craniofacial Module in children and young adults with malocclusion. *Orthodontics & Craniofacial Research*, *24*(4), pp.553-560.

Teasell, R and Hussein, N., 2016. Clinical consequences of stroke. *Evidence-based review of stroke rehabilitation*, pp.1-30.

Teasell, R. and Hussein, N., 2016. Background concepts in stroke rehabilitation. *Evidence-based review of stroke rehabilitation. Heart and Stroke Foundation Canadian Partnership for Stroke Recovery*.
Teddlie, C. and Tashakkori, A. 2009. *Foundations of mixed methods research: Integrating quantitative and qualitative approaches in the social and behavioural sciences*. Sage Publications.

Tempest, S., Harries, P., Kilbride, C. and De Souza, L. 2012. To adopt is to adapt: the process of implementing the ICF with an acute stroke multidisciplinary team in England. *Disability and Rehabilitation* 34(20), pp.

1686–1694. doi: 10.3109/09638288.2012.658489.

Terwee, C. B. et al. 2018. COSMIN methodology for evaluating the content validity of patient-reported outcome measures: a Delphi study. *Quality of Life Research : an international journal of quality of life aspects of treatment, care and rehabilitation*, *27*(5), 1159–1170. https://doi.org/10.1007/s11136-018-1829-0

Thierbach, C., Hergesell, J. and Baur, N. 2020. Mixed Methods Research. In: Atkinson, P. ed. *SAGE Research Methods Foundations*. London: SAGE Publications, Ltd. Available at: https://www.doi.org/10.4135/9781526421036932545. Accessed 20/10/2022

Tourangeau, R. 1984. *Cognitive Science and Survey Methods: A Cognitive Perspective.* In: Jabine, T. et al. eds. Cognitive Aspects of Survey Methodology: Building a Bridge between Disciplines, National Academy Press, Washington DC, 73-100.

Tsalta-Mladenov, M. and Andonova, S. 2021. Health-related quality of life after ischemic stroke: impact of sociodemographic and clinical factors. *Neurological research*, *43*(7), 553–561. https://doi.org/10.1080/01616412.2021.1893563

Tsangaris, E. et al. 2017. Establishing Content Validity of the CLEFT-Q: A New Patient-reported Outcome Instrument for Cleft Lip/Palate. *Plastic and reconstructive surgery. Global open* 5(4), p. 1305. doi: 10.1097/GOX.0000000000001305.

van der Vet, P., Wilson, S., Houwert, R. M., Verleisdonk, E. J., & Heng, M. 2022. Quality and reporting of patient-reported outcomes in elderly patients with hip fracture: a systematic review. *BMJ open*, *12*(12), e058197. https://doi- org.abc.cardiff.ac.uk/10.1136/bmjopen-2021-058197

van Mierlo ML, Schröder C, van Heugten CM, Post MWM, de Kort PLM, Visser-Meily JMA. 2014.The Influence of Psychological Factors on Health-Related Quality of Life after Stroke: A Systematic Review. *International Journal of Stroke*, 9(3):341-348. doi:10.1111/ijs.12149

Van Swieten, J.C., Koudstaal, P.J., Visser, M.C., Schouten, H.J. and Van Gijn, J. 1988. Interobserver agreement for the assessment of handicap in

stroke patients. *Stroke*, *19*(5), pp.604-607.

Vellone, E. et al. 2015. Psychometric evaluation of the stroke impact scale 3.0. *Journal of Cardiovascular Nursing*, *30*(3), pp.229-241.

Vincent-Onabajo, G. and Adamu, A. 2014. Impact of poststroke fatigue on health- related quality of life of Nigerian stroke survivors. *Journal of Stroke*, *16*(3), 195–201. https://doi.org/10.5853/jos.2014.16.3.195

Wade D. 2015. Rehabilitation – a new approach. Part two: the underlying theories. *Clinical Rehabilitation,* 29(12):1145-1154. doi:10.1177/0269215515601175

Wang, R., and Langhammer, B. 2018. Predictors of quality of life for chronic stroke survivors in relation to cultural differences: a literature review. *Scandinavian journal of caring sciences*, *32*(2), 502–514. https://doi.org/10.1111/scs.12533

Wardlaw, J.M. 2014. Thrombolysis for acute ischaemic stroke. *The Cochrane Database of Systematic Reviews* 7, p. 000213. doi: 10.1002/14651858.CD000213.pub3.

Wartenberg, K.E., Henkner, J., Brandt, S., Zierz, S. and Müller, T.J. 2020. Effect of Recanalization on Cerebral Edema, Long-Term Outcome, and Quality of Life in Patients with Large Hemispheric Infarctions. *Journal of Stroke and Cerebrovascular Diseases: The Official Journal of National Stroke Association* 29(12), p.105358. doi:10.1016/j.jstrokecerebrovasdis.2020.105358.

Weldring, T. and Smith, S.M. 2013. Patient-Reported Outcomes (PROs) and Patient- Reported Outcome Measures (PROMs). *Health Services Insights* 6, pp. 61–68. doi: 10.4137/HSI.S11093.

Welsh Government. 2017. *Stroke Delivery Plan 2017-2020*. Cardiff: Welsh Government.

Welsh Government. 2021. *The Quality Statement for Stroke.* Cardiff: Welsh Government.

Wild, D., Grove, A., Martin, M., Eremenco, S., McElroy, S., Verjee-Lorenz, A. and Erikson, P. 2005. Principles of good practice for the translation and cultural adaptation process for patient-reported outcomes (PRO) measures: report of the ISPOR task force for translation and cultural adaptation. *Value in*

Health 8(2), pp. 94–104.

Williams LS, Weinberger M, Harris LE, Clark DO, Biller J. Development of a stroke-specific quality of life scale. *Stroke*. 1999;30(7):1362-1369. doi:10.1161/01.str.30.7.1362

Willis, G. B. 2004. *Cognitive Interviewing: A Tool for Improving Questionnaire Design.* United States: SAGE Publications.

Willis, G. B. 2005. *Cognitive interviewing*. SAGE Publications, Inc., https://doi.org/10.4135/9781412983655

Willis, G. B. 2015. *Analysis of the Cognitive Interview in Questionnaire Design*. Oxford. Oxford University Press.

Wilson, I. B., and Cleary, P. D. 1995. Linking clinical variables with health-related quality of life. A conceptual model of patient outcomes. *JAMA*, *273* (1), 59–65.

Wilson, F.R., Pan, W. and Schumsky, D. 2012. Recalculation of the Critical Values for Lawshe's Content Validity Ratio. In: *Measurement and Evaluation in Counselling and Development.45*., p. 3 197-210. doi: 10.1177/0748175612440286.

Winstein, C. J. et al. 2016. Guidelines for Adult Stroke Rehabilitation and Recovery: A Guideline for Healthcare Professionals from the American Heart Association/American Stroke Association. *Stroke*, *47*(6), e98–e169. https://doi.org/10.1161/STR.0000000000000098

Withers, K. et al. 2021. First steps in PROMs and PREMs collection in Wales as part of the prudent and value-based healthcare agenda. *Qual Life Res* 30, 3157–3170 https://doi.org/10.1007/s11136-020-02711-2

Wolfe, C. D., Rudd, A. G. and McKevitt, C. 2014. *Modelling, evaluating and implementing cost-effective services to reduce the impact of stroke*. NIHR Journals Library.

Wong, H.J., Lua, P.L., Harith, S. and Ibrahim, K.A. 2021. Health-related quality of life profiles and their dimension-specific associated factors among Malaysian stroke survivors: a cross- sectional study. *Health and Quality of Life Outcomes* 19(1), p. 210. doi: 10.1186/s12955-021-01847-0.

World Health Organisation 2002. Towards a common language for functioning, disability and health. *World Health Organisation*. Available at: http://www.who.int/classifications/icf/icfbeginnersguide.pdf?ua=1. Accessed 20/11/2022

World Health Organisation. 2015. WHO global strategy on people-centred and integrated health services: interim report. World Health Organization. https://iris.who.int/handle/10665/155002 Accessed 20/11/2022

Wright, J., Moghaddam, N. and Dawson, D.L. 2021. Cognitive interviewing in patient-reported outcome measures: A systematic review of methodological processes. *Qualitative Psychology* 8(1), pp. 2–29. doi: 10.1037/qup0000145.

Wu, M.J., Zhao, K. and Fils-Aime, F., 2022. Response rates of online surveys in published research: A meta-analysis. *Computers in Human Behavior Reports*, *7*, p.100206.

Wynd, C.A., Schmidt, B. and Schaefer, M.A. 2003. Two Quantitative Approaches for Estimating Content Validity. *Western Journal of Nursing Research* 25(5), pp. 508–518. doi: 10.1177/0193945903252998.

Yeoh, Y.S. 2019. Health-related quality of life loss associated with first-time stroke. *PloS One* 14(1), p. 0211493. doi: 10.1371/journal.pone.0211493.

Yusoff M. 2019. ABC of content validation and content validity index calculation. *Education in Medicine Journal.*11(2):49–54. https://doi.org/10.21315/eimj2019.11.2.6

Zigmond, A. S., and Snaith, R. P. 1983. The hospital anxiety and depression scale. *Acta psychiatrica Scandinavica*, *67*(6), 361–370. https://doi.org/10.1111/j.1600-0447.1983.tb09716.x

Appendices

Appendix i. The PROM-15

PROMIS Scale v1.2 – Global Health

Global Health

Please respond to each question or statement by marking one box per row.

		Excellent	Very good	Good	Fair	Poor
Global01	In general, would you say your health is:	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
Global02	In general, would you say your quality of life is:	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
Global03	In general, how would you rate your physical health?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
Global04	In general, how would you rate your mental health, including your mood and your ability to think?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
Global05	In general, how would you rate your satisfaction with your social activities and relationships?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
Global05r	In general, please rate how well you carry out your usual social activities and roles. (This includes activities at home, at work and in your community, and responsibilities as a parent, child, spouse, employee, friend, etc.)	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
		Completely	Mostly	Moderately	A little	Not at all
Global06	To what extent are you able to carry out your everyday physical activities such as walking, climbing stairs, carrying groceries, or moving a chair?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1

22 August 2016

In the past 7 days…

		Never	Rarely	Sometimes	Often	Always
Global10r	How often have you been bothered by emotional problems such as feeling anxious, depressed or irritable?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1
		None	**Mild**	**Moderate**	**Severe**	**Very severe**
Global08r	How would you rate your fatigue on average?	☐ 5	☐ 4	☐ 3	☐ 2	☐ 1

Global07r	How would you rate your pain on average?	☐ 0 **No pain**	☐ 1	☐ 2	☐ 3	☐ 4	☐ 5	☐ 6	☐ 7	☐ 8	☐ 9	☐ 10 **Worst pain imaginable**

RiksStroke Riksstroke. Medicinsentrum. Norrlands universitetssjukhus

Are you able to walk?

- ☐ Able to walk without help from another person with or without a device
- ☐ Able to walk with help from another person
- ☐ Unable to walk

Do you need help from anybody to go to the toilet?

- ☐ I can manage going to the toilet without assistance
- ☐ I need help to go to the toilet

Do you need help with dressing/undressing?

- ☐ I can manage dressing/undressing without help
- ☐ I need help dressing/undressing

International Consortium for Health Outcomes Measurement (ICHOM) ©ICHOM

Do you need a tube for feeding?

No ☐ Yes ☐

Do you have problems with communication or understanding?

