The development and validation of a condition-specific, patient-reported outcome measure for peripheral nerve disorders of the hand: the Impact of Hand Nerve Disorders (I-HaND©) Scale

A thesis submitted for the degree of Doctor of Philosophy

by

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May 2017

Words: 63,016

Abstract

Nerve disorders of the hand result in impairments as well as activity limitations and participation restrictions. There are currently no patient-reported outcome measures (PROMs), that evaluate this impact specifically in people with a range of nerve conditions. To address this need, the *Impact of Hand Nerve Disorders* (I-HaND©) Scale was developed.

A multi-centre, three-phase study using mixed methods was undertaken to develop and validate the I-HaND. Face-to-face interviews with 14 patients and subsequent pilot-testing with 61 patients resulted in the development of the content of a new 32-item PROM. A final longitudinal, repeated-measures validation study with 82 patients assessed the psychometric properties of the I-HaND.

Patients found the I-HaND to be relevant and highly acceptable. A single-factor structure was confirmed through Principal Components Analysis. A very high internal consistency (Cronbach's alpha = 0.98) and good criterion-related validity with the Quick DASH (Pearson's r = 0.87) were demonstrated. Test-retest reliability was assessed from repeated administration over a 2-week interval. The test-retest reliability was excellent (Intraclass Correlation Coefficients = 0.97; 95% CI = 0.94 to 0.98). Responsiveness was assessed over a 12-week interval and calculated as Cohen's Effect Size (ES) and the Standardised Response Mean (SRM). The I-HaND was able to detect change in a group of patients where change was expected (ES = 0.51; SRM = 0.60) and was marginally more responsive relative to the Quick DASH (ES = 0.42; SRM = 0.56).

The I-HaND is the first condition-specific PROM validated for people with a range of hand nerve disorders. The study also provides new insights into the impact of hand nerve disorders on patients. Subject to further research into its psychometric properties, the I-HaND has the potential to be used alongside other outcome measures for hand nerve disorders and to become part of a core outcome set for use in future clinical trials.

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Acknowledgments

"No man is an island, entire of itself, every man is a piece of the continent, a part of the main" (John Donne).

I would like to express my gratitude to the University of East Anglia for the opportunity to embark on this PhD studentship and for the financial support to complete it. I would like to thank my supervisors, Dr Christina Jerosch-Herold and Professor Lee Shepstone, for their guidance during my research and the preparation of the thesis. I am grateful to them for believing in me and for their support and much valued professional advice. I am particularly grateful to Tina for her expertise in the clinical area and for providing me a good foundation in health outcomes measurement and to Lee for his expert knowledge of medical statistics. I would also like to thank Dr Simon Horton for his informal supervision and for his expert advice on qualitative methodology and PROM development. I also wish to express my gratitude to my examiners, Professor Anthony Arthur and Dr Anita Slade. Thank you for reading my thesis and for your comments and suggestions that have helped to strengthen it.

I am indebted to the local collaborators at each of the eight participating NHS trusts: Mrs Debbie Larson, Mrs Kathryn Johnson, Mrs Caroline Miller, Mr Dominic Power, Mrs Nikki Burr, Mrs Megan Blakeway, Ms Sarah Mee, Mrs Raelene Marx, Dr Niall Fitzpatrick, Miss Sarah Turner and to the members of their clinical teams who participated in this research. Thank you for finding the time for this in your already busy departments. I wish to express my gratitude to all the patients who participated in this research, thank you for your time and for sharing your experiences and thoughts with me. I hope that their endeavours will lead to improvements in the management of future patients with hand nerve disorders.

I would like to acknowledge the many people who have stood by me along the way. Unfortunately, I am unable to list them all individually. I am grateful to past and current members of Team QB (Queen's Building) and the Catholic community at UEA and the Cathedral of St John the Baptist. I am grateful for their motivation and support, and for providing a nurturing working environment. I would like to acknowledge the patience, love and support of my family, especially my brother Paul and my dear friend Colm McAfee. Thank you for your continued encouragement and for always supporting me to pursue my dreams. To my mother and father, Florence and John, for the sacrifices you have made for your children and for your enduring love and belief in me over the years.

Relevant presentations

Conference oral presentations

Ashwood, M. A qualitative study on the experiences of living with a peripheral nerve disorder of the hand. *Annual Conference of the British Association of Hand Therapists, Liverpool, UK, November 2015*.

Ashwood, M. Psychometric evaluation of a new patient-reported outcome measure for nerve disorders of the hand - the Impact of Hand Nerve Disorders (I-HaND ©) Scale. 22nd *Congress of the Federation of European Societies for Surgery of the Hand (FESSH) & 12th Congress of the European Federation for Societies of Hand Therapy (EFSHT), Budapest, Hungary, June 2017.*

List of abbreviations

AUC	Area under the curve
BCTQ	Boston Carpal Tunnel Questionnaire
COSMIN	Consensus-based standards for the selection of health measurement Instruments
CPC	Category probability curves
CTS	Carpal tunnel syndrome
CTT	Classical test theory
DASH	Disabilities of the Arm, Shoulder and Hand
DIF	Differential item functioning
ES	Effect size
FDA	Food and drug administration
GROC	Global rating of change
HRQOL	Health related quality of life
ICC	Intraclass correlations coefficients
ICF	International classification of functioning, disability, and health
I-HAND	Impact of Hand Nerve Disorders
IRT	Item response theory
KMO	Kaiser-Meyer-Olkin
MHQ	Michigan Hand Outcome Questionnaire
NHF	Percentage of normal hand function
PCA	Principal components analysis
PCORI	Patient-Centered Outcomes Research Institute
PEM	Patient Evaluation Measure
PROM	Patient-reported outcome measure
PSI	Person separation index
QOL	Quality of life
ROC	Receiver operating characteristic
SD	Standard deviation
SF-12	Short-form 12
SRM	Standardised response mean
WHO	The World Health Organization

Chapter 1 - Introduction

1.1 Overview

Chapter 1 provides an introduction to health outcome measurement and in particular outcome measurement for people with hand nerve disorders. The value of patient-reported outcomes and the use of patient reported outcome measures (PROMs) in healthcare settings and with this population is emphasised. The overall aims of this research and the structure of the thesis is outlined.

1.2 Introduction

Trauma to the peripheral nerves of the hand and surrounding connective tissue occurs when there is partial or total transection due to stretching, cutting, compression, shearing, or crushing injuries (Robinson, 2000, Taylor et al., 2008, Ciaramitaro et al., 2010). This results in disruption to the electrochemical pathway and can lead to muscle paralysis and a loss of sensory feedback (Lundborg and Rosén, 2007, Schnabl et al., 2011). Hand nerve disorders can have a devastating impact on a person's ability to engage in meaningful activities and to participate in life roles (Isaacs, 2010, Bailey et al., 2009, Novak et al., 2009).

The prevalence of acute nerve injuries has been generally underreported in the literature. A retrospective, descriptive study conducted in the United States reported that 220,593 out of 16 million insured people were diagnosed with limb trauma in the first 9 months of 1998 (Taylor et al., 2008). From this sample, the prevalence of a radial or ulnar nerve injury as a result of humeral fractures was reported as 1.03%. The prevalence of median nerve injuries secondary to ulna fractures was reported as 0.87% (Taylor et al., 2008). Peripheral nerve injuries are the most common type of traumatic injury sustained to the upper or lower limbs (Taylor et al., 2008, Saadat et al., 2011). Men are three times more likely than women to sustain an acute nerve injury (Ciaramitaro et al., 2010). In a Swedish study the age distribution for those sustaining acute nerve disorders showed two peaks: at 15 to 20 years and 45 to 50 years (Rosberg et al., 2005). In a Brazilian study it was reported that in limb trauma, often only one single nerve is involved (83%) (Kouyoumdjian, 2006). The ulnar

nerve is the most common nerve injured, followed by the median and radial nerves as reported by Saadat et al. (2011) from an Iranian sample.

More epidemiological studies have been published relating to chronic nerve compression disorders, particularly for carpal tunnel syndrome (CTS), which is reported as the most common type of nerve compression condition in the upper limb. In a UK study by Bland and Rudolfer (2003), the incidence of CTS was reported to be 105 per 100,000 people, with women twice as likely to be diagnosed. In contrast, men were more likely to acquire a chronic compressive disorder of their ulnar or radial nerves (Latinovic et al., 2006). In a UK study carried out by Latinovic et al. (2006) the age distribution for CTS peaked for women at 45 to 54 years and for men at 75 to 84 years.

1.3 Background

1.3.1 The peripheral nerves of the hand

The central and the peripheral nervous system comprise the brain, spinal cord and peripheral nerves. Peripheral nerves of the hand provide a common pathway for electrochemical impulses, facilitating not only movement of the upper limb in space but also sensory feedback from the hand required for manipulation and fine motor skills (Skirven et al., 2011). The peripheral nerves of the hand originate as spinal nerves, which then become plexuses as they exit the spinal cord. It is from these plexuses that the three main nerves responsible for hand function emerge: the radial, median and ulnar nerves (Tubbs et al., 2015).

The median nerve and its branches primarily innervate the muscles required for fine precision and pinch function of the hand: thenar muscles, index and middle finger lumbricals. It provides sensation to the thumb, index, middle and radial side of the ring finger. The ulnar nerve and its branches are responsible for the innervation of the muscles required for grasping: hypothenar muscles, interossei, adductor pollicis, ulnar lumbricals and the deep head of flexor pollicis brevis. It provides sensation to the ulnar portion of the dorsum of the hand, fifth digit, and ulnar aspect of the ring finger and hypothenar eminence. The radial nerve and its branches primarily innervate the wrist extensors while providing sensation to the radial aspect of the dorsum of the hand, thumb, index finger and radial half

of the ring finger proximal to the distal interphalangeal joints (Kendall et al., 1993, Yu and Strauch, 2004).

1.3.2 Basic anatomy of a nerve

A neuron comprises a cell body, dendrites and an axon. The axon connects the neuron to the end organ. A nerve consists of axons, which are bundled together into groups called fascicles (Figure 1:1). Each fascicle is wrapped in a layer of connective tissue called the perineurium. The entire nerve is wrapped in a further layer of connective tissue called the epineurium. Schwann cells surround the axonal projections, producing myelin, which acts as an electrically insulating layer to aid conduction along the nerve. Motor units contain a single motor neuron, its axonal projection, and the muscle fibres that it innervates. A sensory unit contains a single sensory neuron with all its receptor endings. Sensory neurons are located in the dorsal root ganglia next to the spinal cord; they receive sensory information from cutaneous mechanoreceptors (Brushart, 2011).

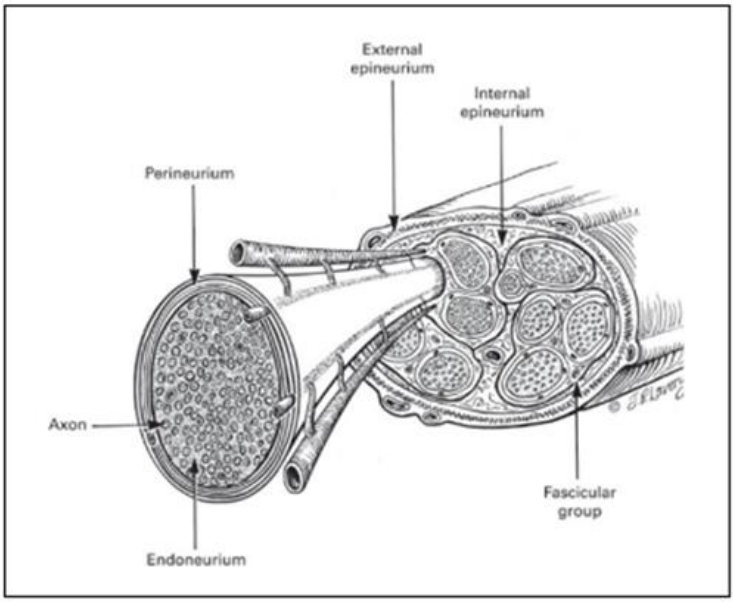


Figure 1:1 The macroscopic organisation of a peripheral nerve (illustration from Brushart, 2011 with permission)

1.3.3 Damage to peripheral nerves

Trauma to a peripheral nerve initiates a sequence of events, proximally and distally. A process known as Wallerian degeneration commences in the distal nerve segment when

the distal axon is separated from the cell body of the neuron (Allodi et al., 2012). This leads to a subsequent process of degeneration, resulting in cell death and atrophy of the denervated end organs (Terenghi et al., 2011). This cascade of events occurs almost immediately after injury and acts as a process of clearing away debris in preparation for re-innervation of the distal segment. Sprouting of new axons growing from the proximal nerve segment into the distal nerve segment occurs as a result of various neurochemical signals being elicited from the proximal nerve end up to the nerve cell body (Farnedo et al., 2013).

When passing the site of injury, regenerating axons must travel through the correct endoneurial tubes so that they journey back to their original target organs: the sensory or motor receptors (Höke and Brushart, 2010). However, it is common for misdirection to occur and this influences the outcome after a nerve injury. The level of injury is also a significant factor, with higher-level injuries requiring axons to travel a longer distance and thus take more time to reach the target organs. This, together with a slow rate of nerve regeneration, which typically occurs at 1 to 2mm/day, means that recovery from a nerve injury can take many months or years (Sulaiman and Gordon, 2013). The mechanism of a nerve injury is significant and different types of nerve injuries require different types of treatment.

1.3.4 Classification of peripheral nerve disorders

In 1942 a nerve injury classification system was introduced by Seddon, based on three main types of injuries to nerve fibres and whether there is continuity of the nerve: neuropraxia, axonotmesis and neurotmesis (Seddon, 1942). Neuropraxia refers to a local conduction block as a result of a compressive force. This disrupts the conduction of electrical signals. However, as the axons remain intact, recovery from neuropraxia injuries is possible without surgery. This process can take weeks or months and occurs when myelin repair processes restore local excitability of nerve fibres (Lundborg, 2004).

Axonotmesis refers to injuries where axons have been disrupted, but the epineurium and perineurium are intact. This allows for outgrowing axons to find their way back to the correct targets and therefore recovery is also possible without surgical intervention (Lundborg, 2004). This type of injury is often the consequence of an advanced nerve compression or a traction injury. Wallerian degeneration of the distal parts occurs and therefore recovery

time is greater, as it corresponds to the time taken for axons to regenerate distally (Sulaiman and Gordon, 2013).

Neurotmesis refers to a complete transection of the nerve and its surrounding tissue, requiring surgery to restore its continuity. These types of nerve injuries require the longest recovery time and also have the added challenge of axonal regrowth across a scar or suture gap (Lundborg, 2004). Seddon's classification system was expanded by Sunderland to five degrees of nerve injury, based on the structures damaged, and is most commonly only observable by histological examination (Sunderland, 1951). More recently a sixth degree of nerve injury has been suggested by Mackinnon to account for a combination of two or more of the first to fifth degree injuries (Lowe III et al., 2002) .

Although the classifications are applicable to acute compression injuries, the different stages of severity are also relevant for chronic nerve compressions. In carpal tunnel syndrome, for example, many of the stages occur among various fibre groups at the same time depending on the force and duration of compression (Lundborg, 2004). In chronic nerve compression, changes begin with the breakdown in the blood-nerve barrier, followed by endoneurial oedema and perineurial thickening. Increasing endoneurial pressure leads to ischemia and can result in demyelination and finally axonal degeneration (Mackinnon and Novak, 2005).

There are many factors believed to be responsible for nerve compression disorders, including genetic predisposition, the longitudinal mobility of the peripheral nerves and certain postures and positions contributing to nerve compression. Recovery from nerve compression depends on the force and duration of compression as well as the nerve type. In some cases, there can be complete recovery without surgery. However, it has been demonstrated that carpal tunnel syndrome is generally managed best with surgery (Mackinnon and Novak, 2005).

1.3.5 Clinical presentation of peripheral nerve disorders

In addition to the classification of nerve injury sustained, the clinical presentation will depend on the particular nerve that has been injured. Table 1:1 below summarises the clinical

features and presentation of a hand nerve disorder for the radial, median and ulnar nerves. This includes the most common ways that they are acquired and the resultant motor, sensory and functional deficits. Hand deformities as a consequence of muscle paralysis and atrophy are illustrated for each nerve: wrist drop, thenar atrophy and claw hand deformity (Figure 1:2).

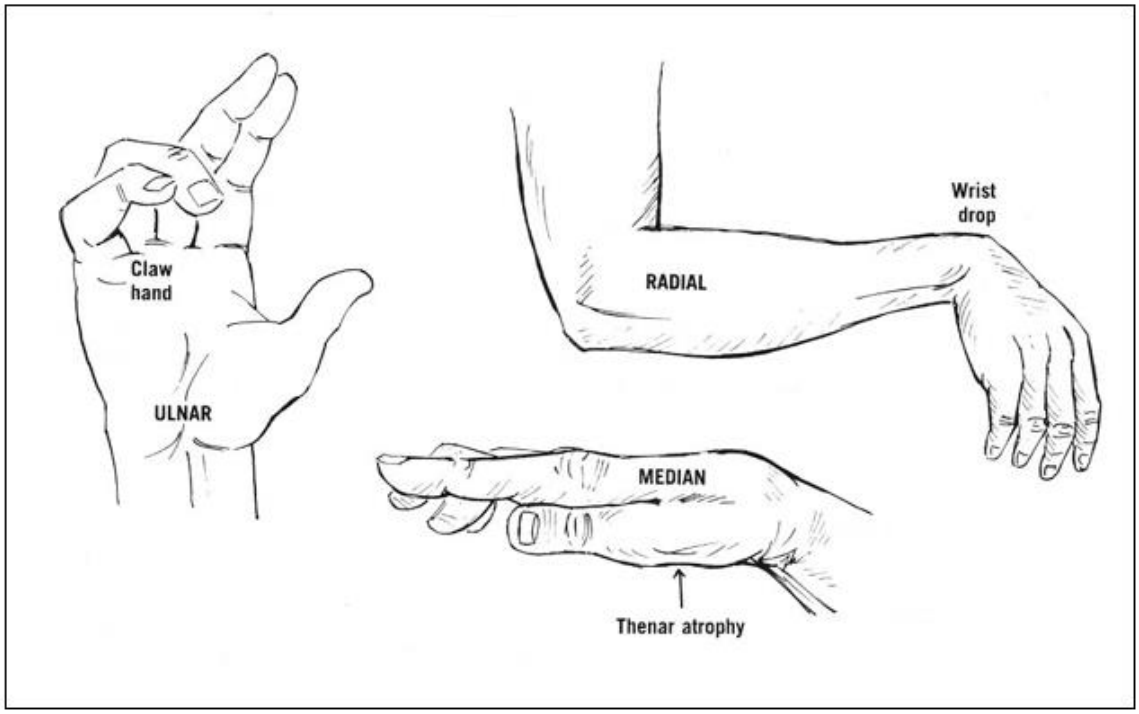


Figure 1:2 Illustration of hand nerve deformities (illustration from Pathak et al., 2012 with permission)

1.3.6 Clinical management of hand nerve disorders

Following a diagnosis of a peripheral nerve disorder, some patients can be managed conservatively, while for others nerve recovery may not be possible without surgical intervention. After surgery, patients are usually followed up by the surgical team and rehabilitation is initiated. Hand therapy combines the clinical skills and experience of occupational therapists and physiotherapists for the non-surgical management of a range of hand and upper limb conditions (MacDermid et al., 2002). If patients have had surgery, hand therapy initially focuses on protection and positioning of the hand to maintain tissue length and joint range, education and advice on caring for the hand and managing basic activities of daily living (Skirven et al., 2011).

Table 1:1 Clinical features and presentation of peripheral nerve disorders of the hand, adapted from (Duff, 2005, Skirven et al., 2011, Burke et al., 2005)

	Radial nerve	Median nerve	Ulnar nerve
Mechanism of injury	Humeral fracture, stabbing, compression at axilla, tight plaster cast or prolonged tourniquet use	Humeral fracture, stabbing, deliberate self-harm at the wrist, compression at the carpal tunnel	Humeral fracture, stabbing, compression at cubital tunnel or Guyon's canal
Motor impairment	Wrist extension, finger metacarpal phalangeal joint (MCPJ) extension	Wrist flexion and abduction, finger flexion, flexion of the ring and little finger distal interphalangeal joint (IPJs) reserved, grip strength and opposition	Wrist flexion and adduction, flexion of ring and little finger MCPJs and distal IPJs, and extension at the IPJs, weak finger abduction, adduction and opposition
Sensory impairment	Radial aspect of the dorsum of the hand, thumb, index finger, radial half of the ring finger proximal to the distal interphalangeal joints	Thumb, index, middle and radial side of the ring finger	Ulnar portion of the dorsum of the hand, fifth digit, and ulnar aspect of the ring finger and hypothenar eminence
Functional limitations	Wrist stabilisation, grip formation and object release	In hand manipulation, lateral pinch, power grasp strength, object recognition and co-ordination	Stability for power grip/pinch and manipulation
Deformity	Wrist drop	Thenar atrophy	Claw hand

As nerve regeneration occurs following acute nerve injuries treatment includes muscle retraining, sensory re-education and functional retraining (Rosén and Jerosch-Herold, 2014). For conservatively managed chronic nerve (compression) disorders the aim of therapy includes off-loading nerve pressure, e.g. by using splints/orthotics, teaching patients to pace activity and to avoid aggravating postures and positions (Cooper, 2013). Despite advances in peripheral nerve surgery, complete sensory-motor recovery in adults is rarely possible (Lundborg, 2004). Patients with nerve disorders are frequently in rehabilitation for many months/years and are left with residual sensory and motor impairments, pain and functional deficits (Chemnitz et al., 2013a). This can have a great impact on psychological well-being, activity and participation (Bailey et al., 2009).

Comprehensive outcome assessment is therefore required, using psychometrically rigorous outcome measures (Wang et al., 2013).

1.4 Health outcome measurement

Evaluation of health has traditionally focused on the presence or absence of disease. With an increase in life expectancy and a rise in disabling, chronic conditions where a cure may not be possible this position has shifted. Instead the focus of treatment has moved from prolonging life to alleviating symptoms and impairments, and assisting patients back to acceptable levels of functioning (Stewart, 1992). There has been a departure from the traditionally perceived biomedical model of health and disease to a broader perspective, which views health not merely as the absence of disease but complete physical, mental and social functioning (WHO, 1947). The biopsychosocial model emerged from this thinking and offered the inclusion of psychological and environmental domains into the biomedical model (Engel, 1977). This shift led to a greater interest in health measurement, and methodological advances have helped to pave the way towards outcome assessments, which are focused on health status, functioning and well-being. The value of patients' perspectives of their health is recognised and outcomes which reflect this are now readily included in clinical practice, research and policy (Greenfield and Nelson, 1992).

Conceptual frameworks, which propose a theoretical link between health problems and the effect on patient functioning, can be useful in understanding their broad-reaching impact (Rothman et al., 2007). Many conceptual models or frameworks are used in health and social care research. In a systematic review (Bakas et al., 2012) which identified and critiqued the most frequently used health models, the three most common and recommended models included those produced by Wilson and Cleary (1995), Ferrans et al. (2005) and the World Health Organization (WHO, 2001).

Wilson and Cleary's (1995) model of health-related quality of life comprises seven domains: biological, symptoms, function, general health perception, individual and environmental characteristics, and overall quality of life. It has been criticised, however, for not adequately defining individual and environmental factors associated with health conditions, and this led to a revision of the model by Ferrans et al. (2005) to provide explicit definitions for these

characteristics. Its use has been advocated for any healthcare setting (Bakas et al., 2012). The World Health Organization's Classification of Functioning, Disability, and Health (WHO ICF) also provides a well-defined conceptual framework that describes the impact of a health condition on the body, activity and participation while also accounting for contextual factors (Figure 1:3). The WHO ICF provides a unified and standard language, and allows for use across a range of disciplines and cultures. It is becoming more widely used in the field of hand surgery and rehabilitation, and a core set for hand conditions has been developed and validated (Kus et al., 2012). It is therefore a desirable framework for guiding the development of a new PROM for hand nerve disorders.

The WHO ICF conceptualises the relationship between the components of body functions (physiological functions of body systems) and structure (anatomical body parts), activity (execution of a task or action) and participation (involvement in a life situation) as a consequence of a health condition. This is experienced as bodily impairments, activity limitations and participation restrictions. It also takes into consideration the importance of the environment which make up the physical, social and attitudinal environments in which we live and personal factors (WHO, 2001).

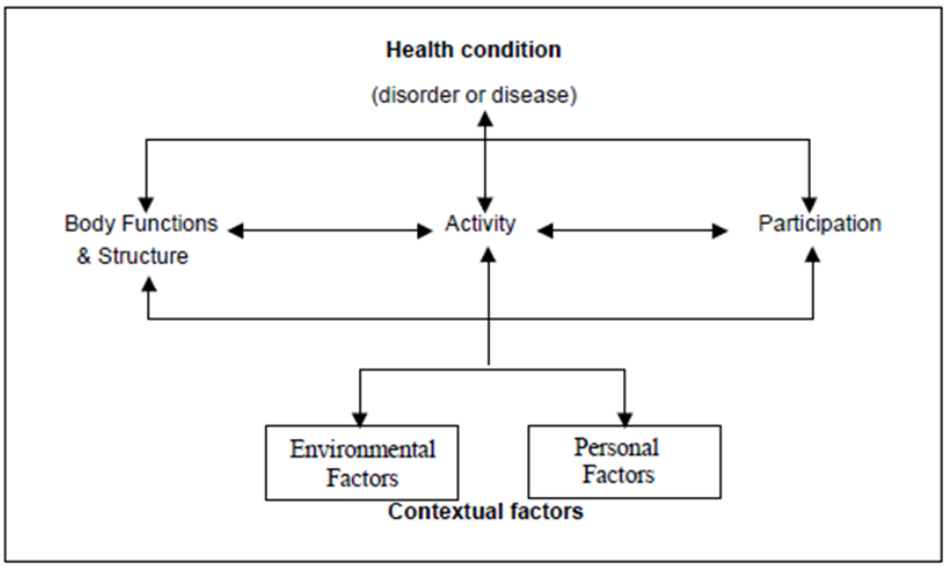


Figure 1:3 WHO ICF Framework showing the dynamic relationship between the different components as a consequence of a health condition (WHO, 2001, with permission)

1.4.1 Patient-reported outcomes

Assessment of patient-reported outcomes is being advocated for many health conditions and there is consensus that they play an important role in clinical practice and research (Black et al., 2016). Patient-reported outcomes are measures of any aspect of a patient's health status, coming directly from the patient, without any interpretation of the patient's response by another. They aim to capture how the person functions or feels in relation to a health condition (Valderas and Alonso, 2008). Unlike directly measured variables (e.g. blood pressure), many phenomena can only be measured indirectly (e.g. how a patient feels). These unobservable variables are called latent variables or theoretical constructs. Instruments (often questionnaires) which attempt to measure one or more latent variables relating to health are classed as patient-reported outcome measures or PROMs. The response options on a PROM range from simple dichotomous 'yes' or 'no' to those with several responses (e.g. Likert scale). The usual intention is to produce a summed score of responses for a particular outcome measure (De Vet et al., 2011).

1.4.2 The use of PROMs in healthcare

The inclusion of PROMs in healthcare evaluation is being increasingly advocated (Black, 2013). PROMs can be used in a variety of ways, e.g. as screening or as evaluative tools (Marshall et al., 2006). They can aid decision-making regarding the best interventions for treating patients (Doward et al., 2010). Using PROMs within multi-disciplinary teams can facilitate increased communication and provide a common language for clinicians (Black, 2013). Data from individual patients can also be aggregated at group level and used to make wider decisions regarding the effectiveness of routine care and to assess the quality of care (Greenhalgh, 2009). A variety of PROM types exist (Table 1:2), including dimension-specific, disease or condition-specific, generic measures, individualised measures, utility measures and more recent additions such as PROMs generated using item banks (Fitzpatrick et al., 1998, Cano and Hobart, 2011).

Table 1:2 A description of different types of PROMs used in research and clinical practice

PROM type	Description
Dimension-specific	Evaluates one particular aspect of health, e.g. Hospital Anxiety and Depression Scale (HADS) (Zigmond and Snaith, 1983)
Disease or condition specific	Evaluates the impact of a specific disease or health problem
Site or region-specific	Evaluates health problems in a more specific part of the body
Generic measures	Capture a very broad range of aspects of health status and can be used with any condition
Individualised measures	Report issues or concerns that are personal to patients, and not predetermined
Utility measures	Evaluate the economic impact of health states on patients
Item banks	Evaluate health problems using targeted items

Generic PROMs evaluate a range of concepts and can be applied across many diseases and outcomes. This makes them useful when making broad comparisons. Disease or condition-specific PROMs, on the other hand, are those directly related to a particular condition. As their content is developed for a specific population, they are often more sensitive to clinical change (Fitzpatrick et al., 1998). The two types of PROMs are not mutually exclusive and the use of each is warranted under different circumstances (Patrick and Deyo, 1989).

Dimension-specific PROMs provide a general evaluation of a specific aspect of health, such as psychological well-being, and site or region-specific PROMs focus on health problems in a particular part of the body, e.g. the upper limb. Individualised measures allow patients to nominate aspects of quality of life and to rate the order of importance for them. This can enhance the content validity of the measure, but at the expense of comparability with other patients. Utility measures are used to estimate the economic impact of health conditions on society and cost-effectiveness of treatments.

A more recent type of rating scale, using item banks, is becoming popular. Patients complete only a sub-set of targeted items from large item banks that have been calibrated using mathematical models. Scale scores are calibrated on the same continuum, allowing comparison of individuals and groups even if they have answered different questions from the item bank. This method also makes it possible to carry out computer adaptive testing (CAT), where only the most informative items from the bank are selected for people using

a computerised algorithm based on previous responses at each point on the test. Items are selected for individuals based on their ability level and other patient characteristics (Linacre, 2000, Lai et al., 2011). The development of item banks is made possible by developments in the psychometric methods used for scale development. This is a consequence of the increasing uptake of PROMs in health measurement and paves the way towards greater standardisation of the use of PROMs. The Patient-Reported Outcomes Measurement Information Systems (PROMIS) programme, which uses item banks and CAT, offers an example of pioneering work towards this end by developing a system of reliable and precise measures that are publicly available through their web site (http://www.healthmeasures.net/explore-measurement-systems/promis).

1.4.3 Psychometrics in health measurement

In healthcare, the development of PROMs has most commonly used psychometric methods. The term 'psychometrics' refers to the science underpinning health measurement according to Streiner et al. (2014), and originates from the disciplines of education and psychology. Psychometric theory is based on the assumption that subjective judgements are measurable (Nunnally, 1959). Psychometrics can be defined as the methods used to construct measurement scales, including modern-day PROMs (Guilford, 1954). The growth in the field of psychometrics reflects the greater understanding of health as described above and in particular an appreciation of the more subjective elements of health (Stewart et al., 1989). The main psychometric approaches include classical test theory (CTT), Rasch measurement modelling (Rasch) and item response theory (IRT).

CTT was developed by psychologists such as Cronbach and Spearman, as a strategy to measure constructs that are not directly observable (Lord et al., 1968). Information about the construct is obtained by measuring items that are expressions of the construct. In classical test theory there is an assumption that item scores can be summed without weighting or standardisation to produce a total score (Hobart and Cano, 2009).

Rasch measurement methods were developed by Georg Rasch and differ from CTT by articulating that a set of requirements must be met before items scores can be summed up to generate a total score (Rasch, 1960). It uses a simple logistic model (Rasch model) to

evaluate the suitability of summing item scores. When data do not fit, the Rasch model tries to explain the misfit (Wright and Linacre, 1989).

IRT was developed by psychologist Birnbaum and others and aims to find the most appropriate statistical models that best explain the observed data (Lord et al., 1968). If the observed data do not fit the chosen model then another is chosen. IRT differs from Rasch, which uses a one-parameter (Rasch) model to create a stable linear measure from the scale data (Andrich, 2004). Psychometric measurement methods will be described in more detail in later chapters of this thesis.

1.4.4 What to consider when selecting PROMs

High-quality PROMs should be able to probe patients in a structured way to give reproducible and meaningful, quantitative assessments about patients' perception of their functional status (FDA, 2009). As an attempt to standardise the use of PROMs in patient-centred outcomes research, guidelines for their design and selection have been produced (PCORI, 2012, FDA, 2009). This ensures that PROMs are developed to the highest standards and are suitable for their purpose. When selecting PROMs, it is important that they have been designed to minimise measurement error and are considered reliable, valid and responsive for the given purpose and population. Until recently, however, there has been no standardised definitions of these terms. (Terwee et al., 2007, Terwee et al., 2012). To clarify and standardise terminology, a team of researchers with expertise in the development and evaluation of health status measurement instruments developed a taxonomy of measurement properties (Mokkink et al., 2010b). The COnsensus-based Standards for the selection of health Measurement Instruments (COSMIN) taxonomy is presented below and will be discussed in more detail in later chapters (Table 1:3).

Table 1:3 Taxonomy of measurement properties (from Mokkink et al., 2010b, with permission)

Term			Definition
Domain	Measurement property	Aspect of measurement property	
Reliability			The degree to which the measurement is free from measurement error
Reliability (extended definition)			The extent to which scores for patients who have not changed are the same for repeated measurement under several conditions: e.g. using different sets of items from the same health related-patient reported outcomes (HR-PRO) (internal consistency); over time (test-retest); by different persons on the same occasion (inter-rater); or by the same persons (i.e. raters or responders) on different occasions (intra-rater)
	Internal consistency		The degree of the interrelatedness among the items
	Reliability		The proportion of the total variance in the measurements which is due to 'true'† differences between patients
	Measurement error		The systematic and random error of a patient's score that is not attributed to true changes in the construct to be measured
Validity			The degree to which an HR-PRO instrument measures the construct(s) it purports to measure
	Content validity		The degree to which the content of an HR-PRO instrument is an adequate reflection of the construct to be measured
	Face validity		The degree to which (the items of) an HR-PRO instrument indeed looks as though they are an adequate reflection of the construct to be measured
	Construct validity		The degree to which the scores of an HR-PRO instrument are consistent with hypotheses (for instance with regard to internal relationships, relationships to scores of other instruments, or differences between relevant groups) based on the assumption that the HR-PRO instrument validly measures the construct to be measured
		Structural validity	The degree to which the scores of an HR-PRO instrument are an adequate reflection of the dimensionality of the construct to be measured
		Hypotheses testing	Idem construct validity
		Cross-cultural validity	The degree to which the performance of the items on a translated or culturally adapted HR-PRO instrument are an adequate reflection of the performance of the items of the original version of the HR-PRO instrument
	Criterion validity		The degree to which the scores of an HR-PRO instrument are an adequate reflection of a 'gold standard'
Responsiveness			The ability of an HR-PRO instrument to detect change over time in the construct to be measured
	Responsiveness		Idem responsiveness
Interpretability*			Interpretability is the degree to which one can assign qualitative meaning - that is, clinical or commonly understood connotations – to an instrument's quantitative scores or change in scores.

† The word 'true' must be seen in the context of the CTT, which states that any observation is composed of two components – a true score and error associated with the observation. 'True' is the average score that would be obtained if the scale were given an infinite number of times. It refers only to the consistency of the score, and not to its accuracy (Streiner & Norman, 2014)* Interpretability is not considered a measurement property, but an important characteristic of a measurement instrument

1.4.5 Assessing outcome of hand nerve disorders

Different aspects of recovery needs to be captured in the evaluation of outcomes following a hand nerve disorder (Table 1:4). Outcome domains include sensory (re-innervation, tactile gnosis, finger dexterity), motor (innervation, grip strength), pain and discomfort (pain, hyperaesthesia, cold intolerance) and function (activity and participation) (Wang et al., 2013).

Table 1:4 Outcome domains and measures used with patients with hand nerve disorders

Domain	Description	Instrument and quantification
Sensory	Re-innervation of peripheral targets	Perception of cutaneous pressure threshold e.g. Semmes-Weinstein Monofilament Test (Weinstein, 1993).
	Tactile gnosis	Recognition of the character of objects, such as shapes, textures, which is a prime marker of functional recovery e.g. Shape Texture Identification Test (STI) (Rosén and Lundborg, 1998)
	Finger dexterity	Performing activities that replicate the main hand grips in daily living e.g. the Sollerman Hand Function Test (Sollerman and Ejeskär, 1995)
Motor	Innervation	Manual Muscle Testing (MMT) e.g. British Medical Research Council muscle-strength grading (James, 2007)
	Grip strength	Grip and pinch (lateral, tip to tip and tripod) tests, e.g. dynometry (Schmidt and Toews, 1970)
Pain and discomfort	Pain and hyperaesthesia	Self-report by patients e.g. Numerical Rating Scale (NRS) for pain (Downie et al., 1978)
	Cold intolerance	Self-report of cold intolerance during daily life, e.g. the Cold Sensitivity Severity Scale (CSS) (McCabe et al., 1991)
Activity and participation	Activity and participation	Self-report of impact on daily life, e.g. Patient Rated Ulnar Nerve Evaluation (PRUNE) (MacDermid and Grewal, 2013).

A composite impairment score for hand nerve injuries has been developed by Rosén and Lundborg (2000): the model 'instrument' or the Rosén score, as it is commonly referred to in the literature. It is purely an impairment-based scoring instrument, which covers the sensory, motor and pain and discomfort domains of body structures/functions. It uses a range of clinician-administered and patient-reported outcomes. The model instrument is a clinically useful tool and demonstrates good psychometric properties (Rosén and Lundborg, 2000). To evaluate how much pain and discomfort impacts on daily activities, there is a single question, which asks patients to rate this using a visual analogue scale, ranging from no impact to maximum impact. A criticism of using a single global question is that it does not adequately explore a rather complex construct of patient function and as the question centres on pain, it is still impairment-focused. In clinical practice, additional PROMs are therefore used alongside the model instrument to obtain more in-depth information relating to activity and participation (Vordemvenne et al., 2007).

1.4.6 The use of PROMs with patients with peripheral nerve disorders

To date only two condition-specific PROMs have been developed for people with peripheral nerve disorders of the hand: the Boston Carpal Tunnel Questionnaire (BCTQ) or Levine score, as it has also been referred to in the literature (Levine et al., 1993), and the Patient Rated Ulnar Nerve Evaluation (PRUNE) (MacDermid and Grewal, 2013). Each PROM was developed for use with individuals with isolated nerve compression disorders, the median and ulnar nerve respectively, and therefore they are not appropriate for patients with traumatic nerve injuries or for individuals with combined nerve disorders. Nor are they suitable when comparing outcomes within groups of patients with different nerve disorders. In the absence of a condition-specific PROM that can be used with patients with a range of peripheral nerve disorders, 'region-specific' PROMs are used. These measures have been developed for a particular limb or joint for a population of patients with a range of musculoskeletal disorders. They may not be conceptually relevant for use with patients with peripheral nerve disorders and may lack responsiveness. To investigate this further, a critical review of the literature on the use of existing PROMs with this population is presented in the next chapter.

1.5 Study aims and structure of the thesis

1.5.1 Aims

This research aimed to develop and validate a new PROM for people with peripheral nerve disorders affecting the hand. It was designed to capture the impact of this condition on body structures, activities and participation. A conceptual framework of disability and functioning for peripheral nerve disorders affecting the hand was developed using the WHO ICF to guide the developmental process. It was envisaged that this new PROM would be used as part of a battery of outcome measures by clinicians and researchers. The instrument would also be a useful tool for hand therapists to select purposeful treatment modalities, to set meaningful goals and to help patients keep track of their progress.

1.5.2 Research overview and outline of thesis

This study was conducted in three phases, with several steps in each phase. The outcome of phases 1 and 2 led to the development of the Impact of Hand Nerve Disorders (I-HaND) Scale. Phase 3 evaluated the measurement properties of the I-HaND Scale (Figure 1:4).

Phase 1 involved developing the content of the new PROM or the 'item generation' phase, a process that included:

Step 1: A narrative literature review was carried out to explore the qualitative literature on the experience of living with a hand nerve disorder. The function of this review was to determine what was known in this area and to inform the design of the qualitative interviews from which to generate the content of the PROM (Chapters 2 and 3).

Step 2: A critical review of the literature on existing PROMs used for individuals with hand nerve disorders was carried out to justify the need for the development of a new PROM. The review first identified suitable PROMs currently used with this population and critically appraised them based on their reported measurement properties. This provided a rationale for the development of a new PROM for people with hand nerve disorders (Chapter 2).

Step 3: Qualitative concept elicitations interviews were carried out to develop a conceptual framework from which to define the concepts being measured and to generate items for the new PROM. A PROM development-working group was also

established to evaluate face validity of version 1.0 of the I-HaND Scale. Modifications were made, leading to version 1.4 of the I-HaND Scale ahead of the next phase of the study (Chapter 3).

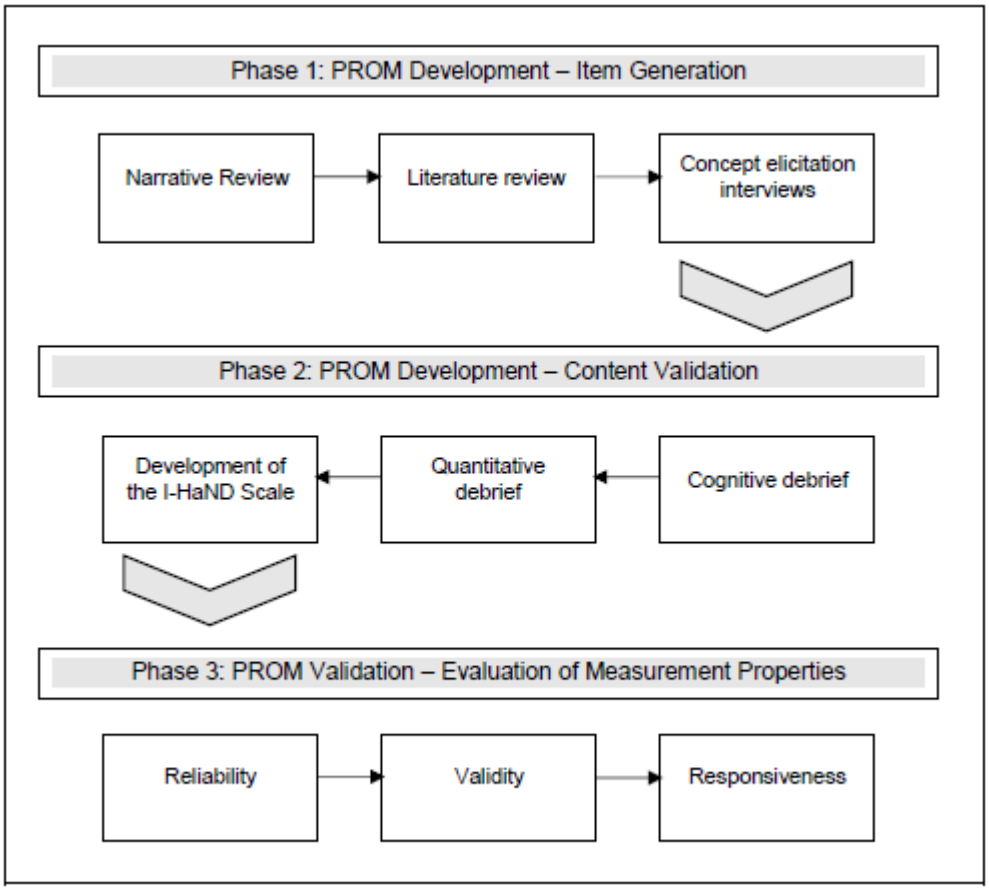


Figure 1:4 Overview of the three main phases and steps followed in the study

The second phase of the study was concerned with establishing content validation for the I-HaND Scale, including:

Step 1: Cognitive interviews were carried out to clarify the most important concepts of the I-HaND Scale for patients. A further function of the interviews was to ensure participants understood how to complete it (Chapter 4).

Step 2: Quantitative methods were used to examine the structural aspects of content validity and included performing a principal components analysis and tests of internal consistency (Chapter 4).

Step 3: Taking into account the findings of qualitative and quantitative methods, final revisions were made to the I-HaND Scale (Chapter 4).

In the final phase of the study, some of the psychometric properties of the I-HaND Scale were evaluated, in three steps:

Step 1: Test-retest reliability was evaluated to assess the reproducibility of the I-HaND Scale (Chapter 5).

Step 2: Evaluation of the structural validity using CTT and Rasch methods and evaluation of construct validity by the testing of hypotheses relating to the performance of the I-HaND Scale with a comparator (Chapter 5).

Step 3: The ability of the I-HaND Scale to detect clinical change over time was also evaluated (Chapter 5).

The final chapter of the thesis presents a discussion of the findings and the main conclusions from this body of work (Chapter 6).

Chapter 2 - Existing region-specific PROMs used with people with a peripheral nerve disorder of the hand

2.1 Overview

Chapter 2 reports the methods and results of a review of the literature intended to identify and evaluate currently available region-specific PROMs used with people with hand nerve disorders. This was to assess their suitability for this population and to determine the need for a new hand nerve disorder-specific PROM.

2.2 Introduction

The development of a new PROM is potentially a long and complex process. It can take many years and requires hard work (Fayers and Machin, 2013). It was prudent, therefore, to examine whether a new measure was needed or if an existing one could be used or adapted (Keszei et al., 2010). This initial step in PROM development involved identifying existing region-specific PROMs that claim to measure the construct of interest, used with the target population and to critically appraise their psychometric properties (PCORI, 2012). A literature review was conducted to identify and evaluate existing region-specific PROMs. This provided the rationale for the development of a new PROM. It was also informative in generating ideas about what a new measure should be like, as existing PROMs that are not applicable, may still provide useful information (De Vet et al., 2011).

Studies that report on the measurement properties of PROMs provide evidence supporting their use in clinical practice and research. A PROM, however, is never universally reliable, valid or responsive, since it depends on the population, the setting or the intervention (Streiner et al., 2014). Therefore, studies of high methodological quality, carried out by a number of independent researchers, reporting similar results are needed.

It is important to consider all the measurement properties of a PROM. However, the most important is its ability to measure the construct that it is supposed to, known as content validity (Lasch et al., 2010). This refers to the degree to which a PROM's content reflects the construct to be measured. Evidence of content validity can be obtained from the development of a conceptual framework from which to generate the items for a PROM (Rothman et al., 2007). It is crucial that qualitative research methods involving patients are used as part of this process (FDA, 2009). Statistical tests of validity can also be used to evaluate the degree to which PROM scores are an adequate reflection of the construct to be measured, providing certainty of what the variables are measuring (Fayers and Machin, 2013). Content validity can therefore be regarded as the cornerstone of measurement properties. Poor content validity can lead to what Cano and Hobart (2011) refer to as a 'house of cards' situation: without the certainty of knowing what an instrument measures, other psychometric properties such as reliability and responsiveness are rendered meaningless.

2.2.1 Aims and objectives

Aims

This review aimed to identify region-specific PROMs commonly used with people with a range of hand nerve disorders. It also sought to evaluate their psychometric properties to determine the suitability of their use with this population.

Objectives

1. To identify region-specific PROMs, which evaluate the impact of a hand condition on body structures, activities and participation used with people with hand nerve disorders.
2. To critically appraise the literature on the psychometric properties of identified region-specific PROMs used with this population.
3. To provide a rationale for the development of a new condition-specific, PROM for peripheral nerve disorders of the hand.

2.3 Methods

A two-stage approach was undertaken, to first identify and select region-specific PROMs that evaluate the impact of a hand condition on body structures, activities and participation, used with people with hand nerve disorders and then secondly to critically appraise the literature on their psychometric properties.

2.3.1 Stage one search strategy

An initial scoping search of the literature on the use of PROMs with patients with upper limb conditions was undertaken. Search terms related to upper limb function, e.g. hand, arm, upper limb, function and activity. The Boolean operator AND was used to combine these terms with terms relating to patient outcome such as: outcome, assessment, measure, instrument, evaluation, questionnaire and patient-reported. This search identified four literature reviews and two systematic reviews, all cataloguing a range of upper limb outcome measures including PROMs (Badalamente et al., 2013, Calfee and Adams, 2012, Changulani et al., 2008, Schoneveld et al., 2009, Smith et al., 2012, Van de Ven-Stevens et al., 2009). Two survey studies were also identified that reported on the clinical application of a range of outcome measures by hand therapists (Valdes et al., 2014, Kennedy and Beaton, 2016). As this search provided a comprehensive catalogue of outcome measures, a pragmatic decision was made to identify suitable PROMs solely from these studies.

2.3.2 Stage two search strategy

A further scoping search of the literature was conducted to establish if systematic reviews reporting on the psychometric properties of any of the PROMS identified in stage one were available. Systematic reviews were already available for two of the selected PROMs (Shauver and Chung, 2013, Kennedy et al., 2013). A user manual for another PROM, providing the results of all published studies on its measurement properties was also identified (Kennedy, 2011). As a significant amount of work had already been recently conducted by others, a pragmatic decision was made to try to search for further studies after the publication date of the systematic reviews and to identify the available literature for PROMs where no systematic reviews were undertaken.

The bibliographic databases Medline (1946 to 2016), AMED (1985 to 2016), Embase (1974 to 2016), PsychINFO and the Cochrane Library were searched. The names of identified PROMs were used as search terms. Short forms and abbreviations were also added. Studies identified during this stage were screened for information on their measurement properties. Bibliographies were also checked to identify studies that were not retrieved through the search. Studies that cited the original validation studies by the developers of each PROM were also checked.

2.3.3 Stage one selection procedure

PROMs were selected if they were 1) patient-reported; 2) specific to the hand; 3) measured impact on body structures, activity and participation; and 4) there was evidence of inclusion of people with a range of hand nerve disorders in the initial development or validation process. PROMs developed for isolated nerve compression syndromes were excluded, as they are not suitable for patients with traumatic nerve injuries or for individuals with combined nerve disorders. The search identified 13 patient-reported outcome measures for people with hand conditions. Eight of these were excluded for either being 1) condition-specific; 2) work-specific; 3) surgery-specific or 4) not being validated for people with hand nerve disorders (Table 2:1).

Table 2:1 Excluded region-specific PROMs and reason for their exclusion

Region-specific PROM	**Reason for exclusion**
Patient-Rated Wrist/Hand Evaluation (PRWHE) (MacDermid and Tottenham, 2004)	Not validated for hand nerve conditions
Upper Extremity Function Scale (Pransky et al., 1997)	Specific to work-related upper limb disorders
Boston Carpal Tunnel Syndrome Questionnaire (Levine et al., 1993)	Specific to median nerve compression
Patient Rated Ulnar Nerve Evaluation (PRUNE) (MacDermid and Grewal, 2013)	Specific to ulnar nerve compression
Australian/Canadian (AUSCAN) Osteoarthritis Hand Index (Bellamy et al., 2002)	Specific to hand osteoarthritis
Hand Function Sort (Matheson et al., 2001)	Focuses on work performance
Subjective Hand Function Scoring System (Watts et al., 1998)	No psychometric validation studies available
The Patient Outcomes of Surgery-Hand/Arm (POS-Hand/Arm) (Cano et al., 2004)	Specific for people having hand/arm surgery

2.3.4 Stage two selection procedure

Systematic reviews on the psychometric properties of identified measures were first identified. Studies reporting on the development and validation process for each identified measure and subsequent validation studies for this population were also identified. Only studies in English were included, and studies reporting solely on cross-cultural validation were excluded.

2.3.5 Quality assessment

To evaluate the quality of the selected articles identified in the second stage of the search modules from the COnsensus-based Standards for the selection of health Measurement Instruments (COSMIN) Checklist were used and are presented in appendix 2.1 (Terwee et al., 2012). This is a standardised tool to assess the methodological quality of studies on measurement properties. The tool developed is modular and individual modules can be chosen depending on the measurement property that is being assessed. For each module, there are four response options: poor, fair, good or excellent. A score is generated per module based on taking the lowest rating of any module, defined as the 'worst score counts' by the developers. A summary of the methodological quality of each study per measurement property is presented in appendix 2.2.

2.4. Results

Three PROMs which met the inclusion criteria were identified: the Patient Evaluation Measure (PEM) (Macey et al., 1995), the Michigan Hand Outcome Questionnaire (MHQ) (Chung et al., 1998) and the Disabilities of the Arm, Shoulder and Hand (DASH) (Hudak et al., 1996). The MHQ and the DASH have shorter versions: the Brief MHQ (Waljee et al., 2011) and the Quick DASH (Kennedy et al., 2013), which were also included in the review (see appendices 2.3 to 2.7). A summary description of the characteristics for each measure is presented below (Table 2:2).

The DASH was the most extensively studied and widely used measure (Valdes et al., 2014). It was reported to be used by 90% of clinicians in an international survey on its clinical application for a range of upper limb conditions, including hand nerve disorders (Kennedy and Beaton, 2016). While less popular relative to the DASH, the MHQ ranked within the 12 most commonly used PROMs in hand rehabilitation and has been reported to be comparable with the DASH in its performance capabilities (Valdes et al., 2014). The PEM was developed in the UK and has cultural relevance. However, there was much less reported in the literature on its measurements properties in comparison to the MHQ and the DASH.

Table 2:2 Description of characteristics of selected existing region-specific PROMs used with people with hand nerve disorders

PROM	Target population	ICF domains	No of sub-scales	No of items	No of response options	Range of scores
PEM	General hand conditions (includes nerve conditions)	Body function/structure Activity Participation	2	18	7	0 to 100
MHQ	General hand conditions (includes nerve conditions)	Body function/structure Activity Participation	6	37	5	0 to 100 combined
Brief MHQ	General hand conditions (includes nerve conditions)	Body function/structure Activity Participation	1	12	5	0 to 100
DASH	General hand and upper limb conditions (includes nerve conditions)	Body function/structure Activity Participation	1 primary 2 optional modules	30 8	5	0 to 100
Quick DASH	General hand and upper limb conditions (includes nerve conditions)	Body function/structure Activity Participation	1 primary 2 optional modules	11 8	5	0 to 100

2.5 The Patient Evaluation Measure (PEM)

The PEM was developed by the audit committee of the British Society for the Hand in 1993 to assess outcomes in hand disorders (Macey et al., 1995). It comprises three scales: opinion on delivery of care, a hand-health profile and overall health. There are 18 items, 10 of which pertain to the hand-health profile. Each sub-scale is combined, producing a total score of 100, a higher score being indicative of greater disability. The PEM was developed using the committee members' clinical expertise and experience in treating hand conditions (Macey et al., 1995). Patients with hand conditions were not involved in the development of the PEM.

During the development of the PEM, evaluation of the structural aspects of its content did not occur. Structural validity has traditionally been evaluated using exploratory factor analysis, and is a key aspect of PROM development (PCORI, 2012). This is an important way of demonstrating that the items on a scale are contributing to the overall construct, and that its scores can be summed to provide a total score. If more than one factor is identified, sub-scales can be created (Streiner et al., 2014). Initial validation work of the psychometric properties of the PEM was not performed by its developers. Instead, it was recommended that this work be undertaken by others (Macey et al., 1995). Subsequent validation studies on the reliability, construct validity and responsiveness of the PEM with a hand nerve disorder population have since been carried out (Dias et al., 2008, Hobby et al., 2005).

2.5.1 Reliability of the PEM

There are two types of reliability that have particular relevance in PROM development studies: internal reliability and test-retest reliability. Internal reliability, often referred to as internal consistency, measures the degree to which the responses to items on a scale are consistent with each other (Portney and Watkins, 2000). In a study by Hobby et al. (2005), the internal reliability of the PEM was evaluated using a sample of (n = 32) patients awaiting carpal tunnel decompression surgery. A high degree of internal consistency ($\alpha = 0.94$) was reported using Cronbach's alpha as an estimate of the inter-correlation of the items (Spector, 1992). The internal reliability of the PEM was also evaluated by Dias et al. (2008). In this study there were three clinical groups of patients consisting of nerve, wrist and finger disorders (n = 100). A sub-group of (n = 26) patients with hand nerve disorders was

included in the analysis. A high degree of internal consistency (α = 0.94) was also reported. Cronbach's alphas >0.90 are considered excellent (Streiner et al., 2014).

Test-retest reliability reflects a PROMs capability to produce the same scores with repeated administrations in patients whose condition is stable, or when no change is expected to have occurred. This is often referred to in the literature as temporal stability or reproducibility (Portney and Watkins, 2000). In the Dias et al. (2008) study the test-retest reliability of the PEM was evaluated from a random selection of (n = 26) patients from the overall sample (n = 100) who completed the PEM on two occasions. The number of patients with nerve conditions was not reported. The time between first and second administration of the measure ranged from 45 minutes to 11 days, with an average time of one day. The authors did not report estimates or reliability coefficients, but instead reported the mean difference between the two test periods (-3.5 with a 95% confidence interval range of -9.3 to 2.3). A score closer to zero indicates perfect agreement between the total score of the PEM on each occasion. Although the mean difference between each administration of the PEM was low (-3.5), the confidence intervals were wide. This represented 11 points or more than 10% of the possible PEM scores.

2.5.2 Construct validity of the PEM

Construct validation involves the testing of hypotheses that relate to the theoretical relationship with other measures of similar or different constructs. Hypotheses should be formed beforehand regarding the expected direction and the magnitude of the correlation. The greater number of correct hypotheses strengthens the evidence of construct validity (Mokkink et al., 2010a). In a study by Dias et al. (2008) the construct validity of the PEM was evaluated by comparing its total scores with results of objective clinical tests for patients with hand nerve disorders. Pearson correlation coefficients were used to express the association between the different outcome measures. A moderate correlation was reported between the PEM and pinch (r = 0.57) and grip (r = 0.52) and a moderate, negative association with tenderness (r = -0.66). No correlation was found with swelling. The PEM scores were also compared to the Levine symptom score (Levine et al., 1993). The Levine, also known as the Boston Carpal Tunnel Questionnaire (BCTQ), was developed for patients with carpal tunnel syndrome (CTS) and is a validated measure of symptoms for this population (Levine et al., 1993). A weak correlation (r = 0.37) was reported between the PEM and the Levine symptom score.

The construct validity of the PEM was evaluated in another study (Hobby et al., 2005) using a sample of 32 pre-operative patients with CTS. Spearman correlation coefficients were used to compare the PEM with the DASH and objective clinical tests. They report a moderate, negative correlation (r = -0.54) between the PEM and grip strength. A moderate correlation (r = 0.47) was reported between the 9-hole peg test and the total score for the PEM. There were no significant correlations reported between static two-point discrimination (2PD) and the total scores for the PEM. A moderate correlation between the PEM and DASH scores (r = 0.66) was reported. In a sub-group (n = 24) of patients with CTS a stronger correlation (r = 0.85) was reported between the DASH and the PEM. It would be expected that the correlation between the PEM and the DASH would be stronger than the PEM and 2PD or grip. This is because both the PEM and the DASH are region-specific PROMs of symptoms and activities. Grip and 2PD on the other hand are single measures of impairment. However, in both studies the hypothesised direction and magnitude of the correlations between the PEM and the other measures were not stated.

2.5.3 Responsiveness of the PEM

Responsiveness refers to the ability of a measure to detect change in the construct of interest, when change has occurred (Mokkink et al., 2010a). It can be thought of as longitudinal validity, where validity refers to the validity of a single score and responsiveness refers to the validity of a change score. Thus it can also be evaluated by hypothesis testing, where hypotheses relate to change scores (De Vet et al., 2011). Observed change is a type of change commonly reported in responsiveness studies. This refers to change in a construct between two occasions, often before and after receiving an intervention known to be effective where a change in scores would be expected.

Effect size (ES) and standardised response mean (SRM) are distribution-based methods used to express the magnitude of change (Kazis et al., 1989, Liang et al., 1990). An advantage of this approach is that it provides a standard unit of measurement and allows for the evaluation of responsiveness, relative to another validated measure used in the same study. The ability of the PEM to measure observed change relative to the DASH was evaluated by Hobby et al. (2005). Effect sizes and standardised response means were calculated for 24 patients, three months following carpal tunnel decompression. Patients

completed each measure before and after surgery. Large effect sizes were found for the PEM (ES = 0.97; SRM = 0.95), which were larger than the DASH (ES = 0.49; SRM: = 0.43).

2.6 The Michigan Hand Outcome Questionnaire (MHQ)

The MHQ was developed by Chung et al. (1998) to assess patients' perception of one or both of their hands for all types of hand and wrist conditions. It comprises six scales covering activities of daily living, pain, work, function, aesthetics and satisfaction. Each sub-scale is combined, producing a total score of 100; a higher score suggests greater disability. The developers reported on face and content validity during the development process. The degree of reliability and construct validity were evaluated during the initial validation process (Chung et al., 1998). The responsiveness of the MHQ was subsequently assessed by the developers (Chung et al., 1999).

The items of the MHQ were generated from a literature search of a range of existing questionnaires containing items that were judged relevant for upper limb function by a panel of clinical experts and patients with hand conditions. Two psychometricians were involved to help with structure and clarity. The number and diagnosis of patients included in this process was not reported. The extent of patient involvement in the development process was not clear. An exploratory factor analysis was used as a method of reducing the initial item pool from 100 to 37. However, insufficient information was provided on the factor structure to evaluate the structural validity of the MHQ.

2.6.1 Reliability of the MHQ

During initial validation of the MHQ, 200 patients with a range of hand conditions were involved. No clinical or diagnostic information about the sample was provided. There was limited information about the test period and the conditions of retesting. Excellent internal consistency was reported in all of the MHQ scales; Cronbach's alphas were all ≥0.86 (ranging from 0.86 to 0.97) (Chung et al., 1998). From a sub-group of (n = 22) patients, excellent test-retest reliability coefficients were also reported for all six scales using intraclass correlations coefficients (ICCs). The ICCs ranged from 0.81 (left-hand aesthetics) to 0.97 (left-hand ADLs) (Chung et al., 1998).

As a further demonstration of reliability, the authors present the limits of agreement between the first and second test administration of the MHQ as a mean difference between the scores between the first and second administration. The mean differences ranged from -2.75 (right hand satisfaction) to 6.03 (both hand ADLs) (Chung et al., 1998). The 95% confidence intervals were reported as all being close to zero. This was based on a scoring scheme of 0 to 100, where there was a difference between the two administrations of less than five points in all but one scale (Chung et al., 1998).

2.6.2 Construct validity of the MHQ

During the development and validation of the MHQ, hypotheses were made concerning the expected direction and magnitude of correlations between its scales and the SF-12, a validated, generic health-status measure (Ware Jr et al., 1996). It was predicted that similar items in the MHQ would correlate moderately with the SF-12. The authors also hypothesised that the functional scales in the MHQ would be significantly correlated with each other. Additionally it was hypothesised that rheumatoid patients with hand deformities would have significantly lower aesthetic scale scores than those with carpal tunnel syndrome.

All the sub-scales were found to correlate in the expected direction with each other and with the SF-12. A weaker correlation between the MHQ aesthetics scale and SF-12 was attributed to it, measuring a different factor from the other functional scales. Independent t-tests were used to compare the mean aesthetics scores between the two groups. There was a statistically significant mean difference between the carpal tunnel group (83.70 points) and the rheumatoid group (50.40 points) ($p = 0.0012$).

2.6.3 Responsiveness of the MHQ

To evaluate the ability of the MHQ to detect change, 92 patients who had participated in the development study completed the MHQ six to 18 months later (Chung et al., 1999). The developers report that their sample included patients with a range of hand conditions, but it was not large enough to stratify for specific conditions. They describe a ‘heuristic’ approach to evaluating change in patients by comparing the patients’ self-reported magnitude of

change of health status with change in MHQ scores. They report statistically significant correlations between patients' self-report scores and in all of the six domains. They ranged from (r = 0.25) for the aesthetic scale to (r = 0.43) for the pain scale.

2.6.4 Further validation studies on the MHQ

2.6.5 Reliability

The reliability of the MHQ has recently been evaluated by its developers with a Canadian population (Chung and Morris, 2014). The sample included patients with a range of hand conditions, including 12 patients with nerve disorders. For the test-retest analysis, between 53 and 77 people completed the MHQ on both occasions. It was reported that test-retest analysis by clinical condition was not possible, as no clinical group had a sufficiently large sample size to make reliable estimations.

Internal consistency was reported to be high in all of its scales; all Cronbach's alphas were ≥0.84 (ranging from 0.84 to 0.95). Bland Altman plots, the mean difference between administrations of the MHQ as well as limits of agreement and ICCs were used to report reproducibility of the MHQ. The mean difference between each administration was low (ranging from -1.5 to 1.8 points) but the magnitudes of the limits of agreement were wide. The limits of agreement represented between 29% and 61% of the total range of possible change in each scale. ICCs were all ≥0.70 (ranging from 0.70 to 0.84).

2.6.6 Construct validity

The construct validity of the MHQ was evaluated by Dias et al. (2008) and has been discussed above for the PEM. In this study, the MHQ correlated with the other outcomes measures including pinch (r = 0.57), grip (r = 0.60) and tenderness (r = 0.64). There was a weak correlation with swelling (r = -0.17) and sensation (r = -0.05). A weak correlation was found (r = 0.31) between the BCTQ and the MHQ. Hypotheses regarding the expected correlation between the MHQ and the other measures were not reported.

2.6.7 Responsiveness

The responsiveness of the MHQ has been evaluated for patients undergoing surgery for CTS. Chatterjee and Price (2009) assessed the responsiveness of the MHQ relative to the BCTQ in patients (n = 42) having carpal tunnel decompression surgery. The magnitude of change for each measure was calculated using the standardised response mean. The MHQ and BCTQ change scores showed significant post-operative improvement. Standardised response means for each measure were large (SRM = ≥0.80). However the BCTQ (SRM = 1.22) demonstrated greater change after carpal tunnel decompression surgery compared to the MHQ (SRM = 0.80).

McMillan and Binhammer (2009) also evaluated the responsiveness of the MHQ relative to the DASH in a sub-group of (n = 20) patients having a carpal tunnel decompression. The magnitude of change for each measure is reported using the standardised response mean. The MHQ (SRM = 1.04) demonstrated greater change after carpal tunnel decompression surgery compared to the DASH (SRM = 0.77). Kotsis and Chung (2005) evaluated the responsiveness of the MHQ compared to the DASH for (n = 50) patients six months following carpal tunnel decompression. All domains of the MHQ improved; change was expressed using the standardised response mean. This was large for the pain scale (SRM: 0.90) and moderate for the function scale (SRM = 0.60). This was comparable with the DASH (SRM = 0.70).

2.6.8 Shorter versions of the MHQ

Having a shorter measure can be advantageous, providing it retains good psychometric properties. Therefore, all shorter versions of existing PROMs require additional validation. During the development of the MHQ, Cronbach's alpha coefficients were used to express how each of the questions correlated with each other. All of the six scales had alphas greater than 0.8 and four of the six scales had alphas greater than 0.9 (Chung et al., 1998). Alphas greater than 0.9 can suggest item redundancy and can be used as a criterion for their removal (Portney and Watkins, 2000). Waljee et al. (2011) used a 'concept retention' approach to reduce items of the MHQ. This method takes into consideration the clinical relevance of the items, rather than basing the decision on statistical estimates alone. This approach resulted in the elimination of 25 items to produce a 12-item PROM, renamed as

the ‘Brief MHQ’. Patients with nerve conditions were not included in the evaluation of the reproducibility of the Brief MHQ.

To evaluate construct validity it was hypothesised that the Brief MHQ scores and the original MHQ scores would be similar within disease groups. Adjusted mean summary scores for a sub-group with CTS (n = 97) were similar for the Brief MHQ (53.20 points) and the full MHQ (52.90 points). Similar correlations were also found between the Brief MHQ and full MHQ with objective measures of hand function. Coefficients for the Brief MHQ and full MHQ with grip were (r = 0.38) and (r = 0.41), respectively, with pinch (r = 0.35) and (r =0.36), respectively and with the Jebson-Taylor test score were (r = 0.35) and (r = 0.30), respectively. This indicates that the Brief-MHQ and the full MHQ are highly correlated. The responsiveness of the Brief MHQ relative to the full MHQ was evaluated for 55 patients having carpal tunnel decompression surgery. Responsiveness indices for the Brief MHQ (SRM = 1.00) and the full MHQ (SRM = 1.01) were almost identical.

Since the development of the Brief MHQ by Waljee et al. (2011), a confirmatory factor analysis of the full MHQ has been performed by Chung and Morris (2015) with a sample of 116 patients with musculoskeletal upper limb conditions. They claim that the factor structure for the original MHQ was insufficient for the model to be retained. They present a strong argument that the Brief MHQ should not be used, based on the concept retention methods that were used to develop it. Instead, they propose an alternative shortened version of the MHQ, with a clarified factor structure, which also has 12 items. Of the 12 items in the Brief MHQ, five of the items were not presented in the new shortened version. Chung and Morris (2015) postulate that the Brief MHQ is not only capturing insufficient information, but also information that does not contribute to hand-health overall. No subsequent validation studies of the new shortened version of the MHQ have been reported to date.

2.7 Disabilities of the Arm, Shoulder, and Hand (DASH)

The DASH was developed as an evaluative outcome measure for patients with upper extremity musculoskeletal conditions. It has one scale, with two optional scales of work and sport/music. The primary scale has 30-items, which aim to measure symptoms associated

with the condition and the impact on activity and participation. The two optional scales have four items each and relate to work and sport/performing arts. Each sub-scale is calculated individually to produce three separate scores of 100, a higher score being indicative of greater disability. The development of the DASH was originally reported by Hudak et al. (1996) while data on its measurement properties were still being collected. The psychometric properties of the DASH were later reported by Beaton et al. (2001b). The developers of the DASH have produced a comprehensive user manual, which was most recently updated in 2011 with information on the development and ongoing studies that report on the measurement performance of the DASH (Kennedy, 2011).

2.7.1 The development of the DASH

The DASH was developed in 1996 by a group with expertise and experience treating upper limb conditions, referred to as the Upper Extremity Collaborative Group (UECG) (Hudak et al., 1996). A conceptual framework was defined by the UECG as an important foundation to developing their measure. Patients were not involved in the initial generation of items (Kennedy, 2011). This was performed by pooling items from existing measures by the UECG, identified through a literature search. The initial item pool was reduced from 821 to 177 potential items specific to the upper limb. A further reduction to 67 items was made based on the clinical judgement of the UECG (Hudak et al., 1996). At this stage, feedback from a group of 20 patients with upper limb conditions on the content, clarity and readability of the DASH was sought and resulted in three items being added, reflecting self-image. (Kennedy, 2011).

The factor structure of the DASH scores was explored with a sample of 407 patients, which included a sub-group of 42 patients with CTS. This informed the removal of items considered not to be sufficiently contributing to the overall construct of disability. The conceptual relevance of items was also considered, by asking a group of 76 patients, including four patients with CTS, to rank the items of the DASH according to severity and importance for them. Differences between the two approaches were reconciled by the UECG to create the 30-item DASH (Kennedy, 2011). A principal components analysis (PCA) was performed on the final 30-item DASH to examine the factor structure. PCA can be used to examine the unidimensionality of a scale by clustering items that correlate with each other into different components, which make up the overall construct (Segars, 1997).

Most of the variance was explained by the first factor (57%). There were some items, which related to symptoms and self-image, which loaded significantly on the first and second factors, although the exact contribution of second factor is not reported. The developers restated their goal to seek a model with a simple factor structure and rejected the two-factor model. They claimed that the DASH was a unidimensional scale, which could produce a single score for the physical function and symptom items. They reported that further empirical work on the factor structure of the DASH should be carried out to determine if symptoms and self-image emerge as separate factors (Kennedy, 2011).

2.7.2 The initial validation of the 30-item DASH

The initial validation of the DASH involved 200 patients with a range of hand and upper limb conditions (Beaton et al., 2001b). The DASH items demonstrated high internal reliability as assessed using Cronbach's alpha ($\alpha = 0.96$). Fifty-six of the 86 people completed the DASH a second time (three to five days after baseline) to evaluate test-retest reliability. It is not reported if any patients with a hand nerve disorder were included in the sample. The ICC was high (ICC = 0.96; 95% CI = 0.93 to 0.98), indicating excellent agreement. Construct validity was assessed according to upper limb region from two groups: a proximal group (shoulder pathology n = 138) and a distal group (hand/wrist pathology n = 62). Patients with CTS were included in the wrist/hand group; the exact number is not reported. To evaluate construct validity for the (wrist/hand) group it was hypothesised that the DASH would correlate positively and strongly with both the symptoms and function scales of the BCTQ. As predicted, correlations were strong for the symptoms scale ($r = 0.70$ in wrist and $r = 0.73$ in hand group) and very strong ($r = 0.92$ in wrist and $r = 0.92$ in hand group) for the function scale.

The ability of the DASH to measure change in patients 12 weeks after receiving treatment for their upper limb condition was evaluated using a range of methods. Firstly, evaluating the magnitude of observed change using effect sizes and the standardised response mean for the entire (n = 172) sample demonstrated a moderate (ES = 0.59; SRM = 0.78) change. This was similar for the wrist/hand patients (ES = 0.57; SRM = 0.74). For the wrist/hand, group the responsiveness of the DASH relative to the BCTQ was evaluated. It was hypothesised that the DASH change scores would be comparable with the BCTQ, which was confirmed (DASH: SRM = 0.74; BCTQ: SRM = 0.76).

Another method of evaluating responsiveness was used, which estimates change measured in a group of patients who have self-reported to have changed. This external indicator or 'anchor' is what differentiates observed change from estimated change. Estimated change was evaluated by correlating change scores on the DASH with changes in pain intensity, function and severity of the problem, using patient-reports of change in function. This was determined by estimating change based on self-reports of function pre and post-treatment using a 'difference in status measure'. A second anchor involved asking patients to rate their change in function after treatment, referred to as a 'transition approach'. DASH scores demonstrated change in all expected situations except for the transition approach. Correlations between differences in patients' self-report of change in function and the DASH status were moderate (r = >0.65) for the difference in status measures. Using the transition approach correlations were weak and ranged from (r = 0.32 to 0.40).

Receiver operating characteristic (ROC) curves were also used to describe the responsiveness of the DASH. ROC curves demonstrate how well change scores of a measure discriminate between patients identifying as improved and not improved. This is defined by an external anchor, such as a global rating of change (GROC) score, which asks patients a single question on whether they feel their condition has improved, is unchanged or has worsened. The accuracy of a measure depends on how well it can separate those who have improved and those who have not. Discrimination is measured by the area under the curve (AUC), where 1.00 represents perfect discrimination. While the AUC value is not provided in the study, the authors conclude that the DASH was capable of making a distinction between improvers and non-improvers (De Vet et al., 2011).

2.7.3 Further validation studies on the DASH

2.7.4 Reliability of the DASH

There are two studies, which report on the test-retest reliability of the DASH for patients waiting to have carpal tunnel decompression surgery. In a sample of 43 patients, Amirfeyz et al. (2009) evaluated the reproducibility of the DASH by getting patients to complete it two and four weeks before surgery. Strong Pearson's coefficient (r = 0.88) of reliability were reported. Similar findings were found by Greenslade et al. (2004) also with a sample of patients (n = 31) awaiting carpal tunnel decompression surgery. They also reported a

strong correlation (r = 0.90) between the two test periods using, Pearson's correlation coefficient.

2.7.5 Construct validity of the DASH

During the development of the DASH, its scores were compared with the BCTQ by Beaton et al. (2001b), where a strong correlation was reported between the two instruments. These findings are in contrast to further evaluative work by Dias et al. (2008). The authors here also used the symptoms scale of the BCTQ to evaluate construct validity with the DASH for a sub-group of patients with a nerve disorder (n = 26). They reported a weak correlation (r = 0.33) between the BCTQ score and the DASH. A further study that explored the construct validity of the DASH relevant for patients with an ulnar nerve disorder (n = 48) was carried out by Zimmerman et al. (2009). In this study the authors demonstrated construct validity by comparing the DASH with the BCTQ and also with grip and pinch strength. Strong correlations were reported between the DASH and the BCTQ symptom scale (r = 0.79) and BCTQ function (r = 0.87) scales. They reported negative, moderate correlations with the DASH and grip (r = -0.53) and pinch (r = -0.49).

2.7.6 Responsiveness of the DASH

Five studies report on the ability of the DASH to measure change in a CTS population undergoing decompression surgery. The relative responsiveness of the DASH with the PEM and MHQ have already been presented above (Hobby et al., 2005, Kotsis and Chung, 2005, McMillan and Binhammer, 2009). The DASH has been reported to be less responsive in comparison with the disease-specific BCTQ in two studies of patients having surgery for CTS. Gay et al. (2003) report the magnitude of change using effect sizes and the standardised response mean, for the DASH for (n = 34) patients following surgery at six weeks (ES = 0.57; SRM = 0.54), and at 12 weeks (ES = 1.01; SRM = 1.13), compared with the BCTQ at six weeks (ES = 1.30; SRM =1.21) and at 12 weeks (ES = 1.71; SRM = 1.66) for a sample of 34 patients. Greenslade et al. (2004) report the standardised response mean for 57 patients which was higher for the DASH at 12 weeks after surgery (SRM = 0.66) compared with the BCTQ symptom scale (SRM = 1.07) and function scale (SRM = 0.62). Amirfeyz et al. (2009) compared the DASH and BCTQ to determine which was more sensitive in detecting change. They report that the DASH and BCTQ showed similar

correlations of 60 - 70% agreement in categorising (n = 43) patients who had self-reported to have changed six weeks after surgery.

2.7.7 Shorter versions of the DASH

During the development of the DASH a shorter version was anticipated, based on suspected redundancy of some items (Beaton et al., 2001b). Shorter questionnaires can be desirable for clinical practice as long as they retain the same measurement properties of the original PROM. The developers of the DASH used three approaches to develop the Quick DASH (Beaton et al., 2005). The methods included a concept-retention approach, which involved selecting items that represented each of the key domains identified in the theoretical framework of the DASH. The items within each domain were ranked according to importance and difficulty for patients.

The second item-reduction approach involved was the equidiscriminative item-total correlation (EITC) method. This statistical approach created three variables, representing the 25th, 50th and 75th percentile values for the distribution of the 30-item DASH scores in the field-testing sample. Participants were assigned a dichotomous (yes/no) variable, depending on whether their score was higher or lower than each of the percentile values. The scale was then created by choosing items with high correlations with overall scores across sub-groups.

The third method used the Rasch model. Here DASH items were ordered and weighted based on their relative probability of being difficult for a person. Items that were identified as poorly fitting were then removed (Beaton et al., 2005, Kennedy, 2011).

The three item-reduction approaches used data from the development of the full DASH. The initial field testing data were used for the concept-retention approach from 76 patients, who were asked to rank items according to severity and importance for them. Four patients had a diagnosis of CTS, and the exact number of patients with a nerve disorder included in the psychometric testing of the full DASH was not reported. Few patients with a nerve disorder were involved in the concept-retention approach. As this approach uses the patient's experience of disability, under-representation of this population makes it difficult to

evaluate the relevance of the content of the Quick DASH for this population. Similarly, it is unclear how many patients with CTS were involved during the other item-reduction approaches, making it difficult to ascertain the transferability of the findings for this population.

2.7.8 The final version of the Quick DASH

The developers of the Quick DASH reported that each method produced similar, although slightly different in content, versions of the Quick DASH. They all correlated with the original DASH. They all had a Cronbach's alpha coefficient of >0.90 and good test-retest reliability was reported (ICC = 0.94) for all three versions. Correlations with the full DASH were highest using the Quick DASH which was developed using the concept-retention approach, when compared with the overall problem (r = 0.70/0.71) and overall pain (r = 0.73/72), and ability to function (r = 0.80/0.79) and ability to work (r = 0.76/0.77) for the Quick DASH and full DASH respectively. This was also the case for responsiveness testing, where large effect sizes were reported: observed change (SRM = 0.79/0.78) and estimated change in those reporting problem as better (SRM = 1.03/1.05). This version of the Quick DASH was also chosen by the UECG, when blinded and asked to choose which of the three versions of the Quick DASH they preferred. This resulted in the Quick DASH, a shortened version of the DASH retaining 11 of the original 30 items (Beaton et al., 2005, Kennedy, 2011).

2.7.9 Further validation studies of the Quick DASH

A systematic review identifying and synthesising the evidence for the measurement properties of the Quick DASH was carried out by Kennedy et al. (2013), identifying two relevant studies with a CTS population (Beaton et al., 2005, Niekel et al., 2009). The Beaton et al. (2005) study has already been reviewed, as this was the original item reduction paper in which the Quick DASH was created. Niekel et al. (2009) evaluated the discriminant validity of both the DASH and Quick DASH with other measures that would be considered to be unlike the DASH, in this instance several measures of psychological factors. They report expected low to medium correlations. However, there was a significant and strong correlation between the DASH and the Quick DASH (r = 0.79) including all patients as well as the CTS sub-group (r = 0.76). A large cohort of patients were included, with a range of

musculoskeletal upper limb disorders two weeks after surgery, including those with CTS (n = 271).

A further study on the structural validity of the Quick DASH is presented by Gabel et al. (2009), who question the validity of producing a single score from the Quick DASH and thus the validity of using this shortened version. The authors carried out an exploratory factor analysis using Quick DASH scores from (n = 137) patients with a range of upper limb musculoskeletal conditions. They conclude that the Quick DASH has a bi-dimensional structure demonstrated by two factors, which broadly divide into activity, and non-activity related items. They postulate that the concept-retention method used to produce the Quick DASH may have been flawed and that no prospective testing occurred to validate this measure. The authors offer an alternative shortened version of the DASH, the Quick DASH-9, which they demonstrate to be unidimensional. They also carried out prospective validation work of the Quick DASH-9. However, patients with hand nerve disorders were not included in the validation process.

2.8 Discussion and conclusions

The aim of this review was to identify commonly used region-specific PROMs used with people with a range of hand nerve disorders, to evaluate their psychometric properties and determine the suitability of their use with this population. Much work has been done by others in identifying and cataloguing a wide range of outcome measures suitable for people with upper limb conditions. Two PROMs were identified which had been developed for people with hand nerve conditions: the BCTQ (Levine et al., 1993) and the PRUNE (MacDermid and Grewal, 2013). These nerve compression-specific PROMs, however, are not appropriate for patients with traumatic nerve injuries or for individuals with combined nerve disorders. Nor are they suitable for comparing outcomes within groups of patients with different nerve disorders. Other region-specific PROMs were deemed unsuitable, as they were either work-specific, for surgical patients or they had not been validated for people with hand nerve disorders. Five PROMs met the search criteria: the PEM, MHQ, DASH, Brief MHQ and the Quick DASH. Available literature reporting on the psychometric properties for each measure were identified and evaluated to determine the appropriateness of their use with this population.

The PROMs identified in this literature review were all designed and developed for use with people with a range of hand and/or upper limb conditions. The initial validation work by the developers of the MHQ and the DASH (no validation work was carried out on the PEM) used a sample of patients with a range of upper limb musculoskeletal conditions. This group of patients was poorly described and none of the validation studies were stratified according to diagnosis. Studies that included patients with hand nerve disorders were mostly limited to those with CTS. Only one study, of poor quality, recruited patients with nerve disorders other than CTS, median nerve (n = 25) and ulnar nerve (n = 1). At best, therefore, the generalisability of this body of work can only be to those with CTS. With the exception of the DASH, there were a small number of studies and the quality of the research was generally poor using the 'worst score counts' approach by COSMIN.

Responsiveness was the most frequently reported measurement property across all the studies. The responsiveness of a measure, however, is less important if an instrument does not measure the construct that it is supposed to. There was limited and conflicting evidence on the construct validity for all of the measures. There was also limited evidence for the reliability of each measure, as often patients with hand nerve disorders were not included in this aspect of the study. While evidence of good reliability, construct validity and responsiveness is important, it is imperative that a PROM is also capable of measuring the construct of interest. This reinforces the central importance of content validity, as posited by Cano and Hobart (2011) in the introduction to this chapter. Patient involvement in the development of each measure was generally poorly reported, with limited clinical or diagnostic information provided. For the PEM there was no evidence of content validity, as patients were not involved in its development. There was also underreporting of the extent of patient involvement in generating items for the MHQ and the DASH. Each measure fell short of current minimum standards on PROM development, which recognise the use of qualitative methods as a crucial foundation for establishing content validity for PROMs (PCORI, 2012).

Evidence for the more structural aspects of validity were also lacking for each measure, particularly in relation to the legitimacy of producing total scores and the methods used to create shorter versions of the MHQ and DASH. No published work could be found on the structural validity of the PEM. The results of the factor analysis for the MHQ were also poorly reported. The developers of the MHQ expressed serious concerns relating to its structure following a recent confirmatory factor analysis and produced a revised version

which has yet to be validated (Chung and Morris, 2015). This would suggest that at present the original MHQ and the Brief MHQ are not appropriate measurement tools as posited by their developers. The factor structure of the DASH was presented in its manual. However, doubts were raised concerning whether it is a unidimensional scale, with the existence of a possible second factor (Kennedy, 2011). Similar concerns have also been raised with the Quick DASH (Gabel et al., 2009). These findings bring the legitimacy of a single summed score for each measure under scrutiny.

2.8.1 Limitations

The importance of conducting a literature review as an important first stage of PROM development has been highlighted. Systematic literature reviews, which use methods conforming to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA), provide a complete summary of all relevant literature and are a popular choice in PROM development (Liberati et al., 2009). A decision was made not to perform this type of review, which could be considered a limitation of this study. This decision was based primarily on an initial scoping review of the literature. The search returned six recent literature reviews, two of which were systematic literature reviews cataloguing a range of upper-limb outcome measures. In addition, for the MHQ and the Quick DASH, two recently published systematic reviews on their measurement properties were identified. Since much quality research had already been recently conducted in the area of interest, it was decided that the resources needed to conduct another systematic review would be at the detriment of time and resources required for the development and validation of the PROM, which was the primary focus of this research. While a systematic review was not conducted an objective and transparent approach was used to minimise bias.

2.8.2 Conclusion

In conclusion, current nerve-specific PROMs, which have been developed for either isolated median or ulnar nerve compression syndromes, were not deemed appropriate for people with traumatic nerve injuries or for those with combined nerve disorders. Nor were the region-specific PROMs identified in this review considered appropriate, as they have mostly been validated for CTS populations, therefore findings cannot be generalised for other nerve conditions. There was insufficient quality and quantity of evidence to support the use

of any of these measures for people with hand nerve disorders. There was insufficient evidence of patient involvement in the generation of items for each measure, which is now regarded as crucial for a measure to be considered truly 'patient-reported' (Lasch et al., 2010). The modification of any of the measures for this population would also not be supported. Arguably the resources that would be required in having to establish content validity for any of the measures, while also assessing for modifications, would be greater than developing a new measure (PCORI, 2012). Furthermore, with the current debate around the factor structure of the MHQ, Brief MHQ, and the new modified MHQ, the DASH, Quick DASH and Quick DASH-9, it was considered best to avoid adding to this confusion in attempting to modify an existing measure. The outcome of this review was that none of the measures could be used with confidence for patients with a range of hand nerve disorders seen in clinical practice, other than CTS. The burden of establishing content validity and modifying any of these measures was considered too great, and the development of a new PROM was supported.

Chapter 3 - Development of the Impact of HaND Nerve Disorders (I-HaND) Scale: item generation

"When developing new PRO instruments, the purpose across all qualitative methods is to understand patients' perspectives and experiences" (Patrick et al., 2011a).

3.1 Overview

The previous chapter demonstrated the need for a new, hand nerve-specific PROM. Chapter 3 reports the methods and results of a qualitative study exploring the impact of hand nerve disorders on individuals. This chapter also includes the methods used to develop a conceptual framework from which to generate items for a new PROM: the Impact of HaND Nerve Disorders (I-HaND) Scale.

3.2 Introduction

When developing a new condition-specific PROM, it is important to gather in-depth and high-quality data about the ways that the condition affects people (Lohr, 2002). The first phase of this study, therefore, involved collecting data about the impact of a hand nerve disorder from the patients' perspective. This information served as a basis for generating the content of the new PROM and is also an innovative piece of qualitative work in its own right. The decision was made to collect original data from patients to form the basis of the questionnaire items, as there are few published qualitative studies on the impact of hand nerve disorders and thus little is known about this experience.

A search for published material on patient experiences of living with a hand nerve disorder identified only four studies, three of which focused solely on carpal and/or cubital syndrome. Martin (2007) explored the health beliefs of individuals receiving conservative treatment for carpal tunnel syndrome to try and understand why patients had delayed seeking treatment. The impact and expectations for those waiting to have carpal decompression surgery was

investigated by Jerosch-Herold et al. (2008). Satisfaction with carpal and cubital tunnel decompression surgery was evaluated by Khu et al. (2011). Only one study investigated the consequences and strategies to facilitate adaptation for individuals who had sustained acute nerve trauma to either the median or ulnar nerves in adolescence (Chemnitz et al., 2013b).

Despite limited qualitative work on the experience of living with a hand nerve disorder, some important findings emerged. Peripheral nerve disorders of the hand cause a significant burden to patients, including sensory-motor disturbance, pain and psychological distress, which contribute to activity limitations and participation restrictions. The recovery time from a nerve injury is long; for some patients it was decades and a full recovery was not possible. Limitations to this work included under-reporting of the research methodology and under-representation of people with a variety of nerve disorders seen in clinical practice, particularly traumatic nerve disorders. Such nerve disorders are commonly acquired by young adults and the current qualitative literature does not adequately include the views of this group (Rosberg et al., 2005). The study participants were all either children or older adults when they acquired their nerve condition.

There was a lack of clarity about to the conceptualisation of the impact of a hand nerve disorder on activity and participation, and the authors emphasised the need for additional exploratory work (Jerosch-Herold et al., 2008, Chemnitz et al., 2013b). To build on this research, further enquiry into the impact of hand nerve disorders on activities and participation with people from a much broader range of nerve disorders (compression and trauma), across the lifespan and at different stages of recovery, was considered necessary. Conducting patient interviews with people from the target population has also been recommended when generating items for new PROMs (Rothman et al., 2007, FDA, 2009).

3.2.1 Aims and objectives

Aims

This study aimed to investigate the impact of a peripheral nerve disorder of the hand, from the perspective of patients, and to develop a conceptual framework from which to design a new, condition-specific PROM for clinical practice and research.

Objectives

1. To use qualitative research methods to gain insight into the experiences of patients with a peripheral nerve disorder of the hand.
2. To use the International Classification of Functioning, Disability and Health (ICF) to guide the development of a conceptual framework, to explore the impact of nerve disorders on activity and participation.
3. To generate items and response categories for a new, condition-specific, PROM for peripheral nerve disorders of the hand.

3.3 Methodology

Qualitative research methodology provides a suitable exploratory approach to understand patient experiences and provides a means from which to obtain a rich and important source of information on the impact of health conditions (Mason, 2002, Sandelowski, 2004, Mays and Pope, 2000). Kathy Charmaz's constructivist grounded theory approach was chosen for this study, to generate theory on the impact of a hand nerve disorder, grounded in the data collected from study participants (Charmaz, 2006, Charmaz, 2014). Grounded theory methodology has been identified as an appropriate approach for the development of new PROMs (Lasch et al., 2010, Patrick et al., 2011a). The constructivist approach acknowledges the role of the researcher as integral to the research process of interpretation and the construction of concepts (Birks and Mills, 2010). Taking this approach was desirable, as the chief investigator is an occupational therapist and has clinical experience of treating patients with hand nerve disorders; these experiences have the potential to influence the interpretation of the data.

There are three major features of grounded theory which distinguish it from other forms of qualitative analysis: coding, memo writing, and theoretical sampling (Glaser and Strauss, 1967, Strauss and Corbin, 1967). Grounded theorists begin coding as soon as they start to collect data to try to make sense of what is happening. Coding becomes more focused and leads to memo writing. Memos are more analytical and are generated by the constant comparison of new data to existing coding; memos act as a bridge between coding and theory construction (Charmaz, 2015). Simultaneous collection and analysis of the data informs the direction of what to collect next and where to find it, referred to as theoretical

sampling. This comparative and interpretive process follows the direction of the theory as it emerges (Charmaz, 2008).

3.4 Methods

Semi-structured, face-to-face individual interviews were used to collect data to inform the development of a conceptual framework for the impact of a hand nerve disorder on body structures/functions, activity and participation. This was preferable to focus groups, to give the patient the freedom to discuss their experiences in a more personal way (Lasch et al., 2010). An interview schedule/topic guide was used that broadly asked patients to talk about the impact of their disorder on activity and participation (appendix 3.1). The questions were chosen to capture aspects of function and disability using ICF domains. Prompts used in the interview, relating to common symptoms experienced by people with hand nerve disorders, were derived from a narrative literature review. Patients were also given the option of taking photographs to visually represent what it is like to live with a nerve disorder, to bring with them for discussion during the interview. Leading up to the interview, participants were encouraged to photograph situations or activities, which they deemed to reinforce the impact of their condition. This method was chosen as it has been reported to help foster a sense of participation from the interviewees and to add novelty to the work; this method has not previously been used in the literature with this population (Clark-Ibanez, 2004, Drew et al., 2010, Guillemin and Drew, 2010).

3.4.1 Ethical considerations

A favourable ethical opinion was granted by the NRES Committee North East – York on 28th July 2014 for all three phases of the HaND Nerve Disorders (HaND) Study (appendix 3.2). An application for proportionate review was submitted as opposed to full ethical approval, as the study was deemed to have no material ethical issues. This research recognises the four basic moral principles of medical ethics and this was embedded in the study protocol. The patient's autonomy to choose or refuse treatment was respected in allowing them to take the study material home and to take sufficient time to make a balanced decision as to whether they wished to participate. They were also informed of their right to leave the study at any time without providing a reason. The best interests of patients were taken into consideration, and while there were no direct benefits of taking part in this study,

the research methods that were chosen have been reported in the literature to foster a sense of autonomy, which can be indirectly beneficial (Clark-Ibanez, 2004, Drew et al., 2010, Guillemin and Drew, 2010).

There was a desire to avoid anything that could have caused distress to patients and it was felt that completing questionnaires would be a relatively low burden. The interviews, on the other hand, carried a risk that patients may have become upset if talking about sensitive topics, e.g. recalling a traumatic injury. Provisions were therefore made to offer sources of help if this occurred and the interviews were conducted by a qualified occupational therapist with experience in recognising the signs of patient distress. Finally, in order not to infringe on patient or clinician's time, and in particular therapy time, patients were invited to take the study materials home and to self-consent. This also allowed them adequate time to think it over and to discuss with friends and family before making a decision.

3.4.2 Recruitment procedure

The study took place in a secondary care setting between August 2014 and May 2015. Potential participants were identified by a member of the clinical team from the Norfolk and Norwich University Hospital (NNUH) from a therapy database kept within the hand therapy department. Eligible patients were provided with a participant information pack (appendix 3.3), during a therapy session if they were currently receiving treatment, or by post if they had been discharged from the service.

Participants were given the option to take a series of photographs during the two weeks before their interview. The theme of the photography was: 'How my nerve disorder affects my daily life'. Information was provided in the participant information pack on appropriate ethical issues in using photography in research. This promoted a common-sense approach such as not photographing children or taking close-ups of people's faces. Participants were given the choice of having an interview at either the University of East Anglia (UEA) or their own homes.

Recruiting clinicians were briefed on how to answer any immediate general questions from patients. Clinicians provided patients with a participant information pack. This provided

more information regarding the purpose of the study, and what was required of them. Patients were advised to read this in their own time. The participant information pack welcomed patients who had further questions to contact a member of the research team, whose details were included in the pack.

Patients who were no longer receiving treatment were sent a participant information pack in the post. Those interested in taking part self-consented by signing an enclosed consent form and posting this back to the chief investigator. Recruiting participants in this way spared the time of busy clinicians, as well as giving patients adequate time to think about whether they wished to take part, without coercion. Only those consenting to take part in the study had their personal details held. All personal data were held in strict compliance with the UEA Research and Enterprise Services policies and Information Governance legislation.

3.4.3 Inclusion and exclusion criteria

Participants were eligible for inclusion into the HaND Study if:

1. They were competent at speaking the English language.
2. They were 18 years or over.
3. They had a confirmed diagnosis of a peripheral nerve disorder affecting the hand.
4. They had an isolated or combined radial, median or ulnar nerve disorder.

Participants were not eligible for inclusion into the HaND Study if:

1. They had substantial co-morbidities that would overshadow the nerve injury, e.g. a cognitive impairment.
2. They had a confirmed diagnosis of a cervical spine injury or any other central nervous system dysfunction that could affect hand function.
3. They had a brachial plexus or dorsal scapular, long thoracic, phrenic, suprascapular, lateral pectoral, musculocutaneous or digital nerve injuries.

3.4.4 Sample

Sample sizes were not calculated beforehand, as is the case for quantitative research. In qualitative research, an adequate sample size is deemed to have been achieved when data saturates or when no new concepts are emerging from the data (Coyne, 1997). To achieve maximum variation in the sample, participants with a range of nerve disorder diagnoses were invited. In addition to variation of diagnosis, participants with a range of sociodemographic factors, such as age and occupation, were also invited.

3.4.5 Data collection and analysis

Interviews were recorded using a digital audio recorder, and then transcribed verbatim. Data collection and analysis occurred simultaneously, in keeping with grounded theory methods (Glaser and Strauss, 1967). The data analysis followed a process of initial, focused and conceptual coding. Initial coding involved naming each line of the written data. Focused coding involved analysis of the most significant or frequent earlier codes. Moving from initial to focused coding provided a sense of the main actions and processes that were occurring in the narrative (Charmaz, 2014). Conceptual codes were generated by applying the ICF as an analytic scheme to organise and analyse data according to first and second-level ICF domains.

In the absence of a core ICF set for hand nerve disorders to guide coding, a modified version presented by Rosén and Jerosch-Herold (2014) was used. Figure 3:1 below illustrates how the authors have populated the first-level ICF categories (in bold) with hypothesised second-level ICF categories specific for nerve disorders of the hand (underneath). Using the ICF allowed for comparison across participants and exploration of the interactions between the different ICF domains. Memos were written to record this comparative process and to assist with the analysis. Data collection and analysis followed an iterative approach. While a topic guide was used, there was freedom to follow up new areas of interest as conceptual codes were created. An explanatory theory, grounded in the data, was constructed by elevating the data from conceptual codes to conceptual categories.

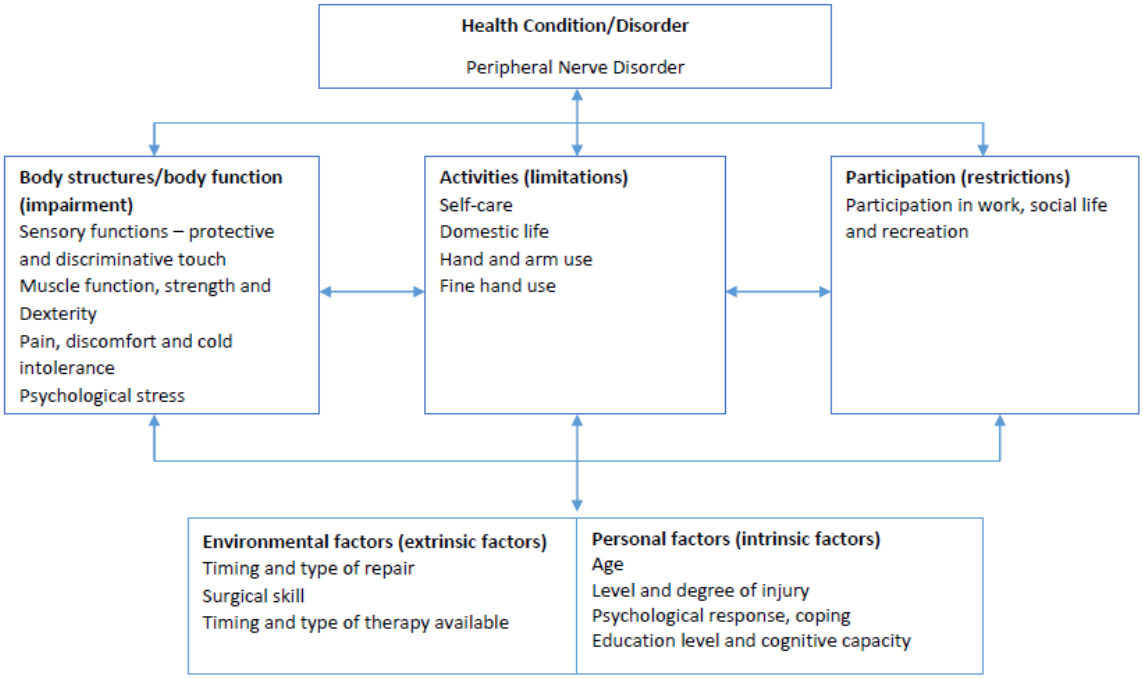


Figure 3:1 First and second-level ICF domains relevant for hand nerve disorders used to guide the coding (illustration from Rosén and Jerosch-Herold, 2014, with permission)

3.5 Results

3.5.1 Sociodemographic characteristics of participants

Fourteen participants took part in the interviews, three of whom brought photographs with them for discussion. There were equal numbers of men and women (Table 3:1). The age of participants ranged from 25 to 74 years, with a mean age of 55 years. Half the participants had injured their dominant hand. There was an equal number of traumatic and compression-type nerve disorders, with a diverse range of diagnoses representing the full spectrum of nerve disorders routinely seen in clinical practice. All of the participants who sustained traumatic injuries also acquired concomitant soft tissue or bone injuries. For individuals with non-traumatic compressive disorders who had undergone surgery, the mean time between first experiencing symptoms and having surgery was 34 months. For those who had undergone surgery, the time since surgery ranged from seven months to over 10 years, with a mean time of 40 months. Six of the participants were in paid employment, two were unemployed, four retired and two others were working in a voluntary

capacity. Half of the participants experienced a change in their work status as a direct result of their nerve disorder.

Table 3:1 A summary of the characteristics of phase one study sample

Participant*	Age (years)	Sex	Condition	Duration of symptoms/time since surgery (months)	Hand affected	Type of surgery	Occupational status
Peter	59	M	Median nerve injury	34/34	D	NR	Metal inspector
Claire	63	F	Median nerve injury	28/28	N/D	NR	Volunteer
James	26	M	Median nerve injury	35/35	D	NR	Unemployed mechanic
Ray	74	M	Ulnar nerve injury	47/47	N/D	NR	Semi-retired stone mason
Gary	25	M	Ulnar nerve injury	25/25	N/D	NR	Unemployed labourer
Richard	66	M	Ulnar nerve injury	7/7	N/D	NR	Retired farmer
Tracey	26	F	Ulnar nerve injury	24/24	D	NG	Sales associate
Jeanette	62	F	Radial nerve injury	72/72	D	DN	Hairdresser
Pat	57	M	Radial nerve injury	44/0	D	N/A	Building manager
Joan	61	F	Radial nerve injury	52/52	D	DN	Office worker
Joy	71	F	Carpal tunnel syndrome	108/108	D	DN	Carer
Lisa	56	F	Carpal tunnel syndrome	39/21	B	DN	Checkout operative
Matthew	59	M	Cubital tunnel syndrome	58/45	N/D	DN, TN	Retired lorry driver
Pam	71	F	Carpal tunnel syndrome and cubital tunnel syndrome	60/22	N/D	DN	Retired secretary

M = male; F = female D = dominant hand; N/D = non-dominant hand; B = bilateral; NR = end to end repair; NG = nerve graft; DN = decompression; TN = transposition of ulnar nerve; N/A = not applicable *Pseudonyms have been used

3.5.2 Data saturation

Interviews were discontinued when no new concepts were emerging from the data or when it saturated (Table 3:2). Interviews were transcribed in groups, with the number of new concept codes per group being recorded. Forty-five percent of the total of new concept codes were generated in the first group, with less than 1% of new codes created in group

five. This demonstrated evidence of data saturation and therefore interviews were discontinued after 14 participants.

Table 3:2 Evidence of data saturation: the number of new concepts generated per transcript group

ICF Domains	Number of new concepts				
	Transcript Group 1 (n=3 transcripts) 1,2,3	Transcript Group 2 (n=3 transcripts) 4,5,6	Transcript Group 3 (n=3 transcripts) 7,8,9	Transcript Group 4 (n=3 transcripts) 10,11,12	Transcript Group 5 (n=2 transcripts) 13,14
Body structures/Body function (impairment)	32	05	01	02	0
Activities (Limitations)	25	25	22	08	0
Participation (Restrictions)	18	08	09	14	0
Environmental factors Temporal factors, interventions, supports	05	04	01	0	0
Personal factors	10	02	01	03	01
No. of new concept codes appearing in each transcript group	90	44	34	27	01
% of total new concept codes	**45.92**	**22.45**	**17.35**	**13.78**	**0.51**

3.5.3 Findings

Initial and focused coding of the data generated hundreds of codes. By using the ICF domains as part of the coding process, the data could be organised at an individual participant level and across participants for each domain. Memos were written to help deconstruct codes and to understand what constituted them (Charmaz, 2009). This process resulted in the collapsing and refinement of codes, reducing the number to 196 conceptual codes. All of the final 196 codes were grouped according to ICF domains to facilitate comparison across all of the domains in the ICF framework. Memos were written to collapse the conceptual codes further to create 29 main conceptual codes. The conceptual codes formed four conceptual categories; 1) struggling, 2) overcoming, 3) accepting and 4)

transforming. This resulted in the construction of a grounded theory, which was named: 'learning to live with a hand nerve disorder'. A diagrammatic representation of the main conceptual codes and categories that formed the theory are presented in Table 3:3.

Table 3:3 A diagrammatic representation of the conceptual codes and categories, which contributed to the construction of the grounded theory: 'learning to live with a hand nerve disorder'

Conceptual codes
Body structure and function
1. Experiencing positive and negative sensory-motor symptoms and impairments 2. Experiencing pain, discomfort and cold intolerance 3. Experiencing psychological symptoms, e.g. PTSD, anxiety and depression 4. Feelings of frustration and anger 5. Emotional response to physical limitations 6. Impact on body image and self-consciousness 7. Further injury as a result of loss of protective sensation 8. Learning to live with sensory-motor symptoms and impairments 9. Self-monitoring for improvement of condition 10. Learning to adapt to sensory-motor deficits
Activity limitation and participation restrictions
1. Activity limitations with self-care, domestic life and hand/arm use 2. Participation restrictions with work and recreation 3. Struggling with physical demands and pace of work 4. Giving up recreational activities 5. Struggling with bilateral activities 6. Learning to change handedness 7. Things becoming like 'second nature' or adaptation 8. Adaptive strategies to manage activities, e.g. extra time, assistive devices, receiving help 9. Adaptive strategies to facilitate participation, e.g. phased return, light duties, changing role 10. Work and recreation having therapeutic benefit
Contextual factors
1. Pre-existing mind-set or personality 2. Understanding of a nerve injury 3. Perception of functional capacity and prognosis 4. Communication from the medical team 5. Rippling effect or the social nature of adaptation 6. Learning to let go of loss 7. Learning to accept the injury 8. Being in the present moment 9. 'Silver linings' or something positive coming from the experience
Conceptual Categories
Struggling Overcoming Accepting Transforming
Constructed ground theory
Learning to live with a hand nerve disorder

3.5.4 Learning to live with a hand nerve disorder: a constructed grounded theory

The following account presents the interpretation of the narrative and is supported by quotations from participants who have been given pseudonyms to maintain confidentiality. Participants' ages, occupations and diagnostic information have not been changed, as this provided important context to their stories.

3.5.5 Struggling

Many of the participants in this study used the word 'struggle' to describe their experience of learning to live with sensory-motor symptoms and impairments, and the challenges that this presented (Table 3:4). The lack of feeling to the hand can result in injury when participants have not been able to feel and have been at risk of burning, cutting or hitting the hand. They have not been aware of this until some visible reminder occurs, such as bleeding, as described by Gary, a 25-year-old, unemployed labourer:

> *"The amount of times that I have cut the little finger and not realised it or whacked it and not realised and all of a sudden there is blood dropping off it".*

Table 3:4 A summary of sensory-motor symptoms and impairments described by participants

Sensory	Motor
Pins and needles	Reduced strength
Hyper-sensitivity	Reduced range of motion
Numbness	Reduced muscle endurance
Clammy and sweaty hands	Muscle atrophy
Impaired proprioception	Reduced dexterity

Participants described a range of painful symptoms, factors that aggravate pain and the quality of their pain (Table 3:5). Sleep is frequently affected due to an inability to position the affected limb in a comfortable position, as reported by Pam, a 71-year-old, retired secretary:

"The aspect of it was when you lie on your arm in bed, when you lie on your left hand side it is extremely uncomfortable".

Table 3:5 A summary of pain symptoms, pain quality and aggravators described by participants

Pain symptoms	**Quality of pain**	**Aggravators**
Stiffness	Duration	Activity
Soft tissue and scar tightness	Severity	Inactivity
Cramping	Frequency	Overuse
Itching		Exercise
Neural pain		Cold
Oedema pain		

All participants were significantly bothered by cold intolerance. James, a 26-year-old unemployed mechanic, said:

"In cold weather my fingertips just go completely cold, as in proper ice cold but this hand is as warm as anything and the fingers on this one are really cold".

There were a number of codes generated which described symptoms associated with post-traumatic stress disorder, anxiety and depression (Table 3:6).

Table 3:6 A summary of symptoms of psychological stress described by participants

Post-traumatic stress disorder	Flash-backs, minimising (denial), disbelief or shock and avoidant behaviours
Anxiety and depression	Automatic negative thoughts, rumination and low mood

It is common for patients who have experienced a traumatic injury to re-experience the event, often referred to as a flashback. This is thought to be one of the ways the brain tries to process what has occurred and to regain a sense of mastery of the event (Van der Kolk, 2002). It is interesting that one participant chose to re-imagine the setting in which he sustained his injury and to photograph this to bring to interview (Figure 3:2). Richard, a 66-year-old, retired farmer, sustained an ulnar nerve injury following an accident using a

chainsaw whilst trimming down the branches of a tree. In this photograph Richard had chosen to re-imagine what happened by laying out the chainsaw and protective clothing he was wearing beside the tree he was cutting at the time of the injury.

The picture on the left is of the chainsaw which caused the injury. Beside it is the protective clothing that was worn at the time. Although not in the picture in the shadow is the tree from which Richard was cutting the branches.

Figure 3:2 Photograph re-imagining of the scene where Richard sustained his injury

Ray, a 74-year-old semi-retired stonemason, describes this experience in relation to his injury that he sustained when falling through a glass greenhouse and severing his ulnar nerve:

> *"After the accident I would say it is a fairly usual thing for you to re-enact it, you recapitulate in your mind what happened. I think it is part of the mind's way of trying to understand what happened, you know. So I did picture myself doing this thing, almost as though, as if by thinking about it, I could go back and alter it and make a different outcome, but you can't and that is the way the mind works in this case".*

A further aspect of trying to understand what happened at the time of the injury can be seen with participants trying to take ownership or responsibility for what happened. This is illustrated by Richard choosing to photograph his protective clothing, a symbol of being safety-conscious. While Richard emphasised throughout the interview that he did not feel responsible for what happened, the fact that he chose to photograph the injury scene and talk about it may reflect some underlying feelings of guilt. This was common for a number of the participants who had traumatic injuries:

> *"Of course, there is self-guilt because you start thinking: 'What a stupid thing you have done'" (Peter).*

"I thought you've had an accident, it is your own stupidity that has caused it. You are gonna have to wait and get better and that is it" (Ray).

"I kind of felt like it was my fault. I've done it to myself" (Tracey).

"It was my fault anyway" (Joy).

"It's something that happened when I was drunk so it was generally my own fault really, to be honest" (James).

"My own stupidity in falling off in the first place" (Pat).

The accounts of the participants here are reminiscent of automatic negative thoughts or the 'inner critic', and are often considered to be a feature of anxiety and depression (Klerman, 1977). Many of the participants described the impact the disorder had on their mood:

"Yes, there were times when I got so low, especially with getting dressed. Just going through your day to day because everything was a challenge. I would cry at times, I was 24/25 at the time and things that I could do, say a month ago, before it happened, it was upsetting" (Tracey).

Some patients waiting to have elective surgery expressed regret at not seeking help sooner, which conveyed a sense of loss:

"I'd advise anyone go and get it done and get it sorted out as quick as possible cos you'll suffer in the long run" (Matthew).

Participants talked about psychological stress in relation to activity and participation. They struggled with reduced self-efficacy and confidence as they started to work towards mastering their environments following injury:

"You are still very sensitive, very conscious, there are limits and you've got to watch what you do" (Peter).

Activities that were previously managed could trigger a range of negative emotions including sadness, frustration, anger and fear:

"That happened two years ago but something like not being able to cut a cucumber the right way can make you a mess" (Tracey).

"Last year I did this and I did that, now you can't do it and I have weepy moments, very weepy but not anger more frustration" (Joy).

Lisa, a 56-year-old checkout operative, said:

"Sometimes temper flares because I am struggling with things like these, cartons of soup and wax cartons of things, some of them you can get with a screw on them to pour".

The impact of the disorder on body image was important to Richard and he chose to photograph this for discussion during the interview (Figure 3:3). The photograph on the left shows a 'claw' deformity associated with an ulnar nerve disorder. The photograph on the right shows the scar from the injury. Feelings about the cosmetic appearance of the hand were negative, and patients felt self-conscious:

"I just try and ignore it but when people bring it up you kind of get a bit awkward" (Tracey).

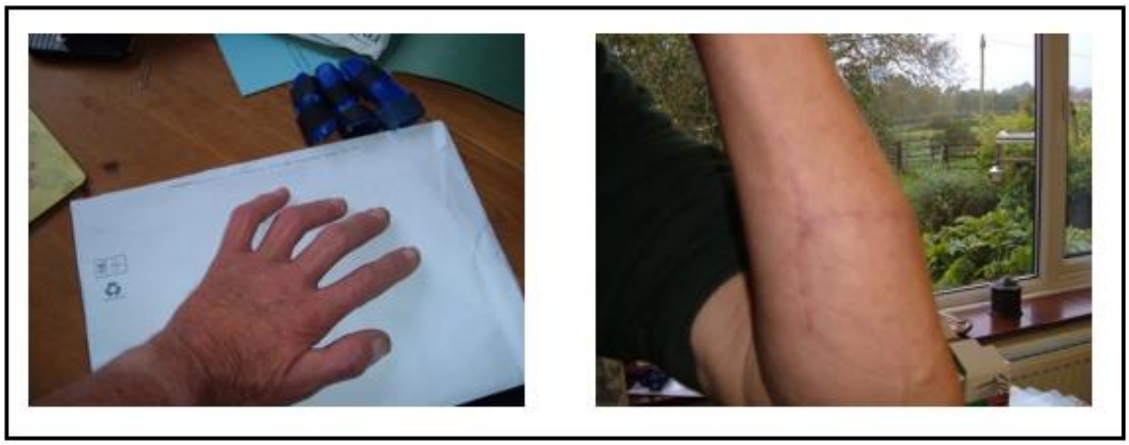


Figure 3:3 Photographs taken by Richard reflecting the impact on body image

Participants had difficulty with a range of daily living activities requiring unilateral and bilateral hand function. This included self-care activities (Table 3:7) and activities relating to domestic life (Table 3:8).

Table 3:7 A summary of self-care activities which participants reported having difficulty with

Doing buttons	Using a knife & fork	Cutting nails
Bath transfers	Childcare tasks	Putting on jewellery
Getting dressed	Putting on a T-Shirt	Brushing teeth
Holding a cup	Putting on a bra	Doing a watch strap
Washing body	Washing hair	Styling hair
Putting on trousers	Putting on deodorant	

All participants struggled with bilateral activities, e.g. cutting food using a knife and fork together, as here participants were forced to use their affected hand and it was more difficult to compensate. For those participants who injured their dominant hand, the process of learning to change handedness either temporarily or permanently was a challenge:

> *"You go to grab something and it just falls out of your hand because you can't feel if you have got it or not. So this weekend I have managed to break a cup and a plate" (Jeanette).*

Table 3:8 A summary of domestic life activities which participants reported having difficulty with

Opening lids and jars	Lifting plates	Wringing a dish cloth
Lifting tea pot or kettle	Carrying heavy shopping bag	Peeling vegetables
Hoovering	Chopping food	Lifting food out of the oven
Emptying kitchen bin	Making beds	Hanging out washing
Lifting pots and pans	Cooking	Ironing
Opening cans	Dropping kitchen items	Using power tools
Making a cup of tea		

Hand nerve disorders can have a significant impact on the ability to work with half of the participants in this study experiencing a change to their occupational status. Time off work is required and for some this can result in loss of earnings. The nature of the work was important, with fast paced and manual work being affected. Bilateral activities were particularly challenging and could be a barrier for participants being able to return to their jobs and thus impacting upon occupational identity. Gary, a 25-year-old, unemployed labourer said:

> *"The biggest thing that I find is two handed work; if I am hammering or chiselling out walls for cables. If I am holding it with one hand I need to make sure I can hold it."*

Pat, a 57-year-old building manager, said:

> *"I started thinking about changing career; you know if you're a builder there's only so many things you can do with one hand".*

James, a 26-year-old unemployed mechanic, added:

> *"I've had a couple of jobs in between, one I started at a scrap yard for I was supposed to have about three months work there but three days later that was it, I*

was done. I couldn't keep up and the bloke said: 'I appreciate that you've had an injury in the wrist but I do need you a bit quicker.'"

Work could be a major source of stress for participants and fear of sustaining further injury and clumsiness with bilateral activities were seen as a hurdle. Participants described having difficulty taking part in recreational activities including playing musical instruments, hobbies and sports. The personal importance and enjoyment of the activity was a significant factor for participants learning to adapt and to become independent. Joan, a 61-year-old local government office worker, said:

"I can't do badminton; I used to do a lot of badminton. I was part of a club and because I can't grip properly and I don't have the same control over my movement, it's just too clumsy to be enjoyable."

Having to give up recreational activities that were previously enjoyed was experienced as a loss. Ray, a 74-year-old semi-retired stonemason, remarked:

"*The only main problem for me is that I can no longer do the one artistic or cultural thing [playing the classical guitar] that I enjoyed doing really. It is not a terrible thing for me, it is a disappointment, and there is a gap in my life because I can't do this thing I did, which I got a lot of pleasure out of."*

3.5.6 Overcoming

Participants described learning to live with impairments, activity limitations and participation restrictions by 'overcoming' or learning to adapt physically and functionally. Features of this included using sight to compensate for reduced sensation, using the non-affected hand or taking extra time. James, a 26-year-old, unemployed mechanic, said:

"Obviously, because of the lack of, how can we say, the sense, the nervous sense, in the three fingers. Obviously you've got to watch your touch and when you're picking things up".

Richard, a 66-year-old retired farmer, adds:

"I have got this feeling that I always have pins and needles in the hand. That is something that I am getting used to".

Having sustained further injury as a result of reduced protective sensation, participants learnt from these experiences and found different ways of adapting:

"I couldn't feel it but these are little things that just happen now and again and you get a bit wiser with it" (Tracey).

Participants also describe learning to adapt to motor impairments, such as reduced proprioception, by using sight to compensate or receiving support from the contralateral hand:

"Yes, I've got a good grip, you know, it's there. I tend to have to look at everything as I'm gripping it to get that surety, rather, whereas before you would reach out for something without and not really be looking at it" (Peter).

This involved a period of time being cautious with motor tasks, as described by Matthew, a 59-year-old, retired lorry driver:

"I thought I had hold of it and I didn't but that was say in the early days, I mean we're very wary of it now" (Matthew).

Participants tried to adapt to pain caused by the cold by wearing gloves or using a heat pack. Joy, a 71-year-old carer, said:

"The cold is very intense, unless it is the summer I always wear a glove on that hand".

Participants learned to adapt to become independent with activities by using their non-affected hand. This was easier when performing activities requiring gross motor skills e.g. opening and closing heavy doors. Activities that required fine sensory-motor skill e.g. handling small coins, were more challenging especially if it had been the dominant hand which was affected. Here compensation with the non-affected hand was clumsy and could result in things being dropped.

"It's just constantly dropping things, you think you've got hold of it and suddenly it's gone" (Matthew).

A variety of the mechanisms of adaptation were described (Table 3:9). Participants expressed being able to manage activities but maybe requiring extra time:

"Now I can do my shoe laces up, but obviously it takes…I can't rush it, you know, you've got to take your time, but I can do my shoe laces up" (Peter).

Assistive devices can be used:

"The other thing I use now is an electric toothbrush, rather than the normal manual" (Peter).

They may receive help from another person:

> *"Having a shower using one hand; I needed a lot of help and support" (Tracey).*
>
> *"I did have difficulty sometimes with dressing when it first happened which I was helped by my wife" (Richard).*

Table 3:9 A summary of the mechanisms of adaptation described by participants

Changing posture	Changing quality of movement	Choosing adapted clothing
One-handed inventions	Receiving help	Changing handedness
Using two hands	Convenience cooking	Changing the environment
Prioritising	Pacing	Using assistive devices
Taking extra time		

A phased return to work and support from employers to attend therapy appointments was beneficial for patients. Participants were very cautious in the work place, and struggled particularly with bilateral tasks. Some participants were unable to return to their jobs. Facilitators and barriers to returning to work are presented in Table 3:10.

Table 3:10 A summary of facilitators and barriers to returning to work described by participants

Barriers	**Facilitators**
Physical demands of work	Being given lighter duties
Pace of work	Support received from employer
Pain	Having a phased return to work
Lack of support from employer	Support received from family

Whether participants were referred to therapy and the type of therapy they received was important. Pat, a 57-year-old, building manager, said:

"After having been told by this other doctor there's nothing we can do and then somebody else says hang on we've got a whole [hand therapy] department which do this".

Therapy was a big commitment and became a part of the participant's routine, as is illustrated by the participant in the photograph below (Figure 3:4). Here, varieties of splints are shown that he wore throughout the day and night as part of his rehabilitation for a traumatic ulnar nerve disorder.

Figure 3:4 A photograph of hand splints worn as part of a hand therapy programme for Richard

Not being referred to therapy or not completing therapy meant that some participants did not understand what was happening and had to try to work things out for themselves:

"Putting your cutlery down your splint, is an adaptation but it might take you six months to find that out. What we need is tricks, to show us how to do simple things from the beginning, that's how it is. I have learned to live with it for six years now" (Jeanette).

"I didn't finish the physio treatment to begin with so I might have missed something… The doctor doesn't really know so that's why he's thinking physio again and like I say hopefully after do a bit better I can start doing things that I used to be able to do" (James).

Being in hand therapy was useful in helping participants keep track of their progress:

"They do measurements and things when you go through the physio so you're seeing the progress as they go along and use it for you to realise how far you've come" (Joan).

The process of struggling and overcoming was not limited to the individual. Partners, family members and employers were also affected. This phenomenon can be likened to a ripple effect, the incremental and outward consequences created by a single action, as illustrated by the diagram on the right in Figure 3:5. As these relationships are changed additional ripples are created, causing further change within the individual as conceptualised by the image of rainfall on water (not taken by a participant) in Figure 3:5. Here, concentric circles ripple out and collide with each other from the impact of the rainfall. Relationships must learn to adapt or they will not last, highlighting the social nature of 'overcoming'.

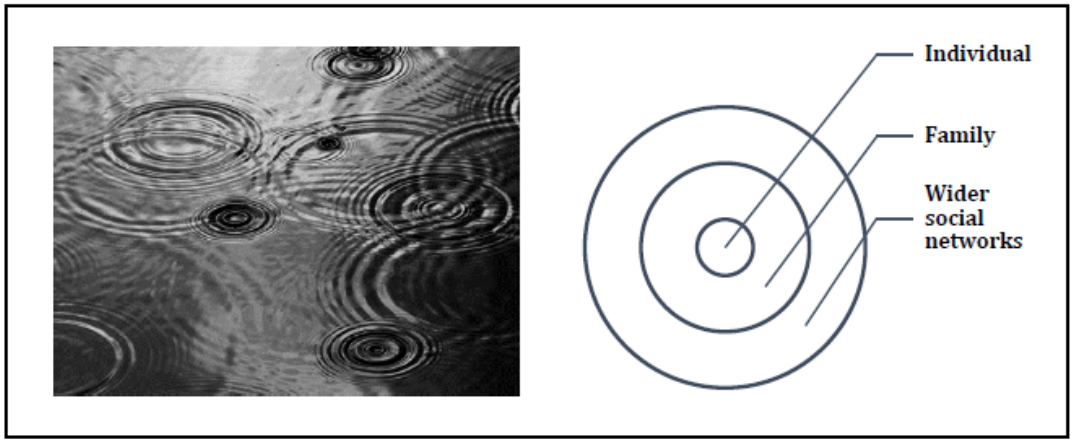


Figure 3:5 Conceptualisation of the social nature of struggling and overcoming

There was an impact on relationships with partners, requiring partners to learn to adapt to the disorder or else relationships can fragment and end. Jeanette, a 62-year-old hairdresser, said:

"*Because I wasn't 'perfect' any more. I was having to rely on him more. That blew his brains, he couldn't cope with it and we agreed that this wasn't working, so we agreed to part. Now I am trying to deal with a relationship which was 11 years old breaking down because of this."*

Relationships with partners that adapted developed resilience and survived. Claire, a 63-year-old volunteer, said:

> *"I guess it brought us a lot closer together I couldn't get embarrassed about anything (laughs). For him I guess it gave him a different understanding of what human beings are about."*

Adaptation also occurred within the family unit; James, a 26-year-old unemployed mechanic, describes this process in relation to his daughter:

> *"She knows that I have damaged it so she's quite a helpful little girl, she does a lot for me. She remembers and knows that I couldn't do it so she doesn't ask me to do anything like that. It's the same with even doing her coat up, now she still doesn't ask me, she will do it herself or get her mum to do it or even ask her bigger sister. So I suppose yes, she's adjusted to it as well."*

The amount of support from employers was an important aspect of the adaptation process. Lisa, a 56-year-old checkout operative, said:

> *"It was done in the July and by the Christmas I was having so much time off I was earning no money and they were threatening me with the sack and they were really giving me a lot of grief and a lot of bullying."*

In contrast, James said:

> *"I couldn't drive so it was a case of mum would come and pick me up, if mum couldn't come and pick me up one of the bosses would take me home as well, so they were very supportive."*

Support from medical personnel and receiving hand therapy led to increased satisfaction for participants and assisted with the 'overcoming' aspect of adaptation, largely due to helping participants understand their condition and their functional prognosis. Joan said:

> *"For the long term support it was the hand therapy, it was extremely good and it was quite hard after a while to stop going because it was just quite nice to get the reassurance of progress, it's getting better."*

Conversely, poor communication or being given unrealistic advice from the medical team could lead to anxiety and low mood. Peter, a 59-year-old metal inspector, remarked:

> *"They come in and they open my notes and they say, 'It was quite horrific, you are lucky you didn't lose your arm'. And then, surprisingly, you get used to people saying that, but when you first hear it is quite a shock."*

Tracey said:

> *"I had to change nappies and bath both my children. Things that the doctors were saying that you can't do. Well, when my partner is at work what am I supposed to do? I can't let him sit in a cot all day, and I was living out in the sticks at the time and my mum worked full time. My dad lived in Wales and he came down for a week or two to try and help and that is all he could offer. I was on my own and I had to do something I couldn't just leave him until my partner got home. So you do have to get them dressed and change their nappies, feed them and do everything that you are not supposed to do."*

3.5.7 Accepting

Learning to live with and adapt to physical and functional impairments was accompanied by an interior process of psychological adaptation, or 'accepting' what has happened. Personality and pre-existing coping strategies may influence how a person responds to the impact of the disorder. Over time, participants learned how to live with and accept their condition. Peter said:

> *"These are the things I've got to live with rather than think there is going to be a cure. There is not going to be a 100% recovery as such".*

Gary said:

> *"It is fine; it is second nature now. It is who I am, it is part of me and I just get on with it. I have hurt myself, I've learned from it, people make mistakes; we gather scars, you try and learn from these things."*

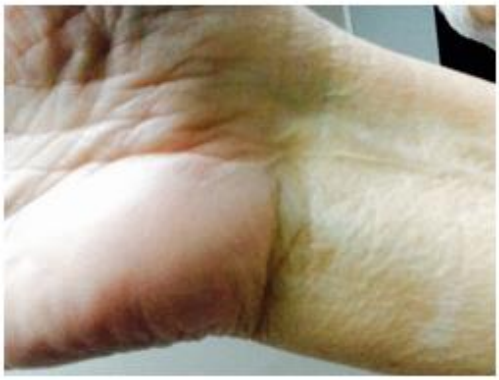
Claire said:

> *"I suppose again it is acceptance, isn't it? There is nothing you can do as you can't turn the clock back. I had to accept that this was the new reality."*

Matthew said:

> *"I think if I'd have had it done [decompression surgery] I would have caught it a lot earlier and probably had more movement in the arms, but you're always wise after the event, as they say."*

Joy, a 71-year-old carer who developed signs of acute carpal tunnel syndrome shortly after having surgery to her wrist, following a fall down the stairs, brought a photograph with her showing the scar on her wrist (Figure 3:6). Over the years, Joy had learned how to adapt to her symptoms and functional difficulties, and described them as being part of her. She described having residual sensory motor symptoms, but also that she was still experiencing nerve recovery. Joy was accepting of her present state and yet hopeful for further improvement. Joy communicated this through the photograph of her surgical scar. The scar is faded but serves as a reminder of what happened, and that while she has learned to adapt to and live with a hand nerve disorder, she still experiences the impact of the condition with ongoing pain and sensory symptoms.



The photograph on the left shows a faded surgical scar. What was striking was that this was the only thing that Joy decided to photograph despite having her injury over ten years ago.

Figure 3:6 Photograph of faded surgical scar taken by Joy

3.5.8 Transforming

Participants described a transformative experience as a result of the journey that they had been on, which for most was expressed as being positive. Tracey used the proverb: 'every cloud has a silver lining' to describe this experience:

> *"It is a bit of a silver-lining really for me…I hate the idea that I have missed an opportunity somewhere or that time with my kids is being wasted or that I am doing something that I shouldn't. I just look at things so differently now, which is good."*

They had developed resilience and seemed more assertive:

> *"Maybe in certain respects a stronger person in character. Being able to not worry about what other people think. To be able to speak out" (Peter).*

Matthew said:

> *"I think I'm more relaxed than I was prior to. I think I was more stressed up while I was working and now I've had this done it's almost a wake-up call to say, well, slow down, ease up."*

This transformative experience fostered in participants a deeper sense of empathy for other people. Claire, a 61-year-old, volunteer, who sustained her nerve injury through deliberate self-harm said:

> *"I think that it has given me a greater understanding of what other people go through; if they need to talk, to give them time and to not say to them to 'pull yourself together'. There has been a lot of positivity that has come out of the negative action."*

The imagery of clouds having a silver lining fits well with that of the rainfall described earlier, to illustrate the nature of 'struggling' and 'overcoming'. Both clouds and rain can be associated with turbulent storms. In the photograph below this motif is built upon by Richard, who chose to photograph a rainbow that appeared over his land after a rainstorm. Richard expressed gratitude for all that was in his life, and for a return to calmness and peace (Figure 3:7).

Figure 3:7 Photograph of a rainbow over Richard's land after a rainstorm

3.5.9 Summary of key findings

This study sought to explore the impact of a peripheral nerve disorder on patients. It specifically aimed to explore the impact on body systems/functions, activity and participation. The participants in this study were required to adapt to nerve impairments and this process formed part of a wider narrative on the experience of living with a hand nerve condition. Activities requiring bilateral hand function were more challenging to adapt to, as was the process of learning to change handedness. This created a significant barrier to participation in recreational activities and work. A process of 'struggling' and then 'overcoming' was experienced. The word 'struggling' was used by participants and related to when they were experiencing sensory-motor impairments. Injury as a result of lack of protective sensation and pain related to cold intolerance were also experienced. Psychological stress was a significant clinical feature, with symptoms of anxiety, depression and post-traumatic stress disorder described by many participants. One feature of struggling was participants trying to make sense of or process what had happened and how this had affected their daily lives. Struggling was also a result of participants trying to participate in life, learning to live with symptoms and using these experiences to become more independent.