No ☐ Yes ☐

Appendix ii. Tabulated results of the literature review studies (Chapter 3)

Study	PROM	Measurement Properties (Mokkink et al. 2010)						
		Validity			*Reliability*			*Responsiveness*
		Content Validity	Construct Validity	Concurrent /Criterion Validity	Internal Consist-ency	Measure-ment Error	Test-retest	
Chou et al. (2015) Taiwan Prospective repeated measures study	SSQoLS;SSQoLS-8; SISv3; SIS-16	N	Y	Y	Y	Y	Y	Y
Heiburg et al. (2018) Norway Validation study	QOLIBRI-OS	N	Y	Y	Y	N	Y	N
Jenkinson et al. (2013) England Validation study	SISv3	N	Y	Y	Y	N	N	N
Katzan and Lapin (2018) USA Validation study	PROMIS-10 GH	N	Y	Y	Y	Y	Y	Y
Lam and Kwa (2018) Netherlands Observational cohort study	PROMIS-10 GH Dutch version	N	Y	Y	Y	N	N	N

MacIsaac et al. (2016) USA Secondary data analysis and validity study	SF-SIS	N	Y	Y	N	N	N	N
Pedersen et al. (2018) Norway Validation study	SS-QOLS Norwegian version	N	Y	Y	Y	N	Y	N
Richardson et al. (2016) Canada Secondary data analysis from a prospective study	SIS v3	N	Y	Y	Y	N	Y	Y
Vellone et al. (2016) Italy Validation study	SISv3 Italian version	N	Y	Y	Y	N	Y	N

Appendix iii. Study approval letter

Ymchwil Iechyd a Gofal Cymru
Health and Care Research Wales

NHS
Health Research Authority

Professor Christine Bundy
13.07 Eastgate House
Newport Road
Cardiff

Email: approvals@hra.nhs.uk
HCRW.approvals@wales.nhs.uk

27 May 2020

Dear Professor Bundy

HRA and Health and Care Research Wales (HCRW) Approval Letter

Study title:	**Evaluating the content validity of a condition- specific Patient Reported Outcome Measure (PROM) for people living with stroke in the community - a mixed methods design content validity study**
IRAS project ID:	**276885**
Protocol number:	**N/A**
REC reference:	**20/LO/0537**
Sponsor	**CARDIFF UNIVERSITY**

I am pleased to confirm that **HRA and Health and Care Research Wales (HCRW) Approval** has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications received. You should not expect to receive anything further relating to this application.

Please now work with participating NHS organisations to confirm capacity and capability, in line with the instructions provided in the "Information to support study set up" section towards the end of this letter.

How should I work with participating NHS/HSC organisations in Northern Ireland and Scotland?
HRA and HCRW Approval does not apply to NHS/HSC organisations within Northern Ireland and Scotland.

If you indicated in your IRAS form that you do have participating organisations in either of these devolved administrations, the final document set and the study wide governance report (including this letter) have been sent to the coordinating centre of each participating nation. The relevant national coordinating function/s will contact you as appropriate.

Please see IRAS Help for information on working with NHS/HSC organisations in Northern Ireland and Scotland.

How should I work with participating non-NHS organisations?
HRA and HCRW Approval does not apply to non-NHS organisations. You should work with your non-NHS organisations to obtain local agreement in accordance with their procedures.

What are my notification responsibilities during the study?

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

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

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

Who should I contact for further information?
Please do not hesitate to contact me for assistance with this application. My contact details are below.

Your IRAS project ID is **276885**. Please quote this on all correspondence.

Yours sincerely,

Kevin Ahmed
Approvals Manager

Appendix iv. Participant information sheet for participants with stroke

(People living with stroke) Participant Invitation/ Information sheet

Date ……

Dear …….

Study title: Evaluating the content validity of a condition specific Patient Reported Outcome Measure (PROM) for people living with stroke in the community.

Researcher: Stephanie Gething
IRAS ID. 276885

I am a Specialist Occupational Therapist working in a local stroke unit in your area and am currently studying for a Doctorate in Advanced Healthcare Practice at Cardiff University. I would like to invite you to take part in my research study evaluating a patient reported outcome measure (PROM) for people living with stroke. Before you decide whether to take part it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with friends and relatives if you wish, to help you decide whether you would like to take part. Please contact me at the e-mail address below if there is anything that is not clear or if you would like more information.

What is the purpose of the study?

A patient reported outcome measure (PROM) is a questionnaire that measures the impact of a condition, such as a stroke, on a person's health related quality of life (HRQoL). The questionnaire is completed by the patient (or advocate) and includes questions about general, physical and mental health and social activity. The information from PROMs is used by healthcare providers to evaluate their services and help to improve them for the benefit of patients and their families.
A PROM for people living with stroke is being introduced across Wales by the Welsh Stroke Implementation Group and my study is investigating whether the PROM accurately reflects and measures peoples' views on the impact of having a stroke on their health and usual activities. I aim to achieve this by carrying out a survey with health professionals who treat people following a stroke and interviewing people living in the community who have had a stroke and their

carers. The information (data) I collect from the interviews will be analysed and I will be able to advise the Stroke Implementation Group on whether the PROM is fit for purpose (has content validity), or if changes need to be made to the questionnaire so that it measures what it is intended to, that is the health related quality of life in people living with stroke from their perspective.

Why have you received this leaflet?

I am inviting you to take part in the study because as a person living with stroke your views about the questionnaire would be extremely valuable.

What will happen if you choose to participate?

I will ask you to complete the questionnaire and then ask for your comments on the ease of completion and whether the questions fully reflect your health- related quality of life following the stroke. I will also ask you for any suggestions you may have for further questions you feel are relevant.
If convenient, I would like to interview you over the phone, which should only take about an hour of your time. Please have a relative or friend with you during the interview if you wish.

What will happen to the information you provide?

I will record the interview for analysis purposes and any information you provide will be considered as confidential and anonymised. All data collected during the study will be stored in a secure location or on computer with an encrypted password for data security. This is in accordance with the Data Protection Act and the Cardiff University Research Integrity and Governance Code of Practice. With your permission, we will use your verbatim ('word-for-word') quotes in final publications and presentations, but no one will be able to identify you from these quotes.

How will we use information about you?

We will need to use information from you for this research project. This information will include your name; initials; contact details and information about your condition and general health. People will use this information to do the research or to check your records to make sure that the research is being done properly. People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead. We will keep all information about you safe and secure. Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have. We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.
Where can you find out more about how your information is used
You can find out more about how we use your information:
by asking one of the research team
by reviewing the Cardiff University Data Protection Policy: https://www.cardiff.ac.uk/public-information/policies-and- procedures/data- protection

by contacting the University's Data Protection Officer by email: inforequest@cardiff.ac.uk or in writing to: Data Protection Officer, Assurance Services, Cardiff University, Friary House, Greyfriars Road, Cardiff CF10 3AE.

What are the advantages?
As the outcomes of the study are unknown, no advantages have yet been identified.

What are the disadvantages?
Thinking about the impact the stroke is having on your health- related quality of life may cause you distress, so you may wish to speak to your stroke clinician or GP if you have any concerns that aren't addressed at the interview. You may also wish to contact the Stroke Association Helpline on 0303 3033 or e-mail helpline@stroke.org.uk.

What if something goes wrong?
If you have any queries about any aspect of this study, please contact me by e-mail at GethingS@cardiff.ac.uk and I will do my best to answer your questions. You can also contact my academic supervisor, Professor Christine Bundy: bundyec@cardiff.ac.uk/ 02920 87842. If you remain unhappy and wish to complain formally, you can do this by contacting the School of Healthcare Sciences Director of Research Governance (Dr Kate Button buttonk@cardiff.ac.uk 02920687734).
In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against Cardiff University but you may have to pay your legal costs.

What will happen if I don't want to carry on with the study?
If you withdraw from the study, all data about you that has been collected during the study will be destroyed and no further contact will be made.
However, we will need to keep a copy of your completed consent form for our records. I will not be able to remove your anonymised data if it has already been included in the final data analysis.

What will happen to the results of the study?
The findings of this study will be sent to you if you wish. They will be written up as a Doctoral thesis and submitted as an original research paper for peer reviewed journals. A study report will be presented to the All Wales Stroke Implementation Group, the Welsh Stroke Association and as a poster presentation at the annualWelsh Stroke Conference. Please be assured that you will not be identifiable from any report or publication placed in the public domain.

Who is sponsoring the study?
Cardiff University.

Who has reviewed the study?
All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. Ethical approval has been provided by NHS ethics via Health Care Research Wales, IRAS ID. 276885.

What should I do now?
You should take at least 24 hours to decide if you wish to take part in the study and if you have any questions please contact me.
I will contact you by phone after 7 days of sending this letter to gain your verbal consent to take part in the phone interview.
Please sign the consent form enclosed and return it in the stamped addressed envelope provided. The original consent form will be stored by me in a secure location and you will be

given a copy. Once you consent to take part you are still free to withdraw from the study at any time and without giving a reason and this will not affect your treatment in any way.

Thank you for reading this participant information sheet and for considering taking part in this study,

Best wishes,

Stephanie (Gething) MSc OT, Dip RCOT GethingS@cardiff.ac.uk

Appendix v. Participant information sheet for informal carers

Informal Carers Participant Invitation/ Information sheet

Date ……

Dear ……..

Study title: Establishing the content validity of a condition specific Patient Reported Outcome Measure (PROM) for people living with stroke in the community.

Researcher: Stephanie Gething

IRAS ID. 276885

I am a Specialist Occupational Therapist working in a local stroke unit in your area and am currently studying for a Doctorate in Advanced Healthcare Practice at Cardiff University. I would like to invite you to take part in my research study evaluating a patient reported outcome measure (PROM) for people living with stroke. Before you decide whether to take part it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with friends and relatives if you wish, to help you decide whether you would like to take part.
Please contact me at the e-mail address below if there is anything that is not clear or if you would like more information.

What is the purpose of the study?

A patient reported outcome measure (PROM) is a questionnaire that measures the impact of a condition, such as a stroke, on a person's health related quality of life (HRQoL). The questionnaire is completed by the patient (or advocate such as a carer) and includes questions about general, physical and mental health and social activity. The information from PROMs is used by healthcare providers to evaluate their services and help to improve them for the benefit of patients and their families. A PROM for people living with stroke is being introduced across Wales by the Welsh Stroke Implementation Group and my study is investigating whether the PROM accurately reflects and measures peoples' views on the impact of having a stroke on their health and usual activities.

I aim to achieve this by carrying out a survey with health professionals who treat people following a stroke and interviewing people living in the community who have had a stroke and their carers. The information (data) I collect from the interviews will be analysed and I will be able to advise the Stroke Implementation Group on whether the PROM is fit for purpose or if changes need to be made to the PROM questionnaire so that it measures what it is intended to, that is the health related quality of life in people living with stroke from *their* perspective.

Why have you received this leaflet?

I am inviting you to take part in the study because as a carer who might complete the questionnaire on the behalf of a person living with stroke, your views about the questionnaire would be extremely valuable.

What will happen if you choose to participate?

If convenient, I would like interview you over the phone, which should only take about an hour of your time. I will ask you to complete the questionnaire and then ask for your comments on the ease of completion and whether the questions fully reflect the health- related quality of life of the person you are caring for following the stroke. I will also ask you for any suggestions you may have for additional questions you feel are relevant. Please have a relative or friend with you during the interview if you wish.

What will happen to the information you provide?

I will record the interview for analysis purposes and any information you provide will be considered as confidential and anonymised. All data collected during the study will be stored in a secure location or on computer with an encrypted password for data security. This is in accordance with the Data Protection Act and the Cardiff University Research Integrity and Governance Code of Practice. With your permission, we will use your verbatim ('word-for-word') quotes in final publications and presentations, but no one will be able to identify you from these quotes.

How will we use information about you?

We will need to use information from you for this research project. This information will include your name; initials and contact details. People will use this information to do the research or to make sure that the research is being done properly.

People who do not need to know who you are will not be able to see your name or contact details. Your data will have a code number instead. We will keep all information about you safe and secure. Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

What are your choices about how your information is used?