This learning process led to people 'overcoming'. Here, a range of effective adaptive strategies were used. The meaning that participants attached to activities was a motivating factor. While overcoming was a largely physical/functional process, it was also accompanied by an interior aspect of adaptation, described as 'accepting'. This involved learning to let go of loss and being in the present moment, irrespective of whether further nerve recovery was possible. This gave rise to participants 'transforming'; being changed as a result of the journey that they had been on. The process that the participants in this study described was a transformative one. Coining each conceptual category in the present tense represents that they are not end-points, as participants must learn to adapt over and over again as they experience further nerve recovery or as they encounter new activities or situations which require them to adapt. The experiences that the participants shared during the interviews provided a rich source of data for the development of a conceptual framework to generate the items for the new PROM.

3.6 Development of the Impact of the HaND Nerve Disorders (I-HaND) Scale

3.6.1 Development of a conceptual framework

When developing a new PROM it is important to first develop a conceptual framework from which to define the concepts being measured (Rothman et al., 2007). The conceptual framework for the proposed PROM is presented in Figure 3:8. It uses the basic structure of the ICF, with its content relevant for individuals with a nerve disorder of the hand. It aims to illustrate the variables and relationships in the conceptual model for this population. Its development was based primarily on the findings of the concept elicitation interviews discussed in the previous section. Secondary data sources also contributed to the development of the framework, including the findings of a narrative literature review on the experiences of living with a nerve disorder. A range of generic, disease and region-specific PROMs used with patients with a range of hand and upper limb disorders were also reviewed and discussed by a PROM development group.

This group consisted of Mark Ashwood (Accredited hand therapist (BAHT)), Dr Christina Jerosch-Herold (Reader in occupational therapy), Professor Lee Shepstone (Professor in medical statistics) and Dr Simon Horton (Lecturer in speech and language therapy). The group has experience in upper limb rehabilitation, outcome measurement and PROM development. The function of this group was to establish face validity of the new PROM, developed for assessing the impact of a range of nerve disorders on individuals. The main impacts of the disease were on body structures/body functions (impairments), activity (limitations) and participation (restrictions). A variety of environmental and personal (contextual) factors are also illustrated. The target patient population for the new PROM included patients with either isolated or combined trauma to their radial, median or ulnar nerves, all of which affect hand function. The new PROM was developed to evaluate the impact of the disorder on activity and participation, both in routine clinical practice and research settings.

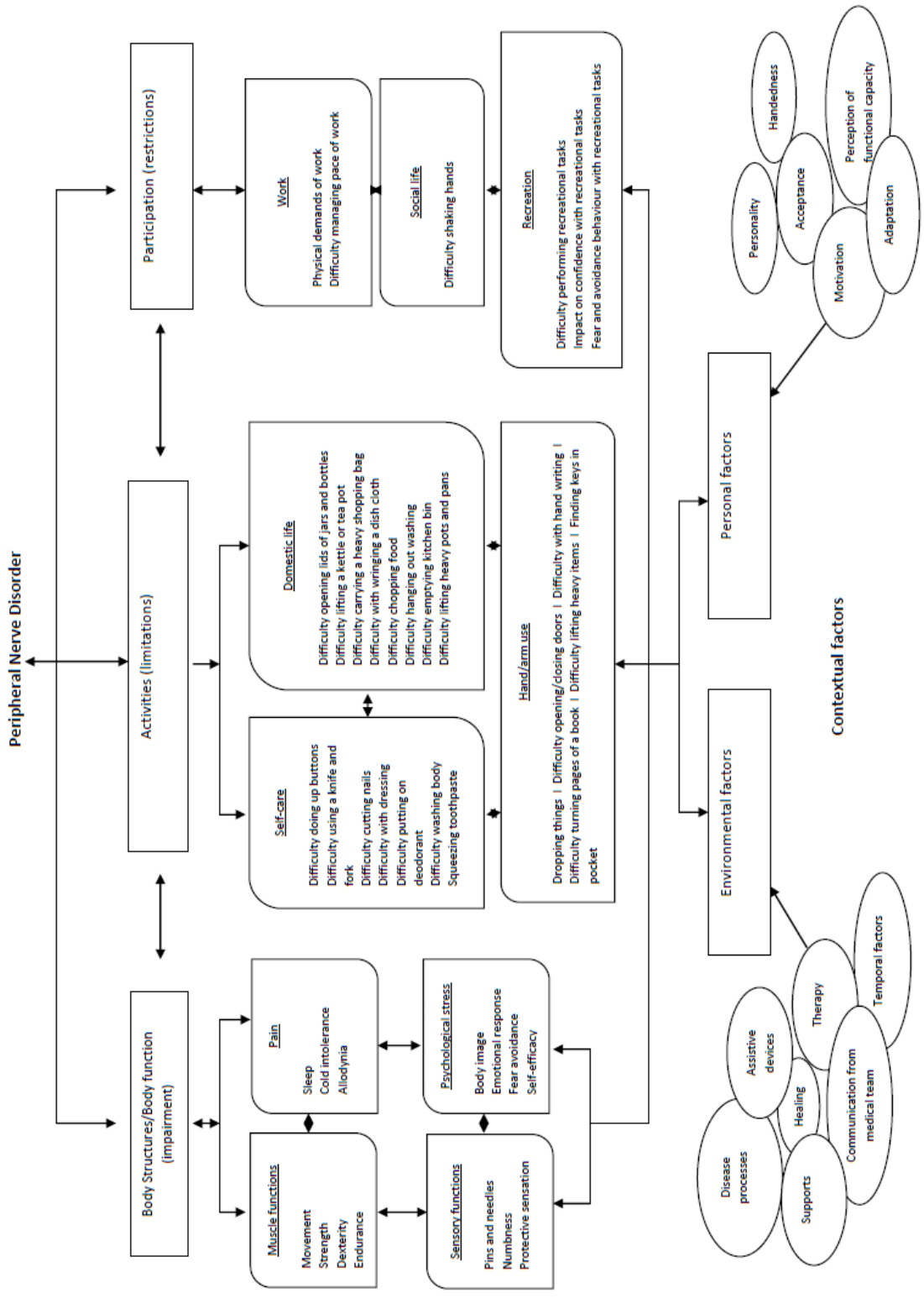


Figure 3:8 Conceptual framework for the impact of hand nerve disorder

3.6.2 Development of the Impact of HaND Nerve Disorders (I-HaND) Scale

All data sources and the conceptual framework were presented to and reviewed by the PROM development group. The output from this workshop informed the first draft of the Impact of HaND Nerve Disorders (I-HaND) Scale, a 42-item scale for people with hand nerve disorders. Guidelines on questionnaire design and item construction were followed (Streiner et al., 2014, McColl et al., 2002, McDowell, 2006). Items were designed to be relevant for adult patients with a range of nerve disorders and applicable across age and gender. Where possible, the language used to create the items reflected patients' own words. Medical or technical language was avoided. A readability check was used to ensure that a 12 to 13-year-old would be able to understand it and was confirmed with an acceptable SMOG Index of 9.6 (Mc Laughlin, 1969). Concise and simple sentences were chosen. Each item was to represent a single concept and be unambiguous. Items were to correspond to the appropriate response formats (Patrick et al., 2011a). This preliminary version was presented to the PROM development group in a follow-up PROM development workshop.

The outcome of this workshop led to changes being made to the layout and structure; response categories; the rewording and clarification of words; and the removal of eight items that were felt to be duplicates or overlapping. These changes were reviewed electronically by the working group and further feedback led to subsequent changes over three more occasions, through versions 1.0, 1.1, 1.2, 1.3 and 1.4. Changes at this time were concerning the layout, response categories and some further clarification of the wording. For a detailed account of these preliminary changes and to view the different drafts of the developing scale from version 1.0 to 1.4, see appendix 3.4. Version 1.4 of the I-HaND scale was deemed ready for pre-testing with a sample of patients with a peripheral nerve disorder in the second phase of the study, which aimed to further strengthen content validity for the I-HaND Scale and is reported in Chapter 4 of the thesis.

3.6.3 Initial item pool of the I-HaND Scale version 1.4

The I-HaND Scale Version 1.4 (Figure 3:9) is a 34-item self-report questionnaire that asks patients to rate the impact of a peripheral nerve disorder on their activities and participation. The PROM comprised four parts containing 10 impairment-related questions, six questions relating to pain, 16 activity-related questions and two questions asking about participation restrictions.

Impact of Hand Nerve Disorders (I-HaND) Scale Version 1-4

Instructions:

This questionnaire asks you to rate the impact that your nerve disorder has on you.

*Please answer **EVERY** question by circling the answer that is most relevant for you.*

Some of the questions ask about your ability to complete certain tasks, if you have not had the opportunity to carry out such tasks please try and estimate how you might have done so.

***Part 1:** The following questions ask about any symptoms that you may have experienced as a result of your nerve disorder of the hand(s). Please circle one answer for each question.*

	In general, over the past week	Very well	Well	Fairly well	Poorly	Very poorly
1	How well did your hand(s) work?	1	2	3	4	5

	Over the past week, how satisfied are you with the following?	Very satisfied	Somewhat satisfied	Neither satisfied nor dissatisfied	Dissatisfied	Very dissatisfied
2	The movement of your hand(s)	1	2	3	4	5
3	The sense of touch in your hand(s)	1	2	3	4	5
4	The strength in your hand(s)	1	2	3	4	5

The following statements relate to physical difficulties experienced by people with a nerve disorder affecting their hand(s).

	Please indicate how often you have experienced these difficulties in the past week	Never	Rarely	Sometimes	Often	Always
5	I can't grip or pinch for very long without my hand getting tired	1	2	3	4	5
6	When I touch certain things it causes pins and needles or tingling	1	2	3	4	5
7	I have hurt my hand and not realised it until later	1	2	3	4	5
8	When I go to grab something it just falls out of my hand	1	2	3	4	5

1

Impact of Hand Nerve Disorders (I-HaND) Scale Version 1-4

The following statements relate to feelings sometimes experienced by people with a nerve disorder affecting their hand(s).

	Please indicate how often you have experienced these feelings in the past week	Never	Rarely	Sometimes	Often	Always
9	Using my hand(s) can bring about strong emotions e.g. frustration, anger, sadness	1	2	3	4	5
10	I feel self-conscious if people look at my hand/arm	1	2	3	4	5

Part 2: *The following questions ask about any pain that you may have experienced as a result of your nerve disorder of the hand(s). Please circle one answer for each question.*

	In general, over the past week	None	Mild	Moderate	Severe	Very severe
11	The pain in my hand(s) has been	1	2	3	4	5

	In general, over the past week	Never	Rarely	Sometimes	Often	Always
12	How often would you say that your pain impacts on your daily routine?	1	2	3	4	5

The following questions asks about situations which may cause discomfort or pain in your hand.

	Over the past week, how much would you agree or disagree with the following statements?	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree
13	I am sensitive in my hand and do not like it to be touched	1	2	3	4	5
14	I feel discomfort or pain in cold weather or when handling cold objects	1	2	3	4	5
15	It is difficult to get a good night's sleep because of the pain in my hand/arm	1	2	3	4	5

2

Impact of Hand Nerve Disorders (I-HaND) Scale Version 1-4

Part 3: *The following questions ask about difficulty with activities that you may have experienced as a result of your nerve disorder of the hand(s). Please circle one answer for each question.*

	In general, over the past week	Very well	Well	Fairly well	Poorly	Very poorly
16	How well have you been able to carry out your daily routine e.g. Getting ready, cooking, childcare etc.	1	2	3	4	5

	Over the past week how difficult has it been for you to complete the following activities	Not at all difficult	A little difficult	Somewhat difficult	Moderately difficult	Very difficult
17	Doing up buttons	1	2	3	4	5
18	Cutting food using a knife & fork together	1	2	3	4	5
19	Cutting your nails	1	2	3	4	5
20	Washing your body	1	2	3	4	5
21	Putting toothpaste on a toothbrush	1	2	3	4	5
22	Getting dressed or undressed	1	2	3	4	5
23	Opening lids of tight jars and bottles	1	2	3	4	5
24	Pouring from a kettle	1	2	3	4	5
25	Carrying a heavy shopping bag	1	2	3	4	5
26	Wringing out a cloth	1	2	3	4	5
27	Preparing a meal	1	2	3	4	5
28	Opening & closing heavy doors	1	2	3	4	5
29	Handwriting	1	2	3	4	5
30	Turning pages of a book, magazine or newspaper	1	2	3	4	5
31	Handling small coins e.g. 5 pence or 1 pence	1	2	3	4	5
32	Using electronic devices e.g. a remote control, mobile phone, tablet or computer	1	2	3	4	5

Impact of Hand Nerve Disorders (I-HaND) Scale Version 1-4

Part 4: *The following questions ask about how your nerve disorder of the hand(s) has affected your ability to take part in your daily work (including paid work, school work or housework) and recreational tasks. Please circle one answer for each question.*

	In general, over the past week	Very well	Well	Fairly well	Poorly	Very poorly
33	How well have you been able to manage the physical demands of your daily work?	1	2	3	4	5
34	How well have you been able to take part in recreational tasks e.g. Hobbies or sport?	1	2	3	4	5

This is the end of the questionnaire, ***THANK YOU*** *very much for completing it*

4

Figure 3:9 The Impact of HaND Nerve Disorders (I-HaND) Scale version 1.4

I-HaND Scale Part 1

Questions 1, 2, 3 and 4 are global questions, which ask about overall hand function, movement, sensation and strength. The remaining questions in Part 1 are a series of statements that relate to physical and emotional difficulties associated with the disorder. Where possible, the words used by participants themselves from the concept elicitation interviews were used in framing these statements. During the early conceptualisation of the new PROM, it was envisaged there would be more focus on activity and participation, moving away from the traditional interest on impairments, which can be assessed by using objective clinical tests. However, the extent to which patients wanted to talk about their symptoms was surprising, and it became apparent that they were important to them and should be included in the PROM.

What also became evident from the interviews is that while other outcome measures may focus on the symptom level, such as sensation, how a patient performs on an objective test may not relate to how the patient perceives it. Therefore, the inclusion of items relating to impairment was considered valuable. The questions were also framed in a way that captured how patients felt about their impairments, as opposed to trying to measure the impairments directly. Before the interviews, it was not envisaged that psychological screening would be an aim of the new PROM. This perhaps stemmed from the knowledge that there are already PROMs that specifically screen for anxiety and depression, such as the Hospital Anxiety and Depression Scale (Zigmond and Snaith, 1983) or for post-traumatic stress disorder, such as the Revised Impact of Events Scale (RIES) (Weiss, 2007). From carrying out the concept elicitation interviews, however, it was clear that these issues were important for participants. This was the story that they wanted to tell and it became the lens through which activity and participation were viewed, emphasising the biopsychosocial impact of the disorder.

I-HaND Scale Part 2

Part 2 asks specifically about pain and discomfort, firstly asking patients to make a global rating of their pain and the impact that this has on their daily routine. What follows are specific situations that may cause pain or discomfort relevant to patients with nerve disorders, such as cold intolerance, interference with sleep and oversensitivity of the hand. These situations were chosen based on the prevalence and severity for participants in the concept elicitation interviews.

I-HaND Scale Part 3

Part 3 opens with a global question on the impact of the disorder on daily routine, followed by specific activities that were reported to be problematic for patients. The insights gained from the concept elicitation interviews into how participants learnt to adapt was crucial in the selection of appropriate activities. The adaptation narratives illustrated that it was bilateral activities that were particularly challenging for individuals, as participants were forced to use their affected hand. Including bilateral activities in the PROM was an effective way of capturing the impact of the disorder on patients. Specific unilateral activities that require good sensory, motor and proprioceptive ability were also included, as these activities were described as being challenging following a nerve disorder of the hand.

I-HaND Scale Part 4

The final part of the I-HaND Scale relates to participation and asks two global questions relating to work and recreation. The participation narratives, while very rich, were difficult to translate into PROM items as they were highly subjective. The key issues that were applicable across all participants were the difficulty associated with the physical demands of work and the pace of work. This was also the case with the recreational activity narratives. The main issues here were around self-consciousness, confidence and the tendency to avoid these tasks often because of the complexity of skill, co-ordination and lack of enjoyment, perhaps compared to a previous level of ability. For these reasons it was felt that more global questions would be preferable, tapping into the core areas of why people have difficulty with these tasks, which included physical demands and pace of work, and then around participation in sport and confidence in doing so.

3.6.4 Response format

When the items for the I-HaND Scale were generated, appropriate response categories were created to fit the item stems (Table 3:11). This involved deciding on the type of scaling to use for the responses, the number of categories and the labels to be used. Concerning the number of categories, Streiner et al. (2014) suggest a ‘seven, plus or minus two rule’ when determining the number of response categories that people are capable of distinguishing from. A 5-point Likert scale was chosen, with higher numbers indicating

greater impact of the disorder. Relevant descriptors were provided for particular items. There were six different response category descriptors used to accurately reflect the nature of the question that was being asked, to ensure that participants would be able to find the correct answer to match the question. A further reason for having a range of questions requiring different responses was to encourage participants to read the questionnaire fully, and not just to select the same response for all the questions.

Table 3:11 A description of the response categories used in the I-HaND Scale

Question type	Response category	Questions
Global ratings	Very well, Well, Fairly well, Poorly and Very poorly	Q 1,16,33-34
Satisfaction	Very satisfied, Somewhat satisfied, Neither satisfied nor dissatisfied, Dissatisfied, Very dissatisfied	Q 2-4
Frequency	Never, Rarely, Sometimes, Often, Always	Q 5- 10, 12
Severity	None, Mild, Moderate, Severe, Very severe	Q 11
Agreement	Strongly disagree, Disagree, Neither agree nor disagree, Agree, Strongly agree	Q 13-15
Difficulty	Not at all difficult, A little difficult, Somewhat difficult, Moderately difficult, Very difficult	Q 17-32

Global rating questions were chosen to determine how well participants felt they were performing overall. Questions to determine how satisfied participants were with certain aspects of their recovery were chosen for some questions. For symptoms such as pain, questions around intensity and severity were asked, as this is a feature of these symptoms. Patients were also asked to give levels of agreement in relation to particular items. For specific activities, participants were asked to rate how difficult they found doing these activities.

3.6.5 Time frame

The time period which patients needed to consider their response was set with the wording of items and responses, and instructions to reflect this choice. The suitability of a recall period depends on a variety of factors, including the nature of the construct, symptoms and frequency of assessment, and most importantly the target population (Norquist et al., 2012). The shortest time period is recommended; one that is too long may be associated with increased recall bias (Frost et al., 2007). A recall period of one week was therefore chosen, as this would give respondents the opportunity to carry out the activities, which make up a large number of the items in the PROM at least once, and would avoid recall bias.

3.6.6 Mode of administration

The mode of administration depends on the target participants, the construct under evaluation, the frequency of assessment and the context in which it will be used (DeVellis, 2012). Paper and pen administration was chosen for the new PROM for ease of administration, making it easy for routine clinical practice. It was designed to be self-administered to minimise the burden on the clinician, for example, allowing it to be completed before or after a treatment session. This was also to facilitate completion at home for participants, which was a feature of the design of this study in collecting follow-up data. This would widen the scope of the measure being used in research settings, where often outcome measures are collected via the post.

3.6.7 Layout and structure

The structure and formatting of the PROM are an important element which can impact on the accuracy and reliability of the data collected (Haynes et al., 1995). Poor formatting of a PROM can result in item non-response and misinterpretation, and can be a respondent and administrative burden (Mullin et al., 2000). To ensure a clear and simple layout and to maximise ease of completion for respondents, the following decisions were made:

1. Items were in a readable size of 11-point font and spread over four A4 pages with lots of white space. The PROM was presented in a folded A3 booklet for ease of use and to ensure no pages could become detached.

2. The creation of four parts to the PROM grouped together items of a similar content.
3. A light grey shading was used between alternate questions to help focus the eye and avoid item non-response.
4. Response categories followed a natural ordering, with responses on the extreme right being indicative of a higher impact of the disorder.
5. Response categories were in bold to stand out from the other text.
6. General instructions were provided at the top of the PROM providing guidance on the construct of interest, with more specific guidance at the introduction of each of the four parts, clarifying what was being measured and the relevant recall period.

3.7 Discussion

The aim of this study was to investigate the impact of a peripheral nerve disorder of the hand, from the perspective of patients and to develop a conceptual framework from which to design a new, condition-specific PROM for clinical practice and research. Concept elicitation interviews were conducted to gain insight into the experience of people with hand nerve disorders and to develop a new PROM for this population, using the ICF as a theoretical scheme. This study provided an in-depth insight into the experiences of patients with a range of nerve disorders affecting the hand. A grounded theory on learning to live with a hand nerve disorder was constructed with four distinct components: struggling, overcoming, accepting and transforming.

A feature of struggling was the experience of sensory-motor and proprioceptive impairments, pain and cold intolerance. These symptoms and impairments associated with a nerve disorder have been described by others as being important for patients and have a significant impact on quality of life (Chemnitz et al., 2013b, Jerosch-Herold et al., 2008, Khu et al., 2011, Martin, 2007). Psychological stress was also a significant feature for those with nerve trauma, with experiences described by participants similar to those reported by Chemnitz et al. (2013b) who have recommended that routine psychological screening be considered with this group. What was interesting about the present study was that patients with compression disorders were also vulnerable to psychological stress, throughout all stages of nerve recovery. As patients began to experience nerve recovery, relearning how to perform activities of daily living was stressful. Skill acquisition and relearning was an

incremental process and occurred over a long period of time. Therefore, careful monitoring of patients with both trauma and compression disorders should be considered.

The consequences of a hand nerve disorder were embedded in a greater narrative on the process of learning to adapt. Adaptation following a hand injury is not a new concept and adaptive strategies have been described by others (Chemnitz et al., 2013b, Jerosch-Herold et al., 2008, Khu et al., 2011, Martin, 2007). In particular, Martin (2007) refers to 'occupational adaptation', a model derived from occupational therapy theory. Here participation in meaningful activities or 'occupations' provides a vehicle for adaptation as well as a desire for adaptation to occur (Schkade and Schultz, 1992). Participation in meaningful activity was a key feature of the 'struggling' experience of participants in this study. It was the experience of the activity and often the mistakes made which facilitated 'overcoming'. The occupational adaptation model, however, accounts primarily for an individual's response to internal and external factors and it has been observed by others to insufficiently capture the social aspects of adaptation, which were a central motif of this study (Bontje et al., 2004).

An alternative perspective on the adaptive process with people with chronic conditions, acknowledging the social context of adaptation, is offered by Charmaz. This perspective firstly centres around the individual but also takes into account the views of significant others and the interactions between them (Charmaz, 1995). It follows three major stages: 1) the experience of illness, 2) weighing up losses and gains and the revision of goals, and 3) surrendering to the sick self by relinquishing control over illness. There are similarities in the process and the experiences of the participants in Charmaz's study with those in the present study. The most obvious difference is that the participants in her study were becoming progressively more ill and less reliant on their bodies, whereas participants in the present study were getting better as they experienced nerve recovery. The passage of time and uncertainty pertaining to functional prognosis is a shared characteristic of people with both progressive chronic conditions and those with a hand nerve disorder. The former group experiences physical and functional difficulties over a period of time requiring them to adapt. The latter group experiences the slow nature of nerve recovery over many years, and do not know how much recovery is possible. Both individuals with chronic conditions as described by Charmaz and those with hand nerve disorders learn to adapt over many times as their conditions change, either by progression of their illness (Charmaz) or functional gains from nerve recovery.

Acceptance has also been described in the literature as integral to the adaptation process following a major hand injury (Hannah, 2011). It has been suggested that acceptance occurs commonly when patients plateau in their rehabilitation and thus patients learn to live with what they have left (Bates and Mason, 2014). While the word 'acceptance' suggests an end-point, the present study offers 'accepting' as a process which is still occurring. Participants were still experiencing nerve recovery for many years and were learning to accept themselves, despite the uncertainty of further recovery. They were accepting of what they have but hopeful for further recovery. Accepting also involved recognition of a strength of character and letting go of a sense of responsibility for how an injury occurred (acute nerve injuries) or for delaying seeking treatment (chronic compression syndromes).

Adaptation following a hand nerve disorder was observed as a social process involving the individual, the family and wider social networks. This has not been explored in depth before in the qualitative literature relating to hand nerve disorders. Schier and Chan (2007) explored how acute hand injuries can affect patients in their roles as spouse, caregiver, and/or worker. They concluded that a hand injury has a profound impact on roles and relationships, which is supported by the present study for people with hand nerve disorders. This study builds on Schier and Chan's findings by suggesting that adaptation also occurs through relationships with others, and this further impacts on the individual and can help them adapt.

Grounded theory methods were chosen as they provide a structured approach to the development of a conceptual framework from which to generate items for a new PROM. The use of the ICF to guide the development of a conceptual framework of nerve disorders on activity and participation allowed for this work to be communicated in a uniform and accessible way. The use of secondary data sources, including a literature review and existing PROMs, further ensured that the items generated were both relevant and appropriate for the target population. A systematic approach to the generation of items and response categories for a new, condition-specific PROM for peripheral nerve disorders of the hand was clearly shown. Using a research-working group combining experience in clinical evaluation of peripheral nerve disorders, outcome measurement and PROM development ensured face validity of the new Impact of HaND Nerve Disorders (I-HaND) Scale.

3.7.1 Strengths and limitations

The chief investigator is an occupational therapist with clinical experience of treating hand nerve conditions. Having reviewed the literature, the researcher may potentially have been constrained during data collection and analysis by preconceived ideas about the relationships between some of the constructs. However, the choice of the constructivist grounded theory approach, acknowledges and values the interpretation of the researcher, and the intention was to provide support for and to build upon the work that had been done before.

The constructed grounded theory approach provides an explanatory theory on living with a hand nerve disorder, providing an in-depth insight into the experiences of patients with a range of nerve conditions, across the lifespan and at different stages of recovery. The primary output of this study was the first draft of a new PROM, therefore much of the focus was on understanding the impact of a hand nerve disorder. More data were generated for the first two stages of the adaptive process, 'struggling' and 'overcoming', with less data generated relating to 'accepting' and 'transforming'. Further exploratory work with these conceptual categories would provide deeper insights into this process. The social nature of adaptation should also be explored further.

Using patient photography was a novel approach that helped to enrich the data analysis. Participants were actively engaged and talked about their experiences on their own terms. Photographs were also a useful way to quickly build rapport between participant and interviewer. Participants took great care in the planning and capturing of images, and this approach arguably generated more considered responses during the interview. Only three participants chose to use visual methods, and one person did not provide copies for publication. When participants were asked why they had chosen not to take photographs, there was a general agreement that they did not know what to photograph. This may have been due to poor communication in the aims of using photography. A further reason, however, could be that the central concepts that the study identified related to adaptation and the psychological impact of the disorder. Neither concept lends itself well to being captured by photography and cannot be observed easily.

Finally, the use of the ICF as an analytic scheme helped to illuminate the interconnectedness between impairments, activities and participation for people with a nerve disorder in a patient-centred way and allowed for communication in a universal language. However, using the ICF could be viewed as hindering the generation of codes from the data and instead forcing codes into predetermined categories. To safeguard against this several steps were taken to ensure the trustworthiness of the research described in greater detail below.

3.7.2 Trustworthiness

In qualitative research quality can be judged in terms of 'trustworthiness' and can be assessed using four criteria: confirmability, dependability, credibility and transferability (Lincoln and Guba, 1999). Confirmability refers to the degree to which the results can be confirmed. In this study, an interview schedule/topic guide was developed to ensure comprehensiveness and avoid using leading questions, and a reflexive diary was kept. Data collection and analysis was conducted in a systematic manner until saturation occurred, evidencing that data interpretations were grounded in actual patient data to avoid researcher bias that could be introduced with familiarisation with the qualitative literature. Illustrative quotations were also used throughout and patients' actual words were used to generate items for the first draft of the PROM.

The aims and objectives of this study were clearly stated (3.2.1), and grounded theory methodology was carefully chosen to not only explore the impact of hand nerve disorders, but also to provide a systematic and endorsed approach to generating items for a new PROM. The primary supervisor read all the interview transcripts independently and coded a random sample of 20%. This provides evidence that the study has been carefully conducted and that results are dependable.

The credibility criteria involve establishing that the results are credible or believable from the participants' perspective. This was insured by conducting cognitive interviews with the same participants in the next phase of this study (Chapter 4) to evaluate the relevance of the content of the new PROM. Interviews were carried out until participants no longer found any issues with the content of the developing PROM.

To enhance transferability, a thorough description of the research context and the assumptions that were central to the research was provided. This allows those in other contexts and settings to determine how transferable the study findings are for them. Participants were carefully recruited, ensuring maximum variation in diagnosis as well as sociodemographic factors such as age, sex and occupation. The constructed grounded theory was contextualised in a greater narrative on adaptation, and the wider clinical implications of the research findings were also fully discussed.

3.8 Conclusions

This qualitative study has provided in-depth insights into the experiences of individuals living with a peripheral nerve disorder affecting their hand, and in particular, how this impacts on activity and participation. This is a valuable contribution to knowledge, as there are few qualitative studies that report on this experience. The issues identified from the qualitative study provide a rich source for the development of the content of new PROM for this population, ensuring that it is appropriate with the right emphasis on issues that are important for this group. The use of the ICF to guide the development of a conceptual framework, having clear criteria for the content and then drafting the content of the new PROM in line with these, further enhances its appropriateness and suitability for patients with a peripheral nerve disorder affecting their hand.

Chapter 4 - Development of the Impact of HaND Nerve Disorders (I-HaND) Scale: Content validation

"Qualitative data are necessary for establishing content validity. While quantitative data (factor analysis, Rasch analysis, item response theory) can be supportive, they are insufficient without qualitative data" (Patrick et al., 2011a).

4.1 Overview

In the previous chapter a new PROM for hand nerve disorders was developed. Chapter 4 reports the methods and results of a mixed-methods study used to validate the content of the I-HaND Scale. Firstly, cognitive interviews were conducted to ensure that the I-HaND was clear, understood and relevant to people with hand nerve disorders. This was followed by a principal components analysis (PCA) to examine structural aspects of its content, before formal psychometric evaluation.

4.2 Introduction

During the first phase of this research, a condition-specific PROM for people with hand nerve disorders was conceptualised and developed. Patients themselves were involved in the item-generation process, increasing the likelihood that the content of the new scale was relevant for this population (Rothman et al., 2007). To ensure clinical relevance, a working group of experts were involved in the development process. This structured and methodical process provided evidence of face validity of the new measure (Mullin et al., 2000). The aim of this chapter was to evaluate and improve the content and structural validity of the I-HaND Scale. The central importance of content validity has been highlighted in previous chapters. This stage of PROM development is important because it provides patients with the opportunity to provide feedback and for changes to be made to the measure based on this (Jobe, 2003). This is often referred to as 'pre-testing' a new PROM before the full validation of the scale with a larger sample.

Cognitive interviews, also referred to as a 'cognitive debrief', were conducted to clarify the most important concepts of the PROM for patients and to ensure that participants understood how to complete it (Watt et al., 2008). Participants can be polite and willing to complete questionnaires; despite at times, not fully understanding what is being asked of them. They may misinterpret questions without even realising it, and thus it is important to check for these misunderstandings (Collins, 2003). This allows for revisions to be made to improve the content of the developing PROM (Sireci, 1998).

Quantitative research methods were used to evaluate the structural elements of the scale, as part of a 'quantitative debrief' (PCORI, 2012). It is important that the items in the scale fit with a single underlying construct, and classical test theory methods can be used to evaluate this (Nunnally et al., 1967). This is important for the scoring of the PROM to ensure that the measurement obtained is meaningful (De Vet et al., 2011). Using statistical methods allows for the identification of poorly fitting items and consideration of their removal (Pesudovs et al., 2007). This ensures that the PROM is acceptable for both patients and clinicians.

4.3 Aims and objectives

Aims

This study aimed to evaluate the content of the I-HaND Scale and to explore the conceptual relevance for patients with a nerve disorder. It also sought to evaluate the appropriateness of the layout, timeframe, response options, framing of items and the administration of the scale. A further aim was to evaluate whether the items of the I-HaND scale fit with a single underlying construct.

Objectives

1. To pre-test the I-HaND Scale through a series of cognitive interviews.
2. To revise as necessary, the I-HaND Scale, based on the findings of the cognitive interviews.
3. To pre-test the I-HaND Scale on a larger sample of patients and perform a principal components analysis (PCA) and tests of internal consistency.

4. To revise as necessary, the I-HaND Scale, based on the findings of the PCA and tests of internal consistency.

4.4 Methodology

This cross-sectional, observational study (administration of a PROM on one occasion) used mixed research methods to evaluate and improve upon the content and structural validity of the I-HaND Scale. In the context of PROM development, the function of cognitive interviewing is to evaluate the degree to which a PROM measures the construct that it intends to, an aspect of content validity (Leidy and Vernon, 2008). The questions, response options and timeframe must therefore not only be conceptually relevant and meaningful for the patient, but also in a format that is understandable and appropriate (Patrick et al., 2011b). Cognitive interviews have their origins in the theory of cognitive science (Ericsson and Simon, 1980). The thoughts or 'cognitions' of the participant, when completing the questionnaire, are of interest to the researcher. Participants are taught how to 'think aloud', either in the present moment or retrospectively (Campanelli, 1997). The findings can provide insight into whether the PROM makes sense to the user and may inform improvements, such as the rephrasing of questions and the addition or removal of items. This type of cognitive debriefing is desirable to determine respondent understanding when developing a new PROM (Castillo-Díaz and Padilla, 2013).

Quantitative methods were used to examine the structural components of the PROM's content (De Vet et al., 2011). The distribution of the item scores can inform whether all the response options are useful. If response categories are frequently not selected by participants, this can indicate ceiling or flooring effects and may justify removal of that item. Missing responses can occur for a variety of reasons, such as participants not knowing the answer or not wishing to give an answer, and can also indicate that an item is not relevant (Pesudovs et al., 2007).

Evaluation of the unidimensionality of the scale is important as this affects how a total score is calculated. PCA can be used to examine the unidimensionality of the scale (Segars, 1997). It does this by clustering items that correlate with each other into different components, which make up the overall construct. This may highlight a single component

or multiple components (De Vet et al., 2005). This method can be useful to identify items that do not have a clear contribution to a component. Inter-item correlations can be examined to explore the relationship between the individual items with the overall scale (Streiner et al., 2014). Cronbach's alpha can be used to evaluate internal consistency. A high Cronbach alpha, e.g. 0.9, is desirable for clinical scales. However, an alpha closer to 1.0 may indicate some redundancy and warrant removal of items (Portney and Watkins, 2000).

4.5 Methods

4.5.1 Phase 2a: 'A cognitive debrief'

Semi-structured, face-to-face cognitive interviews were used to collect the data. An interview schedule/topic guide (appendix 4.1) was used, based on methods described by Gordon Willis (2005). As Willis points out, there is no right or wrong way to approach cognitive interviews, but he warns of the pitfalls of adapting a generic probing approach to each question, or indeed probing every question. Instead, each question should be probed according to the potential issues with that question, and over-probing must be avoided to prevent over-interpretation. Willis suggests being conservative with the number of probes, and to target them around either comprehension, retrieval, decision-making, judgment or response processes. A three-step approach to carrying out the cognitive interviews was taken in this study. Firstly, participants were asked to complete the I-HaND Scale and the time taken was recorded. Next, they were asked to retrospectively share thoughts that they had while completing the I-HaND Scale, i.e. 'think aloud' comments. Finally, participants were asked specific questions that could be an issue for them, i.e. 'verbal probing'. Full ethical approval for all three phases of the HaND Study was previously granted (see 3.4.1).

4.5.2 Recruitment procedure

The study took place in a secondary care setting between August 2015 and September 2015. The eligibility criteria were the same as for the qualitative study in Chapter 3 (see 3.4.3). The participants recruited in phase 1 also consented to being contacted again to participate in later stages of the study. All the participants were therefore sent a participant information pack in the post, which provided more detailed information regarding the purpose of this phase of the study and what was required of them (appendix 4.2).

Participants who were interested in joining the study self-consented by signing an enclosed consent form and posting this back to the chief investigator. Participants had their interviews either at UEA or in their own homes. All personal data were held in strict compliance with the UEA Research and Enterprise Services policies and Information Governance legislation.

4.5.3 Sample

In common with conventional qualitative interviews, sample sizes were not calculated beforehand and are variable; the sample size is reached when the data saturates. This occurs in cognitive interviews when participants cease to find any issues with the content of the developing PROM. Willis (2005) reports that between seven and ten participants are usually sufficient to determine respondent understanding. It was anticipated that recruiting from the 14 participants from phase 1 would therefore provide an adequate sample size.

4.5.4 Data collection and analysis

The cognitive interviews were recorded using a digital audio recorder. Field notes were also taken, to account for any observations and to add depth to what had been said, such as non-verbal cues. The interviews were transcribed and findings documented using item tracking on an electronic version of the I-HaND Scale, an example of which is provided in appendix 4.3. Item tracking was necessary, as data are collected and analysed simultaneously and tracking provides an audit trail of the changes to the scale (Patrick et al., 2011b).

Willis (2005) describes a variety of approaches to analysing the results of cognitive interviews, which include using written notes, listening to the audio recordings and using clinical judgement. This study combined all three methods to improve trustworthiness. An electronic tracking document of the I-HaND Scale was created for each interview. Here, relevant content was highlighted and participant quotes and researcher comments were added. This was guided by the content of the interview transcriptions and field notes, which identified possible problems with comprehension and item content for respondents. A table was created for each interview, summarising the relevant content area, and the meaning or

difficulty that participants may have had as evidenced by their responses. A discussion and suggestions for changes to items or actions to be taken were also documented (appendix 4.4). Consideration of changes to the I-HaND Scale was based on the conceptual and clinical relevance of the items. When no issues with the measure were identified from the interviews, changes were agreed by the working group before another round of interviews commenced. This process would continue until no new or significant changes were being suggested by participants or when the data saturated.

4.5.5 Phase 2b: 'A quantitative de-brief'

Pre-testing studies require the involvement of a larger heterogeneous group of patients that represent the full range of the target population in terms of demographic and clinical characteristics (Fayers and Machin, 2013). Phase 2b followed a cross-sectional design where respondents completed the version 1.8 of the I-HaND scale on a single occasion. A larger sample of patients ($n \geq 50$) was targeted, representing a range of hand nerve disorder diagnoses.

4.5.6 Recruitment procedure

Participants were recruited between September 2015 and January 2016 at three NHS trusts: the Norfolk and Norwich University NHS Foundation Trust, the Royal National Orthopaedic Hospital NHS Trust, London and the University Hospital Birmingham NHS Foundation Trust. Potential participants who met the entry criteria (see 3.4.3) were identified by local collaborators within each centre (appendix 4.5). Patients currently receiving treatment for their nerve disorder were invited to join the study during a treatment session. Patients who had been discharged within the last two years were invited by post. Those eligible were provided with a participant information pack which gave detailed information regarding the purpose of the study and what was required of them (appendix 4.6). Those interested in taking part self-consented by signing an enclosed consent form and posting this back to the chief investigator.

4.5.7 Sample

Sample sizes were selected based on the requirements of the statistical methods that were used. To evaluate the adequacy of sample sizes used in psychometric measurement studies, the COSMIN (COnsensus-based Standards for the selection of health Measurement Instruments) rate a sample of ≥100 as excellent; 50-99 as good; 30-49 as moderate and <30 as small (Terwee et al., 2012). Considering these guidelines, this study aimed to recruit a minimum of 50 participants. This would be rated as a 'good' sample size for the evaluation of internal consistency.

Studies that report on sample sizes needed for PCA suggest either a minimum sample size or a minimum ratio of sample size to the number of variables. There is variation, however, in how this is interpreted in the published literature (MacCallum et al., 1999). COSMIN suggest five to seven times the number of items and ≥100, to achieve adequate stability and recovery of population factors (Terwee et al., 2012). A different perspective on sample sizes has been suggested by MacCallum et al. (1999). They suggest that the required sample size is dependent on several aspects, including amongst other things the communality of the variables. It was not feasible to try and recruit 175 to 245 participants, based on the ratio requirement suggested by Terwee et al. (2012) due to the known difficulty in recruiting patients with a nerve disorder and within the time available in the study. A pragmatic decision was made, therefore, to use PCA to highlight items but that this method would not be used solely to remove items. This would be complemented by clinical judgment and the conceptual relevance of items for patients.

4.5.8 Data collection and analysis

The I-HaND Scale version 1.8 and a clinical record form were used to collect the data (appendix 4.2). All data were entered into a database and the IBM SPSS Statistics Software Package version 22 was used to complete the analyses. The data were initially explored through descriptive analysis of each variable, calculating measures of central tendency (mean), variability (SD) and frequency counts for ordinal and categorical variables. Inter-item correlations, range of scores, homogeneity of items, and distribution of the data and the presence of outliers were also explored. The latent structure of the scale was evaluated

using an un-rotated PCA. The internal consistency of the scale was examined using Cronbach's alpha.

4.6 Results

4.6.1 Phase 2a: Sociodemographic characteristics of participants

Eleven participants took part in the cognitive interviews, six men and five women (Table 4:1). The age of participants ranged from 25 to 75 years with a mean age of 58 years. Five of the participants had injured their dominant hand. There was roughly an equal number of traumatic (n = 6) and compression (n = 5) type nerve disorders, with a range of diagnoses. All the participants who had sustained traumatic injuries also acquired concomitant soft tissue or bone injuries. For individuals with non-traumatic compressive disorders who had undergone surgery the mean time between first experiencing symptoms and having surgery was 23 months. For those who had undergone nerve surgery, the time since surgery ranged from seven months to over 10 years with a mean time of four years. Four of the participants were in paid employment, one was unemployed, four retired and two others were working in a voluntary capacity. Almost half of the participants had experienced a change in their work status as a direct result of their condition.

4.6.2 Main findings of phase 2a

Patients provided overall endorsement of the I-HaND Scale during the cognitive interviews. They reported finding it relatively easy to understand and to complete, more so in fact compared to other outcome measures which they had been asked to complete at hospital. Patients became animated when talking about the relevance of the content with some participants remarking that it was as if the items had been made personally for them. Examples of illustrative quotations from patients for the overall endorsement, content, response categories, instructions, layout and time required to complete the I-HaND Scale are provided in Table 4:2. Three rounds of cognitive interviews took place, with revisions made to the I-HaND Scale after each round. Four items were revised in the first round of interviews, one item in the second and no items in the third and final round. One item was added and no items were removed. The rest of the changes related to instructions,

response categories and layout. The development of the content of the items for each round of interviews is presented in Table 4:3. The changes to the wording of items before and after the cognitive interviews are presented in Table 4:4.

Table 4:1 A summary of the characteristics of phase 2a study sample

Participant*	Age (years)	Sex	Condition	Duration of symptoms/time since surgery (months)	Hand affected	Type of surgery	Occupational status
Peter	60	M	Median nerve injury	46/46	D	NR	Metal inspector
Claire	63	F	Median nerve injury	35/35	N/D	NR	Volunteer
Ray	75	M	Ulnar nerve injury	59/59	N/D	NR	Semi-retired stone mason
Gary	25	M	Ulnar nerve injury	36/36	N/D	NR	Unemployed labourer
Richard	66	M	Ulnar nerve injury	17/17	N/D	NR	Retired farmer
Tracey	26	F	Ulnar nerve injury	31/31	D	NG	Sales associate
Jeanette	62	F	Radial nerve injury	77/77	D	DN	Hairdresser
Pat	58	M	Radial nerve injury	50/0	D	N/A	Building manager
Joy	71	F	Carpal tunnel syndrome	119/119	D	DN	Carer
Matthew	59	M	Cubital tunnel syndrome	58/49	N/D	DN, TN	Retired lorry driver
Pam	72	F	Carpal tunnel syndrome and cubital tunnel syndrome	71/33	N/D	DN	Retired secretary

M = male; F = female D = dominant hand; N/D = non-dominant hand; B = bilateral; NR = end to end repair; NG = nerve graft; DN = decompression; TN = transposition of ulnar nerve; N/A = not applicable *Pseudonyms have been used

Decisions concerning the changes to be made were agreed by the working group at the end of each round. A detailed account of the decision-making process, which led to the changes, is provided in appendix 4.4. The evolution of each version of the I-HaND Scale (versions 1.5, 1.6, 1.7) is presented in appendix 4.7. A decision was made to stop the interviews after 11 participants, as no further issues with the content were being reported.

The creation of version 1.8 of the I-HaND Scale, a 35-item PROM, concluded the qualitative element of the study (Figure 4:1).

Table 4:2 Examples of illustrative quotations from patients for the overall endorsement, content, response categories, instructions, layout and time required to complete the I-HaND Scale

Patient endorsement categories	Examples of illustrative quotations from patients
Overall endorsement	"It's simple to use, it's simple to understand, I don't really think it needs changing".
	"It's nicely set out, it's easy to read, it's easy to mark and it covers everything that should have been asked".
	"I didn't have any trouble answering the questions".
	"I didn't have to think twice about any of the questions".
	"I think it is more simple and straight forward than the majority of questionnaires you get at the hospital".
	"You would think that it was made for me to be honest".
	"Everything in there was what actually occurred and what I have been through".
Content	"One question I like in particular was the question about emotions".
	"Nobody asks about that and you do feel these emotions because you have lost part of you, lost part of the use of you, so you get very frustrated".
	"It seems to cover everything that affects me".
	"As I said it is more or less designed for me that one".
	"It covers everything that should be asked or should have been asked".
	"It's very impressive, I like the way it is all everyday tasks that are being asked about".
Response categories	"I thought it was really good, especially the range of answers. You've got five choices as opposed to three and you can really pin it down".
	"I think it is well thought out; the range of answers".
Instructions	"The instructions are self-explanatory".
	"It was pretty easy to follow, it was good".
Layout	"The layout is lovely, it is fine, I can't pick any holes in it really".
	"The print is a decent size which makes a change for us old people".
	"I like how you have greyed out every other line to make it easier to follow across".
Time frame	"It isn't that long; I've had a lot longer ones to complete".
	"It's quite short really".

Table 4:3 Development of the content of the items of the I-HaND Scale with changes made highlighted in red

Item	Item at pre-test	Round 1	Round 2	Round 3
1	How well did your hand(s) work?	No change	No change	Retained
2	The movement of your hand(s)	No change	No change	Retained
3	The sense of touch in your hand(s)	No change	No change	Retained
4	The strength in your hand(s)	No change	No change	Retained
5	I can't grip or pinch for very long without my hand getting tired	No change	No change	Retained
6	When I touch certain things it causes pins and needles or tingling	No change	No change	Retained
7	I have hurt my hand and not realised it until later	No change	No change	Retained
8	When I go to grab something it just falls out of my hand	**Revised**	No change	Retained
9	Using my hand(s) can bring about strong emotions e.g. frustration, anger, sadness	No change	No change	Retained
10	I feel self-conscious if people look at my hand/arm	No change	No change	Retained
11	The pain in my hand(s) has been (…)	No change	No change	Retained
12	How often would you say that your pain impacts on your daily routine?	No change	No change	Retained
13	I am sensitive in my hand and do not like it to be touched	**Revised**	No change	Retained
14	I feel discomfort or pain in cold weather or when handling cold objects	**Revised**	No change	Retained
15	It is difficult to get a good night's sleep because of the pain in my hand/arm	No change	**Revised**	Retained
16	How well have you been able to carry out your daily routine, e.g. getting ready, cooking, childcare etc.	No change	No change	Retained
17	Doing up buttons	No change	No change	Retained
18	Cutting food using a knife & fork together	No change	No change	Retained
19	Cutting your nails	No change	No change	Retained
20	Washing your body	No change	No change	Retained
21	Putting toothpaste on a toothbrush	No change	No change	Retained
22	Getting dressed or undressed	No change	No change	Retained
23	Opening lids of tight jars and bottles	No change	No change	Retained
24	Pouring from a kettle	No change	No change	Retained
25	Carrying a heavy shopping bag	No change	No change	Retained
26	Wringing out a cloth	No change	No change	Retained
27	Preparing a meal	No change	No change	Retained
28	Opening & closing heavy doors	No change	No change	Retained
29	Handwriting	No change	No change	Retained
30	Turning pages of a book, magazine or newspaper	No change	No change	Retained
31	Handling small coins e.g. 5 pence or 1 pence	No change	No change	Retained
32	Using electronic devices e.g. a remote control, mobile phone, tablet or computer	No change	No change	Retained
33	How well have you been able to manage the physical demands of your daily work?	No change	No change	Retained
34	How well have you been able to take part in recreational tasks, e.g. hobbies or sport?	**Revised**	No change	Retained
35	Driving a car			**Added**

Table 4:4 Development of the content leading to the I-HaND Scale version 1.8 with changes made highlighted in red

I-HaND Scale Version 1.4	I-HaND Scale Version 1.8
How well did your hand(s) work?	How well did your hand(s) work?
The movement of your hand(s)	The movement of your hand(s)
The sense of touch in your hand(s)	The sense of touch in your hand(s)
I can't grip or pinch for very long without my hand getting tired	I can't grip or pinch for very long without my hand getting tired
I feel self-conscious if people look at my hand/arm	I feel self-conscious if people look at my hand/arm
When I touch certain things it feels like pins and needles or tingling	When I touch certain things it causes pins and needles or tingling
Using my hand(s) can bring about strong emotions e.g. frustration, anger, sadness	Using my hand(s) can bring about strong emotions e.g. frustration, anger, sadness
I have hurt my hand and not realised it until later	I have hurt my hand and not realised it until later
When I go to grab something it just falls out of my hand	**When I go to pick something up it falls out of my hand**
The pain in my hand(s) has been (…)	**The pain or discomfort in my hand(s) has been**
How often would you say that your pain impacts on your daily routine?	**How often would you say that your pain or discomfort impacts on your daily routine?**
I am very sensitive in my hand and do not like it to be touched	**My hand feels over sensitive when touched**
I feel discomfort or pain in cold weather or when handling cold objects	**I feel pain or discomfort when my hand is cold**
It is difficult to get a good night's sleep because of the pain in my hand/arm	**It is difficult to get a good night's sleep because of the pain or discomfort in my hand/arm**
How well have you been able to carry out your daily routine, e.g. getting ready, cooking, childcare etc.	How well have you been able to carry out your daily routine e.g. Getting ready, cooking, childcare etc.
Doing up buttons	Doing up buttons
Cutting food using a knife & fork together	Cutting food using a knife & fork together
Cutting your nails	Cutting your nails
Washing your body	Washing your body
Putting toothpaste on a toothbrush	Putting toothpaste on a toothbrush
Getting dressed or undressed	Getting dressed or undressed
Opening lids of tight jars and bottles	Opening lids of tight jars and bottles
Pouring from a kettle	Pouring from a kettle
Carrying a heavy shopping bag	Carrying a heavy shopping bag
Wringing out a cloth	Wringing out a cloth
Preparing a meal	Preparing a meal
Opening & closing heavy doors	Opening & closing heavy doors
Handwriting	Handwriting
Turning pages of a book, magazine or newspaper	Turning pages of a book, magazine or newspaper
Handling small coins e.g. 5 pence or 1 pence	Handling small coins e.g. 5 pence or 1 pence
Using electronic devices e.g. a remote control, mobile phone, tablet or computer	Using electronic devices e.g. a remote control, mobile phone, tablet or computer
How well have you been able to manage the physical demands of your work?	How well have you been able to manage the physical demands of your daily work?
How well have you been able to take part in recreational tasks, e.g. hobbies, Sport or playing an instrument?	**How well have you been able to take part in recreational activities e.g. hobbies or sport?**

Impact of Hand Nerve Disorders (I-HaND) Scale Version 1-8

Instructions:

This questionnaire asks you to rate the impact that your nerve disorder has on you.

Please answer EVERY question by CIRCLING the answer that is most relevant for you.

Some of the questions ask about your ability to complete certain activities, if you have not had the opportunity to carry out these activities please try and estimate how you might have done so.

Part 1: The following questions ask about any symptoms that you may have experienced as a result of your nerve disorder of the hand(s). Please circle one answer for each question.

	In *general*, over the past *week*	Very well	Well	Fairly well	Poorly	Very poorly
1	How well did your hand(s) work?	1	2	3	4	5

	Over the past *week*, how *satisfied* are you with the following?	Very satisfied	Somewhat satisfied	Neither satisfied nor dissatisfied	Dissatisfied	Very dissatisfied
2	The movement of your hand(s)	1	2	3	4	5
3	The sense of touch in your hand(s)	1	2	3	4	5
4	The strength in your hand(s)	1	2	3	4	5

The following statements relate to physical difficulties experienced by people with a nerve disorder affecting their hand(s).

	Please indicate how *often* you have experienced the following in the past *week*	Never	Rarely	Sometimes	Often	Always
5	I can't grip or pinch for very long without my hand getting tired	1	2	3	4	5
6	When I touch certain things it causes pins and needles or tingling	1	2	3	4	5
7	When I go to pick something up it falls out of my hand	1	2	3	4	5

1

Impact of **H**and **N**erve **D**isorders (I-HaND) Scale Version 1-8

The following statements relate to feelings sometimes experienced by people with a nerve disorder affecting their hand(s).

	Please indicate how *often* you have experienced the following in the past *week*	Never	Rarely	Sometimes	Often	Always
8	Using my hand(s) can bring about strong emotions e.g. frustration, anger, sadness	1	2	3	4	5
9	I feel self-conscious if people look at my hand/arm	1	2	3	4	5

Part 2: The following questions ask about any pain or discomfort that you may have experienced as a result of your nerve disorder of the hand(s). Please circle one answer for each question.

	In *general*, over the past *week*	None	Mild	Moderate	Severe	Very severe
10	The pain or discomfort in my hand(s) has been	1	2	3	4	5

	In *general*, over the past *week*	Never	Rarely	Sometimes	Often	Always
11	How often would you say that your pain or discomfort impacts on your daily routine?	1	2	3	4	5

The following questions asks about situations which may cause pain or discomfort in your hand.

	Please indicate how *often* you have experienced the following in the past *week*	Never	Rarely	Sometimes	Often	Always
12	I have hurt my hand and not realised it until later	1	2	3	4	5
13	My hand feels over sensitive when touched	1	2	3	4	5
14	I feel pain or discomfort when my hand is cold	1	2	3	4	5
15	It is difficult to get a good night's sleep because of the pain or discomfort in my hand/arm	1	2	3	4	5

2

Impact of Hand Nerve Disorders (I-HaND) Scale Version 1-8

Part 3: The following questions ask about difficulty with activities that you may have experienced as a result of your nerve disorder of the hand(s). Please circle one answer for each question.

	In *general*, over the past *week*	Very well	Well	Fairly well	Poorly	Very poorly
16	How well have you been able to carry out your daily routine e.g. Getting ready, cooking, childcare etc.	1	2	3	4	5

	Over the past *week* how *difficult* has it been for you to complete the following activities	Not at all difficult	A little difficult	Moderately difficult	Very difficult	Unable
17	Washing your body	1	2	3	4	5
18	Getting dressed or undressed	1	2	3	4	5
19	Doing up buttons	1	2	3	4	5
20	Putting toothpaste on a toothbrush	1	2	3	4	5
21	Cutting your nails	1	2	3	4	5
22	Cutting food using a knife & fork together	1	2	3	4	5

	Over the past *week* how *difficult* has it been for you to complete the following activities	Not at all difficult	A little difficult	Moderately difficult	Very difficult	Unable
23	Opening lids of tight jars and bottles	1	2	3	4	5
24	Pouring from a kettle	1	2	3	4	5
25	Wringing out a cloth	1	2	3	4	5
26	Preparing a meal	1	2	3	4	5
27	Opening & closing heavy doors	1	2	3	4	5

3

Impact of Hand Nerve Disorders (I-HaND) Scale Version 1-8

	Over the past *week* how *difficult* has it been for you to complete the following activities	Not at all difficult	A little difficult	Moderately difficult	Very difficult	Unable
28	Handwriting	1	2	3	4	5
29	Turning pages of a book, magazine or newspaper	1	2	3	4	5
30	Using electronic devices e.g. a remote control, mobile phone, tablet or computer	1	2	3	4	5

	Over the past *week* how *difficult* has it been for you to complete the following activities	Not at all difficult	A little difficult	Moderately difficult	Very difficult	Unable
31	Carrying a heavy shopping bag	1	2	3	4	5
32	Handling small coins e.g. 5 pence or 1 pence	1	2	3	4	5
33	Driving a car	1	2	3	4	5

Part 4: The following questions ask about how your nerve disorder of the hand(s) has affected your ability to take part in your daily work (including paid work, school work or housework) and recreational activities. Please circle one answer for each question.

	In *general*, over the past *week*	Very well	Well	Fairly well	Poorly	Very poorly
34	How well have you been able to manage the physical demands of your daily work?	1	2	3	4	5
35	How well have you been able to take part in recreational activities e.g. Hobbies or sport?	1	2	3	4	5

You have now reached the end of the questionnaire

Please check that you have answered all of the questions

THANK YOU for your time

4

Figure 4:1 I-HaND Scale version 1.8

4.6.3 Phase 2b: Sociodemographic characteristics of participants

In phase 2b, 50 participants were recruited from three centres: the Norfolk & Norwich NHS Foundation Trust, the Royal National Orthopaedic NHS Trust and University Hospitals Birmingham NHS Foundation Trust. A summary of the characteristics of the sample is provided in Table 4:5. Roughly equal numbers of men (54%) and women (46%) were recruited. Participants' ages ranged from 18 to 88, with a mean age of 55. The full spectrum of nerve disorders was represented within the sample, with the highest diagnosis represented being carpal tunnel syndrome. Forty-two percent of participants had concomitant tendon or bone injuries. Most participants had undergone surgery (84%), with half of them having decompression surgery; the remaining half had undergone end-to-end repair (22%), neurolysis (8%), exploration (2%) or tendon transfer (2%). Participants had experienced symptoms for a mean time of 39 months, and the mean time for those that had surgery was 15 months. Most of the participants lived with another person (84%) with around a third having responsibility for caring for others. The majority of participants either were in paid employment (48%) or retired (30%). The remaining participants were either long-term sick (14%), unemployed (6%) or studying (2%). A quarter of the participants had experienced a change in their work status because of their nerve disorder.

4.6.4 Main findings of phase 2b

<u>Distribution of item responses</u>

The 50 participants had a mean I-HaND total score of 87.21 (SD = 39.73); 95% CI (74.83, 99.59). All the items demonstrated a normal distribution, with skewness and kurtosis values being close to zero. The distribution of the responses for individual items is reported in appendix 4.8. For all the items, each of the different options within a response category was used. Missing data was low, at 0.5 %, missing items included questions Q2, Q3, Q4, Q14, Q28, Q33, and Q34. The largest amount of missing data came from Q33: *Driving a car,* with this item being left out three times (6%) and each of the other missing items only occurring once. There were no significant ceiling effects observed (Figure 4:2). However, floor effects were observed with items *Q12: I have hurt my hand and not realised it until later; Q17: Washing your body; Q20: Putting toothpaste on a toothbrush; Q24: Pouring from a kettle; Q33: Driving a car,* with greater than 50% of respondents selecting the lowest category for these questions.

Table 4:5 A summary of the characteristics of the phase 2b study sample

Characteristics	**(N = 50)**
No. (%) of men:	27 (54%)
Mean age (range) in years:	55 (18 to 88)
No. (%) of acute or chronic nerve compression disorders:	23 (46%)
Carpal tunnel syndrome:	20 (40%)
Cubital tunnel syndrome:	1 (2%)
Radial nerve palsy:	14 (24%)
No. (%) of acute nerve injuries:	27 (54%)
Median nerve injury:	7 (14%)
Ulnar nerve injury:	7 (14%)
Involvement of more than one nerve (acute or chronic):	3 (6%)
No. (%) with a concomitant injury:	21 (42%)
No. (%) who had surgery:	42 (84%)
Mean duration of symptoms (range) in months:	39 (2 to 367)
Mean time since surgery (range) in months:	15 (1 to 88)
No. (%) of people with dominant hand affected:	22 (44%)
No. (%) living alone:	8 (16%)
No. (%) caring for others:	17 (34%)
No. (%) working:	42 (51%)
Employee:	21 (42%)
Retired:	15 (30%)
Self-employed:	3 (6%)
Long-term sick:	7 (14%)
Student:	1 (1%)
Unemployed:	3 (6%)
No (%) with a change in work status:	13 (26%)

Internal consistency

The internal consistency of the I-HaND Scale was examined using Cronbach's alpha. It is generally accepted that an alpha of greater than 0.7 is satisfactory (Huck and Cormier, 1996). The alpha for the I-HaND Scale was 0.98, demonstrating excellent internal consistency (DeVellis, 2012). Very high alphas can also indicate potential redundancy (Streiner et al., 2014). A known limitation of Cronbach's alpha is that it is dependent on the number of items: the larger number of items, the higher the alpha. Therefore, to explore this further, item-total and inter-item correlations were examined to highlight potential redundant items (Eisen et al., 1979).

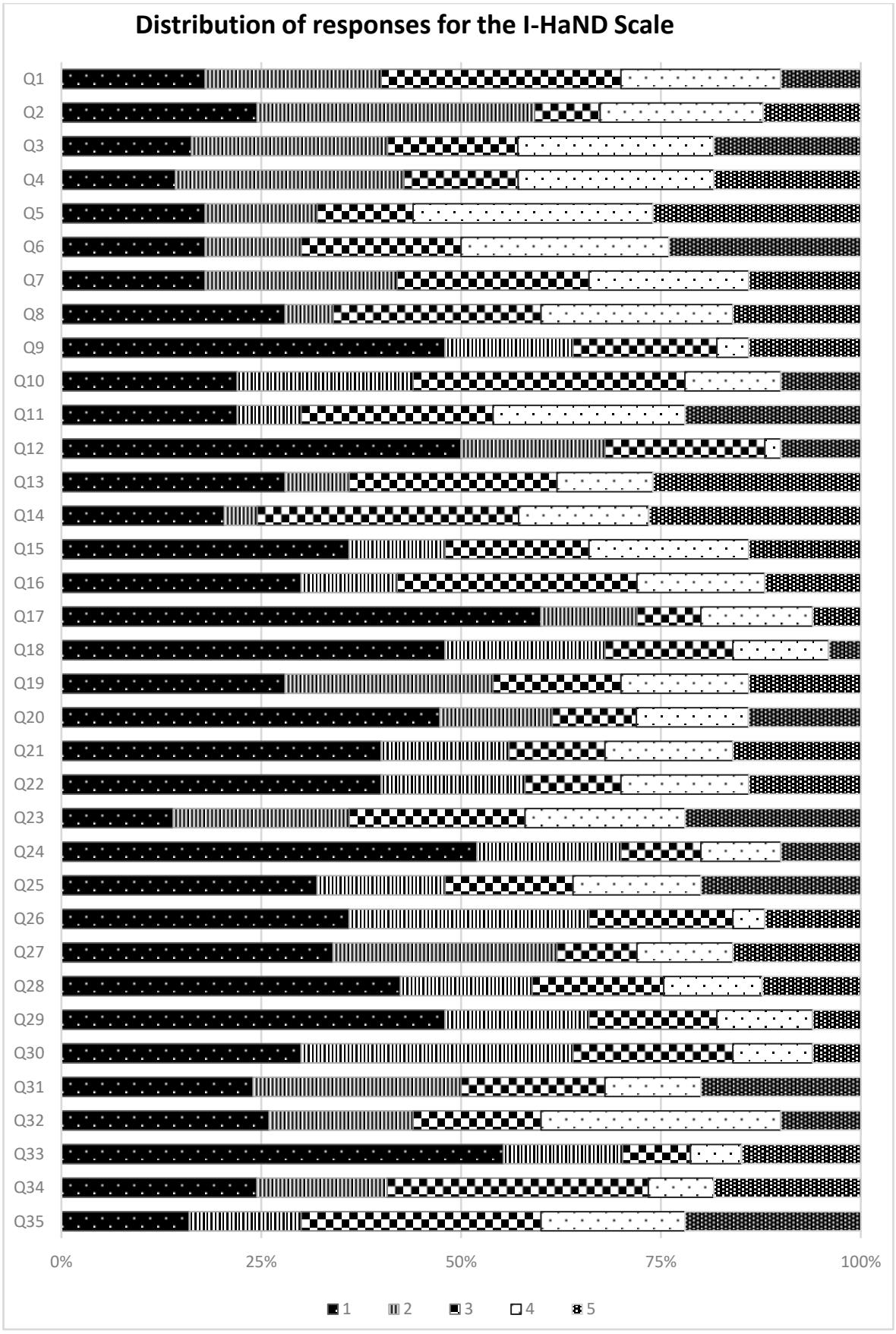


Figure 4:2 Distribution of individual items of the I-HaND Scale

Item-total and inter-item correlations

Item-total correlations were all high, ranging from 0.66 to 0.94. Item-total correlations were >0.9 for five items (Q1, Q16, Q18, Q25, Q26), which could indicate item redundancy. Correlations between the individual items on the I-HaND Scale ranged from 0.35 to 0.94 (appendix 4.9). Three of the items had correlations >0.9 with other items (Table 4:6) further indicating possible redundancy. This overlapping of items can indicate consideration for their removal from the scale, as it indicates that they are potentially measuring the same thing (Pesudovs et al., 2007).