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have, such as your consent form. We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

Where can you find out more about how your information is used?
You can find out more about how we use your information:
by asking one of the research team
by reviewing the Cardiff University Data Protection Policy: https://www.cardiff.ac.uk/public-information/policies-and- procedures/data- protection
by contacting the University's Data Protection Officer by email: inforequest@cardiff.ac.uk or in writing to: Data Protection Officer, Assurance Services, Cardiff University, Friary House, Greyfriars Road, Cardiff CF10 3AE.
What are the advantages?
As the outcomes of the study are unknown, no advantages have yet been identified.

What are the disadvantages?
Thinking about the impact the stroke is having on the health related quality of life of the person you are caring for may cause you distress, so you may wish to speak to your GP if you have any concerns that aren't addressed at the interview. You may also wish to contact the Stroke Association Helpline on 0303 3033 or e-mail helpline@stroke.org.uk for support.

What if something goes wrong?
If you have any queries about any aspect of this study, you should contact me by e- mail at GethingS@cardiff.ac.uk and I will do my best to answer your questions. You can also contact my academic supervisor, Professor Christine Bundy: bundyec@cardiff.ac.uk/ 02920 87842. If you remain unhappy and wish to complain formally, you can do this by contacting the School of Healthcare Sciences Director of Research Governance (Dr Kate Button buttonk@cardiff.ac.uk 02920687734).
In the event that something does go wrong and you are harmed during the research and this is due to someone's negligence then you may have grounds for a legal action for compensation against Cardiff University but you may have to pay your legal costs.

What will happen if I don't want to carry on with the study?
If you withdraw from the study, all data about you that has been collected during the study will be destroyed and no further contact will be made.
However, we will need to keep a copy of your completed consent form for our records. I will not be able to remove your anonymised data if it has already been included in the final data analysis.

What will happen to the results of the study?
The findings of this study will be sent to you if you wish. They will be written up as a Doctorate thesis and submitted as an original research paper for peer reviewed journals. A study report will be presented to the All Wales Stroke Implementation Group, the Welsh Stroke Association and as a poster presentation at the annual Welsh Stroke Conference. Please be assured that you will not be identifiable from any report or publication placed in the public domain.

Who is sponsoring the study?
Cardiff University.

Who has reviewed the study?
All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. Ethical approval has been provided by NHS ethics via Health Care Research Wales (IRAS) Ref: No. 276885.

What should I do now?

You should take at least 24 hours to decide if you wish to take part in the study and if you have any questions please contact me. I will phone you after 7 days of sending this letter to obtain your verbal consent to take part in the interview.

Please sign the consent form enclosed and return it in the stamped addressed envelope provided.

The original consent form will be stored by me in a secure location and you will be given a copy. I will then contact you by phone to arrange a convenient time to phone you for the interview. Once you consent to take part, you are still free to withdraw from the study at any time and without giving a reason. This will not affect future treatment of the person you are caring for in any way.

Thank you for reading this participant information sheet and for considering taking part in this study,

Best wishes,

Stephanie (Gething) MSc OT, Dip RCOT GethingS@cardiff.ac.uk

Appendix vi. Informed consent form for participants with stroke

Patient Participant Consent Form

Study title: Establishing the content validity of a condition specific Patient Reported Outcome Measure (PROM) for people living with stroke in the community.

Researcher: Stephanie Gething

IRAS ID 276885

Please initial box

1. I confirm that I have read the participant information sheet dated.....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, without my medical care or legal rights being affected. ☐

3. I agree to be audio-recorded during the study. ☐

4. 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. ☐

5. I confirm that data from the study can be used in the final report and other academic publications. I understand that these will be used anonymously and that no individual respondent will be identified in such report. ☐

6. I give consent for the use of verbatim anonymised quotes in publications and conference presentations. ☐

7. I understand that the findings and potentially secondary analysis of the findings and associated data from the study may be presented at conference and in scientific journals. I understand that these will be used anonymously and that no individual respondent will be identified in such report. ☐

8. I would like to receive a copy of the final study report. ☐

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

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

Appendix vii. Consent form for informal carers

Carer Participant Consent Form

Study title: Evaluating the content validity of a condition specific Patient Reported Outcome Measure (PROM) for people living with stroke in the community.

Name of Researcher: Stephanie Gething IRAS ID. 276885

Please initial box

1. I confirm that I have read the participant information sheet dated.....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, without my legal rights being affected. ☐

3. I agree to be audio-recorded during the study. ☐

4. 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. ☐

5. I confirm that data from the study can be used in the final report and other academic publications. I understand that these will be used anonymously and that no individual respondent will be identified in such report. ☐

6. I give consent for the use of verbatim anonymised quotes in publications and conference presentations. ☐
7. I understand that the findings and potentially secondary analysis of the findings and associated data from the study may be presented at conferences and in scientific journals. I understand that these will be used anonymously and that no individual respondent will be identified in such reports. ☐
8. I would like to receive a copy of the final study report. ☐
9. I agree to take part in the above study. ☐

Name of Participant	Date	Signature
Name of Person taking Consent	Date	Signature

Appendix viii. Participant information sheet for HCPs

Healthcare Professionals Participant Invitation/ Information sheet

Date

……

Dear colleague,

Study title: Evaluating the content validity of a condition specific Patient Reported Outcome Measure (PROM) for people living with stroke in the community.

Researcher: Stephanie Gething **IRAS ID 276885**

I am a Specialist Occupational Therapist working in a local stroke unit and am currently studying for a Doctorate in Advanced Healthcare Practice at Cardiff University. I would like to invite you to take part in my research study evaluating a patient reported outcome measure (PROM) for people living with stroke. Before you decide whether to take part it is important for you to understand why the research is being done and what it will involve. Please contact me at the e-mail address below if there is anything that is not clear or if you would like more information.

What is the purpose of the study?

A patient reported outcome measure (PROM) is a questionnaire that measures the impact of a condition, such as a stroke, on a person's health related quality of life (HRQoL). The questionnaire is completed by the patient (or advocate) and includes questions about general, physical and mental health and social activity. The information from PROMs is used by healthcare providers to evaluate their services and help to improve them for the benefit of patients and their families.

A PROM for people living with stroke is being introduced across Wales by the Welsh Stroke Implementation Group and my study is investigating whether the PROM accurately reflects and measures peoples' views on the impact of having a stroke on their health and usual activities.

I aim to achieve this by carrying out a survey with health professionals who treat people

following a stroke and interviewing people living in the community who have had a stroke and their informal carers. The information (data) I collect from the survey and interviews will be analysed and I will be able to advise the Stroke Implementation Group on whether the PROM is fit for purpose (has content validity) or if changes need to be made to the PROM so that it measures what it is intended to, that is the health related quality of life in people living with stroke from their
perspective.

Why have you received this leaflet?
I am inviting you to take part in the study because as a healthcare professional working with people who have had a stroke, your views about the PROM would be extremely valuable.

What will happen if you choose to participate?
The website link included in this leaflet will give you access to an on-line survey. It consists of information on the PROM and a consent form you need to complete to access the questionnaire. The questionnaire asks you to rate the relevance of each PROM item to the HRQoL of people living with stroke and asks you for any comments you may have on the PROM.

What will happen to the information you provide?
The survey data will be anonymised and collated for analysis to estimate the content validity of the PROM. All data collected during the study will be stored in a secure location or on computer with an encrypted password for data security. This is in accordance with the Data Protection Act and the Cardiff University Research Integrity and Governance Code of Practice. With your permission, we will use your verbatim ('word-for-word') quotes in final publications and presentations, but no one will be able to identify you from these quotes.

How will we use information about you?
We will need to use information from you for this research project. This
information will include your sex; profession; grade and length of experience working in stroke. People will use this information to do the research or to check that the research is being done properly. We will keep all information about you safe and secure. Once we have finished the study, we will keep some of the data so we can check the results. We will write our reports in a way that no-one can work out that you took part in the study.

What are your choices about how your information is used?
You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have, ie your consent form. We need to manage your records in specific ways for the research to be reliable. This means that we won't be able to let you see or change the data we hold about you.

Where can you find out more about how your information is used?
You can find out more about how we use your information:
by asking one of the research team
by reviewing the Cardiff University Data Protection Policy: https://www.cardiff.ac.uk/public-

information/policies-and- procedures/data- protection
by contacting the University's Data Protection Officer by email: inforequest@cardiff.ac.uk or in writing to: Data Protection Officer, Assurance Services, Cardiff University, Friary House, Greyfriars Road, Cardiff CF10 3AE.

What are the advantages?
As the outcomes of the study are unknown, no advantages have yet been identified.

What are the disadvantages?
You may find aspects of the survey process unsettling or raises issues relating to your practice. You may wish to discuss any concerns with your clinical lead, who is best placed to provide support. Any clinical or professional concerns identified by the researcher will be discussed with a responsible, independent stroke clinician.

What if something goes wrong?
If you have any queries about any aspect of this study, you should contact me by e- mail at stephanie.gething@cardiff.ac.uk and I will do my best to
answer your questions. You can also contact my academic supervisor, Professor Christine Bundy: bundyec@cardiff.ac.uk/ 02920 87842. If you remain unhappy and wish to complain formally, you can do this by contacting the School of Healthcare Sciences Director of Research Governance (Dr Kate Button buttonk@cardiff.ac.uk 02920687734).

What will happen if I don't want to carry on with the study?
If you withdraw from the study, all data about you that has been collected during the study will be destroyed and no further contact will be made.
However, we will need to keep a copy of your completed consent form for our records. I will not be able to remove your anonymised data if it has already been included in the final data analysis.

What will happen to the results of the study?
The findings of this study will be sent to you if you wish. They will be written up as a PhD thesis and submitted as an original research paper for peer reviewed journals. A study report will be presented to the All Wales Stroke Implementation Group, the Welsh Stroke Association and as a poster presentation at the annual Welsh Stroke Conference. Please be assured that you will not be identifiable from any report or publication placed in the public domain.

Who is sponsoring the study?
Cardiff University.

Who has reviewed the study?
All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. Ethical approval has been provided by NHS ethics via Health Care Research Wales, IRAS ID. 276885.

What should I do now?
If you wish to participate in the study, please access the survey via
www.cardiffonlinesurveys.ac.uk/prom-survey-for- hcps.

Thank you for reading this participant information sheet and for considering taking part in this study,

Best wishes,

Stephanie (Gething) MSc OT, Dip RCOT GethingS@cardiff.ac.uk

Appendix ix. Cognitive interview guide

Cognitive Interview Guide for Evaluation of PROM-15 Study

Instructions:

1. In your own words, what are the instructions asking you to do?
2. Are there any words we should change to make the instructions easier to follow?

Items:

1. What did you think the question was asking?

2. What did you think of when answering the question?

3. Was the question worded in a way that made sense to you?
    a. What other words do you think should be used?

4. Was the question about something that is relevant or important to you following your stroke?

5. Were any questions difficult to answer?

    a. Which ones and why?
    b. How can the question/s be changed to make it easier to answer?

Response choices:

1. Did the response choices to the questions make sense?

    a. How could they be changed to make it easier for you to score your answer to the question?

General thoughts about the PROM:

1. In general, please tell me what you thought about the questionnaire?
2. Do you think the questionnaire was relevant to your health-related quality of life after your stroke?
3. Were there any questions you didn't think were relevant?

a. Which ones and why?

4. Is there anything else the questionnaire should have included?

5. Is there anything else you would like to say about the questionnaire?

Appendix x. Transcript of a cognitive interview with a participant with stroke

CONFIDENTIAL

Date Transcribed: 22nd September 2021
Interviewer(s): Stephanie Gething
Respondent(s): Male participant with stroke

INT: Okay, so thanks for answering the phone [laughs].

RES: That's all right.

INT: And have you got the questionnaire in front of you and a pen?

RES: I have, yes.

INT: Lovely, okay thank you very much. So, just to let you know that basically, this is just like an interview really just to get your views and opinions of the questionnaire as we go through it. So, I will be asking you some quite similar questions so I hope you'll bear with me.

RES: That's fine, yes.

INT: Can I just confirm with you that you actually consent to carry out the interview?

RES: Yes, I consent to carry out the interview.

INT: You're happy with that, lovely okay thank you very much. So, if you look at your questionnaire so, if we go to question number one. No, actually first of all if we look at the instructions, can you see at the top it says, "Please respond to each question or statement by marking one box per row," can you see that?

RES: Yes, okay yes.

INT: Yes, so are those instructions easy to follow, are they clear?

RES: Yes, they are.

INT: And are there any words that we should change just to make them easier to follow?

RES: No, seems simple enough.

INT: Pretty straightforward, yes great okay.

RES: Yes.

INT: Okay, so if we go to question number one it should say in general, would you say your health is and then it gives you like a variety of responses for you to choose.

RES: Yes.

INT: So, which one would you score from excellent, very good, good, fair or poor?

RES: Good.

INT: Good, okay. So, what do you think the question is actually asking you?

RES: I'm assuming it's my general health overall.

INT: Yes, brilliant.

RES: Rather than anything specific.

INT: Yes, okay yes that makes sense. So, when you were actually answering the question, how did you choose that response, how did you choose good, what were you thinking about?

RES: Well, I thought about, how would I put it? Yes, it's hard to really to describe that without looking at the other questions where you ask about physical health and mental health.

INT: That's right, yes.

RES: So, going through it I just thought overall how do I feel? And I get up and about, do I feel okay, reasonably well, not depressed, am I in pain or whatever, I just felt yes in general overall.

INT: Yes, pretty good.

RES: If somebody said, "How are you?" I'd say fair [laughs].

INT: Yes, that makes sense okay. So, was the question worded in a way that actually made sense to you?

RES: You could add the word general health because further on you go to actually specify different-

INT: That's right, yes.

RES: You could change, you could say.

INT: Yes, your general health rather than specific necessarily to your stroke, okay.

RES: Yes, yes.

INT: Yes, good comment. So was the question about something that's relevant or important to you after your stroke?

RES: Well, yes I've been asked, "How are you," hundreds of time [laughs].

INT: Yes, aw [laughs] okay.

RES: And to be honest you don't really know what to answer because I don't know, I've never had one before, I don't know how I'm supposed to feel.

INT: To compare it, yes.

RES: Yes, well like I say I've got a bit of numbness and a bit of that and whatever but you know, in general I feel pretty good I've got to be honest, yes.

INT: Good, okay, okay. So, let me think now so, was the question about something that's relevant or important to you following your stroke?

RES: Yes, it is yes, yes.

INT: Yes, okay lovely. So, going onto question number two then, in general again, would you say your quality of life is excellent, very good, good, fair, poor? So, again you've got the choice of five there.

RES: Yes, I've got that down as good.

INT: Right, okay. So, what do you think the question was asking you about?

RES: Whether you can do, whether you still like doing the things you used to do, whether you can do the things you used to do.

INT: Yes, okay, yes.

RES: Yes, or whether you're just existing or do you know that sort of thing.

INT: Right, yes, yes fair enough. And was the question worded in a way that made sense to you?

RES: Yes.

INT: Quite straightforward yes?

RES: Well, yes if what I just said is correct then it made sense to me, yes.

INT: [Laughs] Yes, fine fair enough. And was the question about something that's actually relevant to you after your stroke?

RES: Yes, it is because it can go horribly wrong can't it [laughs] let's be honest after a stroke.

INT: Yea, fair enough yes.

RES: What I found is different this well, not this time but because of the lockdown issues that came in just after I came out of hospital.

INT: Yes, it's very interesting isn't it how that's had an impact on you anyway never mind the fact that you've had a stroke, that's right.

RES: Yes, yes but it didn't because coming up to Christmas and all that when people would normally have been doing things and going places and I probably well, I couldn't have at that point. I didn't come out of hospital until mid-October.

INT: That's right, yes.

RES: I didn't miss out on anything in fact everybody else missed out because they were told they couldn't do it.

INT: [Laughs] I know.

RES: I just got on with getting better. So, from that point of view and going down to the mental health bit it probably helped me a lot there.

INT: Exactly, yes.

RES: Because you know, I didn't feel I was missing out at all.

INT: No, and hopefully as things are starting to open up a bit now that will give you the opportunity to do a bit more you know which will be good.

RES: To test myself and yes.

INT: Yes, fair enough yes, okay. So, do you think the question is about something that's relevant to you?

RES: It definitely is, yes because depending on how bad the stroke is even without you know, the Covid issues, then the quality of life can be drastically changed.

INT: Exactly, okay, fine. So, moving onto the next question then, in general how would you rate your physical health? So, again what do you think the question is asking you about there?

RES: Well, if I can actually get on with you know, physically doing the things I used to do or walking, like getting around the house.

INT: Good, yes.

RES: Things like that.

INT: So, what did you score yourself for that?

RES: I scored myself a good because I can get about but I do get tired yes, I do get tired I will say.

INT: Fair enough yes, that's a fair comment, okay. And so, was the question worded in a way that made sense to you?

RES: Yes.

INT: Quite straightforward, good, and was it about something that's relevant or important to you after your stroke?

RES: Well, it is yes, it is important, [s/l try and get core strength 00:06:52] back together and get a bit of energy and get, build yourself up.

INT: That's right, yes, yes exactly, okay that's grand. So, going onto number four, you're doing really well, [laughs].

RES: [laughs]

INT: In general, how would you rate your mental health including your mood and your ability to think? So, what did you score for that?

RES: I put a good for that.

INT: Right, okay. So, what do you think the question is actually asking you about?

RES: [Pause] Well, because of where the stroke is, it can affect mood.

INT: Yes, yes that's right.

RES: It can cause a certain amount of confusion.

INT: Right, and did you find, did that happen in your case do you think, xxx at the beginning?

RES: Oh, yes I remember doing, yes it was yes.

INT: Yes, okay.

RES: I can remember the first time I went up to B&M in Ebbw Vale.

INT: Yes [laughs].

RES: And you walk through the doors and well, there's a million things to look at you know.

INT: That's right.

RES: I was out the house and, you know, there's just a hundred things goes on. And you know on your computer when the timer goes around and around and it's overloaded?

INT: [Laughs].

RES: It can get like that.

INT: Yes, a bit overwhelming.

RES: There's too much to process.

INT: That's right, that's right yes okay. So, was the question worded in a way that made sense to you?

RES: Yes, it was.

INT: Right, and was it about something that's relevant or important to you after your stroke?

RES: Yes, yes it was because it also covered like lack of patience, general frustration but lack of patience but more with myself than anything.

INT: Yes, yes.

RES: Because I've always been capable and there are things I am not doing or wasn't doing at the time.

INT: That's right.

RES: I do get bloody frustrated [laughs].

INT: Yes, of course that's natural isn't it yes okay.

RES: But overall, I'm mainly in a positive sort of frame of mind.

INT: Brilliant, okay. So, going onto the next question then, in general how would you rate your satisfaction with your social activities and relationships? So, again what did you score for that?

RES: I scored a good for that.

INT: Yes, fine.

RES: And to be honest, I sat down with my wife.

INT: [Laughs].

RES: I went through this and read it and I sat down with her because I thought this would be a good, I'm thinking about starting back to work at some time. I thought let's just see where I am.

INT: That's right, yes good.

RES: And I went through it with her and she actually [laughs] scored me bloody lower than I thought she would.

INT: Did she [laughs]?

RES: But anyway, her thinking was slightly different to mine.

INT: You didn't have a row did you, xxxx?

RES: No, no problem so, I said like if you've got something to say let's be honest and open. And we did, we had a bloody good laugh about it after as well but you know, because there were things she was saying and I thought, *yes, she's right* [laughs].

INT: [Laughs] Fair enough, okay. So, what do you think the question was asking you about?

[00:10:02]

RES: Right, where was we, about my social activities, well, how I get on with people.

INT: Yes, okay.

RES: You know.

INT: Yes, that's fine.

RES: One of the things we have, something I can be a bit sharp, normally I'm fairly laid back [laughs]

INT: Yes, yes.

RES: But yes a bit sharp.

INT: Fair enough.

RES: You know when people, you get a group of people together and they start talking and it gets louder and louder.

INT: Yes [laughs] yes.

RES: And I found that difficult to deal with, it just got too loud you know.

INT: That's right, yes.

RES: And they're not arguing, they're just.

INT: Just a bit of banter isn't it?

RES: Yes, she's got three sisters and I [s/l there were 00:10:45] just laughing and joking. Just too bloody loud. I'm getting better but I found out the other day that I'm still a little bit, I still don't like it as much as I used to. It didn't used to bloody bother me; I was out and about and that was it.

INT: Yes, and that's a good thing to be aware of isn't it you know, at least you're aware of that, that's good.

RES: Yes.

INT: Okay.

RES: My relationships, my daughter has said to me we spend more time talking on the phone that we ever did.

INT: [Laughs].

RES: I mean she used to ring but I would say, "Yes, your mum is here, I'll just pass the phone over." But now because I'm not actually working at the moment.

INT: That's right.

RES: If she phones up I bend her ear a bit.

INT: You have a good old chat yes, good.

RES: [Laughs] Yes.

INT: It's good for you, good for you both.

RES: And then she said she's probably never spoken to me so much than she has.

INT: [Laughs] Before, yes.

RES: I think my relationship with my grandson is only four but that's getting better now over the last couple of weeks.

INT: Right.

RES: And I'm getting stronger.

INT: Yes, yes fair comment.

RES: You know, a four year old will wear you out at the best of the times but that's no good when you're already tired.

INT: Yes, that's right yes.

RES: Start getting back together.

INT: You're getting used to him again.

RES: Get on with having more fun together.

INT: Yes, that's good, good. So, was the question worded in a way that made sense to you, I think you said that it did make sense so that's good.

RES: Yes, yes it did, yes.

INT: And again, is it about something that's actually important to you after your stroke?

RES: Well, it is relevant because as soon as it says it could affect, I think it's on the literature I was given it said that it can affect your ability in social circumstances.

INT: That's right, yes.

RES: And yes of course it is yes and it was nice to actually think about it and talk to the people involved to get their input.

INT: Yes, exactly, okay lovely. So, the next, moving onto the next question Please rate how well you carry out your usual social activities and roles so, things around the house, if you were at work, how you're managing at work, in the community. Just your sort of usual activities and roles realty so, what did you score for that, xxxx?

RES: Well, I put a fair on that.

INT: Right, yes. So, what do you think the question was asking you about?

RES: Well, it's a very wide ranging sort of question and you know, I'd say how I deal with social activities and roles, interaction between people I suppose.

INT: Yes, yes fair enough.

RES: In general, whether it's in work or at home, in some ways that covers a lot of what I've already said.

INT: That's right.

RES: [Unclear 00:13:26] [laughs] we had a good laugh but she said, "Your cleaning isn't as good as it used to be and I end up tidying up around behind you picking things up."

INT: [Laughs] Brilliant.

RES: So, yes well okay and [unclear 00:13:36] any of that.

INT: You're just hoping she won't ask you to do it again, xxxx[laughs].

RES: I know yes but I know I-

INT: It's not working.

RES: -[unclear 00:13:46] how hard can it be to fold a pair of bloody jogging bottoms?

INT: [Laughs].

RES: You know you hold it, you fold, get the legs, put them together, run your hand down, over. I said and it looked like I threw them in there from the other side of the bloody room.

INT: [Laughs] exactly.

RES: And she said, "Yes, you're right [unclear 00:14:01]."

INT: [Laughs].

RES: And yes, I'm getting better but it's been a problem, even so much as you know like the other morning I [unclear 00:14:13] but, to fold a bloody hoody and put it in the top of the wardrobe. It looks like I never even tried.

INT: Takes years of practice, xxxx you know [laughs] okay.

RES: Well, the point is I can do it [laughs] or I could up until last October, I could.

INT: Oh.