Table 4:6 Inter-item correlations of items on the I-HaND Scale of at least 0.9

Item	Related item	Correlation
Q1: How well did your hand(s) work?	Q2: The movement of your hand(s)	0.90
Q18 - Getting dressed or undressed	Q17 - Washing your body	0.92
	Q26 - Preparing a meal	0.94
Q25 - Wringing out a cloth	Q27 - Opening & closing heavy doors	0.91
	Q26 - Preparing a meal	0.90

Principal components analysis

Following the correlation analysis, a PCA was carried out on the I-HaND Scale to explore its dimension structure. PCA is appropriate to identify underlying domains (components) of instruments (Fayers and Machin, 2000). From the 50 participants, 84% (42) of cases were included as the analysis was based on cases with no missing values. Given the small sample size, the appropriateness of using PCA was explored using the Kaiser-Meyer-Olkin (KMO) (Kaiser, 1974) and Bartlett's test of sphericity (Bartlett, 1954). The KMO was 0.8, much higher than the recommended >0.6 threshold and the Bartlett's test was also significant, below the 5% level (Kaiser and Rice, 1974). Components were identified with eigenvalues ≥ 1.00 following Kaiser's criterion rule (Kaiser, 1960). The PCA of the I-HaND Scale revealed a clear unidimensional structure. There were four components with eigenvalues ≥ 1.00 (Table 4:7). However, most of the variance (71.89%) was explained by the first factor, much higher than the minimum recommended 50% value for a stable factor solution (Streiner et al., 2014). The remaining three components were much closer to the Kaiser's criterion cut-off point.

Table 4:7 Principal components analysis of the I-HaND Scale version 1.8

Component	Initial eigenvalues		
	Total	% of variance	Cumulative %
1	25.16	71.89	71.89
2	1.61	4.60	76.49
3	1.32	3.77	80.26
4	1.03	2.93	83.20
5	0.70	2.00	85.19

Cattell's scree plot

Cattell's scree plot (Cattell, 1966) was drawn for the I-HaND Scale (Figure 4:3). The scree plot shows a sharp drop (the point of inflexion) after the first component and then the line becomes more level. The remaining factors explain a very small proportion of the variability and are likely to be unimportant.

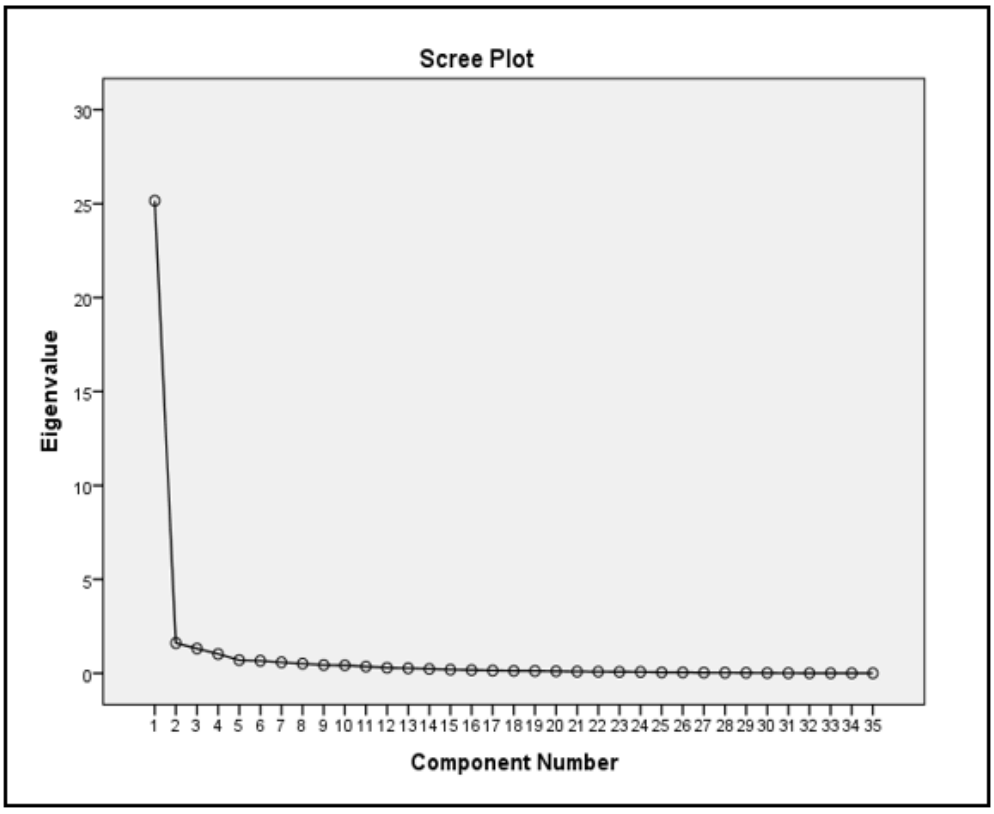


Figure 4:3 Scree plot to show the variance in the components of the I-HaND Scale version 1.8

The component matrix of the I-HaND Scale

The component matrix of the I-HaND Scale presented in Table 4:8 displays each item having a positive loading of >0.6 on the first component which explained 71.90% of the total variance. Communalities for each item were also high, and ranged from 0.65 to 0.94 (mean 0.8), further confirming that each item shared a common variance with other items in the scale.

Table 4:8 Component matrix of the I-HaND Scale version 1.8 ordered from the highest to lowest loading on the 1st component.

	Component			
	1	2	3	4
Q18	0.94	-0.23	0.01	0.07
Q26	0.94	-0.23	-0.09	-0.01
Q25	0.93	-0.04	0.05	-0.05
Q16	0.92	0.04	-0.14	-0.06
Q1	0.91	0.05	-0.21	-0.07
Q27	0.90	-0.18	-0.09	-0.13
Q2	0.90	0.06	-0.25	0.05
Q34	0.89	0.10	-0.08	0.00
Q21	0.88	-0.07	0.23	0.10
Q10	0.88	0.16	-0.21	-0.12
Q7	0.88	-0.01	0.25	0.05
Q23	0.88	0.00	0.03	-0.16
Q22	0.87	-0.20	0.05	0.01
Q20	0.87	-0.26	0.23	0.05
Q24	0.87	-0.31	-0.08	-0.08
Q35	0.87	0.25	0.03	0.03
Q17	0.87	-0.35	0.10	0.02
Q30	0.87	-0.26	0.19	0.09
Q31	0.87	-0.04	-0.18	-0.18
Q4	0.86	0.13	-0.25	-0.15
Q11	0.86	0.35	0.02	-0.11
Q19	0.86	-0.18	0.08	0.00
Q32	0.85	0.05	0.25	0.12
Q28	0.84	-0.04	0.20	0.03
Q15	0.81	0.16	-0.25	-0.22
Q12	0.81	-0.01	-0.26	0.32
Q29	0.80	-0.36	0.16	0.07
Q13	0.79	0.23	0.43	0.07
Q14	0.78	0.33	0.14	0.19
Q33	0.78	-0.26	-0.36	-0.16
Q3	0.77	0.22	-0.11	-0.05
Q6	0.77	0.30	0.29	-0.23
Q5	0.73	0.41	0.20	-0.30
Q9	0.68	0.17	-0.24	0.53
Q8	0.68	0.29	-0.14	0.45

4.7 Item revision leading to the I-HaND Scale Version 2

The working group met to review all of the findings of phase 2b. Poorly fitting items that were identified from the statistical analysis were discussed in terms of their conceptual importance, as previously identified from the concept elicitation interviews, as well as their clinical relevance as determined by the experience of the working group. This triangulated approach was the basis for considering whether items should be removed, leading to the final version of the I-HaND Scale. This led to the decision to remove three items: Q17: *Washing your body*; Q33: *Driving a car* and Q28: *Handwriting* (Table 4:9). The rationale for the removal of the items is provided.

The distribution of item responses identified items having flooring effects (Figure 4:2). This included items Q12: *I have hurt my hand and not realised it until later*; Q17: *Washing your body;* Q20: *Putting toothpaste on a toothbrush;* Q24: *Pouring from a kettle;* Q33: *Driving a car*. For each item (≥ 50%) of respondents selected the lowest category, and this included participants who had been discharged for up to two years. These patients would naturally find some of the activities easier, being further along the rehabilitation process. The items related to self-care and driving, both of which were identified in the concept elicitation interviews as activities that participants learned to become independent with quickly, out of necessity. A further point is that PROMs need to be able to capture different levels of ability, so the fact that some items are easy for some people but not for others is actually desirable and a further reason not to delete items based on flooring effects alone.

The driving item (Q33) was the most frequently missed. Participants frequently had written notes beside this question to say that they did not drive. This highlighted a problem with this question and consideration was given to whether an extra response category should be added or a 'not applicable' box. It was felt that this may have been confusing for participants, as the general instructions of the I-HaND Scale asks participants to imagine how they think they may have performed in an activity, even if they had not had the opportunity to do so. A similar problem occurred with Q28: *Handwriting*. Participants also made written comments that their writing hand was not affected. In this instance participants should have given a 'no difficulty' response, but did not. These issues were not previously identified by participants in the cognitive interviews as being problematic. However, it could

be seen as a potential source of confusion or irritation. It was decided that both Q33 and Q28 should be removed.

Table 4:9 Summary of item-revision process, with changes highlighted in red

Items with poor fit	Reason for selection	Decision
Q1: How well did your hand(s) work?	≥ 0.9 item-total correlation	Retained
	≥ 0.9 inter-item correlation	
Q2: The movement of your hand(s)	≥ 0.9 inter-item correlation	Retained
Q12: I have hurt my hand and not realised it until later	≥ 50% no. 1 responses (floor effect)	Retained
Q16: How well have you been able to carry out your daily routine e.g. Getting ready, cooking, childcare etc.	≥ 0.9 item-total correlation	Retained
Q17: Washing your body	≥ 50% no. 1 responses (floor effect)	**Removed**
	≥ 0.9 inter-item correlation	
Q20: Putting toothpaste on a toothbrush	≥ 50% no. 1 responses (floor effect)	Retained
Q24: Pouring from a kettle	≥ 50% no. 1 responses (floor effect)	Retained
Q33: Driving a car	≥ 50% no. 1 responses (floor effect)	**Removed**
	≥ 5% missing item	
	Written comments from participants	
Q28: Handwriting	Written comments from participants	**Removed**
Q18: Getting dressed or undressed	≥ 50% no. 1 responses (floor effect)	Retained
	≥ 0.9 inter-item correlation	
Q26: Preparing a meal	≥ 0.9 inter-item correlation	Retained
	≥ 0.9 item-total correlation	
Q25: Wringing out a cloth	≥ 0.9 inter-item correlation	Retained
	≥ 0.9 item-total correlation	
Q27: Opening & closing heavy doors	≥ 0.9 inter-item correlation	Retained

The inter-item correlation analysis identified three items which correlated strongly with other items and as this can be a sign of some overlap in what the items are measuring. *Q1: How well did your hand(s) work?* and *Q2: The movement of your hand(s)* correlated strongly. Q1 is a global question relating to overall hand function and Q2, asks about range of movement, as a component of this (as are Q3 and Q4 which ask about strength and sensation). It is not surprising that these items correlate strongly and it was felt that each item provided clinically meaningful information to justify keeping them.

In addition, Q18: *Getting dressed or undressed* correlated strongly with Q17: *Washing your body* and Q26: *Preparing a meal*. Conceptually Q18 and Q17 were very similar as both measure personal care. On review of the activity items in part 3 of the scale, it was noticed that there were six questions relating to personal care but fewer questions relating to other aspects of activities of daily living such as domestic activities. It was agreed that one of these personal care items could be removed. As Q17 had previously been flagged up as having a floor effect this item was chosen for removal. As Q26: *Preparing a meal* was both conceptually very different from Q18: *Getting dressed or undressed* and clinically very relevant, it was decided that this item would be kept.

A strong correlation was also found between Q25: *Wringing out a cloth*; Q27: *Opening & closing heavy doors and* Q26*: Preparing a meal*. Both Q25 and Q27 are measures of strength and are therefore similar. However, they relate to two different aspects of strength. Q25 measures bilateral grip, whereas Q27 measures more general upper limb strength. These different aspects of strength were considered to be different and clinically relevant items, and therefore a decision was made to keep them both in the scale. Q26: *Preparing a meal* was highlighted again and a possible explanation for this is that it is like Q1: it is a global question relating to domestic activities. Preparing a meal requires the interplay of many different aspects of functional capability, and this could explain why this item is correlating strongly with other items which measure components of activity relating to domestic life. The conceptual and clinical value of this item led to a decision for it to be retained in the measure.

The item-total correlation analysis highlighted five items which were >0.9. The conceptual and clinical value of four of these items have been discussed above in the inter-item correlation analysis (Q1, Q18, Q25, Q26). The remaining item (Q16), asks how well

participants have been able to carry out their daily routine. This item is similar to Q26: *Preparing a meal*, as it is also a global question. The value of understanding how patients execute a series of activities, which make up part of their daily routine, was considered valuable and the item was retained.

The statistical analysis was run again with the three items removed, to ensure that their removal would not have any detrimental effects on the scale. On this occasion, the I-HaND Scale showed a higher KMO of 0.9. There were no new item-total or inter-item correlations ≥ 0.9. The PCA revealed three components with eigenvalues ≥ 1.00, which together explained 79% of the variance, with most of the variance (70 %) was explained by the first component, with the remaining two components being much closer to the Kaiser's criterion cut-off point. This supported the presence of a unidimensional scale. It resulted in the final version of the I-HaND Scale, version 2.0, ready for further evaluation of its psychometric properties in phase 3.

Impact of Hand Nerve Disorders (I-HaND) Scale Version 2.0

Participant Identification Number:	Baseline / Follow-up 1 / Follow-up 2

Instructions:

This questionnaire asks you to rate the impact that your nerve disorder has on you.

Please answer EVERY question by CIRCLING the answer that is most relevant for you.

Some of the questions ask about your ability to complete certain activities, if you have not had the opportunity to carry out these activities please try and estimate how you might have done so.

Part 1: The following questions ask about any symptoms that you may have experienced as a result of your nerve disorder of the hand(s). Please circle one answer for each question.

	In *general*, over the past *week*	Very well	Well	Fairly well	Poorly	Very poorly
1	How well did your hand(s) work?	1	2	3	4	5

	Over the past *week*, how *satisfied* are you with the following?	Very satisfied	Somewhat satisfied	Neither satisfied nor dissatisfied	Dissatisfied	Very dissatisfied
2	The movement of your hand(s)	1	2	3	4	5
3	The sense of touch in your hand(s)	1	2	3	4	5
4	The strength in your hand(s)	1	2	3	4	5

The following statements relate to physical difficulties experienced by people with a nerve disorder affecting their hand(s).

	Please indicate how *often* you have experienced the following in the past *week*	Never	Rarely	Sometimes	Often	Always
5	I can't grip or pinch for very long without my hand getting tired	1	2	3	4	5
6	When I touch certain things it causes pins and needles or tingling	1	2	3	4	5
7	When I go to pick something up it falls out of my hand	1	2	3	4	5

1

Impact of Hand Nerve Disorders (I-HaND) Scale Version 2.0

The following statements relate to feelings sometimes experienced by people with a nerve disorder affecting their hand(s).

	Please indicate how *often* you have experienced the following in the past *week*	Never	Rarely	Sometimes	Often	Always
8	Using my hand(s) can bring about strong emotions e.g. frustration, anger, sadness	1	2	3	4	5
9	I feel self-conscious if people look at my hand/arm	1	2	3	4	5

Part 2: The following questions ask about any pain or discomfort that you may have experienced as a result of your nerve disorder of the hand(s). Please circle one answer for each question.

	In *general*, over the past *week*	None	Mild	Moderate	Severe	Very severe
10	The pain or discomfort in my hand(s) has been	1	2	3	4	5

	In *general*, over the past *week*	Never	Rarely	Sometimes	Often	Always
11	How often would you say that your pain or discomfort impacts on your daily routine?	1	2	3	4	5

The following questions asks about situations which may cause pain or discomfort in your hand.

	Please indicate how *often* you have experienced the following in the past *week*	Never	Rarely	Sometimes	Often	Always
12	I have hurt my hand and not realised it until later	1	2	3	4	5
13	My hand feels over sensitive when touched	1	2	3	4	5
14	I feel pain or discomfort when my hand is cold	1	2	3	4	5
15	It is difficult to get a good night's sleep because of the pain or discomfort in my hand/arm	1	2	3	4	5

2

Impact of **Hand Nerve Disorders** (I-HaND) Scale Version 2.0

Part 3: The following questions ask about difficulty with activities that you may have experienced as a result of your nerve disorder of the hand(s). Please circle one answer for each question.

	In *general*, over the past *week*	Very well	Well	Fairly well	Poorly	Very poorly
16	How well have you been able to carry out your daily routine e.g. Getting ready, cooking, childcare etc.	1	2	3	4	5

	Over the past *week* how *difficult* has it been for you to complete the following activities	Not at all difficult	A little difficult	Moderately difficult	Very difficult	Unable
17	Getting dressed or undressed	1	2	3	4	5
18	Doing up buttons	1	2	3	4	5
19	Putting toothpaste on a toothbrush	1	2	3	4	5
20	Cutting your nails	1	2	3	4	5
21	Cutting food using a knife & fork together	1	2	3	4	5

	Over the past *week* how *difficult* has it been for you to complete the following activities	Not at all difficult	A little difficult	Moderately difficult	Very difficult	Unable
22	Opening lids of tight jars and bottles	1	2	3	4	5
23	Pouring from a kettle	1	2	3	4	5
24	Wringing out a cloth	1	2	3	4	5
25	Preparing a meal	1	2	3	4	5
26	Opening & closing heavy doors	1	2	3	4	5

3

Impact of **H**and **N**erve **D**isorders (I-HaND) Scale Version 2.0

	Over the past *week* how *difficult* has it been for you to complete the following activities	Not at all difficult	A little difficult	Moderately difficult	Very difficult	Unable
27	Turning pages of a book, magazine or newspaper	1	2	3	4	5
28	Using electronic devices e.g. a remote control, mobile phone, tablet or computer	1	2	3	4	5

	Over the past *week* how *difficult* has it been for you to complete the following activities	Not at all difficult	A little difficult	Moderately difficult	Very difficult	Unable
29	Carrying a heavy shopping bag	1	2	3	4	5
30	Handling small coins e.g. 5 pence or 1 pence	1	2	3	4	5

Part 4: The following questions ask about how your nerve disorder of the hand(s) has affected your ability to take part in your daily work (including paid work, school work or housework) and recreational activities. Please circle one answer for each question.

	In *general*, over the past *week*	Very well	Well	Fairly well	Poorly	Very poorly
31	How well have you been able to manage the physical demands of your daily work?	1	2	3	4	5
32	How well have you been able to take part in recreational activities e.g. Hobbies or sport?	1	2	3	4	5

PLEASE PROVIDE THE DATE THAT YOU COMPLETED THE I-HAND SCALE HERE: / / 2016

You have now reached the end of the questionnaire

Please check that you have answered all of the questions

THANK YOU for your time

For office use:

4

Figure 4:4 I-HaND Scale version 2.0

4.8 Discussion

The objectives of this study were to evaluate and improve the content validity as established by and for patients and to ensure that the scale was measuring a single construct, and thus whether it was appropriate to derive a summed score. Obtaining good content validity is an important part of the development of new PROMs and can increase the probability of obtaining high construct validity (Haynes et al., 1995). The mixed-methods study design met with methodological standards for content validation, and was effective for highlighting problems with items and questionnaire design early in the development process, and for guiding changes to the layout and content. (FDA, 2009, PCORI, 2012). This crucial stage of PROM development helped to ensure that the items that had been developed were meaningful for the target population. The process also led to a deeper understanding of the construct being measured.

In phase 2a, cognitive interviewing identified problems with content and design, such as items that required rewording, instructions and response options, layout and missing items. In the first round of interviews, four items were revised; one item in the second round and no items in the third round. Overall, only one item was added and no items were removed. The rest of the changes related to instructions, response categories and layout. These relatively minor changes to the items further support the conceptual framework, which was reported in Chapter 3. Carrying out three rounds of interviews until no new issues were emerging from the interviews helped improve the trustworthiness of the findings (Christodoulou et al., 2008).

In phase 2b, the PCA supported a unidimensional structure, with 70% of the variance being explained by the first component (Cattell, 1966). Cronbach's alpha was also high, indicating excellent internal consistency of the scale items. Thirteen items were identified as fitting poorly from a statistical perspective, and after considering the conceptual and clinical relevance of the items, three were removed. In the final analysis, with these items removed, no new issues were identified.

4.8.1 Limitations

The high internal consistency of the I-HaND Scale may have indicated it had too many items. However, a conservative approach was taken in removing only three items. While there is a current trend towards producing shorter versions of PROMs in hand rehabilitation, this can be at the expense of patient and clinical relevance. The time required to complete the I-HaND is relatively short, with participants taking between three and seven minutes, which would be considered a minimal burden. Having a longer PROM that is specific for patients with a nerve disorder was considered not only desirable but preferable, to gather a rich source of information that would both inform and guide the direction of rehabilitation. Patients in this study also reported that completing a measure that was meaningful for them made them feel understood and had a positive effect. One participant remarked: *'Everything in there was what actually occurred and what I have been through'* and another participant said: *'You would think that that was made for me, to be honest'.* A further consideration for not removing items based on statistics alone is that the sample size in this study was smaller than has been recommended for performing a PCA. The factor structure of the I-HaND could also have been explored using Rasch methods. However, this also requires a larger sample size. In phase 3 further exploratory work on the structure of the I-HaND using both classical test theory and Rasch analysis methods was carried out and is reported in Chapter 5.

4.9 Conclusion

A mixed-methods approach was used to evaluate and improve the content validity of the I-HaND Scale. Eleven participants from the target population participated in three rounds of cognitive interviews before the data saturated. In response to findings, changes were made to the I-HaND Scale during each round of interviews, leading to versions 1.5, 1.6, 1.7 and 1.8. In addition to changes to the instructions, layout and response categories, four items were revised and one was added. No items were removed. Version 1.8 of the I-HaND was pre-tested on a larger sample (n = 50) of participants in phase 2b to evaluate the more structural components of its content. This approach highlighted 13 poorly fitting items, from which three were removed. This decision was based on the conceptual importance and clinical relevance of the items. This resulted in the final version of the I-HaND Scale version 2.0, a 32-item unidimensional scale with evidence of sound content validity as determined by importance to patients, clinical relevance and excellent internal consistency (Cronbach's

α = 0.98). This final version of the I-HaND Scale was deemed ready for further validation work to evaluate how valid, reliable and responsive the new measure was in the third and final phase of the research.

Chapter 5 - Validation of the Impact of HaND Nerve Disorders (I-HaND) Scale: Evaluation of psychometric properties

"Scales and questionnaires are an integral part of clinical practice and research. However, they are not all created equally. To be useful, instruments must demonstrate good psychometric properties" (Keszei et al., 2010).

5.1 Overview

In the first phase of this study, a new PROM for people with peripheral nerve disorders of the hand was conceptualised and developed (Chapter 3). In the second phase, the 32-item I-HaND Scale was finalised, following a rigorous content validation and item refinement process (chapter 4). Chapter 5 presents the methods and results of the third and final phase. A longitudinal, repeated-measures study was undertaken to evaluate how valid, reliable and responsive the I-HaND Scale is, and how interpretable its scores are.

5.2 Introduction

This chapter is concerned with the evaluation of construct validity, reproducibility and the responsiveness of the scale. Reproducibility is a key aspect of the measurement process, as it affects other measurement properties, e.g. poor reliability may obscure correlations with other measures in the assessment of convergent validity (Fayers and Machin, 2013). Although a delineation is made among different types of validity (face, content, structural, construct, and criterion validity), a unified perspective of validity that considers all forms of validity is provided under the umbrella term of construct validity (Mokkink et al., 2010a).

To complement the traditional classical test theory (CTT) methods used in scale development and validation, more modern psychometric methods were used based on Rasch measurement theory, to examine the structural validity of the scale (Rasch, 1960, Yen, 1979). It was also possible using Rasch model analysis to examine whether 1) the I-

HaND Scale meets the criteria for interval-level measurement, 2) response options work properly, 3) items are independent of each other and 4) if respondent characteristics, such as hand dominance, influence responses. Using Rasch analysis, therefore, provided an opportunity to explore the structure of the I-HaND Scale in different ways beyond those available using CTT methodology.

In the absence of a 'gold standard' measure, a requirement for criterion validation, hypothesis testing was used to evaluate construct validity (De Vet et al., 2011). This tests the extent to which theoretically derived hypotheses relating to the construct being measured and provides evidence of construct validity. Hypotheses about expected relationships with a comparator, which assesses a related construct or expected differences between known groups of patients, can also provide evidence of construct validity (Terwee et al., 2012).

When a patient is expected to change on the construct to be measured, an instrument needs to be able to detect this (Nunnally and Bernstein, 1994). Responsiveness can also be thought of as longitudinal validity, the difference being that it refers to the validity of a change score (based on two measurements), as opposed to the validity of a single score (based on one measurement). Evaluation of responsiveness, therefore, can be carried out in a similar way to construct validity, by empirically testing hypotheses relating to the construct (De Vet et al., 2011). Establishing that a PROM can produce reliable and valid scores and that it is responsive is not in itself sufficient. It is also necessary that scores can be interpreted (Terwee et al., 2007)

5.2.1 Aims and objectives

Aims

This study aimed to evaluate the reliability, construct validity and responsiveness of the I-HaND Scale using classical test theory methods. A further aim was to assess how the I-HaND fits the Rasch model and to identify potential sources of misfit.

Objectives (classical test theory)

1. To re-evaluate the structural validity of the I-HaND Scale with a combined sample size from phases 2 and 3.
2. To quantify test-retest reliability of the individual items and the overall score of the I-HaND Scale.
3. To test hypotheses relating to scores produced by the I-HaND scale and other measures of disability (convergent validity).
4. To test hypotheses relating to scores produced by the I-HaND scale in a group of patients where there is a known difference (known-groups validity).
5. To test hypotheses relating to change scores produced by the I-HaND Scale in a group where change was expected (responsiveness).
6. To test hypotheses relating to the sensitivity of the I-HaND Scale at detecting change with a population who have self-reported to have either improved, or not improved (responsiveness).
7. To compare the responsiveness of the I-HaND Scale with an existing PROM, measuring a related construct.

Objectives (Rasch method)

1. To evaluate the degree to which observed scores, produced by the I-HaND Scale, fit with expected scores using the Rasch model.
2. To examine the unidimensionality of the I-HaND scale.
3. To examine the ordering of response categories.
4. To examine whether items are independent of each other.
5. To examine the ability of the I-HaND scale to discriminate between groups.
6. To explore the influence that other patient factors, e.g. sex, age, diagnosis, side affected may have on responses.

5.3 Methodology

Classical test theory (CTT) is a traditional psychometric approach for the development of rating scales, using total scores for their analysis (Streiner et al., 2014). CTT comprises a set of principles and related statistical techniques for the development of rating scales and for evaluating reliability and validity (DeVellis, 2006). Measures developed using CTT often use a summated Likert -type rating scale to provide an ordinal level total-score, which does

not approximate interval level measurement (Tennant et al., 2004). A more modern approach for the development of rating scales is provided by the Rasch method. Rasch offers a mathematical model for converting ordinal scale measurements of individual test items into interval level scaling (Wright, 1977). This addresses a concern raised about the validity of using rating scales as outcome measures by ensuring that numbers produced equate to 'measurements' in the scientific sense of the word (Cano and Hobart, 2011). True measurement has been defined as "the quantitative comparison between two magnitudes of the same type, one of which is a standard unit, and in which the comparison is expressed as a numerical ratio" (Hobart and Cano, 2008). This requirement is necessary if the intention is to use rating scales as primary or secondary outcome measures in clinical studies.

Rasch quantifies the interaction between a person's ability and the scale's individual item difficulty. From the Rasch measurement theory perspective, when data do not fit the model they are further examined to understand why (e.g. the response category is not working as intended). This enables the Rasch method to be used as a 'diagnostic' tool for evaluating rating scales (Rasch, 1960). A limitation of the method is that it requires specialist training and software. It is often regarded as complicated and requires advanced mathematical knowledge; consequently, it is not as widely used by clinicians or researchers as it could be (Hobart and Cano, 2009).

Traditional psychometric methods were used to develop the I-HaND Scale, as described in earlier chapters. It was not feasible to use Rasch in the earlier stages due to the software and training limitations mentioned above. In addition, the sample size for the pre-testing study in phase 2 was not large enough to perform a Rasch analysis (Chen et al., 2014). The opportunity to use Rasch became possible, however, in phase 3 of the study, where it was used in a diagnostic capacity to identify sources of misfit with the Rasch model. It was beyond the scope of the research to use Rasch methods to find solutions to the misfit. Instead, Rasch informed a wider discourse on the psychometric properties of the I-HaND Scale and provided insights into the direction of future validation work.

5.4 Methods

A prospective, longitudinal study design was used. A heterogeneous group of patients, actively receiving treatment for their nerve condition, was assessed. At baseline, participants completed the I-HaND Scale, a comparator (Quick DASH) and a global status measure (NHF). A clinical record form collected clinical and demographic information. Participants completed the questionnaires in the hand therapy department or at home. The baseline data were used to evaluate construct validity. At the first follow-up (7 to 14 days), participants completed the I-HaND Scale a second time. This timeframe was chosen as nerve recovery would not be likely and it was sufficiently long enough to minimise recall bias. These data were used to evaluate the reproducibility of the I-HaND scale. At the second follow-up (12 weeks from baseline), participants completed a global change measure (GROC), as well as the I-HaND Scale, the Quick DASH and the NHF. A 12-week follow-up period was chosen, as a proportion of patients would likely have experienced a change in their condition, which is required when evaluating responsiveness (Nunnally and Bernstein, 1994). Table 5:1 illustrates which measures participants completed at each stage of the study. Further information on each outcome measure is provided below (5.4.1).

Table 5:1 A visual representation of the outcome measures completed at baseline and follow-up

	I-HaND Scale	Comparator (Quick DASH)	Global status measure (NHF)	Global change measure (GROC)
Baseline (Day 0)	✓	✓	✓	
Follow-up 1 (7 to 14 days)	✓			
Follow-up 2 (12 weeks)	✓	✓	✓	✓

5.4.1 Outcome measures

The I-HaND Scale was the primary outcome measure, its development and pretesting have been described in earlier chapters, and it is included in the appendix with the other outcome measures used in this phase (appendix 5.1). The Quick DASH was used as a comparator

measure and comprises an 11-item scale, measuring symptoms and disability for people with a range of musculoskeletal conditions of the arm, shoulder and hand. The measurement properties of the Quick DASH were reported in Chapter 2. A global status measure was used to obtain an estimation of function: the percentage of normal hand function (NHF) score. Participants were asked the following question:

> *"A normal hand is one which is pain-free, with a full range of movement, normal strength, dexterity and sensation, and allows you to do what you feel your hand, if normal, should allow you to do. A normal hand is scored as 100 per cent, while a completely useless hand is scored as 0 percent. Overall, where would you rate your hand between 0 and 100 per cent, at this present time?"*

This question was modified from the Stanmore Percentage of Normal Shoulder Assessment (SPONSA), a validated, single-item PROM which asks about shoulder function (Noorani et al., 2012). It was modified by relating the question to the hand instead of the shoulder. A global change measure was also used, the global rating of change (GROC) score, at the second follow-up. Using the GROC, participants were required to rate on a three-point Likert scale whether they felt their condition had improved, stayed the same or worsened since first completing the I-HaND Scale at baseline. A clinical record form asked patients questions about their sociodemographic status and clinicians about the patients' peripheral nerve diagnoses and their surgical history.

5.4.2 Recruitment procedure

The study took place in a secondary care setting between February 2016 and November 2016. Participants were recruited from eight NHS Trusts within the United Kingdom (Table 5:2). Potential participants that met the entry criteria (see 3.4.3) were identified by local collaborators within each centre. Patients were also required to be receiving usual care for their hand nerve condition. Local collaborators provided eligible patients with a brief overview of the study and an information pack, which they were to take home and read before making a decision about joining (appendix 5.2). Patients who wished to participate self-consented by signing a consent form and mailing this, along with the completed study materials, directly to the chief investigator.

5.4.3 Sample

For CTT analyses, the aim was to recruit between 50 and 100 participants. This number was derived following the same rationale as described in Chapter 4 (4.5.7). For the Rasch analysis, the requirement of larger sample sizes (>250 subjects) has been reported to ensure stable and robust estimates of item parameters (Linacre, 2002). Chen et al. (2014) demonstrated in their study that more stable estimates are observed in samples of 100 or more, and that smaller samples should be exploratory only. For the Rasch analysis, a minimum of 100 participants was sought. A pragmatic decision was made to also use data from 50 participants recruited from phase 2b (Chapter 4) to produce a larger sample size.

Table 5:2 NHS Trusts involved in the recruitment of patients for the HaND Study

No	Centre*	Description
1	Norfolk and Norwich University Hospitals NHS Foundation Trust	Regional centre for hand surgery and rehabilitation
2	Royal National Orthopaedic Hospital NHS Trust	Tertiary centre for the treatment of complex peripheral nerve disorders
3	University Hospital Birmingham NHS Foundation Trust	Tertiary centre for peripheral nerve disorders
4	Royal Free London NHS Foundation Trust	Regional centre for hand surgery and rehabilitation
5	St George's University Hospitals NHS Foundation Trust	Regional centre for hand surgery and rehabilitation
6	Chelsea and Westminster Hospital NHS Foundation Trust	Regional centre for hand surgery and rehabilitation
7	Bart's Health NHS Trust	Regional centre for hand surgery and rehabilitation
8	University Hospital of South Manchester	Regional centre for hand surgery and rehabilitation

*Research and development approval was obtained for each trust to become a Patient Identification Centre (PIC) (appendix 5.3).

5.4.4 Data collection and analysis

The I-HaND Scale version 2.0 and the other outcome measures discussed above (5.4.1) were used to collect the data (appendix 5.1). All data were entered into a database and the IBM SPSS Statistics Software Package version 22 was used to complete the analyses. Dr Christina Jerosch-Herold performed the Rasch analysis, using RUMM2030 software.

Raw I-HaND Scale scores (32 to 160) were used for the construct (structural) validity and the test-retest reliability analyses. For the construct (hypothesis testing) validity and responsiveness analyses, where a comparator measure was used, the raw total scores produced by the I-HaND Scale were averaged, producing a score out of five. This value was then transformed to a score out of 100 by subtracting one and multiplying by 25, the higher the score indicating greater disability. The I-HaND score = [(sum of n responses÷ number of responses)-1] x 25, where n is equal to the number of completed responses. At least 29 of the 32 items must have been completed for a score to be calculated. See appendix 5.4 for conversion of raw total scores into percentages. This method was chosen to make it easier to compare with the Quick DASH, which also has a score range of 0 to 100 and uses this scoring algorithm. This measure also allows a score to be generated if less than 10 % of the items are missing.

Construct (structural) validity using classical test theory

Baseline data were initially explored through descriptive analysis of each variable, calculating measures of central tendency (mean), variability (SD) and frequency counts for ordinal and categorical variables. Inter-item correlations, range of scores, homogeneity of items, and distribution of the data and the presence of outliers were also explored. The latent structure of the scale was evaluated using principal components analysis. The internal consistency of the scale was examined using Cronbach's alpha. Unidimensionality was also examined using the Rasch method (see Rasch analysis below).

Construct (structural) validity using the Rasch method

The Rasch analysis was performed using methods for analysing a polytomous scale (Andrich, 1978). A total item-trait chi-square statistic was used to examine the overall fit between the observed I-HaND scores and the expected scores under the Rasch model. A significant p-value (5%) would indicate misfit. Two steps were required to confirm unidimensionality. First, a PCA of the residuals was used to examine how items load onto the components. Using Smith's (2002) method, an independent t-test on the two sub-sets of items, which load positively and negatively (>0.3) on the first component, was performed. If less than 5% of t-tests are significant below 0.05, the scale is deemed to be unidimensional (Smith Jr, 2002). Reliability was examined using the person-separation index (PSI). A PSI of 0.7 or greater is deemed acceptable (Fisher, 1992). Targeting

between item difficulty and person ability was explored visually by a person-item threshold map. Individual item and person fit were assessed by examining fit residuals (± 2.5) and level of significance. Bonferroni corrections were applied by adjusting the p-value divided by number of items (Bland and Altman, 1995, Tennant and Conaghan, 2007). The sources of potential misfit (response thresholds, item dependency and response bias) were also explored.

Construct (hypothesis testing) validity

Pearson's correlation coefficients were used to assess *a priori* hypotheses relating to the relationship between the scores of the I-HaND Scale, Quick DASH and the NHF Score (Portney and Watkins, 2000). It was hypothesised that I-HaND scores would have a positive, moderately strong correlation ($r > 0.60$) with the Quick DASH and a negative, moderately strong correlation ($r > -0.60$) with NHF. A negative correlation was predicted as better function equates a higher NHF score, whereas the Quick DASH and I-HaND scoring indicates higher disability with higher scores. An independent sample t-test was used to compare the means of patients with compression and traumatic hand nerve disorders to determine whether there was statistical evidence that the means were significantly different (Rao and Sinharay, 2006). It was hypothesised that the traumatic group would have greater disability, as evidenced by a higher mean, and that this would be statistically significant at the 5% level.

Reliability (test-retest)

Data from the first follow-up was used to evaluate the reproducibility of the I-HaND scores. Test-retest reliability between total scores from the first (baseline) and second (follow-up) assessments was quantified using Intra Class Correlation (ICC) coefficients using a two-way mixed effects model for average measures, where a value of 1.0 equates perfect reliability (Shrout and Fleiss, 1979).

Responsiveness to change

Data from the second follow-up were used to assess the ability of the I-HaND Scale to detect change, when change was known to have occurred. The magnitude of observed change in the I-HaND scores from baseline to follow-up was calculated using the effect sizes (ES) and standardised response mean (SRM). Effect size is the mean change

between baseline and follow-up scores, divided by the standard deviation of the baseline score (Kazis et al., 1989). Standardised response mean is the mean change between baseline and follow-up score divided by the standard deviation of the change score (Liang et al., 1990). A larger effect size or standardised response mean indicates a higher degree of internal responsiveness. This is based on Cohen's criteria on the interpretation of effect sizes, where 0.2 is small, 0.5 is moderate and 0.8 is large (Cohen, 1988).

The GROC and NHF were used as external anchors to dichotomise the sample into improvers and non-improvers, and effect sizes and standardised response means were generated for each group to determine whether the I-HaND Scale is capable of discriminating between these two groups. Effect sizes and the standardised response mean were also calculated for the Quick DASH to determine which measure was more responsive relative to each other. Pearson's r correlation coefficients were used to analyse the direction and strength of a linear relationship between the I-HaND and Quick DASH change scores.

Receiver operating characteristic (ROC) curves were used to plot sensitivity values (true positives) on the y-axis and 1-specificity values (false positives) on the x-axis for improvers and non-improvers. The area under the curve (AUC) and 95% confidence intervals were calculated to indicate the probability of correctly discriminating between random pairs of improvers and non-improvers. An AUC of 1.00 represents a perfect discrimination; an area of 0.5 represents no discrimination (Mokkink et al., 2010b). ROC curves were also plotted for the Quick DASH to allow for comparison of relative responsiveness between the two measures.

5.5 Results

Sociodemographic characteristics of participants at baseline

Eighty-two people were recruited at baseline (Figure 5:1). Forty-nine (60%) of the participants were male. Ages ranged from 18 to 93 with a mean age of 49. A variety of hand nerve diagnoses were represented; carpal tunnel syndrome was reported as the most common disorder. There were equal numbers of participants who had either a nerve compression disorder or a traumatic nerve injury. The majority of the sample (82%) had

undergone surgery. Most of the participants lived with another person (89%), with around a quarter who had responsibility for caring for others. Just over half of the participants were working. A change in work status was reported by 23 (28%) people because of their condition. A summary of the sociodemographic characteristics of participants at baseline and follow-up is presented Table 5:3.

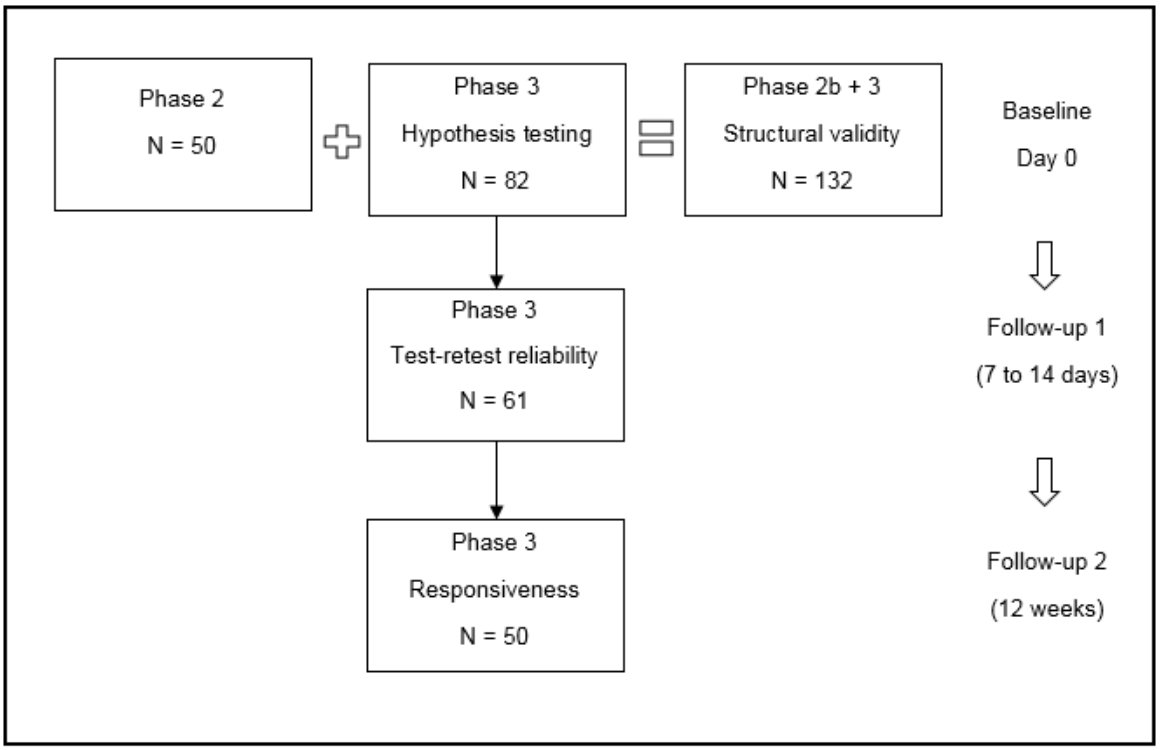


Figure 5:1 Participant flow diagram showing numbers recruited at each stage of the study

5.5.1 Construct (structural) validation

To evaluate the structural validity and to achieve a larger sample size, data collected during the content validation in phase 2b (Chapter 4) were combined with data obtained from this phase of the study. This produced a sample size of 132 participants (Figure 5:1). The sociodemographic characteristics of this combined sample is very similar to the baseline data (Table 5:3). A notable difference is the higher mean times experiencing symptoms and higher mean time since having surgery. This is due to participants from phase 2b including both current and recently discharged patients.

Table 5:3 A summary of the sociodemographic characteristics of participants at baseline and follow-up

	Structural validity (N = 132)	Hypothesis testing (N = 82)	Test-retest reliability (N = 61)	Responsive-ness (N = 50)
No. (%) of men:	72 (55%)	49 (60%)	39 (64%)	29 (58%)
Mean age (range) in years:	52 (18 to 93)	49 (18 to 75)	52 (21 to 93)	54 (21 to 93)
No. (%) acute or chronic nerve compression disorders:	63 (48%)	41 (50%)	31 (51%)	28 (56%)
Carpal tunnel syndrome:	42 (32%)	22 (27%)	13 (27%)	14 (28%)
Cubital tunnel syndrome:	12 (9%)	11 (13%)	8 (13%	9 (18%)
Radial nerve palsy:	19 (14%)	7 (9%)	4 (7%)	4 (8%)
No. (%) acute nerve injuries:	69 (52%)	41 (50%)	30 (49%)	22 (44%)
Median nerve injury:	23 (17%)	16 (20%)	12 (20%)	9 (18%)
Ulnar nerve injury:	19 (14%)	12 (14%)	11 (18%)	8 (16%)
No. (%) more than one nerve (acute or chronic):	17 (13%)	14 (17%)	8 (13%)	6 (12%)
No. (%) with a concomitant injury:	54 (41%)	33 (40%)	22 (36%)	16 (32%)
No. (%) who had surgery:	109 (83%)	67 (82%)	52 (85%)	43 (86%)
Mean duration of symptoms (range) in months:	29 (1 to 367)	22 (1 to 179)	24 (1 to 79)	27 (1 to 79)
Mean time since surgery (range) in months:	9 (1 to 88)	5 (1 to 24)	5 (1 to 20)	5 (1 to 19)
No. (%) of people with dominant hand affected:	55 (42%)	33 (40%)	23 (38%)	19 (38%)
No. (%) living alone:	17 (13%)	9 (11%)	7 (12%)	6 (12%)
No. (%) caring for others:	36 (27%)	19 (23%)	16 (26%)	14 (28%)
No. (%) working:	66 (50%)	42 (51%)	29 (48%)	26 (52%)
Employee:	55 (42%)	34 (42%)	25 (41%)	23 (46%)
Home-maker:	2 (2%)	2 (2%)	1 (2%)	-
Retired:	36 (27%)	21 (26%)	19 (31%)	17 (34%)
Self-employed:	13 (10%)	10 (12%)	6 (10%)	5 (10%)
Long-term sick:	13 (10%)	6 (7%)	5 (8%)	3 (6%)
Student:	2 (2%)	1 (1%)	1 (2%)	-
Unemployed:	11 (8%)	8 (10%)	4 (7%)	2 (4%)
No. (%) with a change in work status:	36 (27%)	23 (28%)	16 (26%)	11 (22%)

Distribution of the data

The distribution of the responses was assessed using descriptive statistics. Only participants with complete data were included in the analysis; these numbered 118. The mean (SD) total score for the sample was 89.98 (31.12) out of a possible 160. The distribution of the individual items is presented in the appendix 5.5. Overall, missing responses from participants were low (0.14%). The largest amount of missing data came from Q20: '*Cutting your nails',* which was left out on only three occasions. All of the different response options for each item were selected by participants (Figure 5:2). There were no significant ceiling effects observed. However, floor effects were observed with items Q9: *I feel self-conscious if people look at my hand/arm*; Q12: *I have hurt my hand and not realised it until later;* Q19: *Putting toothpaste on a toothbrush,* with greater than 40% of respondents selecting the lowest (easiest) category for these questions. All of the items demonstrate a normal distribution with skewness and kurtosis values close to zero.

5.5.2 Construct (structural) validation using classical test theory

Internal consistency

The internal consistency of the I-HaND Scale was examined using Cronbach's alpha (Table 5:4). The alpha for the I-HaND Scale was 0.98, demonstrating excellent internal consistency (DeVellis, 2012). Item-total and item to item correlations were explored to highlight potentially redundant items (Eisen et al., 1979). In Chapter 4 (4.6.4) item-total and inter-item correlations of ≥ 0.9 were identified to signal possible redundancy. No items were identified following this criterion.

Table 5:4 Internal consistency of the I-HaND Scale of raw total I-HaND Scale scores

	Items (scoring range)	**Phase 2b and phase 3 combined baseline data (N = 118)**	
		Mean score (SD)	Cronbach's alpha
I-HaND Scale	32 (32 to 160)	89.98 (31.12)	0.98

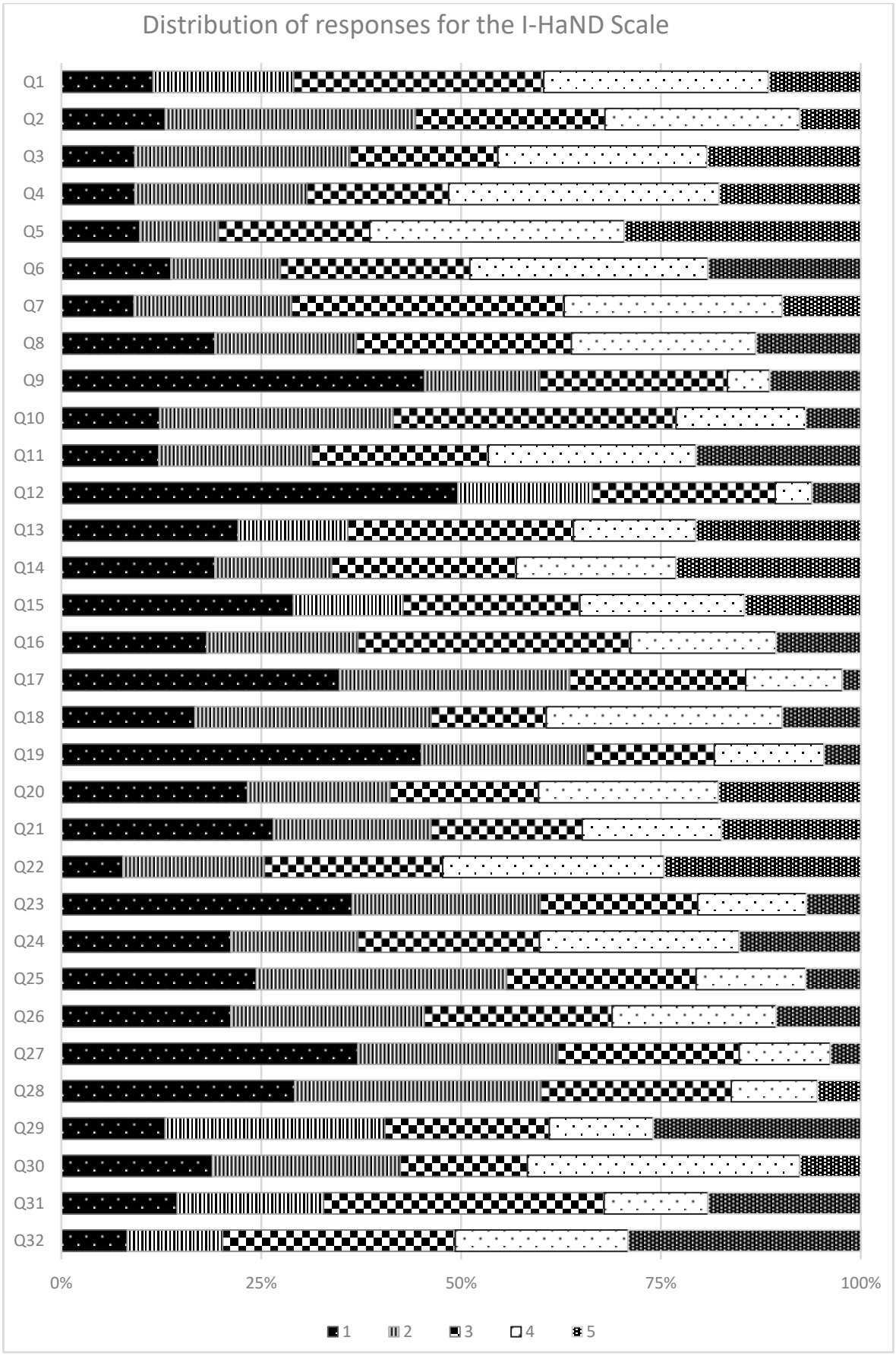


Figure 5:2 Distribution of item responses for the I-HaND Scale

Principal components analysis

A PCA was used to examine the construct validity, in particular the factor structure of the I-HaND Scale. Of the 132 participants, 89% (118) had complete data and were included in the analysis. The results of the Kaiser-Meyer-Olkin (KMO) test of sampling adequacy was high at 0.9, where a KMO of ≥ 0.6 indicates that the sample is adequate for a PCA (Kaiser, 1974). Components were identified with eigenvalues ≥ 1.00, following Kaiser's criterion rule (Kaiser, 1960). The PCA of the I-HaND Scale revealed a clear unidimensional structure (Table 5:5). There were four components with eigenvalues ≥ 1.00, which together explained 74% of the variance. Most of the variance was explained by the first component (58%), higher than the minimum recommended 50% value for a stable one-factor solution but substantially lower than phase 2b, where the first component accounted for 70% of the total variance. (Streiner et al., 2014).

Table 5:5 Principal components analysis of the I-HaND Scale

	Initial eigenvalues		
Component	Total	% of variance	Cumulative %
1	18.60	58	58
2	1.79	6	64
3	1.33	4	68
4	1.13	4	71
5	0.86	2	74

Cattell's scree plot (Cattell, 1966) was drawn for the I-HaND Scale (Figure 5:3). The scree plot shows a sharp drop (the point of inflexion) after the first component and then the line becomes more level. The remaining factors explain a smaller proportion of the variability.

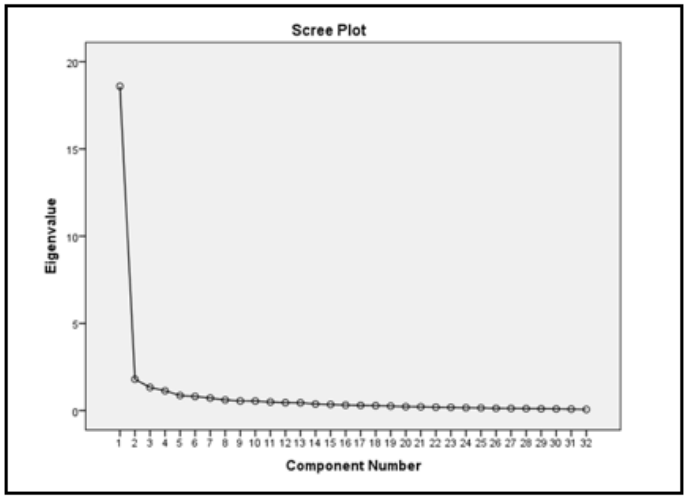


Figure 5:3 Scree plot to show the variance in the components of the I-HaND Scale

The component matrix of the I-HaND Scale

The component matrix of the I-HaND Scale presented below displays each item having a positive loading of >0.5 on the first component which explained 58% of the total variance (Table 5:6). Communalities for each item were also high and ranged from 0.6 to 0.8 (mean = 0.7) further confirming that each item shared a common variance with other items in the scale (MacCallum et al., 1999).

Table 5:6 Component matrix of the I-HaND Scale

	Component			
	1	2	3	4
Q1	0.84	-0.09	-0.10	-0.09
Q2	0.78	0.04	-0.05	-0.01
Q3	0.67	0.35	0.04	0.19
Q4	0.77	0.13	-0.26	-0.03
Q5	0.72	0.13	-0.26	0.25
Q6	0.55	0.44	0.05	0.44
Q7	0.75	-0.06	0.15	0.09
Q8	0.69	0.23	-0.02	-0.45
Q9	0.57	0.29	0.30	-0.50
Q10	0.75	0.27	-0.24	-0.07
Q11	0.79	0.23	-0.25	-0.08
Q12	0.64	0.23	0.22	-0.26
Q13	0.53	0.54	0.19	0.34
Q14	0.60	0.51	0.35	-0.01
Q15	0.68	0.05	-0.37	-0.21
Q16	0.84	-0.08	-0.10	-0.11
Q17	0.87	-0.21	0.04	-0.05
Q18	0.82	-0.19	0.22	-0.06
Q19	0.80	-0.17	0.20	-0.05
Q20	0.83	-0.14	0.17	0.06
Q21	0.84	-0.11	0.11	-0.06
Q22	0.86	-0.01	-0.21	0.10
Q23	0.76	-0.37	-0.06	0.10
Q24	0.83	0.03	-0.12	0.06
Q25	0.87	-0.20	0.11	0.03
Q26	0.83	-0.22	-0.15	0.11
Q27	0.72	-0.27	0.37	0.13
Q28	0.79	-0.28	0.24	0.07
Q29	0.77	-0.12	-0.27	0.13
Q30	0.75	-0.15	0.24	0.13
Q31	0.84	-0.09	-0.15	-0.13
Q32	0.87	0.03	-0.13	-0.02

5.5.3 Construct (structural) validation using the Rasch model analysis

Fit to the Rasch model

Data were available for 132 participants who had completed the I-HAND Scale at baseline in phases 2b and 3. Data for three people, who had extreme values, were excluded by Rasch from the analysis. The total item-trait chi-square statistic was significant at $p < 0.002$ (Bonferroni adjusted for n=32) suggesting that the observed I-HaND scores did not fit the expected scores under the Rasch model (Table 5:7).

Table 5:7 Summary of Rasch analysis of the I-HaND Scale

N =	**Item-fit residual mean (SD)**	**Person-fit residual mean (SD)**	**Item-trait total chi-square**		**PSI**	**Test of unidimensionality (95% CI)**
			(df)	**P**		
129	0.34 (2.19)	-0.01 (1.67)	353.67 (128)	< 0.002	0.96	29.84% (26 to 33.7%)
Ideal values	**Mean = 0 SD < 1.4**	**Mean = 0 SD < 1.4**		**>0.05**	**>0.85**	**< 5%**

Tests of unidimensionality

A PCA of the residuals was performed to show contrasts between opposing factors, not loadings onto one factor, which is the case for a conventional PCA (Tennant et al., 2004). The PCA of the residuals identified eight items with high positive loadings and twelve items with high negative loading (>0.3) on the first component (Table 5:8). Items that loaded positively came from either Part 1 (symptoms) or Part 2 (pain) of the I-HaND scale and collectively measure impairment. The items which loaded negatively came from Part 3 (activity) and Part 4 (participation) of the scale. The differences between positively and negatively loading test items resulted in significant t-tests ($p < 0.05$), for 30% (95% CI = 26 to 34), much higher than the acceptable guideline of < 5% (Smith Jr, 2002). This suggests that the I-HaND is multidimensional.

Table 5:8 1st principal component of residuals, items with positive and negative loadings >0.3 highlighted in bold

Item	Description*	PC1
1	overall hand function	-0.24
2	movement	0.01
3	feeling	**0.40**
4	strength	0.16
5	grip	0.04
6	tingling	**0.52**
7	picking up	-0.14
8	emotions	**0.34**
9	self-conscious	**0.42**
10	pain	0.25
11	pain impact	**0.30**
12	hurt hand & not realised	**0.35**
13	oversensitive	**0.61**
14	cold intolerance	**0.64**
15	sleep disturbance	0.18
16	daily routine	**-0.33**
17	dressing	**-0.56**
18	doing up buttons	**-0.34**
19	toothpaste on brush	**-0.41**
20	cutting nails	**-0.36**
21	knife and fork	**-0.36**
22	opening lids	**-0.33**
23	pouring from kettle	**-0.50**
24	wringing out cloth	-0.25
25	preparing meal	**-0.61**
26	opening & closing heavy doors	**-0.52**
27	turning pages	-0.16
28	using electronic devices	**-0.33**
29	carrying shopping	-0.26
30	handling small coins	-0.10
31	physical demands of daily work	**-0.31**
32	participating in recreation	-0.25

* Items have been abbreviated based on the content for convenience

Reliability

Reliability was examined using the person-separation index (PSI). This was very high (0.96), indicating that the I-HaND Scale can statistically differentiate between seven or more groups of patients. The PSI is also an indicator of the reliability of the fit statistics, with the higher the PSI, the more reliable the fit statistics (Fisher, 1992).

Person-item threshold distribution

To assess the ability of the I-HaND to target the population being measured, person-item threshold maps were inspected (Figure 5:4). A well-targeted scale should include a set of items that span the full range of person estimates (person locations should be covered by items and locations covered by persons). A well-targeted sample is one in which the person distribution closely matches the item distribution when they are both calibrated on the same metric scale. The histogram bars represent the relative location of the items and persons on the same variable. The curve represents where on the continuum the scale performs best (Hobart and Cano, 2009). Item locations are covered by the people and the person locations are well covered by the items. The mean (SD) location score was -0.3 (SD = 1.36), with a value closer to zero indicating a well-targeted measure. The negative mean value for persons indicates that the sample as a whole was located at a lower level of the trait than the scale average (Hagquist et al., 2009). There were few people at the margins of the scale.

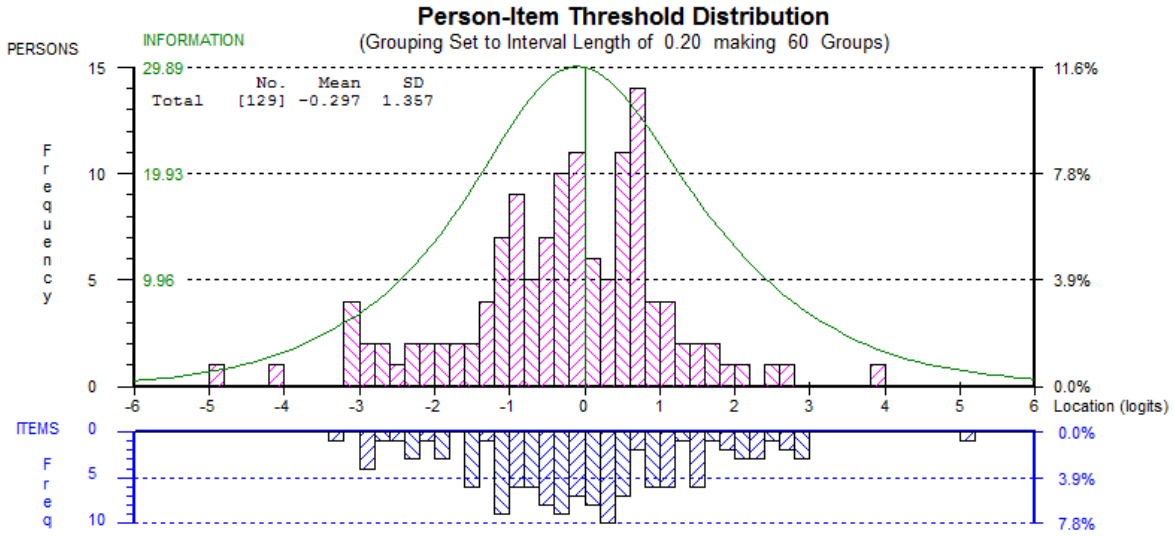


Figure 5:4 Person-item threshold distribution map for the I-HaND Scale

Individual person fit

Examining person fit to the scale checks whether the sample demonstrates different levels of the construct (Tennant and Conaghan, 2007). The person fit residuals for the sample (m = -0.01; SD 1.67), were close to the ideal (m = 0; SD < 1.4) value. Six people had extreme scores. The three who provided the lowest possible scores (more able) were from the

phase 2b sample, and had acquired their injuries up to 18 months previously. The three who had provided the highest possible scores (more disabled) had all undergone surgery within the previous four weeks. Twenty-five people had fit residuals outside the range of ± 2.5, indicating that they did not fit the Rasch model.

Individual item fit

Exploring item fit, informs whether an item reflects a unique difficulty level (Tennant and Conaghan, 2007) The item-fit residuals (m = 0.34; SD 2.19) for the sample were outside the ideal (m = 0; SD < 1.4) values. Item-fit statistics in location order, adjusted for the 32 items ($p<0.001563$), are presented in appendix 5.7. Eight items on the I-HaND Scale demonstrated significant misfit with the Rasch model, with fit residuals outside the range of ± 2.5 (Table 5:9). Items with poor fit were mostly impairment-related questions, with the exception of Q17 and Q25, which are activity, related questions. However, the activity-related questions were much closer to the ± 2.5 threshold (highlighted in bold).

Table 5:9 The item-fit residuals greater than ± 2.5 threshold with activity items highlighted in bold closer to the threshold

	Item	Fit residual
Q5:	I can't grip or pinch for very long without my hand getting tired	5.2
Q6:	When I touch certain things it causes pins and needles or tingling	4.1
Q8:	Using my hand(s) can bring about strong emotions e.g. frustration, anger, sadness	3.1
Q9:	I feel self-conscious if people look at my hand/arm	3.3
Q13:	My hand feels oversensitive when touched	3.6
Q14:	I feel pain or discomfort when my hand is cold	3.5
Q17:	Getting dressed or undressed	**-2.6**
Q25:	Preparing a meal	**-2.8**

Thresholds

A common source of item misfit occurs due to respondents' inconsistent use of response options. Known as disordered thresholds, this is the failure of respondents to use the response options in a manner consistent with the level of the trait being measured (Hagquist and Andrich, 2004). Disordered thresholds occur when people have difficulty consistently discriminating between response options. This can be due to there being too many response options or the labelling is confusing. The term threshold refers to the point between two response options where either is equally probable (Pallant and Tennant, 2007). The ordering of thresholds can be visually inspected using category probability

curves (CPC). The scale (x-axis) from +3 to -3 represents the latent trait and the y-axis represents the probability of the response category being selected (Andrich, 1978). Figure 5:5 illustrates the CPC for items with ordered thresholds with each response option having its own peak. For the I-HaND Scale thresholds were disordered on 10 items. Items with similar disordered thresholds have been grouped together to ease visual inspection and are presented in Figure 5:6 to Figure 5:10. A qualitative explanation is also provided for disordered thresholds in Table 5:10 below.