RES: [unclear 00:14:28] you know, but-

INT: Work in progress, xxxx work in progress [laughs].

RES: That's right yes, it is yes. Other things have been great but stuff like that I know it isn't right. What else have I got; I did write a couple of notes underneath.

INT: Yes, that's good thank you.

RES: Yes, some of the DIY stuff that I could or couldn't do.

INT: Right.

RES: I won't say I can't do them but I'm not.

INT: Not yet.

RES: I managed to paint a fence; I got a couple of doors done.

INT: Yes.

RES: But it's harder work than it should be [laughs].

INT: That's right yes, you'll get there.

RES: [s/l But hopefully 00:15:08] I'll get there yes of course.

INT: Yes, yes sure. So, was the question worded in a way that actually you know, it's quite a long question isn't it? Was it worded in a way that made sense to you?

RES: Yes, it did.

INT: Yes, okay.

RES: Yes, it is but it sort of covers a massive area but I don't know whether-

INT: It does.

RES: -you might want to break it up a little bit or something.

INT: Yes, fair comment yes, fair enough. And was the question about something that's relevant or important to you after your stroke?

RES: Well, it is yes of course it is yes.

INT: Yes, okay, lovely. Moving onto the next question, slightly different response choices there okay?

RES: Yes.

INT: So, what extent are you able to carry out your everyday physical activities such as walking, climbing stairs, carrying groceries or moving a chair? So, what did you score for that?

RES: Mostly.

INT: Mostly, okay.

RES: Yes.

INT: And what do you think the question is asking you there?

RES: It actually, it covers a very- How can I put it yes, it's the physical side not the mental side of it. You know, it's how well I can actually get about to do the things we've already talked about you know.

INT: That's exactly right. Yes, yes that's fair enough, okay. And was the question worded in a way that made sense to you?

RES: Yes, it was, it did yes.

INT: Yes, quite straightforward good.

RES: Yes.

INT: And was it about something that's relevant or important to you after your stroke?

RES: Well, it is because I worked hard on the physical side of it.

INT: Right, that makes sense.

RES: You know, something that core strength I lost a lot of, but it's as simple as trying to get into bed, not even getting out but getting in.

INT: [Laughs] Yes, yes.

RES: And all you can do is bounce across into position which is wonderful for the person sleeping next to you because [unclear 00:17:03].

INT: Bounce them off the bed.

RES: You don't want to do it, but to get into bed and have the strength to put your arm out and pull yourself across into whatever you know.

INT: [Laughs] Brilliant, yes.

RES: But I don't, I have to bounce in to bounce myself out.

INT: [Laughs] Lovely.

RES: You know, [overtalking 00:17:18].

INT: xxxx you've got to laugh.

RES: It's not funny after a while is it?

INT: No, not if you're the one being bounced on, no.

RES: You know yes, so I did actually- I bought an exercise bike and I'd use that to build up some strength or some stamina. And I've got some, not compression bands, the other ones.

INT: Oh, I know the Therabands are they?

RES: Yes, the bands.

INT: I know.

RES: Just to build, you can sit there and do that while you're watching the TV but it does build up a bit of strength.

INT: Yes, exactly, exactly.

RES: I've got a three storey house yes?

INT: Ah, right so the stairs.

RES: So, I'm up and down bloody stairs [unclear 00:17:58]. I can do that and I know now I can walk a reasonable distance.

INT: Good.

RES: And I don't have to sit down. And you know, I can walk to town and back, I can walk to pick up my prescription if I want to.

INT: Yes, yes good, okay.

RES: You know, I've recovered well enough for that.

INT: Yes, so if you turn the page now there's a few more questions there.

RES: There is yes, you caught me out on that.

INT: Ah hah. So, this again, this is slightly different because this is asking you about over the last seven days or the last week.

RES: Yes.

INT: Okay, so how often have you been bothered by emotional problems such as feeling anxious, depressed or irritable? And then you've got a choice of answers there so, you've got never, rarely, sometimes, often and always. So, have a little think about that.

RES: Yes, well I'd mark it as sometimes.

INT: Sometimes, yes okay. So, what do you think the question is asking you there?

RES: Well, have I felt [laughs] anxious, depressed or irritable?

INT: Depressed or irritable, yes.

RES: Yes.

INT: Okay, so a mixture of feelings really isn't it?

RES: Yes.

INT: A mixture of emotions, yes okay. And was the question worded in a way that made sense?

RES: I think it did, yes.

INT: Right, and was it something that's relevant or important to you after your stroke?

RES: Well, it is, it all goes back to physical and you know goes back to mental health.

INT: Yes, yes okay.

RES: If you redo this perhaps you could change it from general sort of physical and mental health and sort of those questions under each other, in the same sort of.

INT: Yes, I know what you mean sort of group them together.

RES: The same subheadings, yes.

[00:19:46]

INT: Yes, okay good comment, that's good to know. Right, so moving onto the next question, question number nine how would you rate your fatigue on average? So, that's over the last seven days.

RES: Oh, that's mild.

INT: Mild, lovely okay. So, again what's the question asking you about?

RES: How tired I feel in general.

INT: Yes, yes okay. And is the question worded in a way that makes sense?

RES: Yes, it is, doing things makes me well, anybody who knew me, I could sleep any bloody where anyway.

INT: [Laughs] On a clothesline, yes.

RES: [Unclear 00:20:23]- Now, things, certain things do make me tired.

INT: Yes, okay. And is it about something that's relevant or important to you?

RES: Yes, of course it is yes.

INT: Yes, fair enough, okay. So, going onto the next question, in the past seven days how would you rate your pain on average? So, 0 is no pain and 10 is the worst pain imaginable.

RES: Well, I went for, what have I done, I've written it down two.

INT: Two, oh right lovely.

RES: Yes.

INT: Okay, so again what do you think the question is asking you about?

RES: Well, it's asking me if I'm struggling with any pain as a result of what's going on.

INT: Yes, yes okay.

RES: And I have my shoulder, my left shoulder, the stroke affected my left side.

INT: Yes, that's right, I remember.

RES: And I lost more or less all the feeling, a lot of the use of my left arm which is now back and working.

INT: Wow, that's good, lovely.

RES: You know, I'm getting better all the time, I can if I have to use a screwdriver and a bloody hammer.

INT: Right.

RES: But what happens, at the time it happened I had to hold the arm to stop it flying off all the time.

INT: Yes, I remember.

RES: My shoulder, and it still feels like I haven't fully built up enough muscle around that joint.

INT: Still feels a bit heavy?

RES: It does well, if I turn it, whether I've got a trapped nerve or something I don't know to be honest.

INT: Okay.

RES: But if I turn the arm a certain way or if I put it out to lean on it, it gives me the feeling I could, I've never dislocated it but it does give me the feeling I could.

INT: Yes, so yes best not to risk it.

RES: And it [overtalking 00:22:07]. Also, if I lie in bed not necessarily on it, if I lie on the other shoulder and you've got the weight of the arm on it, it aches.

INT: Yes, yes okay.

RES: Like the weight of the arm against the joint it makes it ache.

INT: Yes, okay so that's a fair comment there for number two. So, let me see now, was the question about something that's relevant or important to you after your stroke?

RES: Well, it is yes, it is.

INT: Yes, whether or not you're in pain.

RES: About the pain, yes.

INT: Yes, okay, okay.

RES: If I hadn't had a stroke I probably wouldn't have thought about it as much.

INT: No, that's right you do.

RES: But having said that I do get some pain in the fingers as well.

INT: Right.

RES: They say like the muscles have shortened or something.

INT: Can do, can do after a period of time.

RES: You know, and it's not my, I'm right handed so my left hand with all that, I do try to use them as much as possible but probably not as much as I used to, it's certainly not my dominant hand.

INT: That's right, you tend not to use it as much.

RES: [Overtalking 00:23:10] I'm just not using them enough.

INT: Yes, yes fair enough. Okay, so if we go onto the next page there's some pretty straightforward questions.

RES: [Overtalking 00:23:18].

INT: Yes, got it there?

RES: I have.

INT: Okay, so question number 11 is are you able to walk -so what did you score for that?

RES: Just a tick, it's just the one I've got to cross is it, cross the box yes I am able to walk [laughs].

INT: Able to walk without help. Lovely. So, was that question pretty straightforward?

RES: Yes, are you able to walk without help from another person, it's either yes or no. Actually, if you look at it that way, it doesn't actually say what to do, it just asks the question.

INT: Right.

RES: With the box it doesn't say tick it or-

INT: Ah, okay that's a good comment yes so the actual directions there aren't very clear are they, okay.

RES: Yes, it doesn't actually say on there what to do.

INT: No, thanks for that yes so you could be looking at it and thinking. Because with the other ones they're a bit clearer.

RES: But the answer is yes [laughs].

INT: Yes, that's right.

RES: There's no tick or cross it's yes.

INT: No, it doesn't really tell you what to do, that's a good comment, okay thanks for that. So, again, is the question something that's relevant or important to you after your stroke?

RES: Yes, the question is relevant it's just the instructions are a bit...

INT: Yes, okay lovely. And so, going onto number 12, do you need help from anybody to go to the toilet?

RES: The answer is no but again, there's no instructions.

INT: That's yes or no or tick whichever box, that's good to know. Okay, and you know, what was the question asking you [laughs] that was pretty straightforward isn't it?

RES: Yes, yes it was.

INT: And again, is the question about something that's relevant or important to you?

RES: Yes, it is.

INT: Yes, okay.

RES: [s/l I had one sorry story, 00:25:07] before I got transferred up to [the stroke unit] obviously, I was in the stroke room there- It was either that or [the hospital] and I can remember a guy who was opposite me went off to the toilet, came back and he was giving a bit of a fist pump. I said, "What's the matter?" He said, "I've just managed to go to the toilet," he said.

INT: [Laughs] yes.

RES: "And wiped my own backside," and I said.

INT: I know.

RES: And I thought yes, I thought to myself I know exactly what you mean.

INT: Exactly.

RES: You know it's not a lot but it's hell of a box to tick I've got to be honest.

INT: It is yes you're right; it is.

RES: It's a lot off your mind I think.

INT: Yes, and it's that dignity as well isn't it? I think you know that you can actually, wow, I can actually do this myself.

RES: That's right, yes.

INT: Yes, yes. Okay, next question then, do you need help with dressing or undressing?

RES: In general no.

INT: Okay.

RES: But I can manage to get things on backwards, I can do that.

INT: Yes, right [laughs].

RES: Or up until a couple of weeks ago I could put the shoe on the wrong foot especially if I'd put a shoe on

the left foot first, that's the one that's got a numbness. I just slap that in no problem at all and then maybe, and what really annoys me is doing the laces up. I then put the right one on and realise hang on, that's the wrong foot, and I've got to take them all back off again.

INT: Oh, dear.

RES: Yes that's going back to what we were saying about being anxious and depressed because sometimes you do that and you think hang on, I thought we were beyond this nonsense, yes?

INT: Yes, a bit frustrating yes.

RES: That can be frustrating and that can depress you as well and you think, *hang on now, I thought we were beyond this nonsense a week or two, a couple of months ago.*

INT: Yes, sure yes.

RES: That sort of thing can be annoying.

INT: Yes, I get that completely.

RES: Yes.

INT: And is the question about something that's relevant or important to you after your stroke?

RES: Yes, of course it is yes.

INT: Yes, okay.

RES: Yes.

INT: Now, last couple of questions coming up, do you need a tube for feeding?

RES: No.

INT: No, right. And so, again what do you think that question is asking you about?

RES: Well, something I've never actually had, I suppose is it where you can't swallow?

INT: That's right.

RES: [Unclear 00:27:21].

INT: Yes, exactly okay. And was the question worded in a way that made sense?

RES: Yes, and the answers are both there are they yes, you can tick or cross the right box.

INT: That's right, a bit more straightforward than the other ones fair enough yes.

RES: Yes, yes.