Thresholds

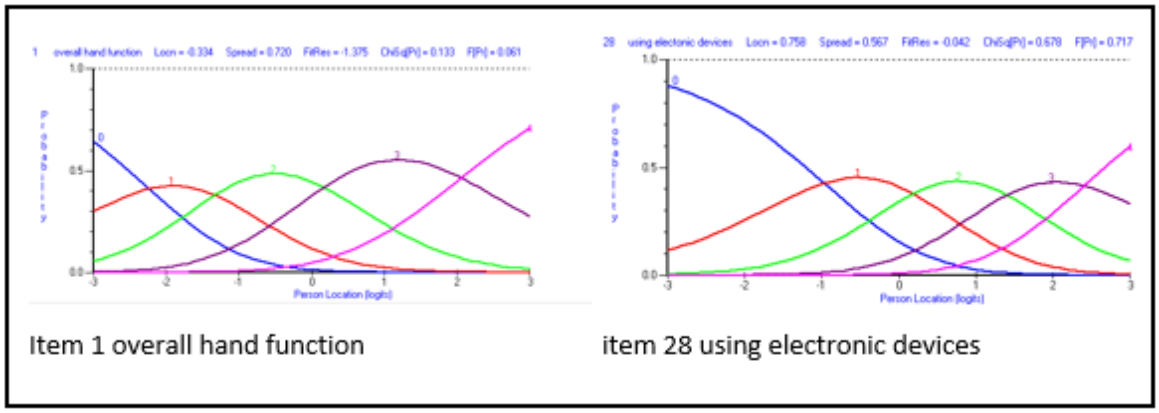


Figure 5:5 An example of ordered thresholds, with each response category clearly demonstrating having its own peak

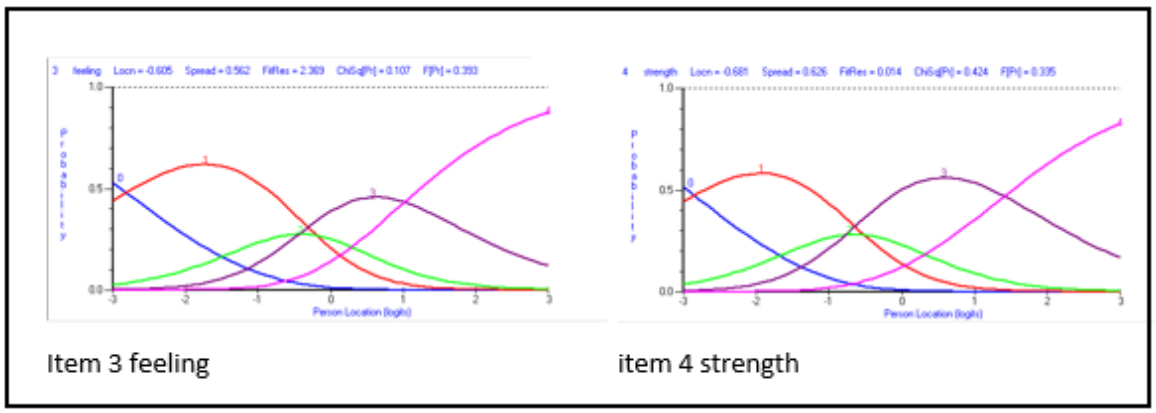


Figure 5:6 Items with disordered thresholds: no peak for response category 'neither satisfied nor dissatisfied'

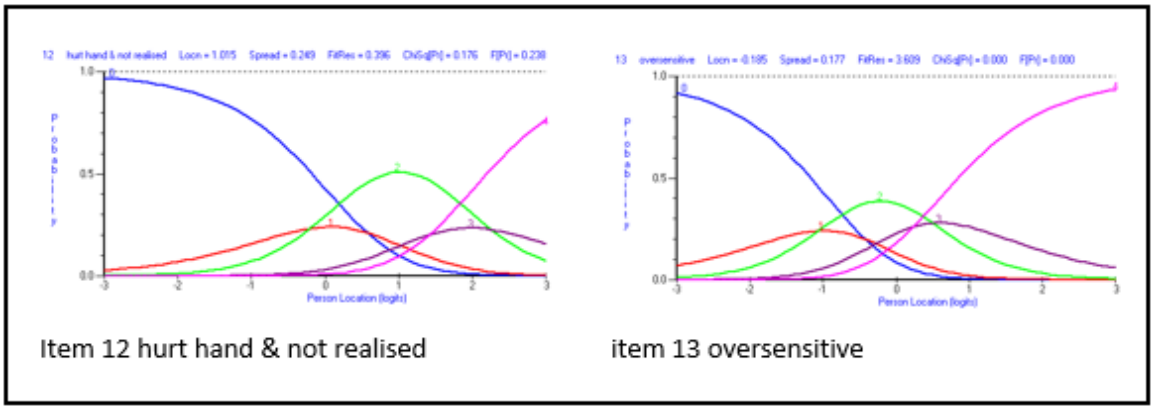


Figure 5:7 Items with disordered thresholds: no peaks for response category ‘rarely’ and ‘often’

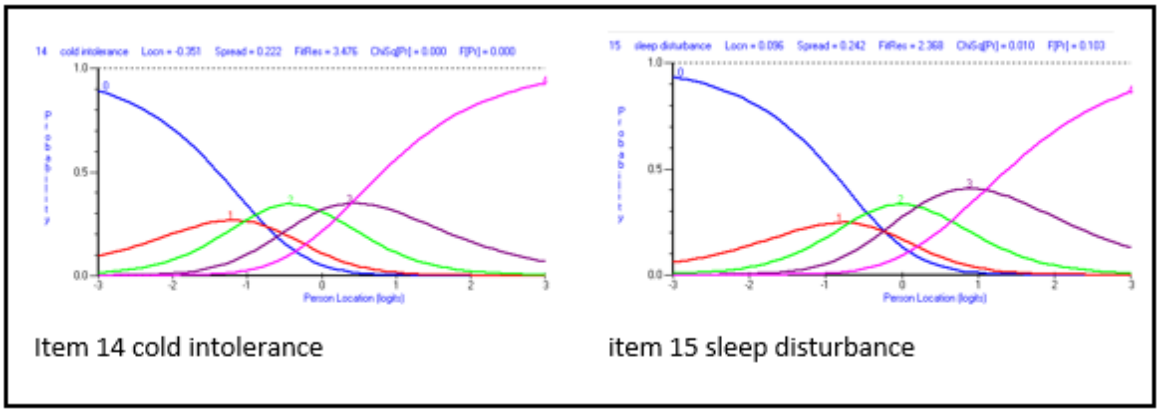


Figure 5:8 Items with disordered thresholds: no peak for response category ‘rarely’

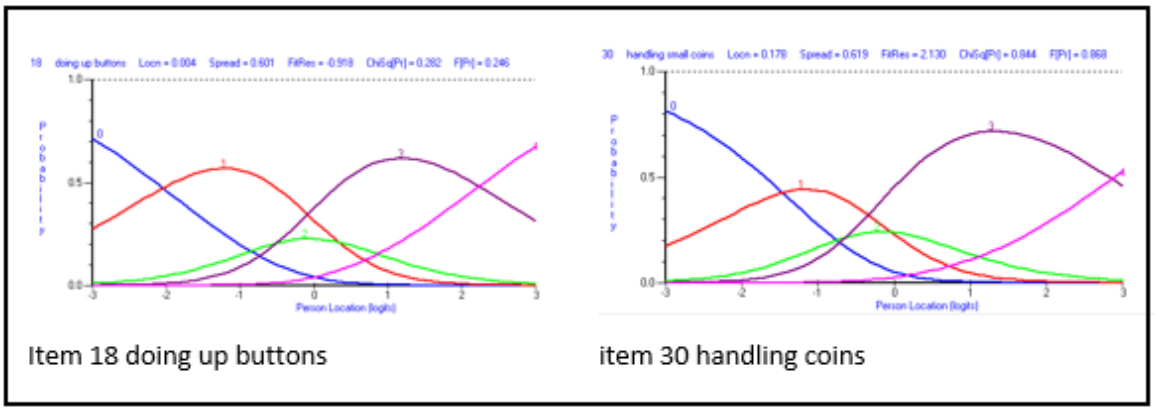


Figure 5:9 Items with disordered thresholds: no peak for ‘moderately difficult’

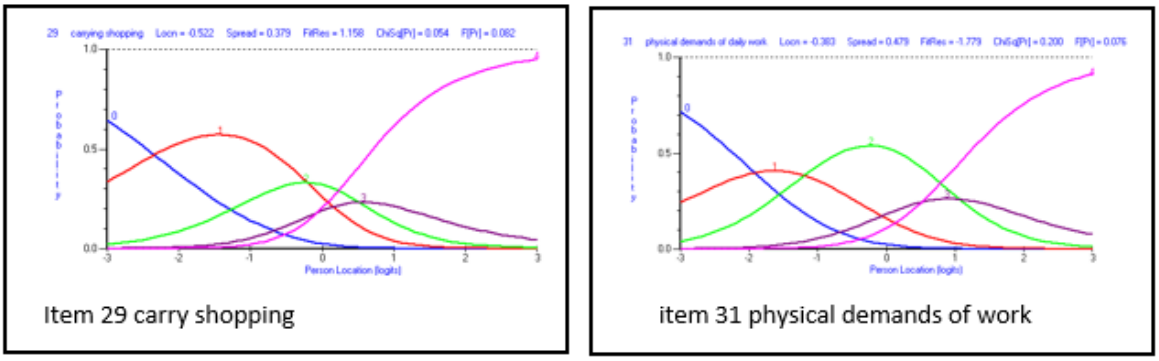


Figure 5:10 Items with disordered thresholds: no peaks for 'moderately 'difficult' and 'very difficult' (item 29); no peak for 'poorly' (item 31)

Table 5:10 A description of disordered thresholds for the I-HaND Scale and possible explanations

Item*	Description	Disordered thresholds	Explanation for threshold
3	Feeling	No peak for response category 'neither satisfied or dissatisfied'	The 'neither satisfied nor dissatisfied' creates a middle category and polarises the scale
4	Strength	No peak for response category 'neither satisfied or dissatisfied'	
12	Hurt hand & not realised	No peak for response categories 'rarely' and 'often'	Hurting the hand due to a lack of protective sensation or oversensitivity may be experienced in a more dichotomised way, sometimes or always. This could suggest too many response options
13	Oversensitive	No peak for response categories 'rarely' and 'often'	
14	Cold intolerance	No peak for response categories 'rarely'	Cold intolerance and sleep disturbance may not be experienced rarely. This could suggest too many response options
15	Sleep disturbance	No peak for response categories 'rarely'	
29	Carrying shopping	No peak for 'moderately difficult' and 'very difficult'	Participants have difficulty distinguishing between 'moderately' and 'very difficult' heavy ADL tasks. This could indicate too many response options
30	Handling small coins	No peak for 'moderately difficult'	Handling coins and doing up buttons both require fine motor skills. It could be that there is no middle ground. That either you can or you cannot do the activity and if you can't it is either a little bit difficult or very difficult
18	Doing up buttons	No peak for moderately difficult	
31	Physical demands of daily work	No peak for 'poorly'	Participants have difficulty distinguishing between 'poorly' and 'very poorly' relating to their work tasks. This could indicate too many response options

* Items have been abbreviated based on the content for convenience

Item dependency

Item dependency in a scale can occur where items are linked in some way, such that the response to one item will determine the response to another. This can be highlighted by inspecting the residual correlations (Hobart et al., 2006). Response dependency was investigated by inspecting residual correlations for pairs of items with correlations exceeding 0.3. Following this criterion, 18 items were identified as correlating with other items (appendix 5.6). As this accounted for more than half the scale, the threshold was raised to >0.4 to inspect the items with the highest residual correlation. This reduced the number of pairs to eight, shown in Table 5:11, with a qualitative explanation for the dependency.

Table 5:11 Pairs of I-HaND items with inter-item residual correlations greater than 0.4

Pairs of items* with residual correlations >0.4				Explanation
1	Overall hand function	2	Movement	Item 1 is a global question and item 2 is a component of this
8	Emotions	9	Self-conscious	Both questions measure psychosocial traits
10	Pain	11	Pain impact	Item 10 is a global question and item 11 is a component of this
13	Oversensitive	14	Cold intolerance	Both questions relate to sensory pain
18	Doing up buttons	27	Turning pages	Both activities require fine motor skills
23	Pouring from kettle	26	Opening & closing heavy doors	Both activities require strength
26	Opening & closing heavy doors	29	Carrying shopping	Both activities require strength
31	Physical demands of daily work	32	Participating in recreation	Both items relate to participation restrictions

* Items have been abbreviated based on the content for convenience

Response bias

A third source of potential misfit to the Rasch model is item bias or differential item functioning (DIF). DIF occurs when different groups of people with the same trait respond differently to a particular item due to another factor, such as gender (Van der Velde et al., 2009). Uniform and non-uniform DIF was examined by sex (male/female), age (18-45, 46-64, 65+), diagnosis (compression/trauma), and whether the dominant hand was affected (ambidextrous/no/yes). The level of significance was adjusted for number of items $p< 0.000521$. In the analysis of the I-HaND, there was no significant DIF by sex and age. Items 11 (pain impact) and 21 (knife and fork) showed uniform DIF by diagnostic group

suggesting that people respond differently to these items if they have either a compressive or a traumatic disorder. Item 19 (toothpaste on brush) shows uniform DIF by side affected. This indicates that people who have injured their dominant hand will respond differently to those who have not.

5.5.4 Construct validity (hypothesis testing) using CTT

To evaluate whether scores produced by the I-HaND Scale are capable of measuring the intended construct, *a priori* hypotheses were made on how its scores would correlate with other scales that measure related constructs. Data were available for 82 participants, whose demographic details are provided in Table 5:3. Seventy-two participants provided complete data; nine participants with missing data < 10% (three or less missing items) were also included in the correlation analysis by substituting missing items with the scale mean. One participant who had more than 10% missing data was excluded. This criterion was derived from the method used to score the comparator (Quick DASH). It was hypothesised that I-HaND scores would have a positive, moderately strong correlation ($r < 0.60$) with Quick DASH scores and a negative, moderately strong correlation ($r < -0.60$) with NHF scores. It was hypothesised that patients with traumatic nerve disorders would have higher mean I-HaND scores (higher disability) compared with those with compression disorders, and this would be statistically significant. Mean total scores are presented for each of the measures in Table 5:12.

Table 5:12 Mean total scores for the I-HaND Scale, Quick DASH and the NHF score

PROMS	**N**	**Mean Total Scores (SD)** **Score range = 0 to 100**
I-HaND Scale	81	48.46 (19.97)
Quick DASH	75	50.51 (23.80)
NHF	67	55.76 (22.19)

Two of the three hypotheses were correct. A positive, strong correlation was found with the Quick DASH ($r = 0.87$) and a negative, moderate correlation with the NHF scores ($r = -0.64$). Table 5:13 shows the correlation coefficients for each measure and scatter plots

were drawn to visually represent the relationship between the I-HaND Scale and the Quick DASH (Figure 5:11) and NHF Score (Figure 5:12). The mean for the trauma group (60.78, SD = 15.42) was higher and going in the direction hypothesised, with this group approximately one third of a standard deviation worse than the compression group (55.84, SD = 16.58). The differences, however, were not statistically significant (p = 0.20, t-test).

Table 5:13 Correlation coefficients for the I-HaND Scale, Quick DASH and NHF Score

	Quick DASH	% NHF
I-HaND Scale	0.87	-0.64
Quick DASH		-0.54

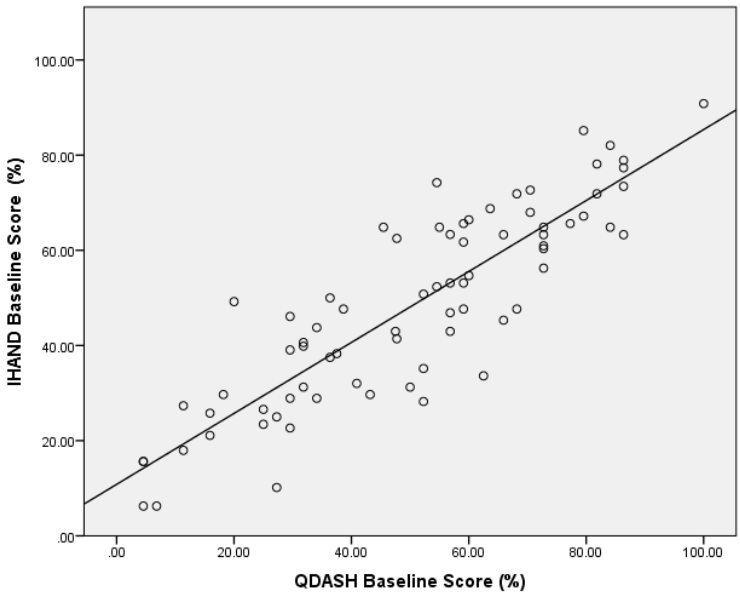


Figure 5:11 Scatter plot with the line of best fit for I-HaND and Quick DASH

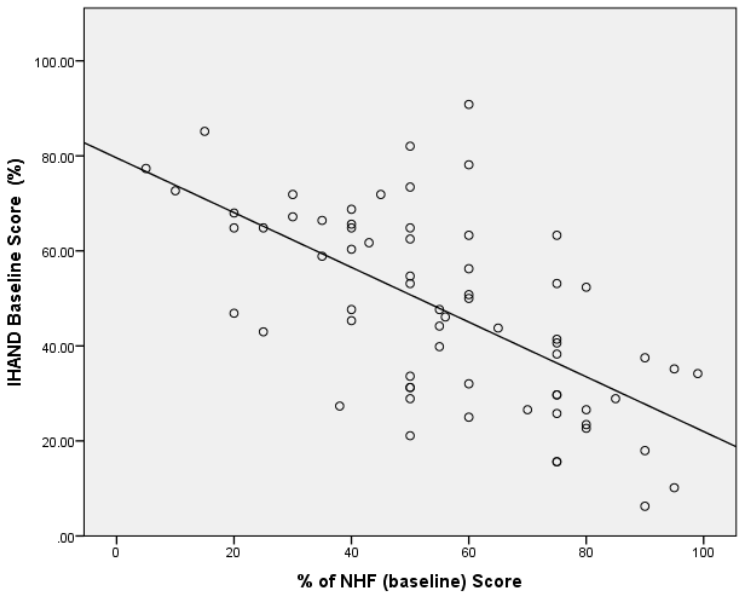


Figure 5:12 Scatter plot with the line of best fit for the I-HaND and the NHF Score

5.5.5 Test-retest reliability

Sixty-one participants completed the I-HaND Scale at baseline and then again, at the first follow-up; 21 participants were lost from baseline to first follow-up. Participants with missing data were excluded. Complete data were available for 56 people and were used in the analysis. The mean recall period was 12 days, ranging from 4 to 30 days. Test-retest reliability for the I-HaND was excellent (ICC = 0.97; 95% CI = 0.94 to 0.98). The individual item scores also showed strong reproducibility with none of the items having an ICC lower than of 0.80 (appendix 5.8).

5.5.6 Responsiveness to change

Fifty participants completed the I-HaND Scale at baseline and at the second follow-up providing data for the responsiveness analysis. The mean age of the participants was 54, and ages ranged from 21 to 93 years. Fifty-eight per cent of the sample were men. There were roughly equal numbers of people with nerve compression disorders and traumatic nerve injuries (Table 5:3). Forty-five participants provided complete data; five participants who had < 10% missing data (three or less missing items) were also included in the analysis, by substituting missing items with the scale mean. One participant who had more than 10% missing data was excluded. Baseline, follow-up and change data (mean and standard deviation), effect size and standardised response mean are presented for the I-HaND Scale

scores and Quick DASH scores (Table 5:14). Effect sizes and standardised response means for the I-HaND (ES = 0.51; SRM = 0.6) were marginally higher than the Quick DASH (ES = 0.42; SRM = 0.56).

Further analysis was carried out on patients who had rated themselves to have either improved or not improved using the global change (GROC) measure. The global status measure (NHF) scores at baseline and follow-up were also converted into a change score (NHF-CS), to dichotomise patients into improvers and non-improvers. This allowed for comparison between the two anchors and to determine if there was a difference in how each anchor dichotomised patients. The number of improvers and non-improvers as categorised for each anchor is shown (Table 5:15). Approximately half of the sample reported to have improved. The NHF-CS categorised slightly more improvers (55%) compared with the GROC (47%) anchor.

Table 5:14 Effect size and standardised response means for the I-HaND Scale and the Quick DASH

	N	I-HaND Scale scoring range (0 to 100)	N	Quick DASH scoring range (0 to 100)
Baseline score, mean (SD)	50	46.15 (20.06)	49	49.30 (24.32)
12-week follow-up score, mean (SD)	49	36.28 (20.72)	49	38.47 (24.17)
Change, Baseline to 12 weeks, mean (SD)		10.13 (16.89)		10.20 (18.14)
Effect size		0.51		0.42
Standardised Response Mean		0.60		0.56

Table 5:15 Number of improvers and non-improvers as categorised by each patient anchor

		Improvers (%)	Non-improvers (%)	Total
Anchor	GROC	23 (47%)	26 (53%)	49
	NHF-CS	27 (55%)	22 (45%)	49

The distribution of the I-HaND Scale change scores at 12 weeks for improvers and non-improvers, using both patient-rated anchors, are illustrated using box plots in Figure 5:13 and Figure 5:14.

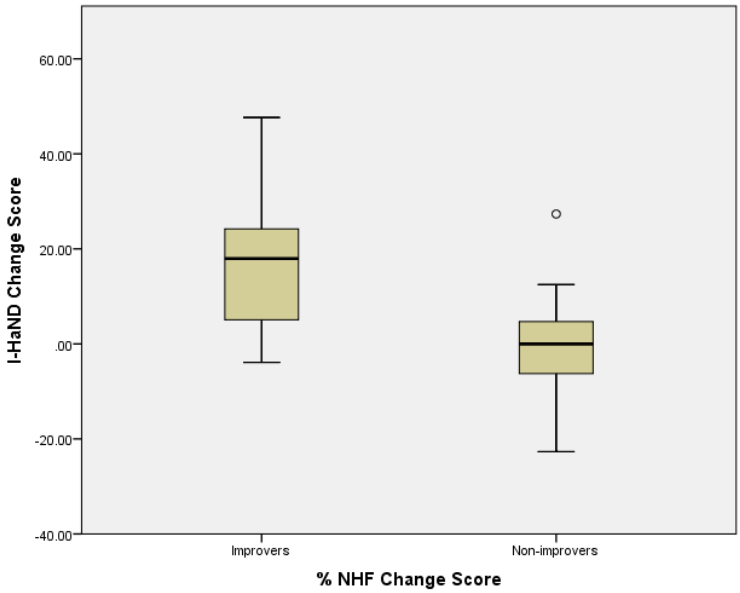


Figure 5:13 Box plot showing distribution of the I-HaND change scores for the improvers and non-improvers using the NHF-CS

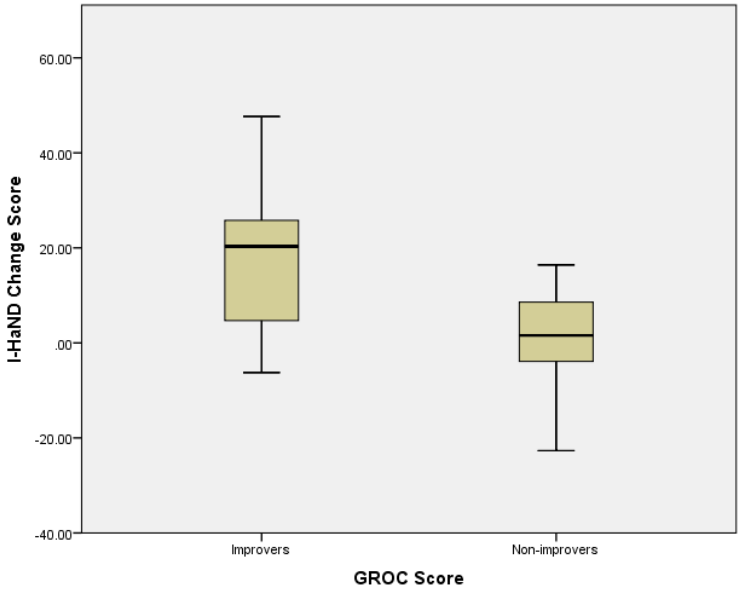


Figure 5:14 Box plot showing distribution of the I-HaND Scale change scores for the improvers and non-improvers using the GROC score

Pearson's r was used to explore the relationship between the I-HaND and Quick DASH change scores. There was a strong, positive correlation between I-HaND and Quick DASH change scores from baseline and the 12-week follow-up (r = 0.83). A scatterplot with the line of best fit was drawn to illustrate this (Figure 5:15).

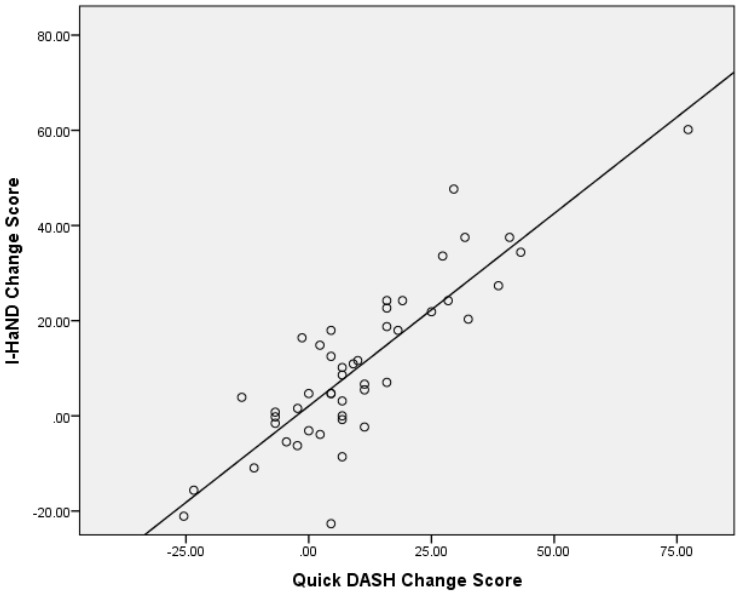


Figure 5:15 Scatter plot with line of best fit for the I-HaND and Quick DASH change scores

The magnitude of change for the I-HaND Scale and the Quick DASH for both the improvers and non-improvers using both patient-reported anchors was calculated using effect sizes and standardised response means (Table 5:16). Using the GROC anchor, large effect sizes and standardised response means were calculated for the I-HaND improvers (ES = 0.89; SRM = 1.24) and Quick DASH improvers (ES = 0.81; SRM = 1.17) with the I-HaND reporting a marginally higher magnitude of change compared to the Quick DASH. For the group of non-improvers, the magnitude of change for both the I-HaND and the Quick DASH was minimal and similar for each measure (ES = 0.03; SRM = 0.07). Using the NHF-CS anchor, effect sizes and standardised response means were large for the I-HaND improvers (ES = 0.75; SRM = 1.21). The amount of change for the Quick DASH was moderate to large (ES = 0.65; SRM = 1.13). For the group of non-improvers, the magnitude of change for the I-HaND was minimal and negative (ES = -0.03; SRM = -0.04). The effect is negative because the mean at baseline is higher than the mean at follow-up, indicating that on average patients got worse after the 12-weeks. For the Quick DASH non-improvers, the magnitude of change was also close to zero (ES = 0.04; SRM = 0.07).

Table 5:16 Magnitude of change for the I-HaND Scale and Quick DASH for improvers and non-improvers

Anchor	N	I-HaND Improvers	N	I-HaND Non-improvers	N	Quick DASH Improvers	N	Quick-DASH Non-improvers
GROC								
Baseline score, Mean (SD)	24	45.44 (20.18)	26	45.45 (20.09)	23	48.21 (22.66)	26	48.79 (25.47)
12 week follow up score, mean (SD)	24	27.45 (16.87)	25	45.22 (20.04)	24	29.89 (18.20)	25	47.16 (25.89)
Change, Baseline to 12 weeks, mean (SD)		17.99 (14.52)		0.70 (10.49)		18.40 (15.64)		0.66 (9.29)
Effect size		0.89		0.03		0.81		0.03
Standardised response mean		1.24		0.07		1.17		0.07
% NHF								
Baseline score, mean (SD)	28	48.79 (21.76)	28	41.19 (16.84)	27	51.46 (24.86)	27	44.90 (22.81)
12-week follow-up score, mean (SD)	28	32.37 (20.97)	28	42.04 (18.79)	27	34.40 (23.53)	27	43.99 (23.75)
Change, baseline to 12 weeks, mean (SD)		16.42 (13.55)		-0.49 (11.75)		16.14 (14.22)		0.91 (12.73)
Effect size		0.75		-0.03		0.65		0.04
Standardised response mean		1.21		-0.04		1.13		0.07

The sensitivity of the I-HaND at being able to discriminate between patients who had reported to have either improved or not improved was evaluated by drawing ROC curves. The ability of the I-HaND to discriminate between the two groups can be estimated by calculating the area under the curve (AUC), the larger the AUC, the greater the ability of the scale to discriminate (Husted et al., 2000). ROC curves were drawn for the I-HaND Scale and the Quick DASH to examine which measure was more sensitive, relative to each other. The group was dichotomised into improvers and non-improvers using both type of anchor (NHF and GROC) to examine if this affected the AUC to discriminate between the two groups (Figure 5:16 and Figure 5:17). The AUC was large for both the I-HaND and the

Quick DASH using both types of anchors. The AUC was marginally larger for the I-HaND Scale (Table 5:17).

Table 5:17 Area under the curve for the I-HaND Scale and the Quick DASH

	PROM (anchor)	AUC	95% CI	
			Lower	Upper
a)	I-HaND Scale (% NHF)	0.85	0.74	0.96
b)	I-HaND Scale (GROC)	0.84	0.72	0.96
c)	Quick DASH (% NHF)	0.81	0.63	0.93
d)	Quick DASH (GROC)	0.83	0.69	0.97

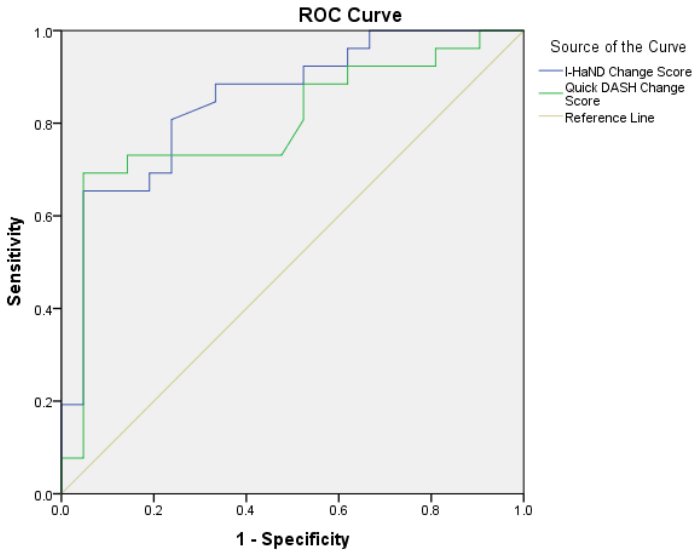


Figure 5:16 ROC curves for the I-HaND Scale and Quick DASH using the NHF-CS anchor

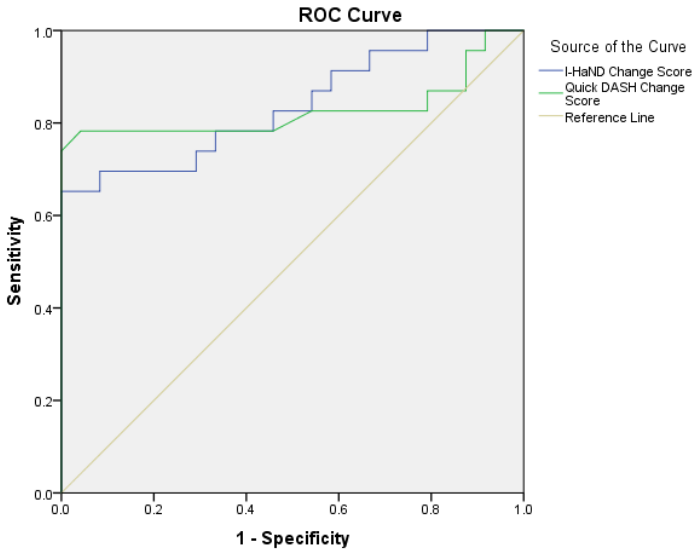


Figure 5:17 ROC curves for the I-HaND Scale and Quick DASH using the GROC anchor

5.5.7 Rescaling of the I-HaND Scale

In this study, the raw total scores produced by the I-HaND Scale were transformed into a score out of 100, the higher the score indicating greater disability. At least 29 of the 32 items must have been completed for a score to be calculated. This method was chosen to make it easier to compare with the Quick DASH, which also has a score range of 0 to 100. This measure also allows a score to be generated if less than 10 % of the items are missing. This does not assume however, that the same value on each measure means the same thing. It could be argued that having a total score of 100 is easier for clinicians and patients to interpret than a total score between 32 and 160 points, on the grounds of the familiarity with using percentages as estimates in daily life. While there is a convenience in this, the true meaning of the percentages for individuals is impossible to understand. One way of helping interpret change at a clinical level, is to examine the mean change for a group of people who have deemed themselves to have improved (Wyrwich et al., 2013). For patients, who had rated themselves as improved using the NHF anchor, this was equivalent to 16 points on the I-HaND Scale. This suggests that on average an increase of around 16 points on the scale may signal an improvement. However, it is not possible to know how meaningful this change would be to an individual patient.

5.5.8 Summary of key findings

A summary of the key findings of the psychometric properties of the I-HaND Scale are presented in Table 5:18 (classical test theory) and in Table 5:19 (Rasch measurement theory).

Table 5:18 Summary of key findings of the psychometric properties of the I-HaND Scale using classical test theory methods

Psychometric property (CTT)	Key findings
Reliability	Test-retest reliability: ICC = 0.97; 95% CI = 0.94 to 0.98
Structural validity	Internal consistency: Cronbach's alpha (0.98)
	PCA: 58% variance explained by 1st PC, no clear interpretation for any of the other factors
Construct (convergent) validity	A positive, moderate to strong correlation expected with the Quick DASH (r = 0.87)
Construct (convergent) validity	A negative, moderate correlation expected with the NHF scores (r = -0.64)
Construct (known groups) validity	Expected differences between compression and trauma patients: (t (70) = -1.31, p = 0.20)
Responsiveness: **Observed change**	12 weeks following mixed interventions (surgical, clinical): (ES = 0.51; SRM = 0.60)
Responsiveness: **Estimated change (using NHF anchor)**	Self-reported to have improved: (ES = 0.75; SRM = 1.20) Self-reported to have not improved: (ES = -0.03; SRM = -0.04)
Responsiveness: **Estimated change (using NHF anchor)**	Discrimination between improvers and non-improvers: (AUC = 0.85; 95% CI = 0.74 to 0.96)
Responsiveness: **Relative to Quick DASH (using NHF anchor)**	Whole group 12 weeks following mixed interventions: (I-HaND: ES = 0.51; SRM = 0.60; Quick DASH: ES = 0.42; SRM = 0.56) Discrimination between improvers and non-improvers: (I-HaND: AUC = 0.85; 95% CI = 0.74 to 0.96; Quick DASH: AUC = 0.81; 95% CI = 0.63 to 0.93)

Table 5:19 Summary of key findings of the psychometric properties of the I-HaND Scale using Rasch measurement theory methods

Psychometric property (Rasch)	Key findings
Reliability	Person-separation index = (0.96)
Fit to Rasch model	A significant ($p < 0.002$) item-trait statistic (353.67 (128) $p< 0.002$
Unidimensionality	PCA of residuals and significant t-tests ($p < 0.05$), for 30% (95% CI = 26 to 34)
Targeting	Well targeted item threshold map Mean (SD) location score = -0.30 (1.36)
Person fit	25 people with residual means outside the range of ± 2.5. Mean = -0.01 (1.67)
Item fit	8 items with residual means outside the range of ± 2.5. Mean (SD) = 0.34 (2.19)
Item response categories	Thresholds were disordered on 10 items
Item dependency	Multiple pairs and groups of items had high inter-item residual correlations
Response bias	3 items showed differential item functioning by diagnosis and by side affected

5.6 Discussion

This study aimed to evaluate the construct validity, reliability and responsiveness of the I-HaND Scale using classical test theory methods. This was complemented using Rasch measurement theory, a more modern psychometric approach that can identify strengths and weaknesses in scales that are beyond conventional CTT methods.

Construct (structural) validity

To evaluate the structural validity of the I-HaND Scale, a larger sample size was generated by combining data from phases 2b and 3. The sample size was still relatively small, at the lower bounds of the minimum required for Rasch analysis, and this could have affected the validity of results (Linacre, 2002). Rasch was used, however, in an exploratory capacity and no changes were made to the I-HaND Scale based on the results. Rasch provides welcome evidence that the I-HaND Scale is a reliable and well-targeted measure. However,

Rasch's full potential was not realised in this study. It was not used to address some of the areas of misfit that it had identified. The opportunity to use it in a diagnostic manner only became possible at the final stages of the research. Rasch also provides useful direction for planned future work.

A range of statistical approaches was used to evaluate the structural validity of the I-HaND Scale. Internal consistency for the I-HaND Scale was very high. An alpha of 0.90 to 0.95 is desirable for clinical interpretation of tests (Bland and Altman, 1997). Cronbach's alpha for the I-HaND Scale ($\alpha = 0.98$) exceeded this requirement and suggests that the overall scale is homogeneous. The very high alpha observed in the I-HaND could suggest that some of the items are redundant. The high alpha may be due to the large number of items, i.e. 32, which tends to inflate the alpha (Tavakol and Dennick, 2011). However, observed moderate to strong item-total correlations, provided further evidence that the items are measuring different aspects of the same construct and there were no correlations >0.9 (Eisen et al., 1979).

The PCA identified that one factor explained over 58% of the score variance thus further confirming the unidimensionality of the scale. All the items positively loaded strongly onto the first component (range 0.53 to 0.87). The amount of variance explained by the first factor was substantially lower than that conducted in phase 2b, where 70% of the variance was explained by the first factor. The difference may be attributed to the difference in sample sizes used in each analysis, with sample sizes in phase 2b relatively small.

The Rasch model analysis provided further opportunities to explore the unidimensionality of the I-HaND Scale. The PCA of residuals and subsequent equating t-test procedure indicated that there is multidimensionality (significant t-tests at $p<0.05$, for 30% (95% CI = 26 to 34). The items with residuals, which loaded positively on the PCA, were all impairment-related items and items with negatively loading residuals were activity-related items. This suggests that the I-HaND Scale may be multidimensional and creating sub-scales for impairment and activities/participation should be explored. Rasch model analysis also identified dependence between items with residual correlations >0.3. This can also indicate duplication and contribute to multidimensionality. Removing items may be one solution. However, this may compromise content validity, especially in light of the strong endorsement by patients in the cognitive debriefing that the I-HaND contained relevant questions.

The Rasch model analysis provided additional insights beyond those offered by traditional psychometric methods. This included the opportunity to examine the interval properties of the I-HaND scale, item dependency and response bias. The Rasch model analysis also provided some new insights into the construct. An example of this can be seen by examining some of the items with disordered thresholds; for example, item 12, which asks about injury to the hand from reduced protective sensation, and item 13, oversensitivity of the hand. Both items had similar disordered thresholds (no peak for response categories 'rarely' and 'often'). This could suggest that hurting the hand due to a lack of protective sensation or oversensitivity may be experienced in a more dichotomised way, sometimes or always. The Rasch model provides the opportunity to explore solutions for minimising any bias by altering the scale. This is an iterative process and it is important to bear in mind fixing one source of misfit could remedy sources of misfit elsewhere. A good starting place would be to explore the response categories of the I-HaND Scale with the view of collapsing some of the response categories, based on some of the possible qualitative explanations provided in Table 5:10. This could also be supplemented by further qualitative work to better understand the construct from the patient perspective. A further avenue could be the creation of sub-tests for items which demonstrate dependency (Table 5:11).

Test-retest reliability

When evaluating test-retest reliability it is important that the recall period is considered long enough to ensure that participants do not remember their initial answers but short enough for their condition to have remained stable (Salek and Kamudoni, 2013). In this study, the mean recall period was 12 days, ranging from 4 to 30 days. The mean time is within the 7 to 14-day range that was aimed for, and while the end range (30 days) may appear rather long, for some, e.g. those with traumatic nerve injuries, nerve recovery may not have occurred within this time. Test-retest reliability has been established with a strong level of agreement and association between the baseline and follow-up I-HaND scores (ICC: 0.97; CI = 0.94 to 0.98). ICCs greater than 0.8 demonstrate excellent reproducibility, which the I-HaND Scale exceeds (McGraw and Wong, 1996) The confidence interval is narrow and the lower limit does not go below 0.9. ICCs of greater than 0.9 have been recommended for PROMs that are to be used in research or clinical settings (Nunnally et al., 1967).

Construct (structural) validity

Construct validation of the I-HaND Scale involved testing three hypotheses relating to the relationship between compression and trauma (known-groups validity) and with two other

PROMs that measure related constructs (convergent validity). The results of the t-test used in the evaluation of known-groups validity showed that the mean I-HaND Scale score for the trauma group was higher than the compression group, and going in the direction hypothesised. This, however, was not statistically significant ($t(70) = -1.31$, $p = 0.20$). This hypothesis assumed that patients with nerve trauma would experience higher levels of disability. Although it may be expected for nerve trauma to have a more life-changing effect, where compression is often deemed a transient condition that is treatable, this was not reflected in the data. Therefore, only two of the three hypotheses were supported. With hindsight, a further hypothesis could also have been formulated on how the I-HaND would correlate with a scale that measures an unrelated construct (divergent validity) to strengthen the evidence of its validity. This, however, would have required patients to complete an additional questionnaire, creating additional burden.

The I-HaND Scale demonstrated moderate to strong correlations with the Quick DASH ($r = 0.87$) and the NHF Score ($r = -0.64$). This observed degree of relationship seemed consistent for PROMs, which measure a related construct. The strong correlation with the Quick DASH could raise the question of why a new PROM is needed, if both measures are so alike, based on the correlation analysis. Condition-specific measures, however, by definition and design contain content relevant only to individuals for whom they were developed. In this study, this is demonstrated by the active involvement of patients in the item generation stage (Chapter 3) and in the content validation stage (Chapter 4). Patient involvement ensured that the content of the measure reflected concepts of importance to them and captured the expressions they used.

Responsiveness

The results of this study provide evidence that the I-HaND Scale can measure change over time, when change is expected. This is a requirement of particular importance for condition-specific PROMs (Guyatt et al., 1987). The evaluation of responsiveness can be problematic and there has been much debate over which methods should be used to do so (Beaton et al., 2001a). Measures of responsiveness, which use distribution-based methods, such as effect sizes and the standardised response mean, have been criticised as inappropriate because they are measures of magnitude of the change scores, rather than the validity of the changes scores. However, their use is deemed acceptable when 1) supplemented with anchor-based methods whereby patients themselves define change, 2) when used in a construct-validity approach with an *a prior* defined hypothesis and 3) when evaluating

responsiveness relative to another measure (De Vet et al., 2011, Wyrwich et al., 2013, Beaton, 2000).

In this study, three well-defined *a priori* hypotheses relating to the responsiveness of the I-HaND Scale were supported. Change was evaluated using both distribution and anchor based methods. Multiple approaches were used in the analysis, including change magnitude coefficients (effect size, standard response mean); and longitudinal convergent validity based on hypotheses around the relationship of change scores, assessed using Pearson's r correlation coefficients and by calculating the area under the curve. This permitted a more refined definition of the change construct, not only evaluating the capability to detect change in patients, but also the capability to differentiate between patients experiencing different levels of change (Stratford et al., 1996).

The results showed that the I-HaND Scale was sensitive to patient change when change was expected (ES = 0.51; SRM = 0.6). It could also discriminate between those who improved (ES = 0.75; SRM = 1.2) and those who did not (ES = -0.03; SRM = -0.04). The area under the curve was large (AUC = 0.85; 95% CI = 0.74 to 0.96). The I-HaND Scale was minimally more efficient at detecting these changes, relative to the Quick DASH (I-HaND: ES = 0.51; SRM = 0.60; QDASH: ES = 0.42; SRM = 0.56). The I-HaND change scores correlated positively and strongly with change scores for the Quick DASH (r = 0.83) as expected.

A limitation of the responsiveness arm of this study is that while the overall sample size was good, when the group was dichotomised into groups of improvers and non-improvers, each sub-group was small (Terwee et al., 2007). Recruiting patients in this study was a challenge, largely due to the low prevalence of hand nerve disorders. Considerable efforts were made to maximise recruitment potential. Eight NHS trusts, which see larger numbers of patients with nerve conditions, two of which were specialist nerve centres, were involved in patient recruitment. Patients were also lost to follow-up, which naturally occurs in longitudinal postal studies.

In responsiveness studies, change is usually reported in relation to an intervention, such as carpal tunnel decompression. However, in this study patients with a range of different nerve diagnoses were recruited, from multiple centres, undergoing a wide range of conservative and surgical treatments. This means that within a 12-week period some patients would have undergone only small changes, for example, patients receiving hand therapy

compared to someone having surgery for acute CTS. However, a benefit of this approach is that the people recruited were representative of the target population. While the 12-week follow-up period was relatively short for patients with hand nerve disorders, a longer period was not feasible with the resources available in the current study. Further empirical work is necessary to evaluate the responsiveness of the I-HaND Scale over a longer period.

Interpretability

An additional aim was to provide information to facilitate the interpretation of the scores produced by the I-HaND Scale. Converting abstract scores into clinically meaningful values can be useful to assist with clinical decision-making (Mokkink et al., 2010b). In routine clinical practice, score interpretation is vital: it is important that there is an understanding of what changes in the score from one visit to the next mean in clinical terms, to help inform treatment decision-making (Salek and Kamudoni, 2013). In this study, the mean change for the group of people who reported having improved was used define the clinically important difference of the I-HaND Scale. A 3-point ordinal GROC was used; however, with hindsight a 5-point scale may have allowed further discrimination between those who improved a little versus a lot. In addition, asking patients to define what constituted meaningful change for them would have helped with the interpretation of the I-HaND scores (Wyrwich et al., 2013).

5.7 Conclusion

This prospective, longitudinal PROM validation study evaluated the psychometric properties of the I-HaND Scale. The measure demonstrated excellent internal consistency according to Cronbach's alpha for the total score ($\alpha = 0.98$). The reproducibility of the I-HaND Scale was also evaluated, showing strong levels of agreement and association between the baseline and follow-up scores in patients whose condition had not changed (ICC: 0.97; CI = 0.94 to 0.98). Unidimensionality of the PROM was supported by the PCA. A Rasch analysis demonstrated that the I-HaND scale was well targeted, as evidenced by the person-item threshold map; however, it failed tests of unidimensionality, which could indicate multidimensionality. Potential sources of misfit were identified and qualitatively explored. Confirmed hypotheses relating to the relationship between the I-HaND Scale and the Quick DASH and the NHF Score provide evidence of construct validity of the measure. Hypotheses relating the responsiveness of the scale were tested using multiple

approaches, which permitted a more refined definition of the change construct. The I-HaND Scale was found to be sensitive to changes in the patient's condition for those who improved, and when change in the patients' condition was defined using patient anchors. The I-HaND was minimally more efficient at detecting these changes, relative to the Quick DASH. The results of this initial validation study provide good estimates of test-retest reliability; construct validity and responsiveness for the final, 32-item I-HaND Scale. Further prospective work, using a larger sample size, is required to independently confirm study findings. Further exploration of the structural validity, using both traditional and modern psychometric theory approaches, is needed to confirm the unidimensionality of the measure. Further evaluation of the I-HaND's capability of measuring change over a longer period of time is also needed.

Chapter 6 - Discussion

6.1 Overview

The aims of this research were to explore the impact of a peripheral nerve disorder of the hand on individuals, determine the need for a new, condition-specific PROM and develop and validate a new outcome measure: the Impact of Hand Nerve Disorders (I-HaND©) Scale. The research methods and findings have been discussed in their respective chapters. This chapter aims to synthesise the main findings from this body of work, discuss study limitations, and consider the implications for clinical practice and research, and the direction of further research.

6.2 Phase 1

> Phase 1 consisted of a literature review (Chapter 2), a qualitative study and the conceptualisation of the first version of the I-HaND Scale (Chapter 3).

A literature review was chosen as the methodology to identify existing PROMs used with people with hand nerve disorders, to appraise their psychometric properties and thus determine how appropriate their use is with people with nerve conditions. No condition-specific PROMs suitable for patients with all types of hand nerve (compression and trauma) disorders were identified. Two disease-specific PROMs exist for patients with compression-type disorders of the median and ulnar nerve respectively: the BCTQ and PRUNE (Levine et al., 1993, MacDermid and Grewal, 2013). However, these are not suitable for patients with nerve trauma. Three PROMs were identified and studies reporting on their psychometric properties were reviewed: the Patient Evaluation Measure (PEM) (Macey et al., 1995), the Michigan Hand Outcome Questionnaire (MHQ) (Chung et al., 1998) and the Disabilities of the Arm, Shoulder and Hand (DASH) (Hudak et al., 1996). The shorter versions of the MHQ and the DASH: the Brief MHQ (Waljee et al., 2011) and the Quick DASH (Kennedy et al., 2013) were also included.

These measures, which were designed and developed more generally for musculoskeletal disorders of the hand and upper limb, all had significant limitations and were deemed not

appropriate for patients with hand nerve disorders. A major shortcoming was that none of the three PROMs met current guidelines from the FDA and PCORI for content validation: namely, qualitative research methods were not used to develop the PROM content (FDA, 2009, PCORI, 2012). Qualitative research methods, in the form of concept elicitation interviews and cognitive debriefing, were not carried out to develop a conceptual framework from which to generate items. Furthermore, in initial and subsequent validation studies, patients with nerve disorders were not included, or were limited to those with carpal tunnel syndrome. This has implications for content validity and applicability of these measures for clinical use with patients with other hand nerve disorders.

Of all the region-specific measures evaluated, the DASH/Quick DASH showed the most promise. There was a substantial body of research published on its psychometric properties. It is endorsed by therapists and is acceptable to patients (Kennedy and Beaton, 2016). However, there was limited evidence of its content validity for a nerve disorders population. Whilst research to establish this was possible, the resources that would be required to establish content validity for the DASH for a nerve disorder population, while also assessing for modifications, would be greater than developing a new measure. It was considered that developing a new measure, using guidelines from the health measurement literature, would provide a vehicle by which data on hand nerve disorders could be collected. The Quick DASH was chosen as the comparator measure in the evaluation of construct (convergent) validity and responsiveness testing.

PROM development needs to have a strong conceptual basis to ensure valid measurement; one that adequately defines the variables and relationships conceptually and gives operational meaning (FDA, 2009). This was achieved primarily by carrying out qualitative interviews with patients. As a preliminary step, the qualitative literature was explored. There was a lack of clarity relating to the conceptualisation of the impact of a hand nerve disorder on activity and participation, and authors recommended further exploratory work in this area to be carried out (Jerosch-Herold et al., 2008, Chemnitz et al., 2013b). Therefore, it was not possible to formulate operational constructs to guide the development of the new, condition-specific PROM based on the published literature alone. This justified the collection of original data from patients, and in particular, it gave voice to those people with diagnoses that had not previously been studied. The limited literature also provided a rationale for choosing an explanatory, theory-generating approach. The previous studies, to a large extent, presented descriptive findings. This resulted in the construction of a grounded theory, which was named: ‘learning to live with a hand nerve disorder’.

Patients are experts on their condition, making the account of their experience a rich and important source of information. The actual phrasing used by patients to describe their condition was helpful to generate items, ensuring that the content was not only relevant but was also appropriate, comprehensible and interpretable. This increased the likelihood of the PROM having good content validity. The qualitative study provided new insights into the experiences of people with hand nerve disorders. It also provided supporting evidence that the content of existing PROMs was not specific for this population, e.g. the Quick DASH has only one symptom item which asks respondents about 'tingling' in the upper limb, which would be considered relevant for people with hand nerve disorders. Furthermore, its content does not cover other experiences that patients in this study identified as important, such as cold intolerance or frustration and self-consciousness. This further confirmed the need for a new, condition-specific PROM.

Using the ICF to guide the analysis of the interviews provided a unique opportunity to explore the interconnectedness between body structures, activities and participation as well as contextual influences as a consequence of a hand nerve condition (WHO, 2001). While the use of the ICF could be viewed as hindering the generation of codes from the data and instead forcing codes into predetermined categories, several steps were taken to safeguard against this and to ensure trustworthiness (see 3.7.2). Long-term outcomes for people with hand nerve disorders were subject to many influences besides surgery or rehabilitation. This included internal as well as external factors, such as coping strategies, the patients' level of self-esteem, the importance attached to their appearance and social support. The qualitative study illustrated that contextual factors played a central role for people learning to adapt following a hand nerve condition. These findings have important clinical implications beyond the development of a new PROM and are discussed further below (see 6.7).

A hand nerve disorder-specific conceptual framework was developed that included four domains: symptoms, pain, activity limitations and participation restrictions. These domains were derived from ICF categories. However, the content was specific to hand nerve disorders. The use of the ICF to develop conceptual frameworks for new PROMs has been endorsed by others (Tucker et al., 2014). The content included overall hand function, movement, sensation and strength. Physical and emotional difficulties associated with the disorder were also included; pain and discomfort and specific situations that may cause pain or discomfort relevant to patients with nerve disorders such as cold intolerance, interference with sleep and over-sensitivity of the hand; the impact of the disorder on daily routine, followed by specific activities that were reported to be problematic for patients, the

physical demands of work and participation in recreational activities. Criteria designed to guide questionnaire design and item construction where followed (Streiner et al., 2014, McColl et al., 2002, McDowell, 2006). Careful consideration of the layout and instructions, framing of questions, response format and recall period was taken to reduce potential biases and cognitive and respondent burden. This research was the first to conceptually map the range and nature of the impact of a hand nerve disorder and to offer an explanatory social theory. It also included adult trauma and other compression disorders that have not previously been described in the literature, such as radial nerve palsy patients. This helped to ensure the relevance of the content for patients with all types of hand nerve conditions.

6.3 Phase 2

In phase 2, thorough and systematic steps were taken to pre-test the I-HaND Scale using mixed methods (Chapter 4). This was conducted to establish content and construct (structural) validity of the I-HaND Scale.

Examining the structure of a measure provides evidence of the rigour of the conceptual framework and its translation into measurement and the rationale for combining items into an overall scale (Rothman et al., 2007, Patrick et al., 2011b). This phase of the research provided opportunities to make final changes to the PROM before the final validation study. This research took an approach to scale refinement that is strongly recommended but differs somewhat from approaches adopted by others in the field of hand surgery and rehabilitation (FDA, 2009, PCORI, 2012). Specifically, the I-HaND Scale was developed on the basis of a conceptual model, which defined the areas for scale development. (Patrick et al., 2011a). In hand rehabilitation it has been typical to develop an item pool based on expert opinion or from the literature, followed by an item-reduction process using factor analysis (Hudak et al., 1996, Chung et al., 1998). With this approach, the content of a scale, rather than the construct intended for measurement, defines what the scale measures (Hobart et al., 2007). Grouping items statistically can be misleading; it assumes, based on correlations between items, that they measure the same thing. However, this does not ensure that items in a group measure the same construct. In phase 2a cognitive interviews were used as the primary method of item refinement, following methods described by Willis (2005).

Patient input proved to be the most important element of the development process. Cognitive interviewing provided evidence that, to a large extent, previous steps taken to

ensure trustworthiness had been effective and that the preliminary I-HaND Scale was clear, understood and relevant for people with nerve conditions. This is best expressed in the words of the patients themselves. One participant remarked: “It’s simple to use, it’s simple to understand, I don’t really think it needs changing”, reinforcing the acceptability of the new measure. The comments of patients towards the individual items of the I-HaND Scale demonstrated that the content was highly pertinent to them. Patients said: “It seems to cover everything that affects me”, and “as I said it is more or less designed for me that one”. Patients reported that the I-HaND items were asking them about things that were personally meaningful. One patient remarked: “Everything in there was what actually occurred and what I have been through”. In that moment they reported feeling understood and validated and a connection was established. Another patient exclaimed: “It covers everything that should be asked or should have been asked”. For this person, we get a sense that the content of previously administered PROMs may not have been relevant for them. This brings to light the questions over the content validity of outcome measures that have been developed previously without a strong conceptual or theoretical basis for patients. The cognitive interview process was effective for not only supporting the conceptual framework, developed in phase 1 (see 3.6.1), but also for identifying further problems with the questionnaire early in the development process, and to guide changes to layout, content and mode of administration. This produced a 35-item I-HaND Scale, which was further tested with a larger, heterogeneous sample of patients in phase 2b.

Pre-testing the I-HaND scale was useful for identifying problems with questionnaire items and responses. The methods informed changes to layout, content, administration mode, and item removal to reduce respondent burden, decrease data errors and non-response, and provide further validity and clinical utility of the scale before formal psychometric evaluation. The use of statistical methods provided a complementary method, alongside cognitive methods, for evaluating the strengths and weaknesses of the developing PROM. Only minor changes were made to the developing scale, as caution should be used when making significant changes to newly developed instruments on the basis of small samples. Decisions to modify, remove or merge items were made after extensive discussion with the PROM working group. In order to justify these decisions, importantly, the items retained were needed for the breadth, range and measurement precision for the construct which they measured. Thus, at this stage of the I-HaND development, a very parsimonious approach was taken to reduce the number of items so as not to compromise content and clinical validity.

6.4 Phase 3

In phase 3 a quantitative longitudinal, repeated-measures study was used to evaluate the psychometric properties of construct validity, reliability and responsiveness of the final 32-item I-HaND Scale (Chapter 5).

A sample of patients with a range of hand nerve disorders, under the care of hand therapists from eight hospitals around the UK, was recruited. This was necessary to achieve the recommended sample sizes required for the evaluation of structural validity. Recruitment was challenging at times, especially as this non-portfolio study did not generate remuneration for the participating centres, and their participation was based on 'good will'. Some of these challenges had been anticipated and mitigated at the design stage of the study by getting patients to take the study materials home and to self-consent rather than asking clinicians to do face-to-face recruitment (see ethical considerations at 3.4.2). This meant less burden on NHS trusts, which were enrolled as Patient Identification Centres (PICs), as opposed to full sites during the NHS R&D approval process. In addition, clinicians were recruited as 'local collaborators' instead of principal investigators, negating the requirement for them to undertake 'Good Clinical Practice' (GCP) training and therefore minimising any additional burden. The clinical experience of the chief investigator, who had good contacts in the field whilst also offering to share knowledge pertaining to the research methodology through in-service teaching at each site were also valuable in getting sites on board. The number of sites from all geographical parts of the country strengthens the external validity of this study, as patients recruited from multiple centres are more likely to be representative of the nerve disorder population than those from only one site.

Traditional psychometric methods to test the reliability, validity and responsiveness were used to evaluate the I-HaND Scale in line with current guidelines (FDA, 2009, PCORI, 2012, Terwee et al., 2012). Overall support was established for the psychometric properties of the I-HaND Scale. The proportion of missing data was low, suggesting that it was acceptable to patients. Scale scores spanned the entire range of response options. There were some floor effects; however, PROMs need to be able to capture different levels of ability so the fact that some items were easy for some people but not for others was actually desirable. The exploratory principal components analysis indicated a unidimensional scale. Standard criteria were effectively satisfied for internal consistency, as demonstrated with a high alpha coefficient and item-total correlations. Test-retest ICCs were high, indicating excellent reliability. Two out of the three *a priori* hypotheses to evaluate the construct

validity of the I-HaND Scale were supported. The generated hypotheses relating to the strength of association with external measures were supported, thus providing evidence of convergent validity. The known-groups validity hypothesis, which predicted that trauma patients would experience statistically significantly higher levels of disability, was not supported, although mean differences showed a trend in the right direction. In hindsight, this hypothesis was perhaps an inaccurate reflection of the true impact of nerve compression, which is often seen as less disabling than traumatic nerve injuries. On revisiting the concept-elicitation interview data, it became apparent that both trauma and compression patients reported significant disability as a consequence of their condition.

All three *a priori* hypotheses to evaluate the responsiveness of the I-HaND Scale were supported. The use of distribution and anchor-based methods provided a more meaningful estimate of change, as patients have defined this themselves (Wyrwich et al., 2013). In addition using two patient anchors, to evaluate both global status and change can help to minimise recall bias and improves confidence in results (Norman et al., 1997). The methodological limitations notably the small sample sizes, the lack of standardisation of the intervention and short follow-up period have been discussed. It is common, however, for PROM developers to carry out initial validation work followed by responsiveness testing in an independent study. Therefore, despite the limitations, having some initial responsiveness data was valuable and the lessons learned during this aspect of the study will inform future empirical work.

The classical test theory approach to psychometric evaluation provided good evidence for the acceptability, reliability, validity and responsiveness of the I-HaND Scale. A preliminary evaluation of the I-HaND using Rasch methods demonstrated that it was reliable, using the person-separation index, and that it was a well-targeted scale as evidenced by the person-item threshold map. I-HaND scores, however, did not fit the expected scores under the Rasch model and unidimensionality was not confirmed. The finding that the scale is multidimensional is in some regards not surprising as the I-HaND was developed using a conceptual framework that hypothesised four domains including symptoms and pain (impairments) as well as activity and participation. Furthermore, the items with residuals, which loaded positively on the PCA, were all impairment-related items and items with negatively loading residuals were activity-related items. This has implications for the interpretation of I-HaND scores.

In its current form the I-HaND does not measure a single underlying construct, which is a prerequisite to the summation of the scale items and is the first step towards achieving

measurement (Tesio, 2003, Tesio, 2004). In addition, the significant total item-trait chi-square statistic suggested that the observed I-HaND scores did not fit the expected scores under the Rasch model, which is also a requirement of true interval level measurement. Further work is required therefore, to explore possible sources of misfit and to find solutions to these. Potential avenues include determining whether some items would benefit from different response categories, e.g. rescoring or even dichotomising responses or creating subtests (testlets) to make the I-HaND Scale psychometrically stronger, yet retaining its clinical meaningfulness. This will help to achieve true scientific measurement and will make it possible for the inclusion of the I-HaND in future clinical trials of interventions for hand nerve disorders (Tesio, 2003, Tesio, 2004, Tennant et al., 2004).

6.5 Summary

The work presented in this thesis contributes towards the evidence base for the evaluation of patient-reported outcomes in the field of peripheral nerve surgery and rehabilitation by:

- Identifying region-specific PROMs which evaluate the impact of a hand condition on body structures, activities and participation used with people with hand nerve disorders and critically appraising the literature on their psychometric properties (Chapter 2).

- Constructing an explanatory social theory grounded in the lived experiences, specifically the impact on activities and participation in life roles, for people with a range of a hand nerve conditions seen in routine clinical practice; thus providing insights into outcome domains of importance for this population (Chapter 3).

- Using the International Classification of Functioning, Disability and Health (ICF) to guide the development of a conceptual framework, to explore the impact of nerve disorders on body structures, activity and participation (Chapter 3).

- Establishing face validity, for a new condition-specific PROM for peripheral nerve disorders of the hand, the Impact of the HaND Nerve Disorders (I-HaND) Scale, by a PROM development group with experience in upper limb rehabilitation, outcome measurement and PROM development (Chapter 3).

- Evaluating the content of the I-HaND Scale by carrying out cognitive interviews and establishing conceptual relevance, an appropriate layout, timeframe, response options, framing of items and administration of the scale (Chapter 4).

- Evaluating the more structural aspects of the content of the I-HaND Scale using quantitative methods, with a larger heterogeneous sample of patients with a range of hand nerve conditions (Chapter 4).

- Evaluating the reliability, construct validity and responsiveness of the I-HaND Scale using classical test theory methods in a longitudinal, repeated-measures study of 132 patients with a range of hand nerve conditions (Chapter 5).

- Assessing how scores produced by the I-HaND Scale fit the Rasch model and identifying sources of misfit (Chapter 5).

6.6 Study limitations

This work is not without limitations, which need to be considered when interpreting results and forming conclusions.

In the qualitative phase of the I-HaND development, in-depth interviews were used to develop and refine the content. Additional qualitative methods, such as focus groups or interviews with the partners of those with a hand condition, may have provided further insights. However, the qualitative interviews were continued to the point at which no new concepts emerged, ensuring that the conceptual framework adequately covered important outcomes for patients. Additionally, comprehensive methods were followed to ensure that the qualitative findings were confirmable, dependable, credible and transferable (see 3.7.2). Subsequent pre-testing with patients confirmed the conceptual framework that emerged from the qualitative work, providing support for the adequacy of the qualitative methods used in this research. The PROM working group members consulted during the development of the I-HaND, were all part of the academic staff at the University of East Anglia, and therefore the opinions expressed may not have been generalisable to others at

different sites. However, consultation was intended to help contextualise the findings from each group member's different skillset and to identify any important methodological errors and missed information.

Key indicators of the quality of PROMs are their reliability, validity and responsiveness. A limitation of this study was that the psychometric properties of the final version of the I-HaND Scale were estimated using data from a single study. The sample sizes were acceptable and were comparable to or better than other hand PROM validation studies (Macey et al., 1995, Chung et al., 1998, Hudak et al., 1996). However, since the psychometric estimates are subject to sampling variation, it is possible that different items might have been selected if more data had been available. Sample sizes were on the borders of acceptability for the assessment of structural validity for both classical test theory and Rasch measurement theory (Mokkink et al., 2010a, Terwee et al., 2012). While evidence indicates that useful estimates can be obtained from small samples, further examination of the structure of the I-HaND Scale is needed (Hobart et al., 2012, Chen et al., 2014, MacCallum et al., 1999).

The known difficulties of recruiting patients with hand nerve disorders have been stated. This resulted in needing to extend recruitment to eight NHS trusts across the UK to identify enough suitable participants. The ethical considerations of patients self-consenting and completing the I-HaND Scale and other outcome measures without supervision have been discussed. A limitation of postal research, however, is that those who take part may not be representative of the hand nerve disorder population and those who respond tend to be better educated and more literate. The response rates can also be lower and patients are naturally lost at follow-up intervals (McColl et al., 2002). For the I-HaND the approximate response rate was 25%, after the first follow-up 25% of participants were lost, and a further 18% were lost at the second follow-up. During its development, considerable effort was made to ensure the I-HaND was acceptable to patients. A readability check was used to ensure that a 12-13 year old would be able to understand it, confirmed by an acceptable SMOG Index of 9.6 (Mc Laughlin, 1969). It was not possible, however, to include patients with cognitive impairments due to the unavoidable difficulty of obtaining informed consent from these patients.

The use of traditional psychometric methods in the development of new PROMs has been criticised as these methods produce measures which are ordinal in nature, in that they describe order but not the relative size or degree of the difference between measurements (Rasch, 1960). A more modern approach to scale development is offered by the Rasch

method which has the ability to construct linear, interval-level measurements from ordinal-level rating scale data (Andrich, 2004, Wright, 1977). While acknowledging the scientific advances of using Rasch, its use as the primary method to develop the I-HaND Scale was not feasible in this study. For a combination of reasons relating to access to software and training, the opportunity to use Rasch only became possible towards the end of the study. Therefore its use was limited to its diagnostic capacity to identify whether I-HaND data fitted the Rasch model and to obtain a different perspective on unidimensionality, a requirement for construct validity (Streiner et al., 2014). Rasch also allowed for exploration of the fit of people and items; and the ordering of response categories and differences in responses from sub-groups in the sample (Hobart and Cano, 2009, Hagquist et al., 2009).

The development and validation of new PROMs takes many years of hard work and is resource-intensive (Fayers and Machin, 2013). Entire teams are dedicated to such effort, for instance, the European Quality of Life (EUROQOL) group and the European Organisation for Research and Treatment of Cancer (EORTC) group, with large budgets. The I-Hand was developed as part of a three-year faculty-funded studentship and highlights the constraints in terms of time, finances and human resources. There is no doubt that the amount and quality of the data collected might have been enhanced without these constraints. Nonetheless, the thorough and systematic process which was followed, ensured rigour of the development process, in spite of such limitations.

6.7 Implications for clinical practice and research

Over half a century ago Moberg (1958) emphasised the importance of activities of daily living as an outcome domain in assessment following nerve repair. It was recognised that patients compensate through the use of vision and bilateral hand use and that tests of impairment do not predict patients' ability to use their hands in a functional capacity (Jerosch-Herold, 1993). This led to the recommendation by Rosén (1996) that the patient's perspective of the impact of a nerve injury on activities and participation should always be sought in parallel with traditional clinician-rated methods for assessing outcome, which focus on impairment. This shift in focus, however, has taken time and this is reflected in the nerve surgery literature. In a literature review carried out by MacDermid (2005) almost a decade later, only one study was identified which included the use of an upper-limb specific PROM to assess impact on activity and participation (the DASH).

In the absence of a condition-specific PROM for hand nerve trauma, the use of region-specific upper limb PROMs such as the DASH or the MHQ was recommended with caution; also that further empirical work was needed to determine that the content of such measures was relevant for people with nerve conditions until a new, condition-specific PROM could be developed (MacDermid, 2005). Over a decade later there was no definitive answer to the question of the validity of using region-specific upper-limb PROMs with this population, and no known condition-specific PROMs suitable for people with hand nerve trauma existed. To address this gap in research the doctoral studentship was conceptualised by the primary supervisor who had specifically been concerned about the validity of using region-specific PROMs in clinical trials of interventions for hand nerve disorders. At this time the chief investigator, whilst working as an occupational therapist at the Royal National Orthopaedic Hospital, Stanmore, was also questioning the content validity of these region-specific PROMs in clinical practice at this specialist nerve surgery and rehabilitation centre.

Patients from throughout the UK attended this national specialist unit for one to two weeks of intensive assessment and rehabilitation for their hand nerve disorder. Unlike a busy out-patient hand clinic, this residential setting afforded patients the opportunity to discuss in a more personal way the impact of their condition on their daily lives. The stories that were being shared with the chief investigator provided deep insights into the experiences of living with a nerve disorder and further confirmed his suspicions that the content of existing region-specific PROMs that were being used at this unit may not be relevant for this population. The opportunity to address this shortcoming through an advertised PhD studentship on this topic was taken. Therefore, this research stemmed from a need for a new, hand nerve disorder-specific PROM for trauma patients for use in clinical practice and research, in order to assess outcomes of importance for this population. The existing and widespread use of region-specific PROMs, without a sound theoretical basis or limited evidence of their appropriateness for people with nerve conditions, motivated this research.

The work undertaken in this present study sought to address these issues and met this need by developing and validating a new, condition-specific PROM for peripheral nerve disorders of the hand: the Impact of the HaND Nerve Disorders (I-HaND) Scale. Using the ICF to guide the development of a conceptual framework illuminated the importance of the impact on body structures for patients, which led to the inclusion of symptom and pain domains. Therefore, the I-HaND Scale offers insight into not only activity limitations and participation restrictions, but also symptoms specific for people with hand nerve conditions.

This provides clinically useful information by offering a patient perspective of impairment, which may differ from conventional clinician-rated assessments. In addition, the I-HaND Scale was developed and validated using patients with a range of hand nerve conditions, making it appropriate for patients with traumatic nerve injuries, compression syndromes and for individuals with combined nerve disorders. The I-HaND Scale can therefore facilitate the comparison of outcome between groups of patients with different nerve disorders.

The construction of an explanatory social theory grounded in the lived experiences of patients also generated new insights into the experience of living with a nerve disorder and has high clinical value. The findings of the qualitative study generated new directions for the future management of hand nerve disorders. The significant amount of psychological distress experienced by patients with a hand nerve condition, provides a rationale for psychological screening and monitoring of patients with both acute and chronic nerve disorders. Two items on the I-HaND Scale reflect psychological distress, targeting emotions and self-consciousness, and could prompt further investigation from clinicians.

The importance of contextual factors in recovery from nerve disorders should inform a broader discourse with patients as part of therapists' subjective assessment. The patients in this study struggled to learn to change handedness, and this had a considerable impact on their ability to participate in work and recreational activities. Having dedicated therapy time to learn how to change handedness such as that proposed by Yancosek and Calderhead (2012), as well as opportunities for recreational and vocational rehabilitation may assist with this transition. The significance of the relationship with others during the adaptation process could signal a need for greater inclusion of family or carers in the rehabilitation process. There may be merit in inviting partners to attend therapy appointments and providing written information for them on hand nerve disorders, especially if they are required to perform a caring role. Clinicians should acknowledge that they, too, are in a relationship with their patients and are required to adapt to ensure that information and advice provided to patients takes into account their individual circumstances and requirements.

There are many benefits of using PROMs in clinical practice, such as the facilitation of clinician-patient communication and shared decision making; identifying and prioritising patient problems; screening for hidden problems; identifying patient preferences and evaluating therapeutic services (Velikova et al., 2004, Higginson and Carr, 2001, Greenhalgh, 2009, Doward et al., 2010). The I-HaND Scale potentially provides a means for assessment of the impact of hand nerve conditions, and a way of quantifying the benefits

of treatment from the patient's perspective. This is now recognised as an essential aspect of healthcare evaluation (Cleary, 1997, Hobart, 2002). Furthermore, in the absence of a condition-specific PROM for hand nerve trauma, clinical trials of the effectiveness of nerve surgery have used region-specific PROMs, which may not be valid, reliable or appropriate for addressing the research questions. This is important as the selection of appropriate outcome measures underpins the interpretation of study results.

PROMs which are used as primary or secondary outcome measures in clinical trials must be of high scientific quality and capable of producing scores which equate to measurement (Tesio, 2003, Tesio, 2004). This is critical because in clinical trials, these scores are used to calculate changes across experimental and control groups and may produce spurious results. This in turn could lead to erroneous conclusions that an intervention is effective, when it is not, or the converse (Tennant et al., 2004). This has the potential to negatively influence decisions that are made regarding the provision of services and ultimately patient care. Subject to further work, the I-HaND Scale could provide a more appropriate and psychometrically robust alternative PROM for use in clinical trials of hand nerve interventions. This could offer a patient-perspective on treatment benefits, particularly as these may differ from other clinical outcomes.

In the hand nerve surgery literature, it is common to find that multiple studies have been conducted to answer similar questions about the effectiveness of treatment. Meta-analyses are statistical techniques for combining the findings from independent studies and can provide a more objective appraisal of the evidence (Egger et al., 1997). A requirement of a meta-analysis is that the same outcomes are measured in the same way across studies, allowing for them to be combined (Huque, 1988). This is often problematic, with a multitude of different outcome measures currently used in trials. A solution to this problem is the creation of core outcome measures to be included in the conducting and reporting of research studies (Clarke, 2007). The I-HaND Scale has the potential to be used as part of an agreed standardised collection of outcomes, known as a core outcome set (COS), for inclusion and reporting in trials for hand nerve interventions, which could provide a greater influence on practice and policy (Williamson et al., 2012). The I-HaND might complement other outcome instruments like the Rosén score, as part of a core outcome set for hand nerve disorders (Rosén and Lundborg, 2000). The latter is a clinician-rated impairment-based scoring instrument, which covers the sensory, motor, pain and discomfort domains of body structures/functions (see 1.4.5). The I-HaND Scale could complement the Rosén score by offering a patient perspective of impairment as well as providing data on the impact

on activities and participation in life roles. This would afford a more holistic and comprehensive evaluation of outcome from hand nerve disorders.

The development of a core outcome set does not restrict the inclusion of other outcome measures; instead it sets a minimum set of primary outcomes which must be included (Williamson et al., 2012). Therefore the I-HaND Scale could be used in conjunction with other PROMs used in hand surgery and rehabilitation, such as the Quick DASH (Beaton et al., 2005). The results of the PROM validation study (Chapter 5) provide good evidence of construct (convergent) validity and responsiveness relative to the Quick DASH, therefore this measure could be used secondary to the I-HaND Scale in research as well as in the collection of routine patient outcomes. This would complement the use of the I-HaND by allowing for comparison with other patients with a range of upper limb musculoskeletal conditions. Similarly, the I-HaND Scale could be used as a secondary PROM in studies reporting on interventions for single nerve compression syndromes, such as carpal tunnel syndrome, where a disease-specific PROM (the BCTQ) exists (Levine et al., 1993). This would allow for comparison with other hand nerve intervention studies. Finally, the I-HaND could be used with other generic measures, such as the SF-12, a validated health-status measure (Ware Jr et al., 1996). This would allow for comparison with many diseases and outcomes other than hand or upper limb conditions.

The use of PROMs in both research and clinical practice is becoming well established and there is an evolving recognition that PROMs can offer much wider contributions to healthcare, such as the evaluation of the quality of care, measuring the performance of healthcare providers and clinical audit (Black et al., 2016). The National Patient Reported Outcome Programme is an example of the innovative use of PROMs in the NHS, to collect information from patients themselves about the outcome of their surgery. Data collected can help trusts to review care pathways and lead to service improvements. Published data on the performance of individual centres can also inform users of services to choose, where appropriate, where they want to be treated (Black, 2013). The programme currently is limited to four surgical procedures: total hip replacement, total knee replacement, varicose veins and groin hernia surgery. The comprehensive development and validation of the I-HaND Scale makes it potentially important as a PROM for hand nerve disorders within the National Patient Reported Outcome Programme, should the programme be extended to cover hand surgery.

6.8 Future research

The Impact of Hand Nerve Disorders (I-HaND ©) Scale was developed following guidelines for the development of PROMs by the Patient-Centered Outcomes Research Institute (PCORI). It was developed and validated using classical test theory methods, demonstrating that is a reliable and valid indicator of the impact of a hand nerve disorder and that it is capable of detecting change. However, the more sophisticated techniques employed in the Rasch analysis uncovered some structural issues, which require further exploration. Traditional psychometric methods are limited in the information they provide at item level, particularly about the adequacy of the response options, and fail to provide specific guidance on how items might be improved. Rasch methods overcome these limitations as they are able to better diagnose specific issues surrounding the performance of rating scales (Andrich, 2002). Therefore, future work to explore and improve the structural validity of the I-HaND Scale using Rasch methods is planned.

The literature and qualitative work in this study has highlighted that people with hand nerve disorders continue to experience improvements in their condition over many years (Chemnitz et al., 2013a, Lundborg, 2004). It is important that the I-HaND is capable of measuring this change. Further longitudinal work to evaluate how sensitive the I-HaND Scale is at measuring change over a longer period of time is therefore needed. In this study, the follow-up period was 12 weeks, which is still within the sub-acute phase of healing. At this time, in addition to nerve recovery, patients are also recovering from concomitant injuries and the trauma of surgery itself. A longer follow-up period of at least one to two years would be recommended. Larger samples of patients would increase the validity of results and also facilitate stratifying by diagnosis and intervention. Therefore, further work is needed to provide more robust evidence of the responsiveness of the I-HaND Scale. Informal discussions about taking part in a future longitudinal study are in progress with the local collaborators from each NHS trust in the HaND study.

In the longer-term, further validation work to confirm the study findings in an independent study with larger samples is needed. There has also been international interest in the I-HaND Scale; therefore, translation and cross-cultural validation work are also possible directions of future research. This would allow the I-HaND to be used clinically in other countries as well as by other non-English-speaking UK residents. This could pave the way towards future multi-national and multi-cultural research projects (Guillemin et al., 1993).

6.9 Summary and conclusions

This research aimed to develop and validate a new, hand nerve-specific PROM for use in clinical practice and research; and to assess outcomes of importance for this population. The use of region-specific PROMs, without a sound theoretical basis or limited evidence of the appropriateness of their content for people with nerve conditions, provided a rationale for this work. Given the limitations of the qualitative research literature, little was known about the experience of a hand nerve disorder. This study was the first to conceptualise the impact from the patient's perspective, and develop a disorder-specific PROM that captures outcomes important to patients. The development and evaluation process employed methods accepted and applied in the current health measurement field. Using mixed methods in an iterative and interactive manner, particularly at early developmental stages, helped to establish content validity.

A PROM for people with hand nerve disorders, the I-HaND Scale was developed and validated. It includes 32 items and covers four outcome domains. The research demonstrates that hand nerve conditions impact on body structures, activities and participation in life roles, and the I-HaND Scale provides a method for evaluating this impact. The I-HaND Scale is intended for self-completion and is currently appropriate for use with adults with a range of hand nerve disorder diagnoses, and suitable for all UK healthcare settings.

This study makes important contributions to the field of hand surgery and rehabilitation, as well as wider health measurement fields. The findings demonstrate that using mixed research methods were a suitable approach to develop a new, hand nerve-disorder specific PROM. The Impact of Hand Nerve Disorders (I-HaND ©) Scale has the potential, subject to further psychometric testing, to be a clinically useful instrument in the evaluation of outcome for peripheral nerve disorders of the hand, outcomes that are ultimately best judged by patients themselves. I-HaND data could provide an important source of information for supporting patient-focused decision making; provide a PROM for intervention and evaluation research; be used as a performance indicator in service contracts; or in evaluating performance of providers of treatment for hand nerve disorders. It has the potential to provide a means for comparison of the quality of care from different service providers and outcomes from different interventions across the entire NHS, which might be useful in decision-making related to commissioning of services, choice of provider or interventions to be covered (Devlin and Appleby, 2010).

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Appendices

Appendix 2.1 COSMIN checklist with 4-point scale

COSMIN checklist with 4-point scale

Contact
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Instructions

This version of the COSMIN checklist is recommended for use in systematic reviews of measurement properties. With this version it is possible to calculate overall methodological quality scores per study on a measurement property. A methodological quality score per box is obtained by taking the lowest rating of any item in a box ('worse score counts'). For example, if for a reliability study one item in the box 'Reliability' is scored poor, the methodological quality of that reliability study is rated as poor. The Interpretability box and the Generalizability box are mainly used as data extraction forms. We recommend to use the Interpretability box to extract all information on the interpretability issues described in this box (e.g. norm scores, floor-ceiling effects, minimal important change) of the instruments under study from the included articles. Similar, we recommend to use the Generalizability box to extract data on the characteristics of the study population and sampling procedure. Therefore no scoring system was developed for these boxes.

This scoring system is described in this paper:

Terwee CB, Mokkink LB, Knol DL, Ostelo RWJG, Bouter LM, de Vet HCW. Rating the methodological quality in systematic reviews of studies on measurement properties: a scoring system for the COSMIN checklist. Quality of Life Research 2011, July 6 [epub ahead of print].

Appendix

Step 1. Evaluated measurement properties in the article

	Internal consistency	Box A
	Reliability	Box B
	Measurement error	Box C
	Content validity	Box D
	Structural validity	Box E
	Hypotheses testing	Box F
	Cross-cultural validity	Box G
	Criterion validity	Box H
	Responsiveness	Box I

Step 2. Determining if the statistical method used in the article are based on CTT or IRT

Box General requirements for studies that applied Item Response Theory (IRT) models				
		excellent	**good**	**fair**	**poor**
1	Was the IRT model used adequately described? e.g. One Parameter Logistic Model (OPLM), Partial Credit Model (PCM), Graded Response Model (GRM)	IRT model adequately described	IRT model not adequately described		
2	Was the computer software package used adequately described? e.g. RUMM2020, WINSTEPS, OPLM, MULTILOG, PARSCALE, BILOG, NLMIXED	Software package adequately described	Software package not adequately described		
3	Was the method of estimation used adequately described? e.g. conditional maximum likelihood (CML), marginal maximum likelihood (MML)	Method of estimation adequately described	Method of estimation not adequately described		
4	Were the assumptions for estimating parameters of the IRT model checked? e.g. unidimensionality, local independence, and item fit (e.g. differential item functioning (DIF))	assumptions of the IRT model checked	assumptions of the IRT model partly checked	assumptions of the IRT model not checked or unknown	

To obtain a total score for the methodological quality of studies that use IRT methods, the 'worse score counts' algorithm should be applied to the IRT box in combination with the box of the measurement property that was evaluated in the IRT study. For example, if IRT methods are used to study internal consistency and item 4 in the IRT box is scored fair, while the items in the internal consistency box (box A) are all scored as good or excellent, the methodological quality score for internal consistency will be fair. However, if any of the items in box A is scored poor, the methodological quality score for internal consistency will be poor.

Step 3. Determining if a study meets the standards for good methodological quality

Box A. Internal consistency	excellent	good	fair	poor
1 Does the scale consist of effect indicators, i.e. is it based on a reflective model?				
Design requirements				
2 Was the percentage of missing items given?	Percentage of missing items described	Percentage of missing items NOT described		
3 Was there a description of how missing items were handled?	Described how missing items were handled	Not described but it can be deduced how missing items were handled	Not clear how missing items were handled	
4 Was the sample size included in the internal consistency analysis adequate?	Adequate sample size (≥100)	Good sample size (50-99)	Moderate sample size (30-49)	Small sample size (<30)
5 Was the unidimensionality of the scale checked? i.e. was factor analysis or IRT model applied?	Factor analysis performed in the study population	Authors refer to another study in which factor analysis was performed in a similar study population	Authors refer to another study in which factor analysis was performed, but not in a similar study population	Factor analysis NOT performed and no reference to another study
6 Was the sample size included in the unidimensionality analysis adequate?	7* #items and ≥100	5* #items and ≥100 OR 6-7* #items but <100	5* #items but <100	<5* #items
7 Was an internal consistency statistic calculated for each (unidimensional) (sub)scale separately?	Internal consistency statistic calculated for each subscale separately			Internal consistency statistic NOT calculated for each subscale separately
8 Were there any important flaws in the design or methods of the study?	No other important methodological flaws in the design or execution of the study		Other minor methodological flaws in the design or execution of the study	Other important methodological flaws in the design or execution of the study
Statistical methods				
9 for Classical Test Theory (CTT), continuous scores: Was Cronbach's alpha calculated?	Cronbach's alpha calculated		Only item-total correlations calculated	No Cronbach's alpha and no item-total correlations calculated
10 for CTT, dichotomous scores: Was Cronbach's alpha or KR-20 calculated?	Cronbach's alpha or KR-20 calculated		Only item-total correlations calculated	No Cronbach's alpha or KR-20 and no item-total correlations calculated
11 for IRT: Was a goodness of fit statistic at a global level calculated? E.g. χ^2, reliability coefficient of estimated latent trait value (index of (subject or item) separation)	Goodness of fit statistic at a global level calculated			Goodness of fit statistic at a global level NOT calculated

NB. Item 1 is used to determine whether internal consistency is relevant for the instrument under study. It is not used to rate the quality of the study.

Box B. Reliability: relative measures (including test-retest reliability, inter-rater reliability and intra-rater reliability)				
	excellent	**good**	**fair**	**poor**
Design requirements				
1 Was the percentage of missing items given?	Percentage of missing items described	Percentage of missing items NOT described		
2 Was there a description of how missing items were handled?	Described how missing items were handled	Not described but it can be deduced how missing items were handled	Not clear how missing items were handled	
3 Was the sample size included in the analysis adequate?	Adequate sample size (≥100)	Good sample size (50-99)	Moderate sample size (30-49)	Small sample size (<30)
4 Were at least two measurements available?	At least two measurements			Only one measurement
5 Were the administrations independent?	Independent measurements	Assumable that the measurements were independent	Doubtful whether the measurements were independent	measurements NOT independent
6 Was the time interval stated?	Time interval stated		Time interval NOT stated	
7 Were patients stable in the interim period on the construct to be measured?	Patients were stable (evidence provided)	Assumable that patients were stable	Unclear if patients were stable	Patients were NOT stable
8 Was the time interval appropriate?	Time interval appropriate		Doubtful whether time interval was appropriate	Time interval NOT appropriate

9	Were the test conditions similar for both measurements? e.g. type of administration, environment, instructions	Test conditions were similar (evidence provided)	Assumable that test conditions were similar	Unclear if test conditions were similar	Test conditions were NOT similar
10	Were there any important flaws in the design or methods of the study?	No other important methodological flaws in the design or execution of the study		Other minor methodological flaws in the design or execution of the study	Other important methodological flaws in the design or execution of the study
Statistical methods					
11	for continuous scores: Was an intraclass correlation coefficient (ICC) calculated?	ICC calculated and model or formula of the ICC is described	ICC calculated but model or formula of the ICC not described or not optimal. Pearson or Spearman correlation coefficient calculated with evidence provided that no systematic change has occurred	Pearson or Spearman correlation coefficient calculated WITHOUT evidence provided that no systematic change has occurred or WITH evidence that systematic change has occurred	No ICC or Pearson or Spearman correlations calculated
12	for dichotomous/nominal/ordinal scores: Was kappa calculated?	Kappa calculated			Only percentage agreement calculated
13	for ordinal scores: Was a weighted kappa calculated?	Weighted Kappa calculated		Unweighted Kappa calculated	Only percentage agreement calculated
14	for ordinal scores: Was the weighting scheme described? e.g. linear, quadratic	Weighting scheme described	Weighting scheme NOT described		

Box C. Measurement error: absolute measures					
		excellent	**good**	**fair**	**poor**
Design requirements					
1	Was the percentage of missing items given?	Percentage of missing items described	Percentage of missing items NOT described		
2	Was there a description of how missing items were handled?	Described how missing items were handled	Not described but it can be deduced how missing items were handled	Not clear how missing items were handled	
3	Was the sample size included in the analysis adequate?	Adequate sample size (≥100)	Good sample size (50-99)	Moderate sample size (30-49)	Small sample size (<30)
4	Were at least two measurements available?	At least two measurements			Only one measurement
5	Were the administrations independent?	Independent measurements	Assumable that the measurements were independent	Doubtful whether the measurements were independent	measurements NOT independent
6	Was the time interval stated?	Time interval stated		Time interval NOT stated	
7	Were patients stable in the interim period on the construct to be measured?	Patients were stable (evidence provided)	Assumable that patients were stable	Unclear if patients were stable	Patients were NOT stable
8	Was the time interval appropriate?	Time interval appropriate		Doubtful whether time interval was appropriate	Time interval NOT appropriate

9	Were the test conditions similar for both measurements? e.g. type of administration, environment, instructions	Test conditions were similar (evidence provided)	Assumable that test conditions were similar	Unclear if test conditions were similar	Test conditions were NOT similar
10	Were there any important flaws in the design or methods of the study?	No other important methodological flaws in the design or execution of the study		Other minor methodological flaws in the design or execution of the study	Other important methodological flaws in the design or execution of the study
Statistical methods					
11	for CTT: Was the Standard Error of Measurement (SEM), Smallest Detectable Change (SDC) or Limits of Agreement (LoA) calculated?	SEM, SDC, or LoA calculated	Possible to calculate LoA from the data presented		SEM calculated based on Cronbach's alpha, or on SD from another population

Box D. Content validity (including face validity)					
		excellent	**good**	**fair**	**poor**
General requirements					
1	Was there an assessment of whether all items refer to relevant aspects of the construct to be measured?	Assessed if all items refer to relevant aspects of the construct to be measured		Aspects of the construct to be measured poorly described AND this was not taken into consideration	NOT assessed if all items refer to relevant aspects of the construct to be measured

Box E. Structural validity					
		excellent	**good**	**fair**	**poor**
1	Does the scale consist of effect indicators, i.e. is it based on a reflective model?				
Design requirements					
2	Was the percentage of missing items given?	Percentage of missing items described	Percentage of missing items NOT described		
3	Was there a description of how missing items were handled?	Described how missing items were handled	Not described but it can be deduced how missing items were handled	Not clear how missing items were handled	
4	Was the sample size included in the analysis adequate?	7* #items and ≥100	5* #items and ≥100 OR 5-7* #items but <100	5* #items but <100	<5* #items
5	Were there any important flaws in the design or methods of the study?	No other important methodological flaws in the design or execution of the study		Other minor methodological flaws in the design or execution of the study (e.g. rotation method not described)	Other important methodological flaws in the design or execution of the study (e.g. inappropriate rotation method)

2	Was there an assessment of whether all items are relevant for the study population? (e.g. age, gender, disease characteristics, country, setting)	Assessed if all items are relevant for the study population in adequate sample size (≥10)	Assessed if all items are relevant for the study population in moderate sample size (5-9)	Assessed if all items are relevant for the study population in small sample size (<5)	NOT assessed if all items are relevant for the study population OR target population not involved
3	Was there an assessment of whether all items are relevant for the purpose of the measurement instrument? (discriminative, evaluative, and/or predictive)	Assessed if all items are relevant for the purpose of the application	Purpose of the instrument was not described but assumed	NOT assessed if all items are relevant for the purpose of the application	
4	Was there an assessment of whether all items together comprehensively reflect the construct to be measured?	Assessed if all items together comprehensively reflect the construct to be measured		No theoretical foundation of the construct and this was not taken into consideration	NOT assessed if all items together comprehen-sively reflect the construct to be measured
5	Were there any important flaws in the design or methods of the study?	No other important methodological flaws in the design or execution of the study		Other minor methodological flaws in the design or execution of the study	Other important methodological flaws in the design or execution of the study

Statistical methods					
6	for CTT: Was exploratory or confirmatory factor analysis performed?	Exploratory or confirmatory factor analysis performed and type of factor analysis appropriate in view of existing information	Exploratory factor analysis performed while confirmatory would have been more appropriate		No exploratory or confirmatory factor analysis performed
7	for IRT: Were IRT tests for determining the (uni-) dimensionality of the items performed?	IRT test for determining (uni)dimension-ality performed			IRT test for determining (uni)dimension-ality NOT performed

Box F. Hypotheses testing					
		excellent	**good**	**fair**	**Poor**
Design requirements					
1	Was the percentage of missing items given?	Percentage of missing items described	Percentage of missing items NOT described		
2	Was there a description of how missing items were handled?	Described how missing items were handled	Not described but it can be deduced how missing items were handled	Not clear how missing items were handled	
3	Was the sample size included in the analysis adequate?	Adequate sample size (≥100 per analysis)	Good sample size (50-99 per analysis)	Moderate sample size (30-49 per analysis)	Small sample size (<30 per analysis)

4	Were hypotheses regarding correlations or mean differences formulated a priori (i.e. before data collection)?	Multiple hypotheses formulated a priori	Minimal number of hypotheses formulate a priori	Hypotheses vague or not formulated but possible to deduce what was expected	Unclear what was expected
5	Was the expected *direction* of correlations or mean differences included in the hypotheses?	Expected direction of the correlations or differences stated	Expected direction of the correlations or differences NOT stated		
6	Was the expected absolute or relative *magnitude* of correlations or mean differences included in the hypotheses?	Expected magnitude of the correlations or differences stated	Expected magnitude of the correlations or differences NOT stated		
7	for convergent validity: Was an adequate description provided of the comparator instrument(s)?	Adequate description of the constructs measured by the comparator instrument(s)	Adequate description of most of the constructs measured by the comparator instrument(s)	Poor description of the constructs measured by the comparator instrument(s)	NO description of the constructs measured by the comparator instrument(s)
8	for convergent validity: Were the measurement properties of the comparator instrument(s) adequately described?	Adequate measurement properties of the comparator instrument(s) in a population similar to the study population	Adequate measurement properties of the comparator instrument(s) but not sure if these apply to the study population	Some information on measurement properties (or a reference to a study on measurement properties) of the comparator instrument(s) in any study population	No information on the measurement properties of the comparator instrument(s)

9	Were there any important flaws in the design or methods of the study?	No other important methodological flaws in the design or execution of the study		Other minor methodological flaws in the design or execution of the study (e.g. only data presented on a comparison with an instrument that measures another construct)	Other important methodological flaws in the design or execution of the study
Statistical methods					
10	Were design and statistical methods adequate for the hypotheses to be tested?	Statistical methods applied appropriate	Assumable that statistical methods were appropriate, e.g. Pearson correlations applied, but distribution of scores or mean (SD) not presented	Statistical methods applied NOT optimal	Statistical methods applied NOT appropriate

Box G. Cross-cultural validity					
		excellent	**good**	**fair**	**poor**
Design requirements					
1	Was the percentage of missing items given?	Percentage of missing items described	Percentage of missing items NOT described		
2	Was there a description of how missing items were handled?	Described how missing items were handled	Not described but it can be deduced how missing items were handled	Not clear how missing items were handled	

3	Was the sample size included in the analysis adequate?	CTT: 7* #items and ≥100 IRT: ≥200 per group	CTT: 5* #items and ≥100 OR 5-7* #items but <100 IRT: ≥200 in 1 group and 100-199 in 1 group	CTT: 5* #items but <100 IRT: 100-199 per group	CTT: <5* #items IRT: (<100 in 1 or both groups
4	Were both the original language in which the HR-PRO instrument was developed, and the language in which the HR-PRO instrument was translated described?	Both source language and target language described			Source language NOT known
5	Was the expertise of the people involved in the translation process adequately described? e.g. expertise in the disease(s) involved, expertise in the construct to be measured, expertise in both languages	Expertise of the translators described with respect to disease, construct, and language	Expertise of the translators with respect to disease or construct poor or not described	Expertise of the translators with respect to language not described	
6	Did the translators work independently from each other?	Translators worked independent	Assumable that the translators worked independent	Unclear whether translators worked independent	Translators worked NOT independent
7	Were items translated forward and backward?	Multiple forward and multiple backward translations	Multiple forward translations but one backward translation	One forward and one backward translation	Only a forward translation
8	Was there an adequate description of how differences between the original and translated versions were resolved?	Adequate description of how differences between translators were resolved	Poorly or NOT described how differences between translators were resolved		

9	Was the translation reviewed by a committee (e.g. original developers)?	Translation reviewed by a committee (involving other people than the translators, e.g. the original developers)	Translation NOT reviewed by (such) a committee		
10	Was the HR-PRO instrument pre-tested (e.g. cognitive interviews) to check interpretation, cultural relevance of the translation, and ease of comprehension?	Translated instrument pre-tested in the target population	Translated instrument pre-tested, but unclear if this was done in the target population	Translated instrument pre-tested, but NOT in the target population	Translated instrument NOT pre-tested
11	Was the sample used in the pre-test adequately described?	Sample used in the pre-test adequately described		Sample used in the pre-test NOT (adequately) described	
12	Were the samples similar for all characteristics except language and/or cultural background?	Shown that samples were similar for all characteristics except language /culture	Stated (but not shown) that samples were similar for all characteristics except language /culture	Unclear whether samples were similar for all characteristics except language /culture	Samples were NOT similar for all characteristics except language /culture
13	Were there any important flaws in the design or methods of the study?	No other important methodological flaws in the design or execution of the study		Other minor methodological flaws in the design or execution of the study	Other important methodological flaws in the design or execution of the study

Statistical methods		
14 for CTT: Was confirmatory factor analysis performed?	Multiple-group confirmatory factor analysis performed	Multiple-group confirmatory factor analysis NOT performed
15 for IRT: Was differential item function (DIF) between language groups assessed?	DIF between language groups assessed	DIF between language groups NOT assessed

Box H. Criterion validity				
	excellent	**good**	**fair**	**poor**
Design requirements				
1 Was the percentage of missing items given?	Percentage of missing items described	Percentage of missing items NOT described		
2 Was there a description of how missing items were handled?	Described how missing items were handled	Not described but it can be deduced how missing items were handled	Not clear how missing items were handled	
3 Was the sample size included in the analysis adequate?	Adequate sample size (≥100)	Good sample size (50-99)	Moderate sample size (30-49)	Small sample size (<30)
4 Can the criterion used or employed be considered as a reasonable 'gold standard'?	Criterion used can be considered an adequate 'gold standard' (evidence provided)	No evidence provided, but assumable that the criterion used can be considered an adequate 'gold standard'	Unclear whether the criterion used can be considered an adequate 'gold standard'	Criterion used can NOT be considered an adequate 'gold standard'

5 Were there any important flaws in the design or methods of the study?	No other important methodological flaws in the design or execution of the study	Other minor methodological flaws in the design or execution of the study	Other important methodological flaws in the design or execution of the study
Statistical methods			
6 for continuous scores: Were correlations, or the area under the receiver operating curve calculated?	Correlations or AUC calculated		Correlations or AUC NOT calculated
7 for dichotomous scores: Were sensitivity and specificity determined?	Sensitivity and specificity calculated		Sensitivity and specificity NOT calculated

Box I. Responsiveness				
	excellent	**good**	**fair**	**poor**
Design requirements				
1 Was the percentage of missing items given?	Percentage of missing items described	Percentage of missing items NOT described		
2 Was there a description of how missing items were handled?	Described how missing items were handled	Not described but it can be deduced how missing items were handled	Not clear how missing items were handled	
3 Was the sample size included in the analysis adequate?	Adequate sample size (≥100)	Good sample size (50-99)	Moderate sample size (30-49)	Small sample size (<30)
4 Was a longitudinal design with at least two measurement used?	Longitudinal design used			No longitudinal design used
5 Was the time interval stated?	Time interval adequately described			Time interval NOT described

6	If anything occurred in the interim period (e.g. intervention, other relevant events), was it adequately described?	Anything that occurred during the interim period (e.g. treatment) adequately described	Assumable what occurred during the interim period	Unclear or NOT described what occurred during the interim period	
7	Was a proportion of the patients changed (i.e. improvement or deterioration)?	Part of the patients were changed (evidence provided)	NO evidence provided, but assumable that part of the patients were changed	Unclear if part of the patients were changed	Patients were NOT changed
Design requirements for hypotheses testing					
	For constructs for which a gold standard was not available:				
8	Were hypotheses about changes in scores formulated a priori (i.e. before data collection)?	Hypotheses formulated a priori		Hypotheses vague or not formulated but possible to deduce what was expected	Unclear what was expected
9	Was the expected *direction* of correlations or mean differences of the change scores of HR-PRO instruments included in these hypotheses?	Expected direction of the correlations or differences stated	Expected direction of the correlations or differences NOT stated		
10	Were the expected absolute or relative *magnitude* of correlations or mean differences of the change scores of HR-PRO instruments included in these hypotheses?	Expected magnitude of the correlations or differences stated	Expected magnitude of the correlations or differences NOT stated		

11	Was an adequate description provided of the comparator instrument(s)?	Adequate description of the constructs measured by the comparator instrument(s)		Poor description of the constructs measured by the comparator instrument(s)	NO description of the constructs measured by the comparator instrument(s)
12	Were the measurement properties of the comparator instrument(s) adequately described?	Adequate measurement properties of the comparator instrument(s) in a population similar to the study population	Adequate measurement properties of the comparator instrument(s) but not sure if these apply to the study population	Some information on measurement properties (or a reference to a study on measurement properties) of the comparator instrument(s) in any study population	NO information on the measurement properties of the comparator instrument(s)
13	Were there any important flaws in the design or methods of the study?	No other important methodological flaws in the design or execution of the study		Other minor methodological flaws in the design or execution of the study (e.g. only data presented on a comparison with an instrument that measures another construct)	Other important methodological flaws in the design or execution of the study
Statistical methods					
14	Were design and statistical methods adequate for the hypotheses to be tested?	Statistical methods applied appropriate		Statistical methods applied NOT optimal	Statistical methods applied NOT appropriate

Interpretability

We recommend to use the Interpretability box to extract all information on the interpretability issues described in this box of the instruments under study from the included articles.

Box Interpretability	
Percentage of missing items	
Description of how missing items were handled	
Distribution of the (total) scores	
Percentage of the respondents who had the lowest possible (total) score	
Percentage of the respondents who had the highest possible (total) score	
Scores and change scores (i.e. means and SD) for relevant (sub) groups, e.g. for normative groups, subgroups of patients, or the general population	
Minimal Important Change (MIC) or Minimal Important Difference (MID)	

Generalizability

We recommend to use the Generalizability box to extract data on the characteristics of the study populations and sampling procedures of the included studies.

Box Generalisability	
Median or mean age (with standard deviation or range)	
Distribution of sex	
Important disease characteristics (e.g. severity, status, duration) and description of treatment	
Setting(s) in which the study was conducted (e.g. general population, primary care or hospital/rehabilitation care)	
Countries in which the study was conducted	
Language in which the HR-PRO instrument was evaluated	
Method used to select patients (e.g. convenience, consecutive, or random)	
Percentage of missing responses (response rate)	

Design requirement for comparison to a gold standard					
	For constructs for which a gold standard was available:				
15	Can the criterion for change be considered as a reasonable gold standard?	Criterion used can be considered an adequate 'gold standard' (evidence provided)	No evidence provided, but assumable that the criterion used can be considered an adequate 'gold standard'	Unclear whether the criterion used can be considered an adequate 'gold standard'	Criterion used can NOT be considered an adequate 'gold standard'
16	Were there any important flaws in the design or methods of the study?	No other important methodological flaws in the design or execution of the study		Other minor methodological flaws in the design or execution of the study	Other important methodological flaws in the design or execution of the study
Statistical methods					
17	for continuous scores: Were correlations between change scores, or the area under the Receiver Operator Curve (ROC) curve calculated?	Correlations or Area under the ROC Curve (AUC) calculated			Correlations or AUC NOT calculated
18	for dichotomous scales: Were sensitivity and specificity (changed versus not changed) determined?	Sensitivity and specificity calculated			Sensitivity and specificity NOT calculated

Appendix 2.2 Methodological quality of each study per measurement property for each PROM

Study, author, year	Reliability			Validity				Responsiveness
	Internal consistency	Reproducibility	Measurement error	Content	Structural	Hypothesis testing	Criterion	Responsiveness
Amirfeyz et al 2009		Fair	Fair					Fair
Beaton et al 2001	Excellent	Good	Good			Good		Good
Beaton et al 2005	Excellent	Excellent				Excellent		Excellent
Chatterjee et al 2009								Fair
Chung & Morris 2014	Excellent	Good	Good					
Chung & Morris 2015	Excellent							
Chung et al 1998	Fair	Poor	Poor	Poor	Poor	Good		
Chung et al 1999								
Dias et al 2008	Poor	Poor	Poor			Poor		
Gabel et al 2009					Good			
Gay et al 2003						Poor		Fair
Greenslade et al 2004	Fair							Fair
Hobby et al 2005	Poor					Poor		Poor
Hudak et al 1996				Fair				
Kotsis & Chung 2005								Good
Macey et al., 1995				Poor				
McMillan & Binhammer 2009								Poor
Niekel et al 2009						Poor		
Waljee et al 2011						Fair		Fair
Zimmerman et al 2009						Fair		

Appendix 2.3 The Patient Evaluation Measure (PEM)

PATIENT EVALUATION MEASURE (PEM)

Part One: Treatment

Please put a circle around the number that is closest to the way you feel about how things have been for you. There are no right or wrong answers.

1. Throughout my treatment I have seen the same doctor:

1	2	3	4	5	6	7
every time						not at all

2. When the doctor saw me, he or she knew about my case:

1	2	3	4	5	6	7
very well						not at all

3. When I was with the doctor, he or she gave me the chance to talk

1	2	3	4	5	6	7
as much as I wanted to						not at all

4. When I did talk to the doctor, he or she listened and understood me:

1	2	3	4	5	6	7
very much						not at all

5. I was given information about my treatment and progress:

1	2	3	4	5	6	7
all that I wanted						not at all

Part Two: How Your Hand is Now

1. The FEELING in my hand is now:

1	2	3	4	5	6	7
normal						abnormal

2. When my hand is cold and/or damp, the PAIN is now:

1	2	3	4	5	6	7
non-existent						unbearable

3. Most of the time, the PAIN in my hand is now:

1	2	3	4	5	6	7
non-existent						unbearable

4. When I try to USE my hand for fiddly things, it is now:

1	2	3	4	5	6	7
skilful						clumsy

5. Generally, when I MOVE my hand it is:

1	2	3	4	5	6	7
flexible						stiff

6. The GRIP in my hand is now:

1	2	3	4	5	6	7
strong						weak

7. For everyday ACTIVITIES, my hand is now:

1	2	3	4	5	6	7
no problem						useless

8. For WORK, my hand is now:

1	2	3	4	5	6	7
no problem						useless

9. When I look at the appearance of my hand now, I feel:

1	2	3	4	5	6	7
unconcerned					embarrassed and self-conscious	

10. Generally, when I think about my hand I feel:

1	2	3	4	5	6	7
unconcerned						very upset

Part Three: Overall Assessment

1. Generally, my treatment at the hospital has been:

1	2	3	4	5	6	7
very satisfactory						very unsatisfactory

2. Generally, my hand is now:

1	2	3	4	5	6	7
very satisfactory						very unsatisfactory

3. Bearing in mind my original injury or condition, my hand is now:

1	2	3	4	5	6	7
better than I expected						worse than I expected

Are there any other comments you wish to make?

Thank you very much indeed for your help

Appendix 2.4 The Michigan Hand Outcomes Questionnaire (MHQ)

Instructions: This survey asks for your views about your hands and your health. This information will help keep track of how you feel and how well you are able to do your usual activities.

Answer ***EVERY*** question by marking the answer as indicated. If you are unsure about how to answer a question, please give the best answer you can.

I. The following questions refer to the function of your hand(s)/wrist(s) *during the past week*. (Please circle one answer for each question). Please answer ***EVERY*** question, even if you do not experience any problems with the hand and/or wrist.

A. The following questions refer to your *right* hand/wrist.

	Very Good	Good	Fair	Poor	Very Poor
1. Overall, how well did your *right* hand work?	1	2	3	4	5
2. How well did your *right* fingers move?	1	2	3	4	5
3. How well did your *right* wrist move?	1	2	3	4	5
4. How was the strength in your *right* hand?	1	2	3	4	5
5. How was the sensation (feeling) in your *right* hand?	1	2	3	4	5

B. The following questions refer to your *left* hand/wrist.

	Very Good	Good	Fair	Poor	Very Poor
1. Overall, how well did your *left* hand work?	1	2	3	4	5
2. How well did your *left* fingers move?	1	2	3	4	5
3. How well did your *left* wrist move?	1	2	3	4	5
4. How was the strength in your *left* hand?	1	2	3	4	5
5. How was the sensation (feeling) in your *left* hand?	1	2	3	4	5

II. The following questions refer to the ability of your hand(s) to do certain tasks *during the past week*. (Please circle one answer for each question). If you do not do a certain task, please estimate the difficulty with which you would have in performing it.

A. How difficult was it for you to perform the following activities using your ***right hand*** ?

	Not at All Difficult	A Little Difficult	Somewhat Difficult	Moderately Difficult	Very Difficult
1. Turn a door knob	1	2	3	4	5
2. Pick up a coin	1	2	3	4	5
3. Hold a glass of water	1	2	3	4	5
4. Turn a key in a lock	1	2	3	4	5
5. Hold a frying pan	1	2	3	4	5

B. How difficult was it for you to perform the following activities using your ***left hand*** ?

	Not at All Difficult	A Little Difficult	Somewhat Difficult	Moderately Difficult	Very Difficult
1. Turn a door knob	1	2	3	4	5
2. Pick up a coin	1	2	3	4	5
3. Hold a glass of water	1	2	3	4	5
4. Turn a key in a lock	1	2	3	4	5
5. Hold a frying pan	1	2	3	4	5

C. How difficult was it for you to perform the following activities using ***both of your hands***?

	Not at All Difficult	A Little Difficult	Somewhat Difficult	Moderately Difficult	Very Difficult
1. Open a jar	1	2	3	4	5
2. Button a shirt/blouse	1	2	3	4	5
3. Eat with a knife/fork	1	2	3	4	5
4. Carry a grocery bag	1	2	3	4	5
5. Wash dishes	1	2	3	4	5
6. Wash your hair	1	2	3	4	5
7. Tie shoelaces/knots	1	2	3	4	5

III. The following questions refer to how you did in your *normal work* (including both housework and school work) during the *past four weeks*. (Please circle one answer for each question).

	Always	Often	Sometimes	Rarely	Never
1. How often were you unable to do your work because of problems with your hand(s)/wrist(s)?	1	2	3	4	5
2. How often did you have to shorten your work day because of problems with your hand(s)/ wrist(s)?	1	2	3	4	5
3. How often did you have to take it easy at your work because of problems with your hand(s)/ wrist(s)?	1	2	3	4	5
4. How often did you accomplish less in your work because of problems with your hand(s)/ wrist(s)?	1	2	3	4	5
5. How often did you take longer to do the tasks in your work because of problems with your hand(s)/ wrist(s)?	1	2	3	4	5

IV. The following questions refer to how much *pain* you had in your hand(s)/wrist(s) ***during the past week***. (Please circle one answer for each question).

A. The following questions refer to **pain** in your *right* hand/wirst.

1. How often did you have pain in your *right* hand(s)/wrist(s)?
   1. Always
   2. Often
   3. Sometimes
   4. Rarely
   5. Never

If you answered **never** to **question IV-A1** above, please skip the following questions and go to the next page.

2. Please describe the pain you had in your *right* hand(s)/wrist(s).
   1. Very mild
   2. Mild
   3. Moderate
   4. Severe
   5. Very severe

	Always	Often	Sometimes	Rarely	Never
3. How often did the pain in your *right* hand(s)/wrist(s) interfere with your sleep?	1	2	3	4	5
4. How often did the pain in your *right* hand(s)/wrist(s) interfere with your daily activities (such as eating or bathing)?	1	2	3	4	5
5. How often did the pain in your *right* hand(s)/wrist(s) make you unhappy?	1	2	3	4	5

B. The following questions refer to **pain** in your ***left*** hand/wirst.

1. How often did you have pain in your ***left*** hand(s)/wrist(s)?
   1. Always
   2. Often
   3. Sometimes
   4. Rarely
   5. Never

If you answered **never** to **question IV-B1** above, please skip the following questions and go to the next page.

2. Please describe the pain you had in your ***left*** hand(s)/wrist(s).
   1. Very mild
   2. Mild
   3. Moderate
   4. Severe
   5. Very severe

	Always	Often	Sometimes	Rarely	Never
3. How often did the pain in your ***left*** hand(s)/wrist(s) interfere with your sleep?	1	2	3	4	5
4. How often did the pain in your ***left*** hand(s)/wrist(s) interfere with your daily activities (such as eating or bathing)?	1	2	3	4	5
5. How often did the pain in your ***left*** hand(s)/wrist(s) make you unhappy?	1	2	3	4	5

V. A. The following questions refer to the appearance (look) of your *right* hand **during the past week**. (Please circle one answer for each question).

	Strongly Agree	Agree	Neither Agree **nor** Disagree	Disagree	Strongly Disagree
1. I am satisfied with the appearance (look) of my *right* hand.	1	2	3	4	5
2. The appearance (look) of my *right* hand sometimes made me uncomfortable in public.	1	2	3	4	5
3. The appearance (look) of my *right* hand made me depressed.	1	2	3	4	5
4. The appearance (look) of my *right* hand interfered with my normal social activities.	1	2	3	4	5

B. The following questions refer to the appearance (look) of your *left* hand **during the past week**. (Please circle one answer for each question).

	Strongly Agree	Agree	Neither Agree **nor** Disagree	Disagree	Strongly Disagree
1. I am satisfied with the appearance (look) of my *left* hand.	1	2	3	4	5
2. The appearance (look) of my *left* hand sometimes made me uncomfortable in public.	1	2	3	4	5
3. The appearance (look) of my *left* hand made me depressed.	1	2	3	4	5
4. The appearance (look) of my *left* hand interfered with my normal social activities.	1	2	3	4	5

VI. A. The following questions refer to your satisfaction with your *right* hand/wrist **during the past week**. (Please circle one answer for each question).

	Very Satisfied	Somewhat Satisfied	Neither Satisfied **nor** Dissatisfied	Somewhat Dissatisfied	Very Dissatisfied
1. Overall function of your *right* hand	1	2	3	4	5
2. Motion of the fingers in your *right* hand	1	2	3	4	5
3. Motion of your *right* wrist	1	2	3	4	5
4. Strength of your *right* hand	1	2	3	4	5
5. Pain level of your *right* hand	1	2	3	4	5
6. Sensation (feeling) of your *right* hand	1	2	3	4	5

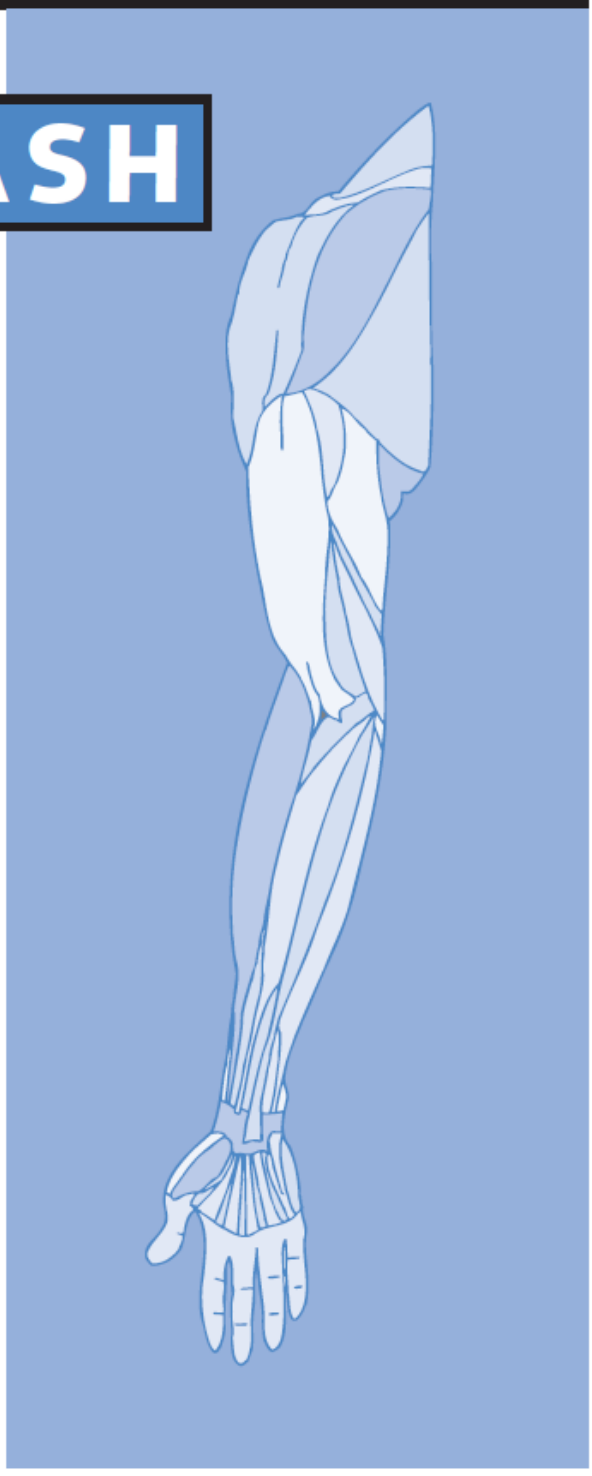
B. The following questions refer to your satisfaction with your *left* hand/wrist **during the past week**. (Please circle one answer for each question).

	Very Satisfied	Somewhat Satisfied	Neither Satisfied **nor** Dissatisfied	Somewhat Dissatisfied	Very Dissatisfied
1. Overall function of your *left* hand	1	2	3	4	5
2. Motion of the fingers in your *left* hand	1	2	3	4	5
3. Motion of your *left* wrist	1	2	3	4	5
4. Strength of your *left* hand	1	2	3	4	5
5. Pain level of your *left* hand	1	2	3	4	5
6. Sensation (feeling) of your *left* hand	1	2	3	4	5

Appendix 2.5 The Disabilities of the Arm, Shoulder and Hand (DASH)

DISABILITIES OF THE ARM, SHOULDER AND HAND

THE DASH



INSTRUCTIONS

This questionnaire asks about your symptoms as well as your ability to perform certain activities.

Please answer *every question*, based on your condition in the last week, by circling the appropriate number.

If you did not have the opportunity to perform an activity in the past week, please make your *best estimate* on which response would be the most accurate.

It doesn't matter which hand or arm you use to perform the activity; please answer based on your ability regardless of how you perform the task.

DISABILITIES OF THE ARM, SHOULDER AND HAND

Please rate your ability to do the following activities in the last week by circling the number below the appropriate response.

	NO DIFFICULTY	MILD DIFFICULTY	MODERATE DIFFICULTY	SEVERE DIFFICULTY	UNABLE
1. Open a tight or new jar.	1	2	3	4	5
2. Write.	1	2	3	4	5
3. Turn a key.	1	2	3	4	5
4. Prepare a meal.	1	2	3	4	5
5. Push open a heavy door.	1	2	3	4	5
6. Place an object on a shelf above your head.	1	2	3	4	5
7. Do heavy household chores (e.g., wash walls, wash floors).	1	2	3	4	5
8. Garden or do yard work.	1	2	3	4	5
9. Make a bed.	1	2	3	4	5
10. Carry a shopping bag or briefcase.	1	2	3	4	5
11. Carry a heavy object (over 10 lbs).	1	2	3	4	5
12. Change a lightbulb overhead.	1	2	3	4	5
13. Wash or blow dry your hair.	1	2	3	4	5
14. Wash your back.	1	2	3	4	5
15. Put on a pullover sweater.	1	2	3	4	5
16. Use a knife to cut food.	1	2	3	4	5
17. Recreational activities which require little effort (e.g., cardplaying, knitting, etc.).	1	2	3	4	5
18. Recreational activities in which you take some force or impact through your arm, shoulder or hand (e.g., golf, hammering, tennis, etc.).	1	2	3	4	5
19. Recreational activities in which you move your arm freely (e.g., playing frisbee, badminton, etc.).	1	2	3	4	5
20. Manage transportation needs (getting from one place to another).	1	2	3	4	5
21. Sexual activities.	1	2	3	4	5

DISABILITIES OF THE ARM, SHOULDER AND HAND

	NOT AT ALL	SLIGHTLY	MODERATELY	QUITE A BIT	EXTREMELY
22. During the past week, *to what extent* has your arm, shoulder or hand problem interfered with your normal social activities with family, friends, neighbours or groups? *(circle number)*	1	2	3	4	5

	NOT LIMITED AT ALL	SLIGHTLY LIMITED	MODERATELY LIMITED	VERY LIMITED	UNABLE
23. During the past week, were you limited in your work or other regular daily activities as a result of your arm, shoulder or hand problem? *(circle number)*	1	2	3	4	5

Please rate the severity of the following symptoms in the last week. *(circle number)*

	NONE	MILD	MODERATE	SEVERE	EXTREME
24. Arm, shoulder or hand pain.	1	2	3	4	5
25. Arm, shoulder or hand pain when you performed any specific activity.	1	2	3	4	5
26. Tingling (pins and needles) in your arm, shoulder or hand.	1	2	3	4	5
27. Weakness in your arm, shoulder or hand.	1	2	3	4	5
28. Stiffness in your arm, shoulder or hand.	1	2	3	4	5

	NO DIFFICULTY	MILD DIFFICULTY	MODERATE DIFFICULTY	SEVERE DIFFICULTY	SO MUCH DIFFICULTY THAT I CAN'T SLEEP
29. During the past week, how much difficulty have you had sleeping because of the pain in your arm, shoulder or hand? *(circle number)*	1	2	3	4	5

	STRONGLY DISAGREE	DISAGREE	NEITHER AGREE NOR DISAGREE	AGREE	STRONGLY AGREE
30. I feel less capable, less confident or less useful because of my arm, shoulder or hand problem. *(circle number)*	1	2	3	4	5

DASH DISABILITY/SYMPTOM SCORE = $\left[\frac{\text{(sum of n responses)}}{n} - 1\right] \times 25$, where n is equal to the number of completed responses.

A DASH score may <u>not</u> be calculated if there are greater than 3 missing items.

DISABILITIES OF THE ARM, SHOULDER AND HAND

WORK MODULE (OPTIONAL)

The following questions ask about the impact of your arm, shoulder or hand problem on your ability to work (including home-making if that is your main work role).

Please indicate what your job/work is:_____

❒ I do not work. (You may skip this section.)

Please circle the number that best describes your physical ability in the past week. Did you have any difficulty:

		NO DIFFICULTY	MILD DIFFICULTY	MODERATE DIFFICULTY	SEVERE DIFFICULTY	UNABLE
1.	using your usual technique for your work?	1	2	3	4	5
2.	doing your usual work because of arm, shoulder or hand pain?	1	2	3	4	5
3.	doing your work as well as you would like?	1	2	3	4	5
4.	spending your usual amount of time doing your work?	1	2	3	4	5

SPORTS/PERFORMING ARTS MODULE (OPTIONAL)

The following questions relate to the impact of your arm, shoulder or hand problem on playing *your musical instrument or sport or both*. If you play more than one sport or instrument (or play both), please answer with respect to that activity which is most important to you.

Please indicate the sport or instrument which is most important to you:_____

❑ I do not play a sport or an instrument. (You may skip this section.)

Please circle the number that best describes your physical ability in the past week. Did you have any difficulty:

		NO DIFFICULTY	MILD DIFFICULTY	MODERATE DIFFICULTY	SEVERE DIFFICULTY	UNABLE
1.	using your usual technique for playing your instrument or sport?	1	2	3	4	5
2.	playing your musical instrument or sport because of arm, shoulder or hand pain?	1	2	3	4	5
3.	playing your musical instrument or sport as well as you would like?	1	2	3	4	5
4.	spending your usual amount of time practising or playing your instrument or sport?	1	2	3	4	5

SCORING THE OPTIONAL MODULES: Add up assigned values for each response; divide by 4 (number of items); subtract 1; multiply by 25.
An optional module score may <u>not</u> be calculated if there are any missing items.

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Appendix 2.6 The Brief MHQ

Instructions: This survey asks you for your views about your hands and your health. This information will help keep track of how you feel and how well you are able to do your usual activities.

Answer ***EVERY*** question by marking the answer as indicated.

If you are unsure about how to answer a question, please give it the best answer you can. **Please answer every question, even if you do not experience problems with the hand or wrist.** Some questions may ask you about your ability to complete certain tasks. If you do not do a certain task, please estimate the difficulty with which you would have in performing it. Questions pertaining to work include occupational work, housework, and school work. Please circle one answer for each question.

1.	Overall, how well did your hand(s) work during the past week?	Very good 1	Good 2	Fair 3	Poor 4	Very Poor 5
2.	How was the sensation (feeling) in your hand(s) during the past week?	Very good 1	Good 2	Fair 3	Poor 4	Very Poor 5
3.	How difficult was it for you to hold a frying pan during the last week?	Not at all difficult 1	A little difficult 2	Somewhat difficult 3	Moderately difficult 4	Very difficult 5
4.	How difficult was it for you to button a shirt or blouse during the past week?	Not at all difficult 1	A little difficult 2	Somewhat difficult 3	Moderately difficult 4	Very difficult 5
5.	In the past 4 weeks, how often were you unable to do your work because of problems with your hand(s)/wrist(s)?	Always 1	Often 2	Sometimes 3	Rarely 4	Never 5

6.	In the past 4 weeks, how often did you take longer to do tasks in your work because of problems with your hand(s)/wrist(s)?	Always 1	Often 2	Sometimes 3	Rarely 4	Never 5
7.	How often did the pain in your hand(s)/wrist(s)? interfere with your daily activities (such as eating or bathing) in the past week?	Always 1	Often 2	Sometimes 3	Rarely 4	Never 5
8.	Describe the pain in your hand(s)/wrist(s) in the past week?	Very mild 1	Mild 2	Moderate 3	Severe 4	Very severe 5
9.	I am satisfied with the look of my hand(s).	Strongly agree 1	Agree 2	Neither agree nor disagree 3	Disagree 4	Strongly disagree 5
10.	In the past week, the appearance of my hand(s) interferes with my normal daily activities.	Strongly agree 1	Agree 2	Neither agree nor disagree 3	Disagree 4	Strongly disagree 5
11.	In the past week, how satisfied are you with the motion of your fingers?	Very satisfied 1	Somewhat satisfied 2	Neither satisfied nor dissatisfied 3	Dissatisfied 4	Very dissatisfied 5
12.	In the past week, how satisfied are you with the motion of your wrist?	Very satisfied 1	Somewhat satisfied 2	Neither satisfied nor dissatisfied 3	Dissatisfied 4	Very dissatisfied 5

Appendix 2.7 The Quick DASH

THE QuickDASH OUTCOME MEASURE

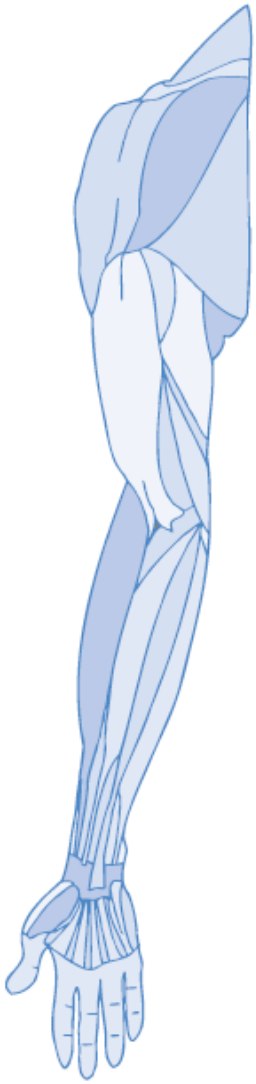
INSTRUCTIONS

This questionnaire asks about your symptoms as well as your ability to perform certain activities.

Please answer *every question*, based on your condition in the last week, by circling the appropriate number.

If you did not have the opportunity to perform an activity in the past week, please make your *best estimate* of which response would be the most accurate.

It doesn't matter which hand or arm you use to perform the activity; please answer based on your ability regardless of how you perform the task.



*Quick*DASH

Please rate your ability to do the following activities in the last week by circling the number below the appropriate response.

	NO DIFFICULTY	MILD DIFFICULTY	MODERATE DIFFICULTY	SEVERE DIFFICULTY	UNABLE
1. Open a tight or new jar.	1	2	3	4	5
2. Do heavy household chores (e.g., wash walls, floors).	1	2	3	4	5
3. Carry a shopping bag or briefcase.	1	2	3	4	5
4. Wash your back.	1	2	3	4	5
5. Use a knife to cut food.	1	2	3	4	5
6. Recreational activities in which you take some force or impact through your arm, shoulder or hand (e.g., golf, hammering, tennis, etc.).	1	2	3	4	5

	NOT AT ALL	SLIGHTLY	MODERATELY	QUITE A BIT	EXTREMELY
7. During the past week, *to what extent* has your arm, shoulder or hand problem interfered with your normal social activities with family, friends, neighbours or groups?	1	2	3	4	5

	NOT LIMITED AT ALL	SLIGHTLY LIMITED	MODERATELY LIMITED	VERY LIMITED	UNABLE
8. During the past week, were you limited in your work or other regular daily activities as a result of your arm, shoulder or hand problem?	1	2	3	4	5

Please rate the severity of the following symptoms in the last week. *(circle number)*	NONE	MILD	MODERATE	SEVERE	EXTREME
9. Arm, shoulder or hand pain.	1	2	3	4	5
10. Tingling (pins and needles) in your arm, shoulder or hand.	1	2	3	4	5

	NO DIFFICULTY	MILD DIFFICULTY	MODERATE DIFFICULTY	SEVERE DIFFICULTY	SO MUCH DIFFICULTY THAT I CAN'T SLEEP
11. During the past week, how much difficulty have you had sleeping because of the pain in your arm, shoulder or hand? *(circle number)*	1	2	3	4	5

*Quick*DASH DISABILITY/SYMPTOM SCORE = $\left(\left[\frac{\text{sum of n responses}}{n}\right] - 1\right) \times 25$, where n is equal to the number of completed responses.

A *Quick*DASH score may not be calculated if there is greater than 1 missing item.

QuickDASH

WORK MODULE (OPTIONAL)

The following questions ask about the impact of your arm, shoulder or hand problem on your ability to work (including homemaking if that is your main work role).

Please indicate what your job/work is:_____

❒ I do not work. (You may skip this section.)

Please circle the number that best describes your physical ability in the past week.

Did you have any difficulty:	NO DIFFICULTY	MILD DIFFICULTY	MODERATE DIFFICULTY	SEVERE DIFFICULTY	UNABLE
1. using your usual technique for your work?	1	2	3	4	5
2. doing your usual work because of arm, shoulder or hand pain?	1	2	3	4	5
3. doing your work as well as you would like?	1	2	3	4	5
4. spending your usual amount of time doing your work?	1	2	3	4	5

SPORTS/PERFORMING ARTS MODULE (OPTIONAL)

The following questions relate to the impact of your arm, shoulder or hand problem on playing *your musical instrument or sport or both*. If you play more than one sport or instrument (or play both), please answer with respect to that activity which is most important to you.

Please indicate the sport or instrument which is most important to you:_____

❑ I do not play a sport or an instrument. (You may skip this section.)

Please circle the number that best describes your physical ability in the past week.

Did you have any difficulty:	NO DIFFICULTY	MILD DIFFICULTY	MODERATE DIFFICULTY	SEVERE DIFFICULTY	UNABLE
1. using your usual technique for playing your instrument or sport?	1	2	3	4	5
2. playing your musical instrument or sport because of arm, shoulder or hand pain?	1	2	3	4	5
3. playing your musical instrument or sport as well as you would like?	1	2	3	4	5
4. spending your usual amount of time practising or playing your instrument or sport?	1	2	3	4	5

SCORING THE OPTIONAL MODULES: Add up assigned values for each response; divide by 4 (number of items); subtract 1; multiply by 25.
An optional module score may not be calculated if there are any missing items.