INT: And was the question about something that's relevant or important to you after your stroke?

RES: Well, it is relevant because I either have a tube either yes or no wouldn't I?

INT: Yes, did you have one when you first came in, did you have a tube down your throat?

RES: No, no.

INT: No, so you didn't need that, okay.

RES: No, that's okay for me [overtalking 00:27:58].

INT: So, last question, do you have problems with communication or understanding?

RES: [Pause] You tell me, I've just done this [laughs].

INT: [Laughs] Well I know the answer but what would your answer be?

RES: [Overtalking 00:28:11] Yes, I'd put no down because I think I'm yes, I think I'm getting it together reasonably well.

INT: And what did you think of that question, what do you think it was asking you about?

RES: Well, yes as I said earlier on about the confusion, it can [unclear 00:28:37]. It's getting better and better and better all the time.

INT: Good, good.

RES: But yes, I think it's a relevant question because obviously, for some people it doesn't clear up does it?

INT: Okay.

RES: What I'm wondering is with those people, would they be able to have filled this is anyway, somebody else would probably had to have filled this questionnaire in.

INT: Yes, well part of the study that I'm doing, xxxx, is I'm going to be asking a couple of carers who are able to fill it in on somebody's behalf. So I'm quite interested to know what their opinion is of the questionnaire as

well because it's important that it makes sense to them and that it's meaningful isn't it you know.

RES: Yes, that's right yes.

INT: So, I've got a couple of willing victims to ask the same questions to, yes.

RES: That's the way.

INT: Yes, okay. Right, well thanks for that so, I've just got a couple of general questions now about the whole questionnaire if that's okay?

RES: Okay.

INT: So, did you find any of the questions hard to answer?

RES: [Pause].

INT: Have a little look through and see what you think.

RES: [Pause] Not so much well, other than what we said if they split the questions up into sort of general health, physical or mental. When it wasn't clear you had to guess.

[00:30:05]

INT: Yes, that one there yes, that's a good comment to make actually, it would be interesting to see if anybody else picks up on that as well, yes okay.

RES: There's the big question, in general- It's a big question you know, covering all of, in general so it covers just in your whole life try and sum it up in a few words. And it's a bit difficult that way.

INT: Yes, so.

RES: That one may need splitting up somehow.

INT: Yes, so would you, is there any other way that they could be worded to make them a bit easier to follow or perhaps more specific to your stroke, what do you think?

RES: It depends- [pause]

INT: Could that be a bit confusing, you know it says in general so, could that mean generally or since your stroke or what, any thoughts there, xxxx?

RES: Yes, yes specifically, maybe more stroke specific if that's the people you're after, yes.

INT: Yes, the first bit is like a general health questionnaire, it's not only for stroke patients so, it covers everybody. But from what you're saying it might be an idea to have you know, "Following your stroke," sort of at the top maybe.

RES: Yes, yes.

INT: Yes, okay that's a good comment. So, and again, do you think the questionnaire as a whole was relevant to your, what they call your health-related quality of life after your stroke?

RES: Yes, it was because like I said I went through it and I thought, I went through it myself and had a few ideas. And I sat down and I said, "Look, this is what I'm going through," and I went through it with the wife and then it was…quite interesting to have her feedback.

INT: Yes, that's good to know.

RES: In fact, it was so much fun that we told all our friends as well, it's like-Mr and Mrs [Laughs].

INT: [Laughs].

RES: If somebody said to me, "How are you," and I said I thought I was doing all right until I had her open and honest feedback, and we all had a damn good laugh about it to be quite honest. Because you know it was exactly how life is.

INT: That's right, xxxx yes.

RES: There we go [laughs].

INT: Okay, were there any questions that you didn't think were relevant, have a little look through, see what you think.

RES: [Pause] No, there's nothing there that wasn't relevant.

INT: Okay.

RES: Just how would you apply that and I [s/l think it's 00:32:53] very strange because you know, well when we're talking about social activities and all the rest of it. We've all spent the last three and a half months where we can't go anywhere near anybody.

INT: Yes, that's right.

RES: So that could skew some of the answers you're going to get.

INT: Yes, I mean I could ask you the same questionnaire in six months' time and Covid is all done and dusted

hopefully, and you might have answered slightly differently. Yes exactly, fair comment. So, is there anything that we've missed, is there anything that the questionnaire should have included with regards to your quality of life after your stroke?

RES: [Pause].

INT: Have a little look through the questions because there's quite a few there and see what you think.

RES: I can't think of anything missing, I went though it a couple of times, I'm trying to think of anything it didn't cover or that could be covered under one of the questions. Because it's basically all physical and mental and that's what it is isn't it?

INT: That's right yes.

RES: So, there's social [overtalking 00:34:08] capability or social-

INT: Yes, physical, mental and social as well, from what you've said. So, it covered all areas pretty well do you think?

RES: It does, yes.

INT: Yes, great.

RES: And some of them are a bit too sort of general rather than specific.

INT: Specific, that's a really good comment, thanks for that. Well, xxxx you'll be pleased to know you've passed with flying colours [laughs].

RES: [Laughs] Good.

INT: Thank you so much for agreeing to have the interview, it's been really helpful.

RES: That's okay.

INT: And I'll let you know how I get on all right, I've got a few more people to interview.

RES: Okay.

INT: And then what I'll do then is look at the results to see if you've made similar comments or any differences.

RES: Yes.

INT: And I can write a report then on the actual questionnaire itself.

RES: Yes, no that's fine and is this for your dissertation or whatever?

INT: It is indeed yes, gosh.

RES: Yes, yes.

INT: Whenever that happens.

RES: Great, have fun.

INT: Oh, thank you, xxxx and give my best regards to your wife as well.

RES: Yes, yes.

INT: All right, thank you so much, take care, xxxx.

RES: Okay, all the best yes, take care.

INT: Cheers now.

RES: Bye bye.

INT: Bye xxxx

[Audio ends: 00:35:38]

Appendix xi. Transcript of a cognitive interview with an informal carer

CONFIDENTIAL

Date Transcribed: 21st September 2021

Interviewer(s): Stephanie Gething

Respondent(s): **Wife of a patient with stroke**

INT: Right, xxxx can I just check that you're happy, that you consent to go ahead with the interview?

RES: Yes, yes.

INT: Oh, lovely okay. So have you got the questionnaire in front of you and a pen?

RES: Yes, I have.

INT: Lovely, okay. Well, as you know this questionnaire can be filled in by people who've had a stroke or their carers. So, you know if they've got a problem with their communication or they just don't feel up to doing it for whatever reason then their carers can actually fill it in on their behalf.

RES: Okay, well we've run through it this morning.

INT: Yes, okay well that's why I'm doing the interview is to see if the questionnaire actually reflects you know what xxxx's quality of life is like after his stroke.

RES: Right, okay.

INT: So, what I'm going to do, is go through the questionnaire with you and you can give me the scores.

RES: Right.

INT: And then I've just got to ask you a couple of questions about your thoughts about each question if that makes any sense.

RES: Oh, right.

INT: All right, okay so here we go. So, number one is in general, would you say your health is excellent, very good, good, fair, poor? So, what do you think he would score for that?

RES: Really sort of good to fair.

INT: Oh, okay so that sounds fine. So, what did you think that question is actually asking?

RES: Well, how his health is, and [pause] his health is reasonably good, he's been quite lucky, it could have been an awful lot worse for him really.

INT: Exactly, yes.

RES: So, in general, I would say that it's good to fair you know.

INT: Yes, yes.

RES: He's got movement of all his limbs and everything.

INT: Good.

RES: He can use everything.

INT: So, he's making a good recovery.

RES: Unfortunately, his sight wasn't so good and we had his visual test at the opticians recently and she said that she didn't think he was fit to drive.

INT: Oh, fair enough well, you've got to be safe at the end of the day haven't you, you know.

RES: Well, that's right.

INT: Yes, fair enough.

RES: Yes.

INT: Okay, so what were you thinking of when you answered that question?

RES: Well, his general health is quite good I think, I'm quite pleased with how he's come on, he's doing really well to be honest so yes.

INT: Brilliant, okay. So, was the question worded in a way that made sense to you, was it quite straightforward to answer?

RES: Yes, I think so really yes.

INT: Yes, okay. And was the question something that is important or relevant to someone following a stroke?

RES: Oh, I think it is relevant, yes.

INT: Yes, okay. So, number two then, in general would you say your quality of life is excellent, very good, good, fair or poor? So, what would you score for that?

RES: I'd say three, good.

INT: Okay, lovely.

RES: You know, at the moment we feel it is quite good, yes his quality of life. But its been a bit difficult with Covid.

INT: Yes, of course. It's been a strange time hasn't it?

RES: Well, exactly, that's exactly what we said, at the moment when he's wanted to be socialising and whatever we haven't really been able to do any of that.

INT: That's right, yes exactly.

RES: Anyway, have we?

INT: So, again what did you think the question was asking you about?

RES: Well, what is your quality of life, what can you do, what can't you do?

INT: Yes, fine okay.

RES: That's what I would have thought that was, that's what that meant.

INT: Yes, and what did you think of when answering the question?

RES: Well, I thought as I say, it was quite good, he can do most things fortunately.

INT: Yes, great good, okay.

RES: Yes.

INT: So, what score did you give for that question?

RES: So, I would say good to that.

INT: Yes, I've ticked that, that's good.

RES: Shall I tick it as well now because I'd only done it in pencil?

INT: Yes, yes can, you don't have to send that to me, you can keep it, that's fine.

RES: Oh, this is for us to keep is it?

INT: Yes, yes.

RES: Okay, okay right.

INT: So, was the question worded in a way that actually made sense to you?

RES: Oh, I think so yes, yes.

INT: Oh, quite clear, good. And was the question about something you think is relevant to someone after a stroke?

RES: Oh, I would think so, yes, yes.

INT: Yes, fair comment, okay.

RES: As I say I think he could have been a lot worse than he is and he's done very well.

INT: Well, yes exactly. So, the next question then is in general, how would you rate your physical health? So, excellent, very good, good, fair, poor.

RES: I'd say good for that one as well, it's reasonably good.

INT: Wonderful, yes. So, what did you think the question was actually asking about?

RES: Well, can he do the things that he used to do I suppose in general.

INT: Lovely.

RES: How would you rate your physical health and he can do most things that he has done.

INT: Fine.

RES: I mean he gets very, very tired that's all I say you know; he does things but he feels fatigue afterwards [unclear 00:05:38].

INT: Yes, yes.

RES: And he has lost weight.

INT: Oh.

RES: So, he's better for that because he was quite heavy.

INT: Well, fair enough, fair enough.

RES: And he's cut down and we've been having smaller meals, he's not drinking anything so physically he's a bit better in that respect as well.

INT: Pretty good, yes so that's a fair score then, yes.

RES: Which is a help for him.

INT: So, was the question worded in a way that made sense to you?

RES: In general, [pause] yes I think so, yes.

INT: Yes, okay. And was it about something that's relevant or important to a person after having a stroke?

RES: Well, yes I would think so definitely, yes.

INT: Yes, okay lovely. So, the next question then in general, how would you rate your mental health including your mood and your ability to think?

RES: Well, he is a bit slower on things definitely.

INT: Right.

RES: I think, I think [laughs].

INT: [Laughs] So what would you score for him there?

RES: I'd put good there really.

INT: Okay, yes that's fine.

RES: Well, I was dithering, it could have been fair to good so I put a little arrow there because it's not always good. You know, he really has to think of things a lot more.

INT: Right.

RES: For instance, when he came home I mean he couldn't remember codes for the computer or phone or anything and he was very frustrated with that. Because he's always been really good on that sort of aspect of things.

INT: Exactly, yes, yes.

RES: But I mean he's come on really well but on other times his memory isn't so good. He might ask me the date three or four times a day.

INT: Yes, it can be a bit up and down can't it?

RES: Yes, yes.

INT: So, if you think about in general.