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Appendix 3.1 Interview schedule/topic guide

Centre Number: 01
REC Reference: 14/NE/1087

Our Vision
To provide every patient with the care we want for those we love the most

Norfolk and Norwich University Hospitals NHS
NHS Foundation Trust

University of East Anglia

Interview Schedule

The Hand Nerve Disorders Study –

'The HaND Study'

1. The following questions can be used with participants who wish to NOT bring photographs for discussion to the interview.
2. When photographs are being used to guide the interview the interviewee can refer to the words in italics as a helpful prompts throughout.

PREAMBLE:

This interview is intended to explore your experiences about your hand condition. The interview will be tape recorded, fully transcribed and analysed for emerging themes to help develop questions for a questionnaire that measures the effects of a nerve disorder on daily life.

WARM-UP:

1. Can you tell me what you enjoy doing in your spare time?

INTERVIEW PROPER:

1. Can you tell me about how your condition has affected your ability to complete *self-care* tasks e.g. Eating, dressing, toileting?
2. Can you tell me about how your condition has affected your ability to engage in *domestic life* e.g. Preparing meals, doing housework, using household appliances?
3. Can you describe any symptoms that you are experiencing as a result of your hand condition e.g. Pain, pins & needles, numbness, cold intolerance?
4. Can you tell me about how your condition has affected your ability to participate in *major life areas* e.g. Work, volunteering, education?
5. Can you tell me about how your condition has affected your ability to participate in *community life* e.g. Arts & culture, crafts, sports?
6. Is there *anything else* you'd like to add?

Thank you for your time

Interview schedule /Version 1 /10-07-2014

Appendix 3.2 Favourable ethical approval letter

NHS
Health Research Authority
NRES Committee North East - York
Jarrow Business Centre
Viking Business Park
Rolling Mill Road
Jarrow, Tyne & Wear
NE32 3DT

Telephone: 0191 4283476

28 July 2014

Mr Mark Ashwood
School of Health Sciences
Room 1-23. PGR Office
The Queen's Building
Norwich
NR4 7TJ

Dear Mr Ashwood

Study title:	**Development and Validation of a Patient-Reported Outcome Measure (PROM) for Peripheral Nerve Disorders of the Hand**
REC reference:	**14/NE/1087**
IRAS project ID:	**155734**

Thank you for email of 28th July 2014, responding to the Proportionate Review Sub-Committee's request for changes to the documentation for the above study.

The revised documentation has been reviewed and approved by the sub-committee.

We plan to publish your research summary wording for the above study on the NRES website, together with your contact details, unless you expressly withhold permission to do so. Publication will be no earlier than three months from the date of this favourable opinion letter. Should you wish to provide a substitute contact point, require further information, or wish to withhold permission to publish, please contact the REC Manager Mrs Hayley Henderson, nrescommittee.northeast-york@nhs.net.

Confirmation of ethical opinion

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

Conditions of the favourable opinion

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

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

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

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

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

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

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

Registration of Clinical Trials

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

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

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

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

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

Ethical review of research sites

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

Approved documents

The documents reviewed and approved by the Committee are:

Document	*Version*	*Date*
Covering letter on headed paper [REC Cover Letter 26.07.2014]		28 July 2014
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [Sponsor Insurance Letter 11.07.2014]		11 July 2014
GP/consultant information sheets or letters [GP Letter Version 1. 10.07.2014]		10 July 2014
Interview schedules or topic guides for participants [Interview Schedule Version 1. 10.07.2014]	1	10 July 2014
Other [Clinical Record Form Version 1. 10.07.2014]	1	10 July 2014
Other [Protocol Version 2 Amendments Guide. Tracked Changes. 26.07.2014]	2.0	26 July 2014
Other [Protocol Version 2. Tracked Changes. 26.07.2014]	2	26 July 2014
Other [REC Form Amendments. Clean. 26.07.2014]		26 July 2014
Other [REC Amendments Guide. Tracked Changes. 26.07.2014]		26 July 2014
Participant consent form [Consent 2b Version 2. 23.07.2014]	2	23 July 2014
Participant consent form [Consent 3 Version 2. 23.07.2014]	2	23 July 2014
Participant consent form [Consent 1 Version 2. 23.07.2014]	2	23 July 2014
Participant consent form [Consent 2a Version 2. 23.07.2014]	2	23 July 2014
Participant information sheet (PIS) [PIS 2b Version 3. Clean. 26.07.2014]	3	26 July 2014
Participant information sheet (PIS) [PIS 2b Version 3. Tracked Changes. 26.07.2014]	3	26 July 2014
Participant information sheet (PIS) [PIS 2a Version 3. Clean. 26.07.2014]	3	26 July 2014
Participant information sheet (PIS) [PIS 2a Version 3. Tracked Changes. 26.07.2014]	3	26 July 2014
Participant information sheet (PIS) [PIS 1 Version 3. Tracked Changes. 26.07.2014]	3	26 July 2014
Participant information sheet (PIS) [PIS 3 Version 3. tracked Changes. 26.07.2014]	3	26 July 2014
Participant information sheet (PIS) [PIS 1 Version 3. Clean. 26.07.2014]	3	26 July 2014
Participant information sheet (PIS) [PIS 3 Version 3. Clean. 26.07.2014]	3	26 July 2014
REC Application Form [REC_Form_28072014]		28 July 2014
Research protocol or project proposal [Protocol Version 2. Clean. 26.07.2014]		26 July 2014
Summary CV for Chief Investigator (CI) [Mark Ashwood CV 10.07.2014]	1	10 July 2014
Summary CV for supervisor (student research) [CV CJH Supervisor 30-06-14]	1	30 June 2014

Statement of compliance

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

After ethical review

Reporting requirements

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

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

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

Feedback

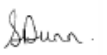
You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website:
http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance

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

14/NE/1087	Please quote this number on all correspondence

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

Yours sincerely
pp.



Peter Heasman
Chair

Email: nrescommittee.northeast-york@nhs.net

Enclosures: *"After ethical review – guidance for researchers" [SL-AR2]*

A Research Ethics Committee established by the Health Research Authority

Copy to:	*Mrs Yvonne Kirkham, University of East Anglia* *Miss Laura Harper, Norfolk and Norwich University Hospital NHS Trust*

Appendix 3.3 Contents of the participant information pack for phase 1

Centre Number: 01
REC Reference: 14/NE/1087

Norfolk and Norwich University Hospitals NHS
NHS Foundation Trust

PARTICIPANT INFORMATION SHEET – PHASE 1

The Hand Nerve Disorders Study –

'The HaND Study'

You are invited to take part in a doctoral research study. Before making a decision it is important for you to understand what taking part involves and why the study is being done. Please take your time to read through this information, discuss it with others or feel free to get in touch if you have any questions. Our contact details are given at the end of this document.

What is the purpose of the study?

Nerve disorders of the hand can have a significant impact on a person's ability to carry out daily life tasks. Patients who sustain a nerve injury often require surgery or rehabilitation to help regain their independence. To evaluate the effectiveness of such treatments, patients are often asked to complete questionnaires. There are currently no questionnaires that look specifically at the impact of a nerve injury on hand function and activities of daily living. This research study therefore aims to develop one. Typically the first step to developing a questionnaire is to gain an understanding of the experiences of people with this condition. This can be done by carrying out face to face interviews. From the interviews we will then design the items that go into the questionnaire. Once we develop the questionnaire we will go on to test it further. The information here relates to the first stage of the project and involves carrying out patient interviews.

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

You have been approached as you are receiving or have received treatment for your hand condition at the Norfolk and Norwich University Hospital (NNUH). We are interested to hear about your experiences of having this condition.

Centre Number: 01
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Do I have to take part?

Participation in this study is voluntary and it is entirely up to you to decide whether or not you want to take part. Discuss it with friends and family if you like, and ask any questions you may have before making a decision. You are free to leave the study at any time, you do not have to give a reason and this will not affect any current or future treatment for your condition.

What will happen if I agree to take part?

If you agree to take part we would like to conduct a face to face interview with you. In this we will explore what it is like to live with your condition. You are free to discuss the issues that are important to you and your own circumstances. You can choose not to discuss anything that you feel may make you uncomfortable. The interview should take less than an hour, but may vary depending on how much you have to say. If you want to stop the interview at any time, you can do so without giving any reason at all. The interview will be audio recorded. You can decide for it to take place at either the University of East Anglia (UEA) or at your own home.

Prior to the interview, you have the option of taking photographs to bring with you. This is to help you document how your condition affects your daily life. The purpose of using photographs in this way is to gain a deeper insight into your experience. While using photographs is a good way to guide the interview, they are not essential should you wish not to. If you do agree to using photography please refer to the 'Taking Photographs' sheet enclosed.

The tape recorded interviews will be fully transcribed and analysed for emerging themes. The key themes identified will be sent to you by post so that you can check if these reflect what you said. This information will help develop questions for the questionnaire. The recording will be kept in a secure place at the UEA. No personal information (e.g. name, address) will be stored with the recording. It will be accessed only by members of the research team.

What if I decide to withdraw after the interview has taken place?

You can leave the study at any time, without giving a reason and without any changes to any treatment you are currently receiving. If you decide to leave after an interview has taken place, any photographs taken, the recording and transcript of your interview will be destroyed.

What are the possible benefits of taking part?

There are no direct benefits to taking part in the overall study. However, taking part in interviews and talking about your experience of your hand condition has been reported by others to be helpful.

Centre Number: 01
REC Reference: 14/NE/1087

Yes, I would like to take part in the study – what do I need to do now?

If you wish to take part please complete the enclosed consent form and return it in the stamped addressed envelope within two weeks. You will then be contacted by telephone to answer any further questions you may have and to discuss what happens next.

I am not sure about taking part – where can I get further information?

We would be very happy to answer any questions you may have. Please contact Mark Ashwood, the chief investigator.

Contact information:

Chief investigator: Mark Ashwood

Telephone 01603 593063 email: M.Ashwood@uea.ac.uk

OR

Primary supervisor: Dr Christina Jerosch-Herold

Telephone: 01603 593316 email: C.Jerosch-Herold@uea.ac.uk

Thank you for taking the time to read this information

NNUH/ PIS 1/Version 3/ 26-07-2014

Centre Number: 01
REC Reference: 14/NE/1087

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UEA
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PARTICIPANT INFORMATION SHEET PHASE 1

'Taking Photographs'

The Hand Nerve Disorders Study –

'The HaND Study'

Thank you for your interest in being interviewed as part of my study. Before the interview we would like you to take some photographs and wanted you to have this sheet to refer to for extra information.

Why am I being asked to take photographs?

Photography is increasingly being used in research to give participants the opportunity to discuss issues in more depth. Rather than simply asking questions at the interview about what it is like for you to live with your hand condition we hope that your photographs will have captured images that represent this more fully. We hope by doing this to get a better understanding of your daily life, from your perspective.

What do you want me to do?

Using the camera we have loaned you, we would like you to build a set of images of what it is like to live with a nerve disorder that affects your hand. We would like you to take pictures of your daily life. This could include areas such as self-care, domestic life, and work or community life. There is no limit to the amount of photographs you might take but if you

would like a guide, anything from 10-25 should give a good representation that we can base our discussion in the interview on.

What happens after I have taken the photographs?

After you have taken the photographs, please give the camera back to me when we meet for the interview.

What care should I take when taking photographs?

There are currently no legal restrictions on taking photos in public places, including photos of people in public places (House of Lords debate, 16 July 2008), but we would like you to take other people's wishes for privacy into consideration. We would ask that you use 'common sense' when taking the photographs and avoid taking photos of children and taking close-ups of people's faces. In terms of the actual photographs we are not looking for professional images it is more that we would like you to capture an image for us to discuss.

What will happen to the photographs that I have taken?

We may like to use the photographs in publications and presentations to illustrate the points we are making about our research findings. We will anonymise who has taken the photographs and faces will be blurred out to be unrecognisable. We will ask you to consent to this and you can choose not to do so. Any photos you provide to us will be treated confidentially and stored securely in the same way as the other research information we receive from you.

Do I have to take photographs?

You are under no obligation to take photographs, and if you decide not to you can proceed with a more traditional interview instead.

Thank you, once again for taking the time to read this information

Centre Number: 01
REC Reference: 14/NE/1087

What are the possible risks and disadvantages involved in taking part?

There are no risks associated with this study. It is possible that talking about your condition and how it has impacted on your life could be upsetting. If this happens the interviewer will offer to stop the interview and offer you sources of help. If you decide to have your interview at UEA you may incur some travel costs which will be reimbursed.

Will my taking part in the study be kept confidential?

Yes, we will follow ethical and legal best practice and all information you provide us will be treated in confidence. Results will be published in a doctoral thesis, scientific peer reviewed journals and presented at meetings or conferences. These reports will not contain any names and we will ensure that individuals cannot be identified from details in the reports or study results. If you desire we will provide you with a summary of the results of the study.

Will I be approached about taking part in other studies?

If you agree to take part in this study, you may be invited to join later stages of the study. You do not have to take part, and will be sent further information before you decide.

Will my GP be informed of my involvement in the study?

We will inform your GP of your involvement in the study.

How do I raise concerns or make a complaint?

If you have concerns about any aspect of this project, you can speak to Mark Ashwood - Chief investigator or Dr Christina Jerosch-Herold – Primary supervisor who will do their best to answer any queries. If you remain unhappy and wish to make a formal complaint, please contact Professor Valerie Lattimer, Head of the School of Health Sciences on 01603 59 7247 or through the normal NHS complaints procedure by contacting your local hospital switchboard.

Who is organising and funding the project?

The chief investigator is a qualified occupational therapist and is carrying out this research as part of his doctoral degree. It is funded by the University of East Anglia.

Who has reviewed this study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your safety, rights, wellbeing and dignity. This study has been reviewed and approved by the York Research Ethics Committee (Ref: 14/NE/1087).

NNUH/ PIS 1/Version 3/ 26-07-2014

Centre Number: 01
REC Reference: 14/NE/1087
Patient Identification Number for this study:

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University of East Anglia

The Hand Nerve Disorders Study –

'The HaND Study'

Personal information (to be completed by the participant)

1. What is your sex? Male ☐ Female ☐
2. What is your date of birth? e.g. DD/MM/YYYY _____
3. Do you live with anyone else? Yes ☐ No ☐ If YES,
   How are you related? *Please tick all that apply:*

   Partner ☐ Parent ☐ Relation – other ☐
   Son or daughter ☐ Grandchild ☐ Unrelated ☐
   Sibling ☐ Grandparent ☐

4. Do you look after, or give any help or support to family members, friends, neighbours or others? Yes ☐ No ☐
   If YES, Can you tell me more about this?
   _____
5. How would you best describe your current work circumstances?

   Working as an employee ☐ What is your job title?_____
   Self-employed or freelance ☐ What is your job title?_____
   Unemployed ☐
   Retired (whether receiving a pension or not) ☐
   A student ☐
   Looking after home or family ☐
   Long-term sick or disabled ☐
   Other ☐ Please state _____
6. Has there has been change in your employment status as a result of your nerve disorder?
   Yes ☐ No ☐
   If YES, Can you tell me more about this?
   _____
7. Please provide us with contact details for both you and your GP.

Your address:	*GP:*
	Address:
Post code:	
Telephone:	*Post code:*

_____ _____ _____
Name of Participant Date Signature

Centre Number: 01
REC Reference: 14/NE/1087
Patient Identification Number for this study:

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The Hand Nerve Disorders Study –

'The HaND Study'

Medical information (to be completed by the clinician)

1. When did the patient begin to experience symptoms or sustain their injury?
   DD/MM/YYYY_____
2. What is the patient's hand dominance? *Please circle* [L] [R] [Ambidextrous]
3. Describe the mechanism of injury or the circumstances in which condition occurred?
   Please tick

Stretching		Cutting	
Compression		Shearing	
Crushing		Other: *Please state* _____	

4. What is the patient's primary diagnosis? Please circle affected side [L] [R] [both]
   Please tick all that apply

Carpal tunnel syndrome		Traumatic median nerve injury	
Cubital tunnel syndrome		Traumatic ulnar nerve injury	
Radial tunnel syndrome		Traumatic radial nerve injury	
Combined nerve compression		Traumatic combined nerve injury	

5. Did the patient sustain a concomitant bone or tendon injury? Yes ☐ No ☐
   If *YES*, please provide details?
   _____

6. Did the patient have any surgery? Yes ☐ No ☐ Please circle affected side [L] [R] [both]
   Please tick all that apply

Decompression		End to end repair	
Neurolysis		Nerve grafting	
Nerve transfer		Other: *Please state* _____	

   If *YES*, please provide details?
   _____

7. When did the participant have their surgery? DD/MM/YYYY_____

_____ _____ _____
Name of Clinician Date Signature

Centre Number: 01
REC Reference: 14/NE/1087
Patient Identification Number for this study:

Our Vision
To provide every patient with the care we want for those we love the most

Norfolk and Norwich University Hospitals NHS
NHS Foundation Trust

UEA
University of East Anglia

PATIENT CONSENT FORM - PHASE 1

The Hand Nerve Disorders Study –

'The HaND Study'

Name of Researcher: Mr Mark Ashwood

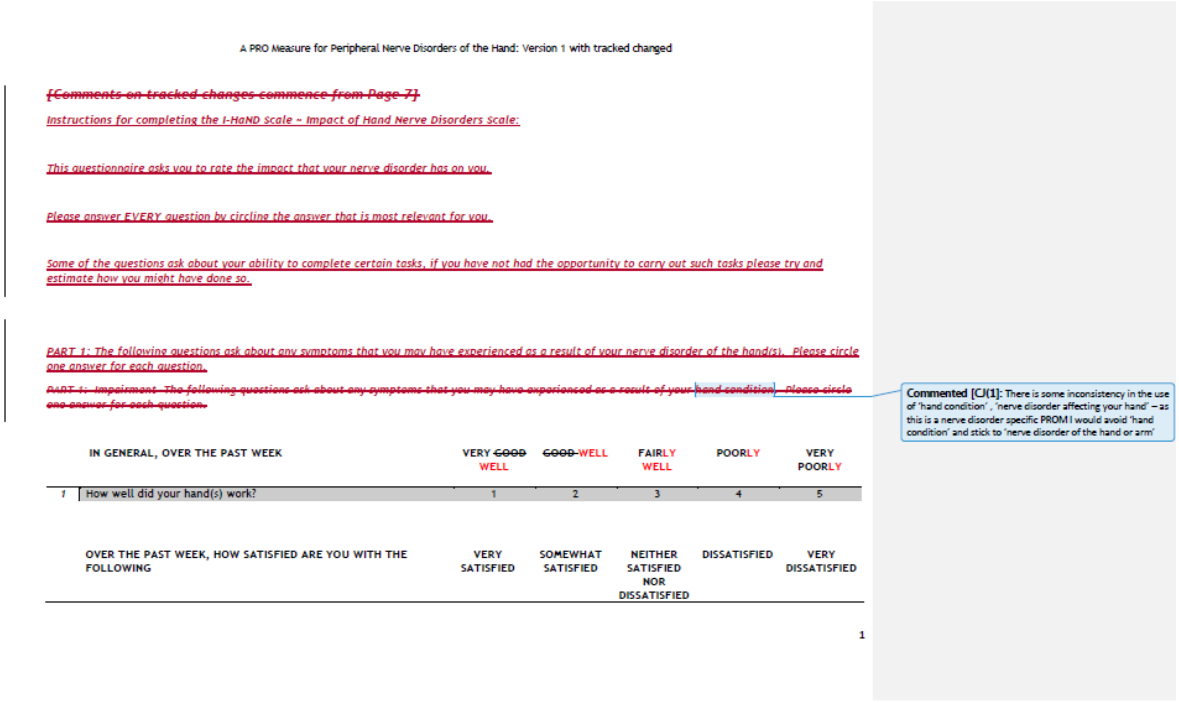
Please initial all boxes

1. I confirm that I have read and understand the information sheet dated 26.07.2014 (version 3) 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 understand that relevant sections of my medical notes and data collected during the study may be looked at by individuals from the Norfolk and Norwich University Hospital (NNUH), from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records. ☐
4. I agree to my GP being informed of my participation in the study. ☐
5. I agree for the interview to be audio taped. ☐
6. I agree that from the interviews direct quotations can be published but that these will be in an anonymised form. ☐
7. I understand that I may be contacted again and invited to participate in later stages of this project. ☐
8. I agree to take part in the above study. ☐
9. OPTIONAL: I agree to take photographs for discussion in the interviews. I am happy for these to be published, understanding that I will not be identified from them. ☐

Name of participant	Date	Signature
Name of person taking consent	Date	Signature

Appendix 3.4 Development of the I-HaND Scale from versions 1 to 1.4

I-HaND Scale version 1



A PRO Measure for Peripheral Nerve Disorders of the Hand: Version 1 with tracked changed

~~[Comments on tracked changes commence from Page 7]~~

Instructions for completing the I-HaND Scale – Impact of Hand Nerve Disorders Scale:

This questionnaire asks you to rate the impact that your nerve disorder has on you.

Please answer EVERY question by circling the answer that is most relevant for you.

Some of the questions ask about your ability to complete certain tasks, if you have not had the opportunity to carry out such tasks please try and estimate how you might have done so.

PART 1: The following questions ask about any symptoms that you may have experienced as a result of your nerve disorder of the hand(s). Please circle one answer for each question.

~~PART 1: Impairment The following questions ask about any symptoms that you may have experienced as a result of your hand condition. Please circle one answer for each question.~~

Commented [CJ(1]: There is some inconsistency in the use of 'hand condition' , 'nerve disorder affecting your hand' – as this is a nerve disorder specific PROM I would avoid 'hand condition' and stick to 'nerve disorder of the hand or arm'

	IN GENERAL, OVER THE PAST WEEK	VERY ~~GOOD~~ WELL	~~GOOD~~ WELL	FAIRLY WELL	POORLY	VERY POORLY
1	How well did your hand(s) work?	1	2	3	4	5

	OVER THE PAST WEEK, HOW SATISFIED ARE YOU WITH THE FOLLOWING	VERY SATISFIED	SOMEWHAT SATISFIED	NEITHER SATISFIED NOR DISSATISFIED	DISSATISFIED	VERY DISSATISFIED

1

Appendix

A PRO Measure for Peripheral Nerve Disorders of the Hand: Version 1 with tracked changed

2	The movement of your hand(s)	1	2	3	4	5
3	The sensation of your hand(s)	1	2	3	4	5
4	~~Your ability to grip an object for any length of time~~ The strength in your hand(s)	1	2	3	4	5

	~~OVER THE PAST WEEK, HOW MUCH WOULD YOU AGREE OR DISAGREE WITH THE FOLLOWING STATEMENTS ABOUT YOUR HAND(S)~~	~~STRONGLY AGREE~~	~~AGREE~~	~~NEITHER AGREE NOR DISAGREE~~	~~DISAGREE~~	~~STRONGLY DISAGREE~~
~~5~~	~~I can't grip or pinch as hard~~	~~1~~	~~2~~	~~3~~	~~4~~	~~5~~
~~6~~	~~I feel self-conscious if people look at my hand/arm~~	~~1~~	~~2~~	~~3~~	~~4~~	~~5~~
~~7~~	~~When I touch certain things it feels like pins and needles or tingling~~	~~1~~	~~2~~	~~3~~	~~4~~	~~5~~
~~8~~	~~Using my hand(s) can bring about strong emotions e.g. frustration, anger, sadness~~	~~1~~	~~2~~	~~3~~	~~4~~	~~5~~
~~9~~	~~I have hurt my hand and not realised it until later~~	~~1~~	~~2~~	~~3~~	~~4~~	~~5~~
~~10~~	~~I avoid things that I know I can't cope with~~	~~1~~	~~2~~	~~3~~	~~4~~	~~5~~
~~11~~	~~I go to grab something and it just falls out of my hand~~	~~1~~	~~2~~	~~3~~	~~4~~	~~5~~
~~12~~	~~I am very conscious of my limits when using my hand~~	~~1~~	~~2~~	~~3~~	~~4~~	~~5~~

	THE FOLLOWING STATEMENTS RELATE TO PHYSICAL PROBLEMS EXPERIENCED BY PEOPLE WITH A NERVE DISORDER AFFECTING THEIR HAND(S). PLEASE INDICATE HOW OFTEN YOU HAVE EXPERIENCED THESE PROBLEMS	~~NEVER~~ ~~ALWAYS~~	~~RARELY~~ ~~OFTEN~~	~~SOMETIMES~~ ~~SOMETIMES~~	~~OFTEN~~ ~~RARELY~~	~~ALWAYS~~ ~~NEVER~~
5	I can't grip or pinch for very long without my hand getting tired	1	2	3	4	5
~~7~~ 6	When I touch certain things it causes pins and needles or tingling	1	2	3	4	5
~~9~~ 7	I have hurt my hand and not realised it until later	1	2	3	4	5

A PRO Measure for Peripheral Nerve Disorders of the Hand: Version 1 with tracked changed

~~11~~ 8	When I go to grab something ~~and~~ it just falls out of my hand	1	2	3	4	5

	THE FOLLOWING STATEMENTS RELATE TO EMOTIONAL PROBLEMS EXPERIENCED BY PEOPLE WITH A NERVE DISORDER AFFECTING THEIR HAND(S). PLEASE INDICATE HOW OFTEN YOU HAVE EXPERIENCED THESE PROBLEMS	~~NEVER~~ ~~ALWAYS~~	~~RARELY~~ ~~OFTEN~~	~~SOMETIMES~~ ~~SOMETIMES~~	~~OFTEN~~ ~~RARELY~~	~~ALWAYS~~ ~~NEVER~~
~~8~~ 9	Using my hand(s) can bring about strong emotions e.g. frustration, anger, sadness	1	2	3	4	5
~~6~~ 10	I feel self-conscious if people look at my hand/arm	1	2	3	4	5

Commented [CJ(2]: Emotional problems may be seen as a bit judgemental, suggest you use a more neutral word such as 'feelings'

Commented [MA(3R2]:

Commented [CJ(4]: Avoid labelling it as a 'problem' so use 'feelings'

A PRO Measure for Peripheral Nerve Disorders of the Hand: Version 1 with tracked changed

PART 2: The following questions ask about any pain that you may have experienced as a result of your nerve disorder of the hand(s). Please circle one answer for each question.

~~*PART 3: Pain - The following questions ask about any pain that you may experience as a result of your hand condition. Please circle one answer for each question.*~~

		~~NONE~~ VERY MILD	~~MILD~~MILD	~~MODERATE~~ MODERATE	~~SEVERE~~SEVERE	~~VERY SEVERE~~VERY SEVERE
~~13~~ 11	Over the last week, the pain in my hand(s) has been	1	2	3	4	5

Commented [CJ(5]: This needs to include a 'none' or 'no pain' option and if sticking to a 5 point scale just drop the 'very severe' and leave 'severe' as the highest label

	IN GENERAL, OVER THE PAST WEEK	~~NEVER~~ALWAYS	~~RARELY~~OFTEN	~~SOMETIMES~~SOMETIMES	~~OFTEN~~RARELY	~~ALWAYS~~NEVER
~~14~~ 12	~~How often would you say that your pain impacts on your daily routine?~~	1	2	3	4	5

	OVER THE PAST WEEK, HOW MUCH WOULD YOU AGREE OR DISAGREE WITH THE FOLLOWING STATEMENTS ~~ABOUT YOUR CONDITION~~ WHICH ASK ABOUT SITUATIONS THAT CAN ~~BRING ON YOUR PAIN~~ CAUSE DISCOMFORT OR PAIN	~~STRONGLY DISAGREE~~STRONGLY AGREE	~~DISAGREE~~AGREE	~~NEITHER AGREE NOR DISAGREE~~NEITHER AGREE NOR DISAGREE	~~AGREE~~DISAGREE	~~STRONGLY AGREE~~STRONGLY DISAGREE
~~15~~ 13	I am ~~very~~ sensitive in my hand and do not like it to be touched	1	2	3	4	5
~~16~~ 14	~~When I go outside my hand can feel cold and numb.~~ My hand is bothered by the cold e.g. I feel discomfort or pain in cold weather or when handling cold objects	1	2	3	4	5
~~17~~ 15	It is difficult to get a good night's sleep because of the pain in my hand/arm	1	2	3	4	5

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A PRO Measure for Peripheral Nerve Disorders of the Hand: Version 1 with tracked changed

PART 3: ~~Activity~~ The following questions ask about activities that can be difficult for people experiencing a nerve disorder affecting their hand(s). Please circle one answer for each question.

	IN GENERAL, OVER THE PAST WEEK	VERY ~~GOOD~~ WELL	~~GOOD~~ WELL	FAIRLY WELL	POORLY	VERY POORLY
~~18~~ 16	How well have you been able to carry out your daily routine e.g. Getting ready, cooking, childcare etc.	1	2	3	4	5

	OVER THE PAST WEEK HOW DIFFICULT HAS IT BEEN FOR YOU TO COMPLETE THE FOLLOWING ACTIVITIES	NOT AT ALL DIFFICULT	A LITTLE DIFFICULT	SOMEWHAT DIFFICULT	MODERATELY DIFFICULT	VERY DIFFICULT
~~19~~	~~Self-care tasks that require fine hand use e.g. Fastening up a watch strap or a necklace, shaving or putting on make-up~~	~~1~~	~~2~~	~~3~~	~~4~~	~~5~~
~~20~~ 17	Doing up buttons	1	2	3	4	5
~~21~~ 18	Cutting food using a knife & fork together	1	2	3	4	5
~~22~~ 19	Cutting your nails	1	2	3	4	5
~~23~~	~~Putting on deodorant~~	~~1~~	~~2~~	~~3~~	~~4~~	~~5~~
~~24~~ 20	Washing your body	1	2	3	4	5
~~25~~ 21	~~Squeezing toothpaste~~ Putting toothpaste on a toothbrush	1	2	3	4	5
~~26~~ 22	Getting dressed or undressed	1	2	3	4	5
~~27~~ 23	Opening lids of tight jars and bottles	1	2	3	4	5
~~28~~ 24	Pouring from a kettle	1	2	3	4	5
~~29~~ 25	Carrying a heavy shopping bag	1	2	3	4	5
~~30~~ 26	Wringing out a ~~dish~~ cloth	1	2	3	4	5

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A PRO Measure for Peripheral Nerve Disorders of the Hand: Version 1 with tracked changed

~~31~~ 27	Preparing a meal ~~e.g. Peeling & chopping vegetables and cutting meat~~	1	2	3	4	5
~~32~~ 28	Opening & closing heavy doors	1	2	3	4	5
~~33~~ 29	Handwriting	1	2	3	4	5
~~34~~ 30	Turning pages of a book, magazine or newspaper	1	2	3	4	5
~~35~~ 31	Handling small ~~coins~~ change e.g. 5 pence or 1 pence	1	2	3	4	5
~~36~~	~~Finding something in your pocket e.g. Keys or coins~~	1	2	3	4	5
~~37~~ 32	Using ~~a phone~~ electronic devices e.g. a remote control, mobile phone, tablet or computer	1	2	3	4	5
~~38~~	~~Using the keyboard of a laptop or personal computer~~	~~1~~	~~2~~	~~3~~	~~4~~	~~5~~

7

A PRO Measure for Peripheral Nerve Disorders of the Hand: Version 1 with tracked changed

~~PART 4:~~ The following questions ask about how your nerve disorder of the hand(s) has affected your ability to take part in your daily work (including paid work, school work or housework) and recreational tasks. Please circle one answer for each question.

~~PART 4: Participation. The following questions ask about how your hand condition has affected your ability to take part in your daily work (occupational work, including paid work, school work or housework) and recreational tasks. Please circle one answer for each question.~~

	IN GENERAL, OVER THE PAST WEEK	VERY ~~GOOD~~ WELL	~~GOOD~~ WELL	FAIRLY WELL	POORLY	VERY POORLY
~~39~~ 33	How well have you been able to manage the physical demands of your daily work?	1	2	3	4	5
~~40~~ 34	How well have you been able to take part in recreational tasks e.g. Hobbies or sport? ~~or playing an instrument?~~	1	2	3	4	5

	~~OVER THE PAST WEEK, HOW MUCH WOULD YOU AGREE OR DISAGREE WITH THE FOLLOWING~~	~~STRONGLY AGREE~~	~~AGREE~~	~~NEITHER AGREE NOR DISAGREE~~	~~DISAGREE~~	~~STRONGLY DISAGREE~~
~~41~~	~~I am able to manage the pace of my work~~	~~1~~	~~2~~	~~3~~	~~4~~	~~5~~
~~42~~	~~I feel confident taking part in recreational tasks~~	~~1~~	~~2~~	~~3~~	~~4~~	~~5~~

8

Summary of changes

Removal of word 'Impairment' and replacement with general instruction for part 1.

Change of response categories to match the wording of question 1.

Removal of question on endurance as felt this would be better placed in the next set of questions. Replaced with a more global question on strength to match other questions in this category.

Removal of table which combined sensory, motor and psychological questions in favour of two separated tables asking about physical and emotional problems. Change of response categories to match the wording of questions 5-10.

Q5 changed from 'I can't grip or pinch as hard' to 'I can't grip or pinch for very long without my hand getting tired' to measure endurance.

Q7 (new Q6) reworded from 'When I touch certain things it feels like pins and needles or tingling' to 'When I touch certain things it causes pins and needles or tingling' for clarity.

Q10 'I avoid things that I know I can't cope with' and Q12 'I am very conscious of my limits when using my hand' both removed as felt that conceptually too difficult to measure.

Removal of word 'Pain' and replacement with general instruction for part 2.

Change of wording for instruction to Q15-17 (new Q13-15).

Q16 (new Q14) change in wording from 'When I go outside my hand can feel cold and numb' to 'My hand is bothered by the cold e.g. cold weather or handling cold objects' to better capture phenomenon of cold intolerance.

Removal of word 'Activity' and replacement with general instruction for part 3.

Change of response categories to match the wording of Q18 (new 16).

Q19 'Self-care tasks that require fine hand use e.g. fastening up a watch strap or a necklace, shaving or putting on make-up' removed as felt covered by other questions.

Q21 (new Q18) reworded from 'Cutting food using a knife & fork' to 'Cutting food using a knife & fork together' to better reflect a bilateral task.

Q23 removed as felt that not all participants carry out this task.

Q25 (new Q21) reworded from 'Squeezing toothpaste' to 'Putting toothpaste on a toothbrush' to accommodate both squeeze and pump type toothpaste and also to reflect a bilateral task.

Q26 (new Q22) reworded from 'Getting dressed' to 'Getting dressed or undressed' to better reflect the activity.

Q31 (new Q27) reworded from 'Preparing a meal e.g. Peeling & chopping vegetables and cutting meat' to 'Preparing a meal' to be more open with the variety of ways that participants may approach this activity.

Q34 (new Q30) reworded from 'Turning pages of a book' to 'Turning pages of a book, magazine or newspaper' to be more inclusive.

Q35-36 (new Q32) merged to form a new question: Handling small change e.g. 5p or 1p.

Q37-38 (new Q32 merged to form a new question: Using electronic devices e.g. a remote control, mobile phone, tablet or computer.

Q39 (new Q33) reworded from 'How well have you been able to manage the physical demands of your work?' to 'How well have you been able to manage the physical demands of your daily work?' for clarity.

Removal of word 'Participation' and replacement with general instruction for part 4.

Change of response categories to match the wording of Q39 – 40 (new Q33-34).

Q40 (new Q34) reworded from' How well have you been able to take part in recreational tasks e.g. Hobbies or sport or playing an instrument?' to 'How well have you been able to take part in recreational tasks e.g. Hobbies or sport?' for clarity.

Q42-43 removed as felt covered by global questions.

I-HaND Scale version 1.1

A PRO Measure for Peripheral Nerve Disorders of the Hand: Version 1.1

Instructions for completing the (PRO) Measure:

This questionnaire is interested in the impact that your nerve disorder which affects your hand(s) has on your daily life. This information will be helpful in monitoring the improvement of your condition.

*Please answer **EVERY** question by circling the answer that is most relevant for you.*

Some of the questions ask about your ability to complete certain tasks, if you have not had the opportunity to carry out such tasks please try and estimate how you might have done so.

***PART 1:** The following questions ask about any symptoms that you may have experienced as a result of your hand condition. Please circle one answer for each question.*

	IN GENERAL, OVER THE PAST WEEK	VERY WELL	WELL	FAIRLY WELL	POORLY	VERY POORLY
1	How well did your hand(s) work?	1	2	3	4	5

A PRO Measure for Peripheral Nerve Disorders of the Hand: Version 1.1

	OVER THE PAST WEEK, HOW SATISFIED ARE YOU WITH THE FOLLOWING	VERY SATISFIED	SOMEWHAT SATISFIED	NEITHER SATISFIED NOR DISSATISFIED	DISSATISFIED	VERY DISSATISFIED
2	The movement of your hand(s)	1	2	3	4	5
3	The sensation of your hand(s)	1	2	3	4	5
4	The strength in your hand(s)	1	2	3	4	5

	THE FOLLOWING STATEMENTS RELATE TO PHYSICAL PROBLEMS EXPERIENCED BY PEOPLE WITH A NERVE DISORDER AFFECTING THEIR HAND(S). PLEASE INDICATE HOW OFTEN YOU HAVE EXPERIENCED THESE PROBLEMS IN THE PAST WEEK	ALWAYS	OFTEN	SOMETIMES	RARELY	NEVER
5	I can't grip or pinch for very long without my hand getting tired	1	2	3	4	5
6	When I touch certain things it causes pins and needles or tingling	1	2	3	4	5
7	I have hurt my hand and not realised it until later	1	2	3	4	5
8	I go to grab something and it just falls out of my hand	1	2	3	4	5

	THE FOLLOWING STATEMENTS RELATE TO EMOTIONAL PROBLEMS EXPERIENCED BY PEOPLE WITH A NERVE DISORDER AFFECTING THEIR HAND(S). PLEASE INDICATE HOW OFTEN YOU HAVE EXPERIENCED THESE PROBLEMS IN THE PAST WEEK	ALWAYS	OFTEN	SOMETIMES	RARELY	NEVER
9	Using my hand(s) can bring about strong emotions e.g. frustration, anger, sadness	1	2	3	4	5
10	I feel self-conscious if people look at my hand/arm	1	2	3	4	5

PART 2: The following questions ask about any pain that you may experience as a result of your hand condition. Please circle one answer for each question.

		VERY MILD	MILD	MODERATE	SEVERE	VERY SEVERE
11	Over the last week, the pain in my hand(s) has been	1	2	3	4	5

	IN GENERAL, OVER THE PAST WEEK	ALWAYS	OFTEN	SOMETIMES	RARELY	NEVER
12	How often would you say that your pain impacts on your daily routine?	1	2	3	4	5

	OVER THE PAST WEEK, HOW MUCH WOULD YOU AGREE OR DISAGREE WITH THE FOLLOWING STATEMENTS WHICH ASK ABOUT SITUATIONS THAT CAN BRING ON YOUR PAIN	STRONGLY AGREE	AGREE	NEITHER AGREE NOR DISAGREE	DISAGREE	STRONGLY DISAGREE
13	I am sensitive in my hand and do not like it to be touched	1	2	3	4	5
14	My hand is bothered by the cold e.g. cold weather or handling cold objects	1	2	3	4	5
15	It is difficult to get a good night's sleep because of the pain in my hand/arm	1	2	3	4	5

PART 3: The following questions ask about activities that can be difficult for people experiencing a nerve disorder affecting their hand(s). Please circle one answer for each question.

	IN GENERAL, OVER THE PAST WEEK	VERY WELL	WELL	FAIRLY WELL	POORLY	VERY POORLY
16	How well have you been able to carry out your daily routine e.g. Getting ready, cooking, childcare etc.	1	2	3	4	5

	OVER THE PAST WEEK HOW DIFFICULT HAS IT BEEN FOR YOU TO COMPLETE THE FOLLOWING ACTIVITIES	NOT AT ALL DIFFICULT	A LITTLE DIFFICULT	SOMEWHAT DIFFICULT	MODERATELY DIFFICULT	VERY DIFFICULT
17	Doing up buttons	1	2	3	4	5
18	Cutting food using a knife & fork together	1	2	3	4	5
19	Cutting your nails	1	2	3	4	5
20	Washing your body	1	2	3	4	5
21	Putting toothpaste on a toothbrush	1	2	3	4	5
22	Getting dressed or undressed	1	2	3	4	5
23	Opening lids of tight jars and bottles	1	2	3	4	5
24	Pouring from a kettle	1	2	3	4	5
25	Carrying a heavy shopping bag	1	2	3	4	5
26	Wringing out a cloth	1	2	3	4	5
27	Preparing a meal	1	2	3	4	5
28	Opening & closing heavy doors	1	2	3	4	5
29	Handwriting	1	2	3	4	5
30	Turning pages of a book, magazine or newspaper	1	2	3	4	5
31	Handling small change e.g. 5p or 1p	1	2	3	4	5
32	Using electronic devices e.g. a remote control, mobile phone, tablet or computer	1	2	3	4	5

PART 4: *The following questions ask about how your hand condition has affected your ability to take part in your daily work (occupational work, school work or housework) and recreational tasks. Please circle one answer for each question.*

	IN GENERAL, OVER THE PAST WEEK	VERY WELL	WELL	FAIRLY WELL	POORLY	VERY POORLY
33	How well have you been able to manage the physical demands of your daily work?	1	2	3	4	5
34	How well have you been able to take part in recreational tasks e.g. Hobbies or sport?	1	2	3	4	5

I-HaND Scale version 1.2

Instructions for completing the **I**mpact of **Ha**nd **N**erve **D**isorders (I-HaND) Scale:

This questionnaire asks you to rate the impact that your nerve disorder has on you.

*Please answer **EVERY** question by circling the answer that is most relevant for you.*

Some of the questions ask about your ability to complete certain tasks, if you have not had the opportunity to carry out such tasks please try and estimate how you might have done so.

***PART 1:** The following questions ask about any symptoms that you may have experienced as a result of your nerve disorder of the hand(s). Please circle one answer for each question.*

	IN GENERAL, OVER THE PAST WEEK	VERY WELL	WELL	FAIRLY WELL	POORLY	VERY POORLY
1	How well did your hand(s) work?	1	2	3	4	5

	OVER THE PAST WEEK, HOW SATISFIED ARE YOU WITH THE FOLLOWING	VERY SATISFIED	SOMEWHAT SATISFIED	NEITHER SATISFIED NOR DISSATISFIED	DISSATISFIED	VERY DISSATISFIED
2	The movement of your hand(s)	1	2	3	4	5
3	The sensation of your hand(s)	1	2	3	4	5
4	The strength in your hand(s)	1	2	3	4	5

	THE FOLLOWING STATEMENTS RELATE TO PHYSICAL DIFFICULTIES EXPERIENCED BY PEOPLE WITH A NERVE DISORDER AFFECTING THEIR HAND(S). PLEASE INDICATE HOW OFTEN YOU HAVE EXPERIENCED THESE DIFFICULTIES IN THE PAST WEEK	NEVER	RARELY	SOMETIMES	OFTEN	ALWAYS
5	I can't grip or pinch for very long without my hand getting tired	1	2	3	4	5
6	When I touch certain things it causes pins and needles or tingling	1	2	3	4	5
7	I have hurt my hand and not realised it until later	1	2	3	4	5
8	When I go to grab something it just falls out of my hand	1	2	3	4	5

	THE FOLLOWING STATEMENTS RELATE TO FEELINGS EXPERIENCED BY PEOPLE WITH A NERVE DISORDER AFFECTING THEIR HAND(S). PLEASE INDICATE HOW OFTEN YOU HAVE EXPERIENCED THESE FEELINGS IN THE PAST WEEK	NEVER	RARELY	SOMETIMES	OFTEN	ALWAYS
9	Using my hand(s) can bring about strong emotions e.g. frustration, anger, sadness	1	2	3	4	5
10	I feel self-conscious if people look at my hand/arm	1	2	3	4	5

Impact of Hand Nerve Disorders (I-HaND) Scale

PART 2: *The following questions ask about any pain that you may have experienced as a result of your nerve disorder of the hand(s). Please circle one answer for each question.*

		NONE	MILD	MODERATE	SEVERE	VERY SEVERE
11	Over the last week, the pain in my hand(s) has been	1	2	3	4	5

	IN GENERAL, OVER THE PAST WEEK	NEVER	RARELY	SOMETIMES	OFTEN	ALWAYS
12	How often would you say that your pain impacts on your daily routine?	1	2	3	4	5

	OVER THE PAST WEEK, HOW MUCH WOULD YOU AGREE OR DISAGREE WITH THE FOLLOWING STATEMENTS WHICH ASK ABOUT SITUATIONS THAT CAN CAUSE DISCOMFORT OR PAIN	STRONGLY DISAGREE	DISAGREE	NEITHER AGREE NOR DISAGREE	AGREE	STRONGLY AGREE
13	I am sensitive in my hand and do not like it to be touched	1	2	3	4	5
14	I feel discomfort or pain in cold weather or when handling cold objects	1	2	3	4	5
15	It is difficult to get a good night's sleep because of the pain in my hand/arm	1	2	3	4	5

Version 1.2

Impact of Hand Nerve Disorders (I-HaND) Scale

PART 3: *The following questions ask about difficulty with activities that you may have experienced as a result of your nerve disorder of the hand(s). Please circle one answer for each question.*

	IN GENERAL, OVER THE PAST WEEK	VERY WELL	WELL	FAIRLY WELL	POORLY	VERY POORLY
16	How well have you been able to carry out your daily routine e.g. Getting ready, cooking, childcare etc.	1	2	3	4	5

	OVER THE PAST WEEK HOW DIFFICULT HAS IT BEEN FOR YOU TO COMPLETE THE FOLLOWING ACTIVITIES	NOT AT ALL DIFFICULT	A LITTLE DIFFICULT	SOMEWHAT DIFFICULT	MODERATELY DIFFICULT	VERY DIFFICULT
17	Doing up buttons	1	2	3	4	5
18	Cutting food using a knife & fork together	1	2	3	4	5
19	Cutting your nails	1	2	3	4	5
20	Washing your body	1	2	3	4	5
21	Putting toothpaste on a toothbrush	1	2	3	4	5
22	Getting dressed or undressed	1	2	3	4	5
23	Opening lids of tight jars and bottles	1	2	3	4	5
24	Pouring from a kettle	1	2	3	4	5
25	Carrying a heavy shopping bag	1	2	3	4	5
26	Wringing out a cloth	1	2	3	4	5
27	Preparing a meal	1	2	3	4	5
28	Opening & closing heavy doors	1	2	3	4	5
29	Handwriting	1	2	3	4	5
30	Turning pages of a book, magazine or newspaper	1	2	3	4	5
31	Handling small change e.g. 5 pence or 1 pence	1	2	3	4	5
32	Using electronic devices e.g. a remote control, mobile phone, tablet or computer	1	2	3	4	5

4

Version 1.2

Impact of Hand Nerve Disorders (I-HaND) Scale

PART 4: *The following questions ask about how your nerve disorder of the hand(s) has affected your ability to take part in your daily work (including paid work, school work or housework) and recreational tasks. Please circle one answer for each question.*

	IN GENERAL, OVER THE PAST WEEK	VERY WELL	WELL	FAIRLY WELL	POORLY	VERY POORLY
33	How well have you been able to manage the physical demands of your daily work?	1	2	3	4	5
34	How well have you been able to take part in recreational tasks e.g. Hobbies or sport?	1	2	3	4	5

This is end of the questionnaire, thank you very much for completing it

I-HaND Scale version 1.3

Impact of Hand Nerve Disorders (I-HaND) Scale

Instructions for completing the Impact of Hand Nerve Disorders (I-HaND) Scale:

This questionnaire asks you to rate the impact that your nerve disorder has on you.

*Please answer **EVERY** question by circling the answer that is most relevant for you.*

Some of the questions ask about your ability to complete certain tasks, if you have not had the opportunity to carry out such tasks please try and estimate how you might have done so.

***PART 1:** The following questions ask about any symptoms that you may have experienced as a result of your nerve disorder of the hand(s). Please circle one answer for each question.*

	IN GENERAL, OVER THE PAST WEEK	VERY WELL	WELL	FAIRLY WELL	POORLY	VERY POORLY
1	How well did your hand(s) work?	1	2	3	4	5

	OVER THE PAST WEEK, HOW SATISFIED ARE YOU WITH THE FOLLOWING	VERY SATISFIED	SOMEWHAT SATISFIED	NEITHER SATISFIED NOR DISSATISFIED	DISSATISFIED	VERY DISSATISFIED
2	The movement of your hand(s)	1	2	3	4	5
3	The sensation of your hand(s)	1	2	3	4	5
4	The strength in your hand(s)	1	2	3	4	5

The following statements relate to physical difficulties experienced by people with a nerve disorder affecting their hand(s).

	PLEASE INDICATE HOW OFTEN YOU HAVE EXPERIENCED THESE DIFFICULTIES IN THE PAST WEEK	NEVER	RARELY	SOMETIMES	OFTEN	ALWAYS
5	I can't grip or pinch for very long without my hand getting tired	1	2	3	4	5
6	When I touch certain things it causes pins and needles or tingling	1	2	3	4	5
7	I have hurt my hand and not realised it until later	1	2	3	4	5
8	When I go to grab something it just falls out of my hand	1	2	3	4	5

Impact of Hand Nerve Disorders (I-HaND) Scale

The following statements relate to feelings sometimes experienced by people with a nerve disorder affecting their hand(s).

	PLEASE INDICATE HOW OFTEN YOU HAVE EXPERIENCED THESE FEELINGS IN THE PAST WEEK	NEVER	RARELY	SOMETIMES	OFTEN	ALWAYS
9	Using my hand(s) can bring about strong emotions e.g. frustration, anger, sadness	1	2	3	4	5
10	I feel self-conscious if people look at my hand/arm	1	2	3	4	5

PART 2: *The following questions ask about any pain that you may have experienced as a result of your nerve disorder of the hand(s). Please circle one answer for each question.*

		NONE	MILD	MODERATE	SEVERE	VERY SEVERE
11	Over the last week, the pain in my hand(s) has been	1	2	3	4	5

	IN GENERAL, OVER THE PAST WEEK	NEVER	RARELY	SOMETIMES	OFTEN	ALWAYS
12	How often would you say that your pain impacts on your daily routine?	1	2	3	4	5

The following questions asks about situations which may cause discomfort or pain in your hand.

	OVER THE PAST WEEK, HOW MUCH WOULD YOU AGREE OR DISAGREE WITH THE FOLLOWING STATEMENTS	STRONGLY DISAGREE	DISAGREE	NEITHER AGREE NOR DISAGREE	AGREE	STRONGLY AGREE
13	I am sensitive in my hand and do not like it to be touched	1	2	3	4	5
14	I feel discomfort or pain in cold weather or when handling cold objects	1	2	3	4	5
15	It is difficult to get a good night's sleep because of the pain in my hand/arm	1	2	3	4	5

Impact of Hand Nerve Disorders (I-HaND) Scale

PART 3: The following questions ask about difficulty with activities that you may have experienced as a result of your nerve disorder of the hand(s). Please circle one answer for each question.

	IN GENERAL, OVER THE PAST WEEK	VERY WELL	WELL	FAIRLY WELL	POORLY	VERY POORLY
16	How well have you been able to carry out your daily routine e.g. Getting ready, cooking, childcare etc.	1	2	3	4	5

	OVER THE PAST WEEK HOW DIFFICULT HAS IT BEEN FOR YOU TO COMPLETE THE FOLLOWING ACTIVITIES	NOT AT ALL DIFFICULT	A LITTLE DIFFICULT	SOMEWHAT DIFFICULT	MODERATELY DIFFICULT	VERY DIFFICULT
17	Doing up buttons	1	2	3	4	5
18	Cutting food using a knife & fork together	1	2	3	4	5
19	Cutting your nails	1	2	3	4	5
20	Washing your body	1	2	3	4	5
21	Putting toothpaste on a toothbrush	1	2	3	4	5
22	Getting dressed or undressed	1	2	3	4	5
23	Opening lids of tight jars and bottles	1	2	3	4	5
24	Pouring from a kettle	1	2	3	4	5
25	Carrying a heavy shopping bag	1	2	3	4	5
26	Wringing out a cloth	1	2	3	4	5
27	Preparing a meal	1	2	3	4	5
28	Opening & closing heavy doors	1	2	3	4	5
29	Handwriting	1	2	3	4	5
30	Turning pages of a book, magazine or newspaper	1	2	3	4	5
31	Handling small change e.g. 5 pence or 1 pence	1	2	3	4	5
32	Using electronic devices e.g. a remote control, mobile phone, tablet or computer	1	2	3	4	5

Impact of Hand Nerve Disorders (I-HaND) Scale

PART 4: *The following questions ask about how your nerve disorder of the hand(s) has affected your ability to take part in your daily work (including paid work, school work or housework) and recreational tasks.* *Please circle one answer for each question.*

	IN GENERAL, OVER THE PAST WEEK	VERY WELL	WELL	FAIRLY WELL	POORLY	VERY POORLY
33	How well have you been able to manage the physical demands of your daily work?	1	2	3	4	5
34	How well have you been able to take part in recreational tasks e.g. Hobbies or sport?	1	2	3	4	5

This is the end of the questionnaire, THANK YOU very much for completing it

Comments from working group

SH - The scale looks pretty good – one thing to say is that CAPS are not supposed to be easy to read for some people – I would avoid them, maybe put these in another font (maybe in bold?)

CJH - I agree with Simon about the CAPS and that these should be in lower case if possible. Having become more aware of the Intellectual property development regs at UEA we also need to embed in the footer of the scale the following on each page: © 2015. University of East Anglia. All Rights Reserved. This means that the textual presentation of the questionnaire and formatting is protected. Can you please make sure you add this. It is does not preclude you from modifying it in the future.

LS - Looks good to me! Some minor points though. At the moment the 'stem' of the question runs a bit to close (in position and style) to the response labels. So, in question 1, for example, "In general, over the past week" is the same font style as "Very Well" etc. I'd suggest moving the response labels down, if possible, and changing the style in some way. For question 3, perhaps change 'sensation' to 'feeling' or 'sense of touch'? It seems odd to ask how satisfied someone is with the sensation in their hands, as 'satisfaction' implies intention and I'm not sure there is any intent in a sensation. For question 31, I'd suggest using the word 'coins' on place of 'change' to make it more explicit.

I-HaND Scale version 1.4

Impact of Hand Nerve Disorders (I-HaND) Scale Version 1-4

Instructions:

This questionnaire asks you to rate the impact that your nerve disorder has on you.

*Please answer **EVERY** question by circling the answer that is most relevant for you.*

Some of the questions ask about your ability to complete certain tasks, if you have not had the opportunity to carry out such tasks please try and estimate how you might have done so.

***Part 1:** The following questions ask about any symptoms that you may have experienced as a result of your nerve disorder of the hand(s). Please circle one answer for each question.*

	In general, over the past week	Very well	Well	Fairly well	Poorly	Very poorly
1	How well did your hand(s) work?	1	2	3	4	5

	Over the past week, how satisfied are you with the following?	Very satisfied	Somewhat satisfied	Neither satisfied nor dissatisfied	Dissatisfied	Very dissatisfied
2	The movement of your hand(s)	1	2	3	4	5
3	The sense of touch in your hand(s)	1	2	3	4	5
4	The strength in your hand(s)	1	2	3	4	5

The following statements relate to physical difficulties experienced by people with a nerve disorder affecting their hand(s).

	Please indicate how often you have experienced these difficulties in the past week	Never	Rarely	Sometimes	Often	Always
5	I can't grip or pinch for very long without my hand getting tired	1	2	3	4	5
6	When I touch certain things it causes pins and needles or tingling	1	2	3	4	5
7	I have hurt my hand and not realised it until later	1	2	3	4	5
8	When I go to grab something it just falls out of my hand	1	2	3	4	5

1

Impact of Hand Nerve Disorders (I-HaND) Scale Version 1-4

The following statements relate to feelings sometimes experienced by people with a nerve disorder affecting their hand(s).

	Please indicate how often you have experienced these feelings in the past week	Never	Rarely	Sometimes	Often	Always
9	Using my hand(s) can bring about strong emotions e.g. frustration, anger, sadness	1	2	3	4	5
10	I feel self-conscious if people look at my hand/arm	1	2	3	4	5

Part 2: *The following questions ask about any pain that you may have experienced as a result of your nerve disorder of the hand(s). Please circle one answer for each question.*

	In general, over the past week	None	Mild	Moderate	Severe	Very severe
11	The pain in my hand(s) has been	1	2	3	4	5

	In general, over the past week	Never	Rarely	Sometimes	Often	Always
12	How often would you say that your pain impacts on your daily routine?	1	2	3	4	5

The following questions asks about situations which may cause discomfort or pain in your hand.

	Over the past week, how much would you agree or disagree with the following statements?	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree
13	I am sensitive in my hand and do not like it to be touched	1	2	3	4	5
14	I feel discomfort or pain in cold weather or when handling cold objects	1	2	3	4	5
15	It is difficult to get a good night's sleep because of the pain in my hand/arm	1	2	3	4	5

2

Impact of Hand Nerve Disorders (I-HaND) Scale Version 1-4

Part 3: *The following questions ask about difficulty with activities that you may have experienced as a result of your nerve disorder of the hand(s). Please circle one answer for each question.*

	In general, over the past week	Very well	Well	Fairly well	Poorly	Very poorly
16	How well have you been able to carry out your daily routine e.g. Getting ready, cooking, childcare etc.	1	2	3	4	5

	Over the past week how difficult has it been for you to complete the following activities	Not at all difficult	A little difficult	Somewhat difficult	Moderately difficult	Very difficult
17	Doing up buttons	1	2	3	4	5
18	Cutting food using a knife & fork together	1	2	3	4	5
19	Cutting your nails	1	2	3	4	5
20	Washing your body	1	2	3	4	5
21	Putting toothpaste on a toothbrush	1	2	3	4	5
22	Getting dressed or undressed	1	2	3	4	5
23	Opening lids of tight jars and bottles	1	2	3	4	5
24	Pouring from a kettle	1	2	3	4	5
25	Carrying a heavy shopping bag	1	2	3	4	5
26	Wringing out a cloth	1	2	3	4	5
27	Preparing a meal	1	2	3	4	5
28	Opening & closing heavy doors	1	2	3	4	5
29	Handwriting	1	2	3	4	5
30	Turning pages of a book, magazine or newspaper	1	2	3	4	5
31	Handling small coins e.g. 5 pence or 1 pence	1	2	3	4	5
32	Using electronic devices e.g. a remote control, mobile phone, tablet or computer	1	2	3	4	5

3

Impact of Hand Nerve Disorders (I-HaND) Scale Version 1-4

Part 4: *The following questions ask about how your nerve disorder of the hand(s) has affected your ability to take part in your daily work (including paid work, school work or housework) and recreational tasks. Please circle one answer for each question.*

	In general, over the past week	Very well	Well	Fairly well	Poorly	Very poorly
33	How well have you been able to manage the physical demands of your daily work?	1	2	3	4	5
34	How well have you been able to take part in recreational tasks e.g. Hobbies or sport?	1	2	3	4	5

This is the end of the questionnaire, ***THANK YOU*** *very much for completing it*

Changes to produce I-HAND Scale V1-4

All of the wording made sentence case.

Columns and margins moved about to have a clearer distinction between the question and responses, which are now in bold.

'Sensation' changed to 'sense of touch' and 'change' to 'coin'.

UEA copyright logo added to the footer.

Changed the top line from 'Instructions for completing the Impact of Hand Nerve Disorders (I-HaND) Scale' to 'Instructions:' as the name of the scale is already in the header.

4

Appendix 4.I Cognitive interview schedule

Cognitive Interview Schedule

The Hand Nerve Disorders Study –

'The HaND Study'

Instructions to participants:

Thank you for agreeing to take part in the HaND Study. We have now developed the first draft of the new questionnaire which we have named the Impact of Hand Nerve Disorders (I-HaND) Scale and are keen to hear what you think about it.

During this interview you will be required to:

1. Complete the I-HaND Scale like you would a regular questionnaire.
2. Tell me what you thought about while completing it.
3. Answer some questions about specific aspects of the questionnaire.

Interview process:

Step 1 Timed administration of the Impact of Hand Nerve Disorders (I-HaND) Scale

---

Step 2 Thoughts while completing the I-HaND Scale or 'Think Aloud' comments

Instructions to participants:

Can you tell me what you were thinking about while you were completing the I-HaND Scale? You may wish to tell me about how easy or difficult it was to:

1. Follow the instructions.
2. Understand the meaning of the questions.
3. Understand the response categories.
4. Complete any questions that you thought were sensitive.

Or tell me about anything else that you think may be important.

Cognitive Interview Schedule / Version 1 /07-08-2015

Step 3 Issues to investigate or 'Verbal Probing'

Probing questions about the instructions to the questions:

Probe: In the instructions section can you tell me what the introduction is telling you?

Probe: In the instructions to Part 1 what does the word 'symptoms' mean to you as it is used in this statement?

Probe: In the instructions to questions 2-4 what does the word 'satisfied' mean to you as it is used in this question?

Probe: In the instructions to questions 9-10 what does the word 'feelings' mean to you as it is used in this question?

Probe: In the instructions to Part 4 what does the term 'daily work' mean to you as it is used in this question?

Probe: In the instructions to Part 4 what does the term 'recreational tasks' mean to you as it is used in this statement?

Probing questions about Part 1:

Question 1: How well did your hand(s) work?

Probe: How easy or difficult was it for you to find your answer on that list?

Probe: You said [answer]. How well does that apply for you?

Question 3: Over the past week, how satisfied are you with the following? 'The sense of touch in your hand(s)'

Probe: Can you tell me in your own words what that question was asking?

Question 7: Please indicate how often you have experienced these difficulties in the past week. 'I have hurt my hand and not realised it until later'.

Probe: Tell me what you were thinking when answering this question?

Question 8: Please indicate how often you have experienced these difficulties in the past week. 'When I go to grab something it just falls out of my hand'.

Probe: Tell me what you were thinking when answering this question?

Question 9: Please indicate how often you have experienced these feelings in the past week. 'Using my hand(s) can bring about strong emotions e.g. frustration, anger, sadness'

Probe: Is it ok to talk about this in a questionnaire, or is it uncomfortable?

Probe: In general, how do you feel about this question?

Question 10: Please indicate how often you have experienced these feelings in the past week. 'I feel self-conscious if people look at my hand/arm'.

Probe: What do the words 'self-conscious' mean to you as it's used in this question?

Probing questions about Part 2:

Question 15: Over the past week, how much would you agree or disagree with the following statements? 'It is difficult to get a good night's sleep because of the pain in my hand/arm'.

Probe: Can you tell me in your own words what that question was asking?

Probing questions about Part 3:

Questions 17-32:

Probe: How easy or difficult was it for you to choose answers to these questions?

Question 18: Over the past week how difficult has it been for you to complete the following activities: Cutting food using a knife & fork together.

Probe: Tell me what you were thinking when answering this question?

Question 27: Over the past week how difficult has it been for you to complete the following activities: Preparing a meal.

Probe: Tell me what you were thinking when answering this question?

Question 32: Over the past week how difficult has it been for you to complete the following activities. Using electronic devices e.g. a remote control, mobile phone, tablet or computer.

Probe: Tell me what you were thinking when answering this question?

Thank you for your time

Appendix 4.2 Contents of the participant information pack for phase 2a

Centre Number: 01
REC Reference: 14/NE/1087

Our Vision
To provide every patient with the care we want for those we love the most

Norfolk and Norwich University Hospitals NHS
NHS Foundation Trust

UEA
University of East Anglia

PARTICIPANT INFORMATION SHEET – PHASE 2A

The Hand Nerve Disorders Study –

'The HaND Study'

You are invited to take part in a doctoral research study. Before making a decision it is important for you to understand what taking part involves and why the study is being done. Please take your time to read through this information, discuss it with others or feel free to get in touch if you have any questions. Our contact details are given at the end of this document.

What is the purpose of the study?

Nerve disorders of the hand can have a significant impact on a person's ability to carry out daily life tasks. Patients who sustain a nerve injury often require surgery or rehabilitation to help regain their independence. To evaluate the effectiveness of such treatments, patients are often asked to complete questionnaires. There are currently no questionnaires that look specifically at the impact of a nerve injury on hand function and activities of daily living. This research study therefore aims to develop one. During the first stage of this project we created a draft questionnaire. Now we want to test it further by seeking your opinion on whether the questions are relevant to you, what they mean to you and how easy it is to complete. Based on the information from these interviews we will then make further refinements to the questionnaire.

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

You have been approached as you are receiving, or have received treatment for your hand condition at the Norfolk and Norwich University Hospital (NNUH). We are interested to hear about your views on our new questionnaire which asks about the impact of a nerve disorder affecting your hand(s).

Do I have to take part?

Participation in this study is voluntary and it is entirely up to you to decide whether or not you want to take part. Discuss it with friends and family if you like, and ask any questions you may have before making a decision. You are free to leave the study at any time, you do not have to give a reason and this will not affect any current or future treatment for your condition.

NNUH/ PIS 2a /Version 3 / 26-07-2014

Centre Number: 01
REC Reference: 14/NE/1087

What will happen if I agree to take part?

If you agree to take part we would like to conduct a face to face interview with you. Prior to this we will get you to complete the questionnaire we have designed. The questionnaire will ask about how your hand condition affects your daily life. Afterwards we will commence the interview which will be a discussion on what it is like to complete the questionnaire. We are interested to know what the questions mean to you, how relevant the questions are and the ease with which it is to read and complete the questionnaire. There are no right or wrong answers and it is your personal view that we are interested in. The interview should take less than an hour, but may vary depending on how much you have to say. If you want to stop the interview at any time, you can do so without giving any reason at all. The interview will be audio recorded. You can decide for it to take place at either the University of East Anglia (UEA) or at your own home.

The tape recorded interviews will be fully transcribed and analysed for emerging themes. The key themes identified will be sent to you by post so that you can check if these reflect what you said. This information will help us to make improvements to the questionnaire. The recording will be kept in a secure place at the UEA. No personal information (e.g. name, address) will be stored with the recording. It will be accessed only by members of the research team.