RES: If he's tired, if he's tired as well I think he's not quite so sharp which I don't suppose any of us are if we're tired isn't it?

INT: Exactly. So, what were you thinking about when you were actually answering that question?

RES: Well, I was thinking about his mental health you know, the moods, he does get a bit, I think it's frustration more than anything with him.

INT: Fair enough, yes.

RES: And as I say he does sometimes, he has to stop and have a good think about things.

INT: About what he's doing, okay.

RES: Yes, yes.

INT: So, was the question worded in a way that made sense to you?

RES: Yes, I think so yes.

INT: Yes, quite straightforward.

RES: It was quite straightforward most of them.

INT: Yes, yes which is good isn't it?

RES: Yes, yes.

INT: So, was the question about something that you think's relevant to someone who's had a stroke?

RES: Well, yes because that is a problem that he has, remembering things.

INT: Right.

RES: And as I say using technical stuff like the computer and that it was second nature to him, he was really good at it. And those sorts of things he's worked on and in all fairness he'll stick to it until he tries to do it you know.

INT: Great, yes**.**

RES: He has tried and I think he's done really well with it to be honest.

INT: Yes, yes fair enough, okay.

RES: But since, I think, shall I say as an instance he was looking at the car the other day, put oil and water in. And he said to me, "xxxx I don't know where to put the oil," and I said, "There's no good asking me to put it in."

INT: [Laughs] yes.

RES: [Laughs] but he stayed out a little while, I said, "Look, I'll get the book, we'll have a look at the car book." And then by the time I came back he said, "It's okay, I've got it, I remember it now."

INT: He'd worked it out, aw.

RES: He tries to bring things forward.

INT: That's right yes, he just needs to take a bit more time I think yes.

RES: Yes, so in that respect.

INT: Okay, so the next question then in general, how would you rate your satisfaction with your social activities and relationships?

RES: Well, they've been absolutely nil haven't they because we can't see anybody you know. Yesterday was the first afternoon we sat in the garden with our sons and their partners and wives and with their kids, So, that was really lovely but of course, we haven't really been anywhere

INT: Right, yes so what would you score for that then?

RES: I'd say good then, I thought that was quite good.

INT: Okay, yes lovely. And I think you know, once it all settles down hopefully it's going to improve, you never know, yes.

RES: Yes, and that's why he doesn't want to go out at the moment.

INT: Fair enough.

RES: Because I've had my two jabs but he's still waiting for the second one.

INT: Right, yes interesting.

RES: So, [unclear 00:09:51] a number of weeks now so I think once he's had that I think he will feel a lot safer to go out.

[00:09:57]

INT: A bit more confident, yes exactly.

RES: Because after being in hospital and that he said, "There's no way I want to go in hospital."

INT: No.

RES: And we've been really careful sort of well, whatever with Covid

INT: Yes, exactly, okay. So, what did you think the question was asking?

RES: Well, how does he, how is he getting on, does he want to mix I suppose.

INT: Right.

RES: Does he want to well; does he want to do any activities as yet? And what's his relationship with other people and the children and us you know?

INT: Yes, yes.

RES: I don't know what else you could say because we couldn't.

INT: No, that's fine.

RES: Not able to, he hasn't had that properly since he's come home really.

INT: Exactly, because of the Covid, yes.

RES: Because of Covid.

INT: Yes, so what were you thinking about when you were answering the question?

RES: Well, all the things I've just said to you really, he is, he's always been a very sociable person.

INT: Right.

RES: And I'm sure he will be okay; I think he's fine in that respect really.

INT: Yes, it's just, it's been such a strange time hasn't it?

RES: Yes, yes.

INT: I think that's the thing, yes.

RES: I mean we've sort of had our ups and downs [laughs].

INT: [Laughs] yes.

RES: We're fed up of each other.

INT: [Laughs] Yes.

RES: You know in the confinement of the house and whatever.

INT: Aw.

RES: But other than that, though, I don't think he's got many problems there.

INT: Okay, and do you think that question is relevant to somebody's quality of life after a stroke?

RES: Well, I would think so yes, I mean under normal circumstances perhaps if he was gone a bit introverted, didn't want to go out and didn't want to do this and that I would think there was something wrong.

INT: Yes, fair comment, okay. So, let me think, next question so, in general please rate how well you carry out your usual social activities and roles. So, that's things around the home, if you're working, in the community, responsibilities as a parent.

RES: Yes, well he doesn't do any work at all, we're both retired.

INT: Yes, okay.

RES: So, around the home he is doing you know most things.

INT: Right.

RES: Well, I say that you know he makes a cup of tea, which is good.

INT: For a man [laughs].

RES: Yes, things like that [laughs]

INT: So, what would you score for that then?

RES: Yes, he did some jobs on the car and that, I would have said three to four again.

INT: Okay, yes.

RES: Because as I say he's really quite good with that.

INT: Wonderful. And sorry to ask you the same questions but what do you think the question was asking?

RES: Well, obviously if he was somebody who went out and did activities, is he able to do that at the moment? But he doesn't do anything now, he used to play golf years ago but he doesn't do that now.

INT: Right, right.

RES: He does like to do carpentry but he hasn't done any of that.

INT: Okay, okay plenty of time.

RES: But we don't have an indoors to do that, he normally does that if it's outside. So, weather permitting you know, he hasn't done a lot of that either.

INT: No, fair enough.

RES: Really at the moment.

INT: So, what were you thinking about when answering the question?

RES: Well, all what I've said to you really about how he is and how he's coping with it all.

INT: Yes, yes that's right, yes that's good. And was the question worded in a way that made sense to you?

RES: Yes, yes.

INT: Yes, good. And was the question about something you think is relevant or important after a stroke?

RES: Well, I would think so yes definitely.

INT: Yes, because it sounds like he was quite active before so, you know that's important to him isn't it by the sounds of it?

RES: Yes, yes.

INT: Yes, okay. So, the next question then is slightly different answering as you can see, slightly different scoring.

RES: Yes, yes.

INT: To what extent are you able to carry out your everyday physical activities such as walking, climbing stairs, carrying groceries or moving a chair?

RES: Oh, he could do all of that mostly, what have we got here completely, mostly, mostly he can do most things.

INT: Mostly, lovely.

RES: He [unclear 00:13:51] down the stairs and all that sort of thing.

INT: Great, so what do you think the question was asking about?

RES: Well, it's self-explanatory really, are you able to carry out your everyday physical activities such as walking, climbing? Yes, he can do those things yes, he hasn't been hindered in that way at all.

INT: No, and what were you thinking about when you were actually choosing your responses, what were you thinking about for the question?

RES: Well, he is doing most of his physical activities such as walking. We haven't gone for many long walks or anything either because he's not keen to do that.

INT: Oh, okay.

RES: Because of Covid.

INT: Well, yes.

RES: And we're very hilly where we are.

INT: Right.

RES: Which now we'd be able to go in the car somewhere you know flatter and whatever and he could have a walk there and I'm hoping he's going to do that.

INT: That will make a difference I think yes, definitely.

RES: Yes, because he needs that really.

INT: Yes, so was the question worded in a way that made sense to you?

RES: Yes, it does, yes.

INT: Right, and do you think it's something that's relevant or important to someone after a stroke?

RES: Well, yes definitely.

INT: Yes, okay, lovely. Right, turn over the page okay so.

RES: Okay.

INT: Now, again slightly different so, if you think about the last sort of seven days, how often have you been bothered by emotional problems such as feeling anxious, depressed or irritable?

RES: Seven days on this one, didn't say that on the other one did it?

INT: No you're right.

RES: How often have you been bothered by emotional problems such as feeling anxious, depressed or irritable? Yes, he does get a bit anxious sometimes.

INT: Fair enough.

RES: Because he does get anxious and he gets fed up and a bit depressed, yes he does.

INT: Fair enough, fair enough. So, what did you think the question was asking you there?

RES: Well, sorry but it says at it says isn't it, how often have you been bothered by emotional problems in the last seven days? So, I would say once.

INT: Yes, right and so, what were you thinking about when answering the question?

RES: I just think it's self-explanatory [laughs].

INT: Yes, that's right yes, yes and this is all good stuff because it means the questionnaire makes sense to you.

RES: Yes.

INT: So, don't worry, there's not a right or wrong [laughs] you're doing really well.

RES: [Laughs] okay.

INT: Okay, and was the question worded in a way that made sense to you?

RES: Yes, yes it was yes.

INT: Wonderful, and was it about something that's important or relevant to someone after their stroke?

RES: Well, yes I would think it is isn't it, yes?

INT: Yes, yes fair enough, okay. And next question then, how do you think xxxx would rate his fatigue on average over the last seven days?

RES: I'd say, moderate. It isn't bad really, as I said he was working on the car and he's been doing stuff in the garden but he does get tired when he's done it where normally he wouldn't be as tired.

INT: OK and so what did you think the question was asking?

RES: Well, asking exactly about fatigue. Is he tired all the time or not but he's not.

INT: That's right, yes, yes okay lovely. And was the question worded in a way that made sense?

RES: Yes, it was yes.

INT: Yes, quite straightforward aren't they?

RES: Yes.

INT: And was it about something that you think is important after a stroke?

RES: Oh, yes definitely I think isn't it?

INT: Okay.

RES: To know how he is when he's gone back to his normal sort of things.

INT: That's right.

RES: How he's coping.

INT: Yes, okay. So, now the next, last well, almost the last question, is again slightly different scoring. So, how would xxxx rate his pain on average? So, 0 would be no pain and 10 would be the worst pain imaginable, where would he put himself do you think on that?

RES: I think about three.

INT: Right.

RES: He still gets what he calls a bit of a sensation in his face.

INT: Oh, okay.

RES: The right side of his face.

INT: Is that when he's tired?

RES: Pardon?

INT: Is that when he gets tired, does he notice it more?

RES: No, it's there all the time.

INT: Right, OK

RES: Yes, some days it's worse than others and the same shoulder.

INT: Yes, fair enough.

RES: He feels a bit more uncomfortable, more like what did you say today, you said it's more like?

RES2: Well, it's like pins as well, like pins and needles.

RES: Pins and needles, so it's more of a nuisance than a pain if you know what I mean, it's just there all the time. Yes, but he's not quite right on that side you know.

INT: Okay, okay, sorry to hear that. So, again what did you think the question was asking you about?

RES: Well, asking what sort of pain and how severe is it for him.

INT: Yes, that's great.

RES: As I say, it's more of a sensation he feels than a pain you know.

INT: Yes, yes that makes sense, that makes sense.

RES: It's there anyway a lot of the time.

INT: Okay.

RES: And that's about the worst thing that bothers him.

INT: Yes, so was the question worded in a way that made sense to you?

RES: Yes, it did, yes.

INT: Great, and was it about something you think that's relevant or important to someone after a stroke?

RES: I would think so, yes.

INT: Yes, okay. Right, nearly there [laughs] you're doing very well, you're nearly at the finishing line.

RES: Right.

INT: Okay, so if you turn to the next page now.

RES: Right.

INT: There's a few pretty simple questions.

RES: Yes.

INT: So, the first question is are you able to walk?

RES: Yes.

INT: So, what would he tick, what would you think to score from those?

RES: Well, he is able to walk without help from any other person with or without a device.

[00:20:01]

INT: Great, okay.

RES: And yes, he's been like that since he came home.

INT: Yes, so what do you think the question was asking about?

RES: Well, is he able to walk?

INT: Yes, fine.

RES: I would think.

INT: Fine, fine yes.

RES: Yes.

INT: And was the question worded in a way that made sense to you?

RES: Yes, yes.

INT: Yes, and is it something that's relevant or important to somebody after a stroke?

RES: Yes, I would think so isn't it?

INT: Yes, yes okay lovely. Next one, do you need any help from anybody to go to the toilet?

RES: No, he can manage going on his own and he's done that from the day he's come home as well.

INT: Great, lovely. And so, again what do you think the question was asking you about?

RES: Well, can he manage to look after himself in the bathroom?

INT: Go to the loo [laughs].

RES: And yes, he can.

INT: Yes, yes and again, was the question worded in a way that made sense to you?

RES: Yes, yes.

INT: Lovely.

RES: It's very clear isn't it?

INT: Yes, yes and was it about something that's relevant or important to xxxx after his stroke?

RES: Well, I should think it's very important for anyone after a stroke isn't it, yes.

INT: Yes, fair enough.

RES: To be able to do that.

INT: Okay, nearly there.

RES: And obviously, from reading this we can see how you know; these things obviously are a lot worse for other people.

INT: Yes, that's a good comment yes, yes.

RES: Yes.

INT: So, does xxxx need help with dressing or undressing?

RES: No, none at all.

INT: Great, okay. So, again what do you think the question was asking?

RES: Exactly what it says.

INT: Yes [laughs] quite straightforward isn't it?

RES: Quite straightforward, you can understand it can't you?

INT: Yes, and was the question worded in a way that made sense to you?

RES: Yes, yes.

INT: Yes, and do you think it's about something that's relevant or important to somebody after a stroke?

RES: Yes, it is important isn't it, and he's lucky he can do it.

INT: Yes, true, true. Okay, last couple of questions then, underneath quite a big heading, it says do you need a tube for feeding?

RES: No.

INT: No, okay. So, again what did you think the question was asking you?

RES: Well, did he need assistance with feeding by a tube and he hasn't needed it at all.

INT: Great, great. And was the question worded in a way that made sense to you?

RES: Yes, definitely.

INT: Yes, and was it something that someone would feel is relevant or important after a stroke?

RES: Well, it is important and I can see why you would need to know that, but it doesn't affect him.

INT: No.

RES: He's okay with that.

INT: That's an interesting comment yes, thanks for that okay. And the last one you'll be pleased to know [laughs].

RES: [Laughs].

INT: Does xxxx have problems with communication or understanding?

RES: No, not really, no.

INT: That's right, okay. So, finally what did you think the question was asking?

RES: Well, exactly what it says.

INT: What it says on the tin, yes fine.

RES: Quite straightforward and you would, yes, you would need to know that wouldn't you, obviously some people are not able to communicate and whatever.

INT: That's right. And was the question worded in a way that made sense to you?

RES: Yes, it was.

INT: Okay, and do you think it's something that might be relevant or important to xxxx after his stroke?

RES: I should think it's important to everybody yes after their stroke, yes.

INT: Yes, fair comment, xxxx yes okay oh, thanks for filling that in. Now, I've got a couple of extra questions now, if you just have a little look through the questionnaire. Were any of the questions difficult for you to answer on xxxxs behalf if you like, as a carer?

RES: No, no.

INT: Good.

RES: I think they're all very straightforward.

INT: Yes, fine.

RES: To be honest aren't they, very straightforward.

INT: Yes, and did the response choices to the questions make sense?

RES: Yes.

INT: Good, okay. So, in general, tell me what did you think about the questionnaire in general?

RES: I thought it was quite good, as I say obviously, you know for me it was very straightforward. But I can understand the questions and why they would be needed to ask, why you'd need to know what state people are. And how they're suffering after a stroke and how they're coping, yes.

INT: Yes, and you know as a carer filling it in on xxx's behalf, have you got any views in particular on filling it in? Have you got any views about the questionnaire?

RES: No, no I think.

INT: Fine, yes.

RES: I think anybody can understand that you know.

INT: Right, great.

RES: Yes, it's very straightforward I think for anybody to understand and it's very useful I can imagine.

INT: Yes, do you think so?

RES: For you to know.

INT: Yes, I mean you've answered my next question actually, do you think the questionnaire is relevant to quality of life after someone's had a stroke?

RES: Yes, yes I'm sure it must be very relevant, yes.

INT: Yes, okay. And were there any of the questions that you didn't think were relevant?

RES: No, I don't think so, it's all the things that people do have problems with after their stroke isn't it?

INT: Yes, yes.

RES: No, I thought it was very good actually, yes.

INT: Okay.

RES: There were lots of things, yes.

INT: And was there anything else, do you think the questionnaire should have included anything else, any other questions or any other areas?

RES: Well, not for us no, I don't think so.

INT: No, fair enough. And is there anything you'd like to say about the questionnaire, about what it looks like or how easy it is to answer or anything like that?

RES: No, I think it is quite straightforward and the questions are put quite clearly I think for people to understand.

INT: Great, great lovely.

RES: And I'm sure the answers must be a big help to you.

INT: Yes, well.

RES: Which I think is quite good.

INT: Yes, well I mean that's why I'm doing this study is because hopefully we're going to be using this with people like yourselves.

RES: Yes.

INT: To help inform services and polices and things like that.

RES: Yes.

INT: So, it's really helpful to have your views on it you know.

RES: Yes, yes.

INT: Okay.

RES: Well, I think it is quite straightforward.

INT: Yes, good thank you.

RES: Quite simple but definitely you know [unclear 00:26:00] but yes, I think it was quite good really, yes.

INT: Great, well xxxx, you'll be pleased to know that's the end so you can go and have a nice cup of tea now [laughs].

RES: [Laughs] okay.

INT: And thank you so much for helping me with my research, it's going to be very helpful.

RES: I'm glad we've been able to help.

INT: Yes, thank you, all the best to you and xxx, take care now.

RES: No thank you, bye bye.

INT: Thank you bye, bye, bye bye.

[Audio ends: 0:26:48

Appendix xii. Table of HCPs' on-line survey free text comments on the content of PROM-15

PROM-15	COMMENTS	Participant No.	HCP/Band
Instructions	• No comments	N/A	N/A
Response options	• No comments	N/A	N/A
Item 1	• Answer may be influenced by the current situation and may not reflect general health (Judgement)	PC01	PT/B8
Item 2	• I think quality of life may need further explaining as this is not always a term people are familiar with (Comprehensibility) • Think this question is highly relevant but often my experience is that people don't always know what 'quality of life' means. I think a few examples for this would be good. (Comprehensibility)	PC03 PC 04	SLT/B7 CP/B7
Item 3	• I'm not sure how much this differs from Q1 (Comprehensibility) • This is similar to question 1 (Comprehensibility)	PC04 PC05	CP/B7 OT/B6
Item 4	• Mood is different to cognition so 2 questions in one? (Comprehensibility)	PC06	OT/B6
Item 5	• No comments	N/A	N/A
Item 6	• This is similar to question 5 (Comprehensibility) • This might be confused with the last question as wording is similar (Comprehensibility)	PC05 PC08	OT/B6 PT/B6
Item 7	• The person might not have been able to do this before the stroke (Judgement)	PC08	PT/B6
Item 8	• No comments	N/A	N/A
Item 10	• The numbers in the question may be confusing for some respondents (Response) • This might not be due to the person's stroke (Judgement) • Pain might not be due to the stroke (Judgement)	PC01 PC07 PC08	PT/B8 SFSC PT/B6
Item 11	• No comments	N/A	N/A

Appendix xii cont.

Item 12	• No comments	N/A	N/A
Item 13	• No comments	N/A	N/A
Item 14	• Again, I wonder whether this needs to be more specific in case there are people who use NG tubes or PEGS for other health conditions. Eg. Do you need a tube for feeding since your stroke? (Judgement) • May be difficult to understand this question (Comprehensibility) • Would the person be at home if they had a feeding tube? (Relevance)	PC04 PC05 PC07	CP/B6 OT/B6 SFSC
Item 15	• Could look at opening this out: Do you have trouble speaking to or understanding loved ones, friends, family, strangers, professionals etc (Comprehensibility) • Two questions in one ie. communication and understanding do they mean understanding language? (Comprehensibility) • This would be difficult for a person with this problem to answer (Comprehensibility)	PC03 PC05 PC07	SLT/B7 OT/B6 SFSC

Key. CP = Clinical psychologist; OT = Occupational Therapist; PT = Physiotherapist; SFSC = Stroke family support coordinator; SLT = Speech Language Therapist.

Appendix xiii. Consent form in HCPs' on-line PROM survey

Page 2: PROM-15
HCP Survey v1

CONSENT FORM

Study Title: Evaluating the content validity of a condition specific Patient Reported Outcome Measure (PROM) for use with people living with stroke in the community

IRAS No. 275885

Name of Principal Investigator: Stephanie Gething

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

- Yes
- No

2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my legal rights being affected *Required*

- Yes
- No

3. 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. *Required*

- Yes
- No

4. I confirm that data from the study can be used in the final report and other academic publications. I understand that these will be used anonymously and that no individual respondent will be identified in such reports *Required*

- Yes
- No

5. I give consent for the use of verbatim anonymised quotes in publications and conference presentations *Required*

- Yes
- No

6. I understand that the findings and potentially secondary analysis of the findings and associated data from the study may be presented at conferences and in scientific journals. I understand that these will be used anonymously and that no individual respondent will be identified in such reports. *Required*

- Yes
- No

7. I would like to receive a copy of the final study report *Required*

- Yes
- No

8. I agree to take part in the above study *Required*

- Yes
- No

Appendix xiv. COSMIN Study Design Checklist for Patient-Reported Outcome Measurement Instruments (Mokkink et al. 2019)

Recommendations for the design of a study on measurement properties

Recommendation	*Recommendation met*
Research aim	
1 Provide a clear research aim, including -	
(1) the name and version of the PROM,	**YES**
(2) the target population, and	**YES**
(3) the measurement properties of interest clearly described	**YES**
PROM	
2 Provide a clear description of the construct to be measured	**YES**
3 Provide a clear description of the development process of the PROM, including a description of the target population for which the PROM was developed	**YES**
4 The origin of the construct should be clear: provide a theory, conceptual framework (i.e. reflective or formative model) or disease model used or clear rationale to define the construct to be measured	**YES**
5 Provide a clear description of the structure of the PROM (i.e. the number of items and subscales included in the PROM, instructions given and response options) and its scoring algorithm	**YES**
6 Provide a clear description of existing evidence on the quality of the PROM	**YES**
7 Provide a clear description of the context of use	**YES**
Target population	
8 Provide a clear description of in- and exclusion criteria to select patients, e.g. in terms of disease condition and characteristics like age, gender, language or country, and setting (e.g. general population, primary care or hospital/rehabilitation care)	**YES**

9 Provide a clear description of the method used to select the patients for the study (e.g. convenience, consecutive, or random)	**YES**
10 Describe whether the selected sample is representing the target population in which the PROM will be used in terms of age, gender, important disease characteristics (e.g. severity, status, duration)	**YES**
Assessment of Content Validity	
Content validity of existing PROMs can be assessed by asking patients and professionals about the relevance, comprehensiveness and comprehensibility of the items, response options, and instructions.	**YES**
Study design requirements-	
1 From the perspective of the patients: use an appropriate method for assessing	
❖ the *relevance* of each item for the patients' experience with the condition, AND	**YES**
❖ the *comprehensiveness* of the PROM, AND	**YES**
❖ the *comprehensibility* of the PROM instructions, items, response options, and recall period	**YES**
2 From the perspective of professionals: use an appropriate method for assessing	
❖ the *relevance* of each item for the construct of interest, AND	**YES**
❖ the *comprehensiveness* of the PROM	**YES**
3 Include professionals from all relevant disciplines	**PARTIALLY**
4 Evaluate each item in an appropriate number of patients or professionals	
❖ For qualitative studies ≥7	**YES**
❖ For quantitative (survey) studies ≥50	**Unable due to resource limitations**
5 Use skilled group moderators or interviewer	**YES**
6 Base the group meetings or interviews on an appropriate topic or interview guide	**YES**

7 Record and transcribe verbatim the group meetings or interviews	**YES**
Analyses	
8 Use an appropriate approach to analyse the data	**YES**
9 Involve at least two researchers in the analysis	**NO due to resource limitations**