What if I decide to withdraw?

You can leave the study at any time, without giving a reason and without any changes to any treatment you are currently receiving.

What are the possible benefits of taking part?

There are no direct benefits to taking part in the overall study. However, you will be helping us to develop and refine a new questionnaire which can be used to assess the effect of treatments in the future and which is relevant to patients with a nerve disorder affecting the hand(s).

What are the possible risks and disadvantages involved in taking part?

There are no risks associated with this study. If you decide to have your interview at UEA you may incur some travel costs which will be reimbursed.

Will my taking part in the study be kept confidential?

Yes, we will follow ethical and legal best practice and all information you provide us will be treated in confidence. Results will be published in a doctoral thesis, scientific peer reviewed journals and presented at meetings or conferences. These reports will not contain any names and we will ensure that individuals cannot be identified from details in the reports or study results. If you desire we will provide you with a summary of the results of the study.

Will I be approached about taking part in other studies?

If you agree to take part in this study, you may be invited to join later stages of the study. You do not have to take part, and will be sent further information before you decide.

Centre Number: 01
REC Reference: 14/NE/1087

Will my GP be informed of my involvement in the study?

We will inform your GP of your involvement in the study.

How do I raise concerns or make a complaint?

If you have concerns about any aspect of this project, you can speak to Mark Ashwood - Chief investigator or Dr Christina Jerosch-Herold – Primary supervisor who will do their best to answer any queries. If you remain unhappy and wish to make a formal complaint, please contact Professor Valerie Lattimer, Head of the School of Health Sciences on 01603 59 7247 or through the normal NHS complaints procedure by contacting your local hospital switchboard.

Who is organising and funding the project?

The chief investigator is a qualified occupational therapist and is carrying out this research as part of his doctoral degree. It is funded by the University of East Anglia.

Who has reviewed this study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your safety, rights, wellbeing and dignity. This study has been reviewed and approved by the York Research Ethics Committee (Ref: 14/NE/1087).

Yes, I would like to take part in the study – what do I need to do now?

If you wish to take part please complete the enclosed consent form and return it in the stamped addressed envelope within two weeks. You will then be contacted by telephone to answer any further questions you may have and to discuss what happens next.

I am not sure about taking part – where can I get further information?

We would be very happy to answer any questions you may have. Please contact Mark Ashwood, the chief investigator.

Contact information:

Chief investigator: Mark Ashwood

Telephone 01603 593063 email: M.Ashwood@uea.ac.uk

OR

Primary supervisor: Dr Christina Jerosch-Herold

Telephone: 01603 593316 email: C.Jerosch-Herold@uea.ac.uk

Thank you for taking the time to read this information

Centre Number: 01
REC Reference: 14/NE/1087
Patient Identification Number for this study:

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To provide every patient with the care we want for those we love the most

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The Hand Nerve Disorders Study –

'The HaND Study'

Personal information (to be completed by the participant)

1. What is your sex? Male ☐ Female ☐
2. What is your date of birth? e.g. DD/MM/YYYY _____
3. When did you begin to experience symptoms or sustain your injury?

   DD/MM/YYYY_____
4. What is your hand dominance? *Please circle* [L] [R] [Ambidextrous]
5. Can you tell me which side has been affected? *Please circle* [L] [R] [Both]
6. Can you tell me about how your injury happened or the circumstances in which your condition occurred?

   _____

   _____
7. Do you live with anyone else? Yes ☐ No ☐ If YES,

   How are you related? *Please tick all that apply:*

Partner ☐	Parent ☐	Relation – other ☐
Son or daughter ☐	Grandchild ☐	Unrelated ☐
Sibling ☐	Grandparent ☐	
8. Do you look after, or give any help or support to family members, friends, neighbours or others? Yes ☐ No ☐

   If YES, Can you tell me more about this?

   _____

Centre Number: 01
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Patient Identification Number for this study:

9. How would you best describe your current work circumstances?

   Working as an employee ☐ What is your job title?_____

   Self-employed or freelance ☐ What is your job title?_____

   Unemployed ☐

   Retired (whether receiving a pension or not) ☐

   A student ☐

   Looking after home or family ☐

   Long-term sick or disabled ☐

   Other ☐ Please state _____

10. Has there has been change in your employment status as a result of your nerve disorder?

    Yes ☐ No ☐

    If YES, Can you tell me more about this?

    _____

11. Please provide us with contact details for both you and your GP.

Your address:	*GP:*
Post code:	*Address:*
Telephone:	*Post code:*

_____ _____ _____

Name of Participant Date Signature

Centre Number: 01
REC Reference: 14/NE/1087
Patient Identification Number for this study:

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To provide every patient with the care we want for those we love the most

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NHS Foundation Trust

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The Hand Nerve Disorders Study –

'The HaND Study'

Medical information (to be completed by the clinician)

1. What is the patient's primary diagnosis? *Please circle affected side* [L] [R] [both]

   Please tick all that apply

Carpal tunnel syndrome		Traumatic median nerve injury	
Cubital tunnel syndrome		Traumatic ulnar nerve injury	
Radial tunnel syndrome		Traumatic radial nerve injury	
Combined nerve compression		Traumatic combined nerve injury	

2. Did the patient sustain a concomitant bone or tendon injury? Yes ☐ No ☐

   If *YES*, please provide details?

   _____

3. Did the patient have any surgery? Yes ☐ No ☐ *Please circle affected side* [L] [R] [both]

   Please tick all that apply

Decompression		End to end repair	
Neurolysis		Nerve grafting	
Nerve transfer		Other: *Please state* _____	

   If *YES*, please provide details?

   _____

4. When did the participant have their surgery? DD/MM/YYYY_____

_____ _____ _____

Name of Clinician Date Signature

Centre Number: 01
REC Reference: 14/NE/1087
Patient Identification Number for this study:

Our Vision
To provide every patient with the care we want for those we love the most

Norfolk and Norwich University Hospitals NHS
NHS Foundation Trust

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PATIENT CONSENT FORM – PHASE 2A

The Hand Nerve Disorders Study –

'The HaND Study'

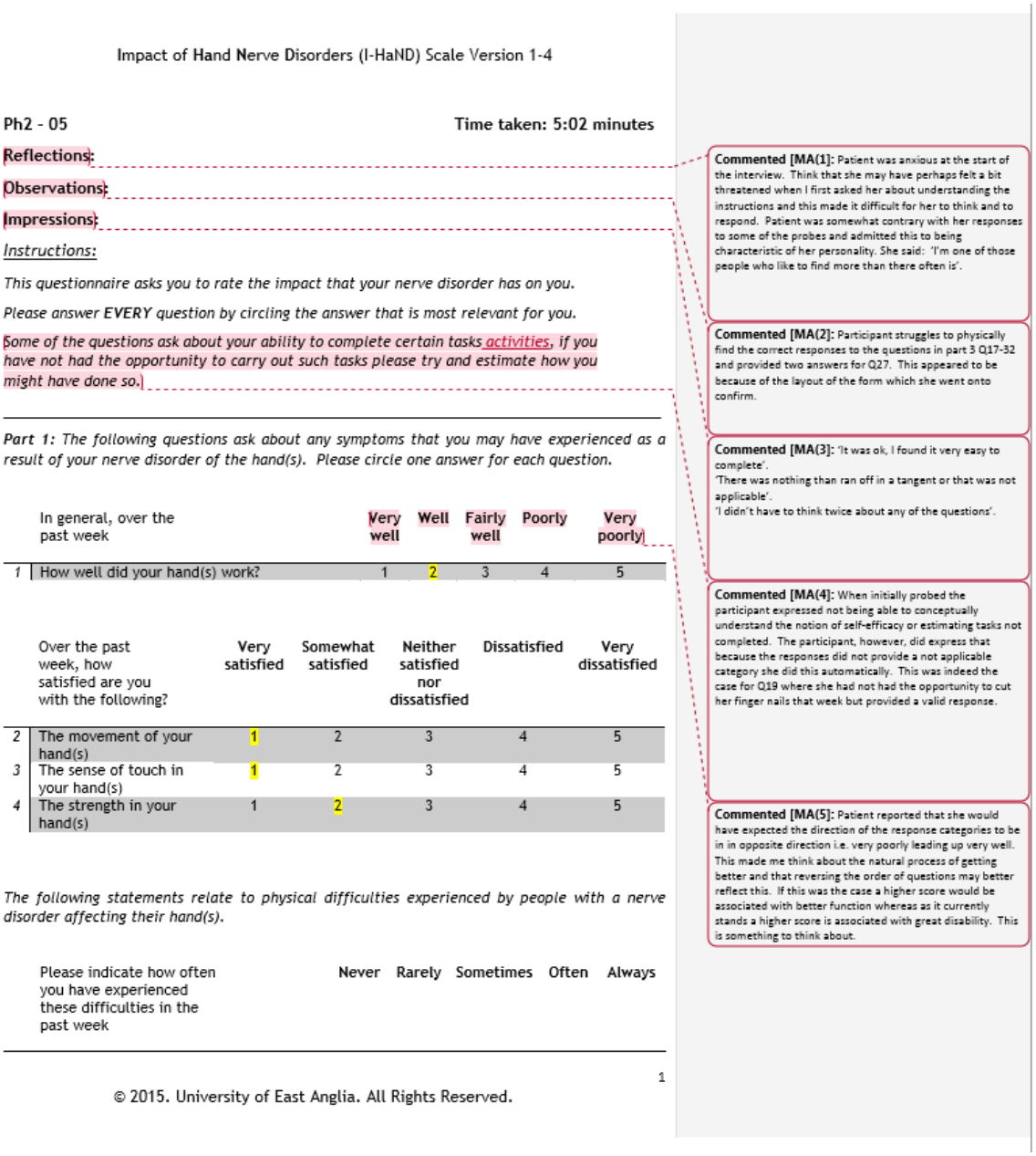
Name of Researcher: Mr Mark Ashwood

Please initial all boxes

1. I confirm that I have read and understand the information sheet dated 26.07.2014 (version 3) 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 understand that relevant sections of my medical notes and data collected during the study may be looked at by individuals from the Norfolk and Norwich University Hospital (NNUH), from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records. ☐
4. I agree to my GP being informed of my participation in the study. ☐
5. I agree for the interview to be audio taped. ☐
6. I agree that from the interviews direct quotations can be published but that these will be in an anonymised form. ☐
7. I understand that I may be contacted again and invited to participate in later stages of this project. ☐
8. I agree to take part in the above study. ☐

Name of participant	Date	Signature
Name of person taking consent	Date	Signature

Appendix 4.3 Cognitive interview tracking



Impact of Hand Nerve Disorders (I-HaND) Scale Version 1-4

Ph2 - 05 Time taken: 5:02 minutes

Reflections:

Observations:

Impressions:

Instructions:

This questionnaire asks you to rate the impact that your nerve disorder has on you.

Please answer EVERY question by circling the answer that is most relevant for you.

Some of the questions ask about your ability to complete certain tasks activities, if you have not had the opportunity to carry out such tasks please try and estimate how you might have done so.)

Part 1: The following questions ask about any symptoms that you may have experienced as a result of your nerve disorder of the hand(s). Please circle one answer for each question.

	In general, over the past week	Very well	Well	Fairly well	Poorly	Very poorly
1	How well did your hand(s) work?	1	2	3	4	5

	Over the past week, how satisfied are you with the following?	Very satisfied	Somewhat satisfied	Neither satisfied nor dissatisfied	Dissatisfied	Very dissatisfied
2	The movement of your hand(s)	1	2	3	4	5
3	The sense of touch in your hand(s)	1	2	3	4	5
4	The strength in your hand(s)	1	2	3	4	5

The following statements relate to physical difficulties experienced by people with a nerve disorder affecting their hand(s).

Please indicate how often you have experienced these difficulties in the past week	Never	Rarely	Sometimes	Often	Always

1

Commented [MA(1]: Patient was anxious at the start of the interview. Think that she may have perhaps felt a bit threatened when I first asked her about understanding the instructions and this made it difficult for her to think and to respond. Patient was somewhat contrary with her responses to some of the probes and admitted this to being characteristic of her personality. She said: 'I'm one of those people who like to find more than there often is'.

Commented [MA(2]: Participant struggles to physically find the correct responses to the questions in part 3 Q17-32 and provided two answers for Q27. This appeared to be because of the layout of the form which she went onto confirm.

Commented [MA(3]: 'It was ok, I found it very easy to complete'.
'There was nothing than ran off in a tangent or that was not applicable'.
'I didn't have to think twice about any of the questions'.

Commented [MA(4]: When initially probed the participant expressed not being able to conceptually understand the notion of self-efficacy or estimating tasks not completed. The participant, however, did express that because the responses did not provide a not applicable category she did this automatically. This was indeed the case for Q19 where she had not had the opportunity to cut her finger nails that week but provided a valid response.

Commented [MA(5]: Patient reported that she would have expected the direction of the response categories to be in in opposite direction i.e. very poorly leading up very well. This made me think about the natural process of getting better and that reversing the order of questions may better reflect this. If this was the case a higher score would be associated with better function whereas as it currently stands a higher score is associated with great disability. This is something to think about.

Appendix 4.4 A discussion and suggestions for changes to items or actions to be taken for each round of cognitive interviews

Round 1 summary of actions to develop the I-HaND Scale version 1.6

Interview and question no.	Content area e.g. instructions, item	Comments and discussion	Action to be taken
Interview 1			
Q7	I have hurt my hand and not realised it until later	This question may be better as an 'agree' or 'disagree' question? Perhaps under the pain section? Q13-15	Move to Pain section to become new question 13
Q13	I am sensitive in my hand and do not like it to be touched	This question is asking two things (1) sensitivity and (2) being touched	Re-wording of the question to: 'My hand feels sensitive when touched'
Q14	I feel discomfort or pain in cold weather or when handling cold objects	The timeframe is not suitable for the response as it is conditional on the season	Re-wording of the question to: 'I feel discomfort or pain when my hand is cold'
Interview 2			
Q1	In general, over the past week: How well did your hand(s) work?	Difficulty for the participant to view her condition generally or on average. The participant generally read questions very quickly and may not have read instruction 'in general'. On review of this decided that selective italics could be useful not only for the words in general but also the week timeframe and response categories	Selective italics for the words: General Week Satisfied Often Agree or disagree Difficult
Part 3 layout	Missing items or double items provided in part 3	Missing items or double items provided. On review of the layout, the proportions of white and grey space are not equal	Change layout to have more equal proportion of white and grey space. Ask participants to check that they have answered all of the questions alongside the thank you note.
Interview 3			No actions
Interview 4			No actions
Interview 5			
Part 3	Layout: Double items provided in part 3	Insufficient space in this section making reading difficult, similar problem in interview 2	Change layout to have more equal proportion of white and grey space

Q8	When I go to grab something it just falls out of my hand	The definition of the word 'grab' is something done in haste and is not suitable for use. Participant's suggestion of 'pick something up' is a good alternative	Change wording of the question from: 'When I go to grab something it just falls out of my hand' to When I go to pick something up it falls out of my hand
Part 4 Q34	Instructions: Wording 'recreational tasks'	The definition of task is associated with work and this is not suitable. The word recreation on its own seems insufficient	Change from 'recreational tasks' to 'recreational activities'
Interview 6			
Q7	'I have hurt my hand and not realised it until later'.	The participant made a passing comment about the timeframe only being a week and not being sufficient for this to happen as this may not happen frequently. This was considered from a reflection from a previous interview and on the back of this this question may be better off as an 'agree' or 'disagree' question Perhaps under the pain section? Q13-15	Validated - Move to Pain section to become new question 13 No new action
Q34	The wording of 'recreational task'	The wording of 'recreational task' is not appropriate as task refers to more of a chore and is not appropriate to be used with the word leisure. The participant put forward the word recreational activity. This was also flagged up by a previous participant and this needs to be changed. The word recreational activity is an appropriate rewording	Validated - Change recreational task to recreational activity. No new action.

PROM development meeting 27-08-2015

Interview and question no.	Content area e.g. instructions, item	Comments and discussion	Action to be taken
Q13	'My hand feels sensitive when touched'	CJH suggested changing wording from: 'My hand feels sensitive when touched' to 'My hand feels over sensitive when touched' to capture better hypersensitivity. LS & MS agreed that this captures this phenomenon better	Changing wording from: 'My hand feels sensitive when touched' to 'My hand feels over sensitive when touched'
Q12-15	Response categories	CJH suggested changing response categories for Q12-15 from agreement responses to frequency responses as this is consistent with other similar questions in the PROM and that agreement is opinion and not appropriate for this type of measure. LS & MA agreed that this is more appropriate	Response categories changed from agreement responses: Strongly disagree, Disagree, Neither agree nor disagree, Agree, Strongly agree to frequency responses: Never, Rarely, Sometimes, Often, Always
Q5-6 **Q8-9** **Q12-15**	Instructions	Q12-15 instructions changed in light of changes to response categories. Q5-6, Q8-9 also require changing to be consistent	Change instructions to Q5-6, Q8-9, Q12-15 to: 'Please indicate how often you have experienced the following in the past week'

MA: Mark Ashwood CJH: Christina Jerosch-Herold LS: Lee Shepstone

Round 2 summary of actions to develop the I-HaND Scale version 1.7

Interview and Ques no.	Content area e.g. instructions, item	Comments and discussion	Action to be taken
Interview 7			
Q15	It is difficult to get a good night's sleep because of the pain in my hand/arm	The participant commented that she has difficulty getting into a comfortable position and that this can affect sleep but that this is not painful. On further discussion we felt that it may be better if the statement said: It is difficult to get a good night's sleep because of the pain or discomfort in my hand/arm'	Change wording of the question to be more inclusive of this phenomenon to: It is difficult to get a good night's sleep because of the pain or discomfort in my hand/arm'.
Q17-32	Response categories	Participants asked: what is the difference between 'somewhat difficult and moderately difficult'. This brought up a previous thought about the lack of an unable category and the decision to change responses.	Change response categories: merge 'somewhat difficult and moderately difficult' and create new category 'unable'
Interview 8			
Part 2 wording	Pain	The participant explained that she does not experience pain as such but this is more of discomfort. Having pain alongside discomfort is appropriate to be more general and to be consistent with all of the questions	Change wording to all parts or questions that use to word pain to 'pain or discomfort'.
Clinician instructions		The participant mentioned having any other comments section and another participant had mentioned this. Perhaps there is a need to provide advice to contextualise the use for the clinician i.e. the place of the PROM in the assessment battery and perhaps mention that it is to be used in collaboration with discussion about other areas that may be specific to the patient. Also may be useful to provide advice on the administration i.e. self-administered but if not how to go about this.	Provide instructions to the clinician providing the measure to participants. To be separate from actual measure
Interview 9			
No new action			

Additional working group changes

Interview no and Ques no	Content area e.g. instructions, item	Comments and discussion	Action to be taken
General instruction	Wording	The use of the word task in the general instructions should be changed in light of feedback from interview 5 that 'task' refers to work. Activity would be a better replacement	Replace 'tasks' to 'activities' Replace 'such tasks' to 'these activities' as 'such activities' does not read well
Consistency	Wording	Instruction and global questions should say hand(s) to be consistent.	Changes to instructions to Q12-15 Decision to use hand(s) for instructions and global questions but to leave other questions as hand as this starts to complicate matters for if Q13 were changed it would say: My hand(s) feel(s) over sensitive when touched OR Q14: I feel pain or discomfort when my hand(s) is/are cold. This has a negative impact on the readability therefore best left as 'hand' for non-instruction or global questions

Round 3 summary of actions to develop the I-HaND Scale version 1.8

Interview and ques no.	Content area e.g. instructions, item	Comments and discussion	Action to be taken
Interview 10			
	Part 3 content	Participant commented that having a question about driving would have been useful as this was a major difficulty for him. All the participants reported this as a problem. It was initially left out as all participants returned to driving within the first few months. The merits of having different activities that reflected different ability levels at various stage of the recovery was considered. If necessary, this item can be removed in phase 2b.	Add new item: 'driving a car'
Interview 11			
	Part 3 layout	Participant left out three questions in part 3 19, 22, 26 Participant claims that this was because of rushing. 'That's because I was in a rush'. 'I think it is me rushing through it'. While he claims that it was not due to the layout of the form and that he was rushing. This section is the only section where participants have left out items. This is likely due to the fact that there are 16 questions in one table and having this broken up into sections would be helpful. On review of the content of these questions, they fall into self-care, domestic tasks and community tasks. While they do not need to be labelled in this way the table could we separated into three sections to break it up and make it easier on the eye.	Break up part 3 into three sections

Appendix 4.5 Patient identification centre approval

Royal National Orthopaedic Hospital NHS
NHS Trust

Research & Innovation Centre
UCL-IOMS
Royal National Orthopaedic Hospital NHS Trust
Brockley Hill
Stanmore HA7 4LP
Tel: 020 8909 5529
Fax: 020 8909 5273
E-mail: research@moh.nhs.uk

29th September 2015

Mrs Kathryn Johnson

NHS R&D Management Approval Letter for Research

Project Title: Development and Validation of a Patient Reported Outcome Measure (PROM) for Peripheral Nerve Disorders of the Hand

REC Ref: 14/NE/1087
R&D Ref. 15.020
Protocol Ref: N/A
IRAS ID: 155734

Sponsor: University of East Anglia

I am writing on behalf of the Royal National Orthopaedic Hospital NHS Trust Stanmore, to confirm that the above named project has been approved by the Trust and may now proceed.

To maintain this approval, the following conditions must be met:

1. All staff involved in the running of this study must adhere to Trust and Research Governance Framework requirements.

2. As Chief/Principal Investigator you are required to formally advise the R&D Office of **ANY** changes to the project including:
   - status of the project, e.g. abandoned, completed etc
   - protocol – however minor.
   - funding arrangements.

3. The Chief/Principal Investigator is also required to:
   - Notify the R&D, in a timely fashion, any Serious Adverse Events relating to the Research and the appropriate urgent safety measures taken in line with ICH GCP requirements.
   - Ensure that the R&D Office has copies of all annual and final progress reports.
   - Ensure that annual progress report forms are submitted to REC that issued the favourable opinion.
   - Ensure all researchers involved in the project hold the necessary expertise required and have Honorary Contracts should they need to.
   - Ensure adequate and accurate reporting and monitoring for the project.
   - Co-operate with all internal Trust monitoring and auditing procedures.

4. Because it is a statutory requirement to submit annual reports, this approval will automatically lapse if no annual report on this study is received at the R&D office, 14 months from the date of this letter. If you need help on how to prepare your annual report, please contact the R&D Office at the address on this letter.

Yours sincerely,

Research Management and Governance Lead
Research and Innovation Centre

cc. Mrs Yvonne Kirkham, University of East Anglia y.kirkham@uea.ac.uk
Mr Mark Ashwood, University of East Anglia, M.Ashwood@uea.ac.uk

R&D Governance Office University Hospitals Birmingham NHS
NHS Foundation Trust

(Nov16)

Notice of No Objection

Project reference:**RRK 5595**

Mark Ashwood
School of Health Sciences
Room 123.
PGR Office
The Queen's Building University of East Anglia
Norwich
NR4 7TJ

UHB Research Governance Office
1st Floor, Institute of Translational Medicine
Heritage Building
Queen Elizabeth Hospital Birmingham
Mindelsohn Way
Edgbaston
Birmingham B15 2WG
Tel. 0121 371 4185
Fax 0121 371 4204

Trust Reference RRK5595

Main REC reference: 14/NE/1087 IRAS Project ID 155734

19 November 2015
Dear Mr Ashwood

Development and Validation of a PatientReported Outcome Measure (PROM) for Peripheral Nerve Disorders of the Hand

Thank you for providing details of this study. I understand that the only involvement of UHB in this study is to identify potential participants and to provide them with information about the study. Anyone interested in taking part in the study will contact the Chief Investigator or their research team directly. Participants will not be consented at UHB nor will any study-related procedures be carried out here. On this basis I am happy to confirm there are no objections to the study and you may proceed with it.

If circumstances change, in particular if participants are consented here or any procedures are to be carried out here, then you will need to submit a fresh application for a full review of the study.

Please be sure to inform the R&D office at University Hospitals Birmingham of any amendments to the study.

Sponsorship
University of East Anglia has agreed to act as sponsor for this study.

Indemnity arrangements.
You are not indemnified by University Hospital Birmingham against any claims arising out of this study unless you hold a substantive or honorary contract with the Trust. Liability will remain with your employer.

Annual Reports
We may ask you to provide an annual update of progress with this study.

Yours sincerely,

19 November 2015

R&D Office
Head of R&D Governance: Dr Christopher Counsell
Head of R&D Operations: Joanne Plumb
R&D Office, 1st Floor, ITM, Heritage Building, Queen Elizabeth Hospital Birmingham, Edgbaston Birmingham B15 2WG
Tel: 0121 371 4185 *Fax:*0121 371 4204 *Email:* R&D@uhb.nhs.uk
Website: www.research.uhb.nhs.uk
Projects database: //uhb/userdata/R & D/R&D database/distributed database 2002.mdb

R&D Governance Office

University Hospitals Birmingham NHS
NHS Foundation Trust

Dr Christopher Counsell
Head of R&D Governance

Copies to: Mr Ashwood
Service Departments
Division Manager,

R&D Office
Head of R&D Governance: Dr Christopher Counsell
Head of R&D Operations: Joanne Plumb
R&D Office, 1st Floor, ITM, Heritage Building, Queen Elizabeth Hospital Birmingham, Edgbaston Birmingham B15 2WG
Tel: 0121 371 4185 *Fax:*0121 371 4204 *Email:* R&D@uhb.nhs.uk
Website: www.research.uhb.nhs.uk
Projects database: //uhb/userdata/R & D/R&D database/distributed database 2002.mdb

Appendix 4.6 Contents of the participant information pack for phase 2b

REC Reference: 14/NE/1087

Our Vision
To provide every patient with the care we want for those we love the most

Norfolk and Norwich University Hospitals NHS
NHS Foundation Trust

UEA
University of East Anglia

PARTICIPANT INFORMATION SHEET – PHASE 2B

The Hand Nerve Disorders Study –

'The HaND Study'

You are invited to take part in a doctoral research study. Before making a decision it is important for you to understand what taking part involves and why the study is being done. Please take your time to read through this information, discuss it with others or feel free to get in touch if you have any questions. Our contact details are given at the end of this document.

What is the purpose of the study?

Nerve disorders of the hand can have a significant impact on a person's ability to carry out daily life tasks. Patients who sustain a nerve injury often require surgery or rehabilitation to help regain their independence. To evaluate the effectiveness of such treatments, patients are often asked to complete questionnaires. There are currently no questionnaires that look specifically at the impact of a nerve injury on hand function and activities of daily living. The overall aim of this research study therefore aims to develop such a questionnaire. We have completed the first stages of this project by developing a draft questionnaire. In this phase of the study we would like people with a nerve disorder to try the questionnaire in practice. So that we can then analyse how well it performs in the clinical setting. Based on the findings of these tests we can make further improvements to the questionnaire.

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

You have been approached as you are receiving, or have received treatment for your nerve disorder at the Norfolk and Norwich University Hospital (NNUH). We would like you to trial our new questionnaire which asks about the impact of a nerve disorder affecting your hand(s).

Do I have to take part?

Participation in this study is voluntary and it is entirely up to you to decide whether or not you want to take part. Discuss it with friends and family if you like, and ask any questions you may have before making a decision. You are free to leave the study at any time, you do not have to give a reason and this will not affect any current or future treatment for your condition.

REC Reference: 14/NE/1087

What will happen if I agree to take part?

If you agree to take part, we ask you to complete the enclosed questionnaire and demographic form and return it in the pre-paid envelope. Completion of the questionnaire should take around 5 minutes. The questionnaire will be kept in a secure place at the UEA. No personal information (e.g. name, address) will be stored with it. It will be accessed only by members of the research team.

What are the possible benefits of taking part?

There are no direct benefits to taking part in the overall study. However, you will be helping us to develop a questionnaire which can be used to assess the results of treatment in the future and which is relevant to patients with a nerve disorder affecting the hand(s).

What are the possible risks and disadvantages involved in taking part?

There are no risks associated with this study. Completing the questionnaire will take around 5 minutes of your time.

Will my taking part in the study be kept confidential?

Yes, we will follow ethical and legal best practice and all information you provide us will be treated in confidence. Results will be published in a doctoral thesis, scientific peer reviewed journals and presented at meetings or conferences. These reports will not contain any names and we will ensure that individuals cannot be identified from details in the reports or study results. If you desire we will provide you with a summary of the results of the study.

Will I be approached about taking part in other studies?

If you agree to take part in this study, you may be invited to join later stages of the study. You do not have to take part, and will be sent further information before you decide.

Will my GP be informed of my involvement in the study?

We will inform your GP of your involvement in the study.

How do I raise concerns or make a complaint?

If you have concerns about any aspect of this project, you can speak to Mark Ashwood - Chief investigator or Dr Christina Jerosch-Herold – Primary supervisor who will do their best to answer any queries. If you remain unhappy and wish to make a formal complaint, please contact Professor Valerie Lattimer, Head of the School of Health Sciences on 01603 59 7247 or through the normal NHS complaints procedure by contacting your local hospital switchboard.

Who is organising and funding the project?

The chief investigator is a qualified occupational therapist and is carrying out this research as part of his doctoral degree. It is funded by the University of East Anglia.

NNUH PIS 2b /Version 3.2 / 08-09-2015

REC Reference: 14/NE/1087

Who has reviewed this study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your safety, rights, wellbeing and dignity. This study has been reviewed and approved by the York Research Ethics Committee (Ref: 14/NE/1087).

Yes, I would like to take part in the study – what do I need to do now?

If you wish to take part:-

1. Complete the enclosed questionnaire.
2. Complete the yellow demographic information form.
3. Complete the patient consent form.
4. Return these documents along with the medical information form (completed by your therapist) in the stamped addressed envelope provided within two weeks.

I am not sure about taking part – where can I get further information?

We would be very happy to answer any questions you may have. Please contact Mark Ashwood, the chief investigator.

Contact information:

Chief investigator: Mark Ashwood

Telephone 01603 593093 email: M.Ashwood@uea.ac.uk

OR

Primary supervisor: Dr Christina Jerosch-Herold

Telephone: 01603 593316 email: C.Jerosch-Herold@uea.ac.uk

Thank you for taking the time to read this information

NNUH PIS 2b /Version 3.2 / 08-09-2015

Centre Number: 01
REC Reference: 14/NE/1087
Patient Identification Number for this study:

Our Vision
To provide every patient with the care we want for those we love the most

Norfolk and Norwich University Hospitals NHS
NHS Foundation Trust

University of East Anglia

The Hand Nerve Disorders Study –

'The HaND Study'

Personal information (to be completed by the participant)

1. What is your sex? Male ☐ Female ☐
2. What is your date of birth? e.g. DD/MM/YYYY _____
3. When did you begin to experience symptoms or sustain your injury?

   DD/MM/YYYY_____
4. What is your hand dominance? *Please circle* [L] [R] [Ambidextrous]
5. Can you tell me which side has been affected? *Please circle* [L] [R] [Both]
6. Can you tell me about how your injury happened or the circumstances in which your condition occurred?

   _____

   _____
7. Do you live with anyone else? Yes ☐ No ☐ If YES,

   How are you related? *Please tick all that apply*:

Partner ☐	Parent ☐	Relation – other ☐
Son or daughter ☐	Grandchild ☐	Unrelated ☐
Sibling ☐	Grandparent ☐	
8. Do you look after, or give any help or support to family members, friends, neighbours or others? Yes ☐ No ☐

   If YES, Can you tell me more about this?

   _____

Centre Number: 01
REC Reference: 14/NE/1087
Patient Identification Number for this study:

9. How would you best describe your current work circumstances?

   Working as an employee ☐ What is your job title?_____

   Self-employed or freelance ☐ What is your job title?_____

   Unemployed ☐

   Retired (whether receiving a pension or not) ☐

   A student ☐

   Looking after home or family ☐

   Long-term sick or disabled ☐

   Other ☐ Please state _____

10. Has there has been change in your employment status as a result of your nerve disorder?

    Yes ☐ No ☐

    If YES, Can you tell me more about this?

    _____

11. Please provide us with contact details for both you and your GP.

Your address:	*GP:*
	Address:
Post code:	
Telephone:	*Post code:*

_____ _____ _____

Name of Participant Date Signature

Centre Number: 01
REC Reference: 14/NE/1087
Patient Identification Number for this study:

Our Vision
To provide every patient with the care we want for those we love the most

Norfolk and Norwich University Hospitals NHS
NHS Foundation Trust

University of East Anglia

PATIENT CONSENT FORM – PHASE 2B

The Hand Nerve Disorders Study –

'The HaND Study'

Name of Researcher: Mr Mark Ashwood

Please initial all boxes

1. I confirm that I have read and understand the information sheet dated 08.09.2015 (version 3.2) 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 understand that relevant sections of my medical notes and data collected during the study may be looked at by individuals from the Norfolk and Norwich University Hospital (NNUH), from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records. ☐
4. I agree to my GP being informed of my participation in the study. ☐
5. I understand that I may be contacted again and invited to participate in later stages of this project. ☐
6. I agree to take part in the above study. ☐

Name of participant	Date	Signature
Name of person taking consent	Date	Signature

Appendix 4.7 Evolution of the I-HaND Scale during the cognitive interviews

Version 1.5

Impact of **H**and **N**erve **D**isorders (I-HaND) Scale Version 1-5

Instructions:

This questionnaire asks you to rate the impact that your nerve disorder has on you.

*Please answer **EVERY** question by circling the answer that is most relevant for you.*

Some of the questions ask about your ability to complete certain tasks, if you have not had the opportunity to carry out such tasks please try and estimate how you might have done so.

***Part 1:** The following questions ask about any symptoms that you may have experienced as a result of your nerve disorder of the hand(s). Please circle one answer for each question.*

	In *general*, over the past *week*	Very well	Well	Fairly well	Poorly	Very poorly
1	How well did your hand(s) work?	1	2	3	4	5

	Over the past *week*, how *satisfied* are you with the following?	Very satisfied	Somewhat satisfied	Neither satisfied nor dissatisfied	Dissatisfied	Very dissatisfied
2	The movement of your hand(s)	1	2	3	4	5
3	The sense of touch in your hand(s)	1	2	3	4	5
4	The strength in your hand(s)	1	2	3	4	5

The following statements relate to physical difficulties experienced by people with a nerve disorder affecting their hand(s).

	Please indicate how *often* you have experienced these difficulties in the past *week*	Never	Rarely	Sometimes	Often	Always
5	I can't grip or pinch for very long without my hand getting tired	1	2	3	4	5
6	When I touch certain things it causes pins and needles or tingling	1	2	3	4	5
7	When I go to pick something up it falls out of my hand	1	2	3	4	5

1

Impact of Hand Nerve Disorders (I-HaND) Scale Version 1-5

The following statements relate to feelings sometimes experienced by people with a nerve disorder affecting their hand(s).

	Please indicate how *often* you have experienced these feelings in the past *week*	Never	Rarely	Sometimes	Often	Always
8	Using my hand(s) can bring about strong emotions e.g. frustration, anger, sadness	1	2	3	4	5
9	I feel self-conscious if people look at my hand/arm	1	2	3	4	5

Part 2: *The following questions ask about any pain that you may have experienced as a result of your nerve disorder of the hand(s). Please circle one answer for each question.*

	In *general*, over the past *week*	None	Mild	Moderate	Severe	Very severe
10	The pain in my hand(s) has been	1	2	3	4	5

	In *general*, over the past *week*	Never	Rarely	Sometimes	Often	Always
11	How often would you say that your pain impacts on your daily routine?	1	2	3	4	5

The following questions asks about situations which may cause discomfort or pain in your hand.

	Over the past *week*, how much would you *agree or disagree* with the following statements?	Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree
12	I have hurt my hand and not realised it until later	1	2	3	4	5
13	My hand feels sensitive when touched	1	2	3	4	5
14	I feel discomfort or pain when my hand is cold	1	2	3	4	5
15	It is difficult to get a good night's sleep because of the pain in my hand/arm	1	2	3	4	5

2

Impact of **H**and **N**erve **D**isorders (I-HaND) Scale Version 1-5

Part 3: *The following questions ask about difficulty with activities that you may have experienced as a result of your nerve disorder of the hand(s). Please circle one answer for each question.*

	In *general*, over the past *week*	Very well	Well	Fairly well	Poorly	Very poorly
16	How well have you been able to carry out your daily routine e.g. Getting ready, cooking, childcare etc.	1	2	3	4	5

	Over the past *week* how *difficult* has it been for you to complete the following activities	Not at all difficult	A little difficult	Somewhat difficult	Moderately difficult	Very difficult
17	Doing up buttons	1	2	3	4	5
18	Cutting food using a knife & fork together	1	2	3	4	5
19	Cutting your nails	1	2	3	4	5
20	Washing your body	1	2	3	4	5
21	Putting toothpaste on a toothbrush	1	2	3	4	5
22	Getting dressed or undressed	1	2	3	4	5
23	Opening lids of tight jars and bottles	1	2	3	4	5
24	Pouring from a kettle	1	2	3	4	5
25	Carrying a heavy shopping bag	1	2	3	4	5
26	Wringing out a cloth	1	2	3	4	5
27	Preparing a meal	1	2	3	4	5
28	Opening & closing heavy doors	1	2	3	4	5
29	Handwriting	1	2	3	4	5
30	Turning pages of a book, magazine or newspaper	1	2	3	4	5
31	Handling small coins e.g. 5 pence or 1 pence	1	2	3	4	5
32	Using electronic devices e.g. a remote control, mobile phone, tablet or computer	1	2	3	4	5

3

Impact of **H**and **N**erve **D**isorders (I-HaND) Scale Version 1-5

Part 4: *The following questions ask about how your nerve disorder of the hand(s) has affected your ability to take part in your daily work (including paid work, school work or housework) and recreational activities. Please circle one answer for each question.*

	In *general*, over the past *week*	Very well	Well	Fairly well	Poorly	Very poorly
33	How well have you been able to manage the physical demands of your daily work?	1	2	3	4	5
34	How well have you been able to take part in recreational activities e.g. Hobbies or sport?	1	2	3	4	5

You have now reached the end of the questionnaire

Please check that you have answered all of the questions

THANK YOU *for your time*

4

Version 1.6

Impact of Hand Nerve Disorders (I-HaND) Scale Version 1-6

Instructions:

This questionnaire asks you to rate the impact that your nerve disorder has on you.

*Please answer **EVERY** question by circling the answer that is most relevant for you.*

Some of the questions ask about your ability to complete certain tasks, if you have not had the opportunity to carry out such tasks please try and estimate how you might have done so.

***Part 1:** The following questions ask about any symptoms that you may have experienced as a result of your nerve disorder of the hand(s). Please circle one answer for each question.*

	In *general*, over the past *week*	Very well	Well	Fairly well	Poorly	Very poorly
1	How well did your hand(s) work?	1	2	3	4	5

	Over the past *week*, how *satisfied* are you with the following?	Very satisfied	Somewhat satisfied	Neither satisfied nor dissatisfied	Dissatisfied	Very dissatisfied
2	The movement of your hand(s)	1	2	3	4	5
3	The sense of touch in your hand(s)	1	2	3	4	5
4	The strength in your hand(s)	1	2	3	4	5

The following statements relate to physical difficulties experienced by people with a nerve disorder affecting their hand(s).

	Please indicate how *often* you have experienced the following in the past *week*	Never	Rarely	Sometimes	Often	Always
5	I can't grip or pinch for very long without my hand getting tired	1	2	3	4	5
6	When I touch certain things it causes pins and needles or tingling	1	2	3	4	5
7	When I go to pick something up it falls out of my hand	1	2	3	4	5

Impact of Hand Nerve Disorders (I-HaND) Scale Version 1-6

The following statements relate to feelings sometimes experienced by people with a nerve disorder affecting their hand(s).

	Please indicate how *often* you have experienced the following in the past *week*	Never	Rarely	Sometimes	Often	Always
8	Using my hand(s) can bring about strong emotions e.g. frustration, anger, sadness	1	2	3	4	5
9	I feel self-conscious if people look at my hand/arm	1	2	3	4	5

Part 2: *The following questions ask about any pain that you may have experienced as a result of your nerve disorder of the hand(s). Please circle one answer for each question.*

	In *general*, over the past *week*	None	Mild	Moderate	Severe	Very severe
10	The pain in my hand(s) has been	1	2	3	4	5

	In *general*, over the past *week*	Never	Rarely	Sometimes	Often	Always
11	How often would you say that your pain impacts on your daily routine?	1	2	3	4	5

The following questions asks about situations which may cause discomfort or pain in your hand.

	Please indicate how *often* you have experienced the following in the past *week*	Never	Rarely	Sometimes	Often	Always
12	I have hurt my hand and not realised it until later	1	2	3	4	5
13	My hand feels over sensitive when touched	1	2	3	4	5
14	I feel discomfort or pain when my hand is cold	1	2	3	4	5
15	It is difficult to get a good night's sleep because of the pain in my hand/arm	1	2	3	4	5

2

Impact of **H**and **N**erve **D**isorders (I-HaND) Scale Version 1-6

Part 3: *The following questions ask about difficulty with activities that you may have experienced as a result of your nerve disorder of the hand(s). Please circle one answer for each question.*

	In *general*, over the past *week*	Very well	Well	Fairly well	Poorly	Very poorly
16	How well have you been able to carry out your daily routine e.g. Getting ready, cooking, childcare etc.	1	2	3	4	5

	Over the past *week* how *difficult* has it been for you to complete the following activities	Not at all difficult	A little difficult	Somewhat difficult	Moderately difficult	Very difficult
17	Doing up buttons	1	2	3	4	5
18	Cutting food using a knife & fork together	1	2	3	4	5
19	Cutting your nails	1	2	3	4	5
20	Washing your body	1	2	3	4	5
21	Putting toothpaste on a toothbrush	1	2	3	4	5
22	Getting dressed or undressed	1	2	3	4	5
23	Opening lids of tight jars and bottles	1	2	3	4	5
24	Pouring from a kettle	1	2	3	4	5
25	Carrying a heavy shopping bag	1	2	3	4	5
26	Wringing out a cloth	1	2	3	4	5
27	Preparing a meal	1	2	3	4	5
28	Opening & closing heavy doors	1	2	3	4	5
29	Handwriting	1	2	3	4	5
30	Turning pages of a book, magazine or newspaper	1	2	3	4	5
31	Handling small coins e.g. 5 pence or 1 pence	1	2	3	4	5
32	Using electronic devices e.g. a remote control, mobile phone, tablet or computer	1	2	3	4	5

3

Impact of **H**and **N**erve **D**isorders (I-HaND) Scale Version 1-6

Part 4: *The following questions ask about how your nerve disorder of the hand(s) has affected your ability to take part in your daily work (including paid work, school work or housework) and recreational activities. Please circle one answer for each question.*

	In *general*, over the past *week*	Very well	Well	Fairly well	Poorly	Very poorly
33	How well have you been able to manage the physical demands of your daily work?	1	2	3	4	5
34	How well have you been able to take part in recreational activities e.g. Hobbies or sport?	1	2	3	4	5

You have now reached the end of the questionnaire

Please check that you have answered all of the questions

THANK YOU *for your time*

4

Version 1.7

Impact of Hand Nerve Disorders (I-HaND) Scale Version 1-7

Instructions:

This questionnaire asks you to rate the impact that your nerve disorder has on you.

Please answer EVERY question by CIRCLING the answer that is most relevant for you.

Some of the questions ask about your ability to complete certain activities, if you have not had the opportunity to carry out these activities please try and estimate how you might have done so.

Part 1: The following questions ask about any symptoms that you may have experienced as a result of your nerve disorder of the hand(s). Please circle one answer for each question.

	In *general*, over the past *week*	Very well	Well	Fairly well	Poorly	Very poorly
1	How well did your hand(s) work?	1	2	3	4	5

	Over the past *week*, how *satisfied* are you with the following?	Very satisfied	Somewhat satisfied	Neither satisfied nor dissatisfied	Dissatisfied	Very dissatisfied
2	The movement of your hand(s)	1	2	3	4	5
3	The sense of touch in your hand(s)	1	2	3	4	5
4	The strength in your hand(s)	1	2	3	4	5

The following statements relate to physical difficulties experienced by people with a nerve disorder affecting their hand(s).

	Please indicate how *often* you have experienced the following in the past *week*	Never	Rarely	Sometimes	Often	Always
5	I can't grip or pinch for very long without my hand getting tired	1	2	3	4	5
6	When I touch certain things it causes pins and needles or tingling	1	2	3	4	5
7	When I go to pick something up it falls out of my hand	1	2	3	4	5

Impact of Hand Nerve Disorders (I-HaND) Scale Version 1-7

The following statements relate to feelings sometimes experienced by people with a nerve disorder affecting their hand(s).

	Please indicate how *often* you have experienced the following in the past *week*	Never	Rarely	Sometimes	Often	Always
8	Using my hand(s) can bring about strong emotions e.g. frustration, anger, sadness	1	2	3	4	5
9	I feel self-conscious if people look at my hand/arm	1	2	3	4	5

Part 2: The following questions ask about any pain or discomfort that you may have experienced as a result of your nerve disorder of the hand(s). Please circle one answer for each question.

	In *general*, over the past *week*	None	Mild	Moderate	Severe	Very severe
10	The pain or discomfort in my hand(s) has been	1	2	3	4	5

	In *general*, over the past *week*	Never	Rarely	Sometimes	Often	Always
11	How often would you say that your pain or discomfort impacts on your daily routine?	1	2	3	4	5

The following questions asks about situations which may cause pain or discomfort in your hand.

	Please indicate how *often* you have experienced the following in the past *week*	Never	Rarely	Sometimes	Often	Always
12	I have hurt my hand and not realised it until later	1	2	3	4	5
13	My hand feels over sensitive when touched	1	2	3	4	5
14	I feel pain or discomfort when my hand is cold	1	2	3	4	5
15	It is difficult to get a good night's sleep because of the pain or discomfort in my hand/arm	1	2	3	4	5

2

Impact of **H**and **N**erve **D**isorders (I-HaND) Scale Version 1-7

Part 3: The following questions ask about difficulty with activities that you may have experienced as a result of your nerve disorder of the hand(s). Please circle one answer for each question.

	In *general*, over the past *week*	Very well	Well	Fairly well	Poorly	Very poorly
16	How well have you been able to carry out your daily routine e.g. Getting ready, cooking, childcare etc.	1	2	3	4	5

	Over the past *week* how *difficult* has it been for you to complete the following activities	Not at all difficult	A little difficult	Moderately difficult	Very difficult	Unable
17	Doing up buttons	1	2	3	4	5
18	Cutting food using a knife & fork together	1	2	3	4	5
19	Cutting your nails	1	2	3	4	5
20	Washing your body	1	2	3	4	5
21	Putting toothpaste on a toothbrush	1	2	3	4	5
22	Getting dressed or undressed	1	2	3	4	5
23	Opening lids of tight jars and bottles	1	2	3	4	5
24	Pouring from a kettle	1	2	3	4	5
25	Carrying a heavy shopping bag	1	2	3	4	5
26	Wringing out a cloth	1	2	3	4	5
27	Preparing a meal	1	2	3	4	5
28	Opening & closing heavy doors	1	2	3	4	5
29	Handwriting	1	2	3	4	5
30	Turning pages of a book, magazine or newspaper	1	2	3	4	5
31	Handling small coins e.g. 5 pence or 1 pence	1	2	3	4	5
32	Using electronic devices e.g. a remote control, mobile phone, tablet or computer	1	2	3	4	5

3

Impact of **H**and **N**erve **D**isorders (I-HaND) Scale Version 1-7

***Part 4**: The following questions ask about how your nerve disorder of the hand(s) has affected your ability to take part in your **daily work** (including paid work, school work or housework) and **recreational activities**. Please **circle** one answer for each question.*

	In *general*, over the past *week*	Very well	Well	Fairly well	Poorly	Very poorly
33	How well have you been able to manage the physical demands of your daily work?	1	2	3	4	5
34	How well have you been able to take part in recreational activities e.g. Hobbies or sport?	1	2	3	4	5

You have now reached the end of the questionnaire

Please check that you have answered all of the questions

***THANK YOU** for your time*

4

Appendix 4.8 Distribution of the individual items (data collected using version 1.8 of the I-HaND Scale)

	Number							
	Valid	Missing	Mean	Std. Deviation	Variance	Skewness	Kurtosis	Sum
Q1	50	0	2.82	1.24	1.54	0.09	-0.89	141
Q2	49	1	2.61	1.38	1.91	0.45	-1.15	128
Q3	49	1	3.04	1.38	1.92	-0.03	-1.29	149
Q4	49	1	3.04	1.37	1.87	0.03	-1.31	149
Q5	50	0	3.32	1.46	2.14	-0.42	-1.24	166
Q6	50	0	3.26	1.43	2.03	-0.35	-1.16	163
Q7	50	0	2.88	1.32	1.74	0.12	-1.09	144
Q8	50	0	2.94	1.45	2.10	-0.14	-1.31	147
Q9	50	0	2.20	1.44	2.08	0.91	-0.51	110
Q10	50	0	2.66	1.24	1.54	0.29	-0.70	133
Q11	50	0	3.16	1.45	2.10	-0.29	-1.21	158
Q12	50	0	2.04	1.31	1.71	1.12	0.24	102
Q13	50	0	3.00	1.55	2.41	-0.03	-1.44	150
Q14	49	1	3.24	1.44	2.06	-0.32	-1.06	159
Q15	50	0	2.64	1.50	2.24	0.23	-1.43	132
Q16	50	0	2.68	1.38	1.90	0.17	-1.15	134
Q17	50	0	1.94	1.35	1.81	1.11	-0.26	97
Q18	50	0	2.04	1.23	1.51	0.89	-0.39	102
Q19	50	0	2.62	1.41	2.00	0.40	-1.15	131
Q20	50	0	2.04	1.38	1.92	1.08	-0.18	102
Q21	50	0	2.52	1.54	2.38	0.45	-1.36	126
Q22	50	0	2.46	1.50	2.25	0.51	-1.25	123
Q23	50	0	3.14	1.37	1.88	-0.06	-1.21	157
Q24	50	0	2.08	1.40	1.95	1.02	-0.35	104
Q25	50	0	2.76	1.55	2.39	0.21	-1.47	138
Q26	50	0	2.26	1.32	1.75	0.93	-0.14	113
Q27	50	0	2.48	1.47	2.17	0.62	-1.06	124
Q28	49	1	2.35	1.45	2.11	0.64	-1.00	115
Q29	50	0	2.10	1.30	1.68	0.86	-0.50	105
Q30	50	0	2.28	1.18	1.39	0.75	-0.19	114
Q31	50	0	2.78	1.46	2.13	0.32	-1.26	139
Q32	50	0	2.80	1.39	1.92	-0.01	-1.39	140
Q33	47	3	2.11	1.51	2.27	1.05	-0.47	99
Q34	49	1	2.80	1.40	1.96	0.24	-1.05	137
Q35	50	0	3.16	1.36	1.85	-0.15	-1.06	158

Appendix 4.9 Inter-item correlations (data collected using version 1.8 of the I-HaND Scale)

Correlations between items of the I-HaND Scale version 1.8 (part 1)

	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Q10	Q11	Q12
Q2	0.90											
Q3	0.74	0.82										
Q4	0.83	0.87	0.76									
Q5	0.66	0.60	0.58	0.64								
Q6	0.67	0.59	0.64	0.70	0.77							
Q7	0.77	0.77	0.64	0.67	0.64	0.68						
Q8	0.62	0.66	0.53	0.58	0.50	0.44	0.53					
Q9	0.62	0.62	0.49	0.56	0.39	0.44	0.55	0.70				
Q10	0.85	0.80	0.73	0.82	0.64	0.72	0.72	0.60	0.62			
Q11	0.82	0.77	0.71	0.81	0.79	0.78	0.76	0.64	0.57	0.87		
Q12	0.79	0.82	0.68	0.74	0.42	0.53	0.64	0.64	0.74	0.77	0.65	
Q13	0.63	0.64	0.64	0.57	0.68	0.81	0.78	0.51	0.48	0.65	0.72	0.61
Q14	0.70	0.71	0.63	0.66	0.66	0.66	0.72	0.58	0.66	0.70	0.73	0.67
Q15	0.82	0.72	0.64	0.80	0.64	0.65	0.67	0.52	0.60	0.87	0.82	0.61
Q16	0.89	0.85	0.68	0.81	0.68	0.65	0.80	0.64	0.62	0.85	0.85	0.72
Q17	0.77	0.76	0.61	0.70	0.51	0.60	0.77	0.51	0.49	0.70	0.64	0.68
Q18	0.85	0.86	0.68	0.78	0.60	0.65	0.82	0.59	0.64	0.76	0.73	0.78
Q19	0.75	0.70	0.63	0.69	0.56	0.62	0.81	0.54	0.56	0.72	0.74	0.63
Q20	0.74	0.70	0.60	0.68	0.56	0.66	0.80	0.49	0.55	0.69	0.69	0.69
Q21	0.74	0.74	0.64	0.68	0.63	0.70	0.83	0.59	0.60	0.72	0.71	0.65
Q22	0.77	0.77	0.64	0.69	0.55	0.59	0.82	0.53	0.52	0.75	0.64	0.70
Q23	0.77	0.71	0.67	0.78	0.64	0.70	0.73	0.56	0.50	0.80	0.76	0.67
Q24	0.79	0.76	0.57	0.78	0.57	0.57	0.71	0.49	0.54	0.70	0.65	0.73
Q25	0.83	0.80	0.62	0.73	0.72	0.70	0.83	0.56	0.62	0.77	0.76	0.71
Q26	0.89	0.87	0.70	0.79	0.58	0.65	0.78	0.56	0.59	0.81	0.71	0.79
Q27	0.83	0.78	0.61	0.73	0.64	0.61	0.75	0.54	0.56	0.81	0.69	0.66
Q28	0.73	0.71	0.65	0.73	0.68	0.70	0.71	0.60	0.52	0.65	0.72	0.67
Q29	0.66	0.64	0.52	0.61	0.43	0.55	0.77	0.46	0.44	0.66	0.60	0.66
Q30	0.73	0.68	0.55	0.67	0.52	0.63	0.80	0.54	0.56	0.70	0.67	0.68
Q31	0.80	0.84	0.71	0.77	0.66	0.59	0.71	0.52	0.52	0.77	0.67	0.69
Q32	0.73	0.75	0.72	0.62	0.66	0.66	0.82	0.63	0.59	0.67	0.73	0.60
Q33	0.76	0.75	0.58	0.72	0.45	0.51	0.55	0.44	0.53	0.73	0.53	0.64
Q34	0.82	0.82	0.63	0.75	0.66	0.67	0.78	0.63	0.64	0.79	0.81	0.71
Q35	0.76	0.80	0.64	0.79	0.74	0.71	0.80	0.72	0.61	0.75	0.79	0.66

Correlations between items of the I-HaND Scale version 1.8 (part 2)

	Q13	Q14	Q15	Q16	Q17	Q18	Q19	Q20	Q21	Q22	Q23	Q24
Q14	0.78											
Q15	0.52	0.58										
Q16	0.64	0.67	0.83									
Q17	0.63	0.57	0.61	0.76								
Q18	0.70	0.68	0.71	0.85	0.92							
Q19	0.63	0.58	0.75	0.80	0.76	0.86						
Q20	0.69	0.62	0.62	0.75	0.90	0.89	0.83					
Q21	0.76	0.77	0.63	0.73	0.85	0.85	0.72	0.84				
Q22	0.63	0.70	0.64	0.78	0.86	0.86	0.73	0.78	0.83			
Q23	0.69	0.69	0.75	0.80	0.77	0.76	0.72	0.78	0.79	0.79		
Q24	0.56	0.55	0.69	0.79	0.85	0.89	0.76	0.85	0.77	0.79	0.80	
Q25	0.74	0.76	0.72	0.88	0.77	0.88	0.78	0.80	0.83	0.86	0.81	0.83
Q26	0.68	0.66	0.73	0.86	0.87	0.94	0.85	0.83	0.81	0.84	0.77	0.88
Q27	0.61	0.67	0.75	0.85	0.81	0.86	0.80	0.78	0.79	0.88	0.83	0.84
Q28	0.67	0.64	0.61	0.71	0.82	0.81	0.71	0.82	0.76	0.76	0.77	0.79
Q29	0.66	0.46	0.58	0.71	0.78	0.84	0.83	0.81	0.71	0.68	0.63	0.78
Q30	0.71	0.65	0.62	0.76	0.83	0.85	0.84	0.85	0.82	0.81	0.79	0.79
Q31	0.61	0.63	0.71	0.79	0.71	0.78	0.65	0.70	0.73	0.75	0.81	0.80
Q32	0.79	0.69	0.63	0.75	0.74	0.79	0.75	0.78	0.85	0.70	0.69	0.65
Q33	0.43	0.46	0.67	0.68	0.72	0.78	0.66	0.60	0.67	0.69	0.67	0.75
Q34	0.74	0.66	0.73	0.86	0.67	0.82	0.74	0.71	0.69	0.70	0.74	0.75
Q35	0.76	0.77	0.71	0.78	0.67	0.77	0.69	0.67	0.76	0.74	0.76	0.69

Correlations between items of the I-HaND Scale version 1.7 (part 3)

	Q25	Q26	Q27	Q28	Q29	Q30	Q31	Q32	Q33	Q34
Q26	0.88									
Q27	0.91	0.90								
Q28	0.73	0.76	0.71							
Q29	0.71	0.83	0.68	0.66						
Q30	0.81	0.85	0.84	0.75	0.82					
Q31	0.84	0.83	0.86	0.66	0.63	0.69				
Q32	0.79	0.76	0.74	0.76	0.72	0.76	0.75			
Q33	0.73	0.84	0.83	0.56	0.63	0.65	0.83	0.59		
Q34	0.85	0.83	0.78	0.65	0.73	0.74	0.80	0.72	0.69	
Q35	0.82	0.74	0.74	0.69	0.62	0.69	0.77	0.72	0.60	0.87

Appendix 5.1 Outcome measures used in phase 3

Clinical record form

Centre Number: 01
REC Reference: 14/NE/1087
Patient Identification Number for this study:

Our Vision
To provide every patient with the care we want for those we love the most

Norfolk and Norwich University Hospitals NHS
NHS Foundation Trust

University of East Anglia

The Hand Nerve Disorders Study –

'The HaND Study'

Personal information (to be completed by the participant)

1. What is your sex? Male ☐ Female ☐
2. What is your date of birth? e.g. DD/MM/YYYY _____
3. When did you begin to experience symptoms or sustain your injury?

   DD/MM/YYYY_____
4. What is your hand dominance? *Please circle* [L] [R] [Ambidextrous]
5. Can you tell me which side has been affected? *Please circle* [L] [R] [Both]
6. Can you tell me about how your injury happened or the circumstances in which your condition occurred?

   _____

   _____
7. Do you live with anyone else? Yes ☐ No ☐ If YES,

   How are you related? *Please tick all that apply:*

Partner ☐	Parent ☐	Relation – other ☐
Son or daughter ☐	Grandchild ☐	Unrelated ☐
Sibling ☐	Grandparent ☐	
8. Do you look after, or give any help or support to family members, friends, neighbours or others? Yes ☐ No ☐

   If YES, Can you tell me more about this?

   _____

Centre Number: 01
REC Reference: 14/NE/1087
Patient Identification Number for this study:

9. How would you best describe your current work circumstances?

   Working as an employee ☐ What is your job title?_____

   Self-employed or freelance ☐ What is your job title?_____

   Unemployed ☐

   Retired (whether receiving a pension or not) ☐

   A student ☐

   Looking after home or family ☐

   Long-term sick or disabled ☐

   Other ☐ Please state _____

10. Has there has been change in your employment status as a result of your nerve disorder?

    Yes ☐ No ☐

    If YES, Can you tell me more about this?

    _____

11. Please provide us with contact details for both you and your GP.

Your address:	*GP:*
Post code:	*Address:*
Telephone:	*Post code:*

_____ _____ _____

Name of Participant Date Signature

Centre Number: 01
REC Reference: 14/NE/1087
Patient Identification Number for this study:

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The Hand Nerve Disorders Study –

'The HaND Study'

Medical information (to be completed by the clinician)

1. What is the patient's primary diagnosis? *Please circle affected side* [L] [R] [both]

   Please tick all that apply

Carpal tunnel syndrome		Traumatic median nerve injury	
Cubital tunnel syndrome		Traumatic ulnar nerve injury	
Radial tunnel syndrome		Traumatic radial nerve injury	
Combined nerve compression		Traumatic combined nerve injury	

2. Did the patient sustain a concomitant bone or tendon injury? Yes ☐ No ☐

   If *YES*, please provide details?

   _____

3. Did the patient have any surgery? Yes ☐ No ☐ *Please circle affected side* [L] [R] [both]

   Please tick all that apply

Decompression		End to end repair	
Neurolysis		Nerve grafting	
Nerve transfer		Other: *Please state* _____	

   If *YES*, please provide details?

   _____

4. When did the participant have their surgery? DD/MM/YYYY_____

_____ _____ _____

Name of Clinician Date Signature

I-HaND Scale version 2.0

Impact of Hand Nerve Disorders (I-HaND) Scale Version 2.0

Participant Identification Number:	Baseline / Follow-up 1 / Follow-up 2

Instructions:

This questionnaire asks you to rate the impact that your nerve disorder has on you.

Please answer EVERY question by CIRCLING the answer that is most relevant for you.

Some of the questions ask about your ability to complete certain activities, if you have not had the opportunity to carry out these activities please try and estimate how you might have done so.

Part 1: The following questions ask about any symptoms that you may have experienced as a result of your nerve disorder of the hand(s). Please circle one answer for each question.

	In *general*, over the past *week*	Very well	Well	Fairly well	Poorly	Very poorly
1	How well did your hand(s) work?	1	2	3	4	5

	Over the past *week*, how *satisfied* are you with the following?	Very satisfied	Somewhat satisfied	Neither satisfied nor dissatisfied	Dissatisfied	Very dissatisfied
2	The movement of your hand(s)	1	2	3	4	5
3	The sense of touch in your hand(s)	1	2	3	4	5
4	The strength in your hand(s)	1	2	3	4	5

The following statements relate to physical difficulties experienced by people with a nerve disorder affecting their hand(s).

	Please indicate how *often* you have experienced the following in the past *week*	Never	Rarely	Sometimes	Often	Always
5	I can't grip or pinch for very long without my hand getting tired	1	2	3	4	5
6	When I touch certain things it causes pins and needles or tingling	1	2	3	4	5
7	When I go to pick something up it falls out of my hand	1	2	3	4	5

1

Impact of **H**and **N**erve **D**isorders (I-HaND) Scale Version 2.0

The following statements relate to feelings sometimes experienced by people with a nerve disorder affecting their hand(s).

	Please indicate how *often* you have experienced the following in the past *week*	Never	Rarely	Sometimes	Often	Always
8	Using my hand(s) can bring about strong emotions e.g. frustration, anger, sadness	1	2	3	4	5
9	I feel self-conscious if people look at my hand/arm	1	2	3	4	5

Part 2: The following questions ask about any pain or discomfort that you may have experienced as a result of your nerve disorder of the hand(s). Please circle one answer for each question.

	In *general*, over the past *week*	None	Mild	Moderate	Severe	Very severe
10	The pain or discomfort in my hand(s) has been	1	2	3	4	5

	In *general*, over the past *week*	Never	Rarely	Sometimes	Often	Always
11	How often would you say that your pain or discomfort impacts on your daily routine?	1	2	3	4	5

The following questions asks about situations which may cause pain or discomfort in your hand.

	Please indicate how *often* you have experienced the following in the past *week*	Never	Rarely	Sometimes	Often	Always
12	I have hurt my hand and not realised it until later	1	2	3	4	5
13	My hand feels over sensitive when touched	1	2	3	4	5
14	I feel pain or discomfort when my hand is cold	1	2	3	4	5
15	It is difficult to get a good night's sleep because of the pain or discomfort in my hand/arm	1	2	3	4	5

2

Impact of Hand Nerve Disorders (I-HaND) Scale Version 2.0

Part 3: The following questions ask about difficulty with activities that you may have experienced as a result of your nerve disorder of the hand(s). Please circle one answer for each question.

	In *general*, over the past *week*	Very well	Well	Fairly well	Poorly	Very poorly
16	How well have you been able to carry out your daily routine e.g. Getting ready, cooking, childcare etc.	1	2	3	4	5

	Over the past *week* how *difficult* has it been for you to complete the following activities	Not at all difficult	A little difficult	Moderately difficult	Very difficult	Unable
17	Getting dressed or undressed	1	2	3	4	5
18	Doing up buttons	1	2	3	4	5
19	Putting toothpaste on a toothbrush	1	2	3	4	5
20	Cutting your nails	1	2	3	4	5
21	Cutting food using a knife & fork together	1	2	3	4	5

	Over the past *week* how *difficult* has it been for you to complete the following activities	Not at all difficult	A little difficult	Moderately difficult	Very difficult	Unable
22	Opening lids of tight jars and bottles	1	2	3	4	5
23	Pouring from a kettle	1	2	3	4	5
24	Wringing out a cloth	1	2	3	4	5
25	Preparing a meal	1	2	3	4	5
26	Opening & closing heavy doors	1	2	3	4	5

3

Impact of **H**and **N**erve **D**isorders (I-HaND) Scale Version 2.0

	Over the past *week* how *difficult* has it been for you to complete the following activities	Not at all difficult	A little difficult	Moderately difficult	Very difficult	Unable
27	Turning pages of a book, magazine or newspaper	1	2	3	4	5
28	Using electronic devices e.g. a remote control, mobile phone, tablet or computer	1	2	3	4	5

	Over the past *week* how *difficult* has it been for you to complete the following activities	Not at all difficult	A little difficult	Moderately difficult	Very difficult	Unable
29	Carrying a heavy shopping bag	1	2	3	4	5
30	Handling small coins e.g. 5 pence or 1 pence	1	2	3	4	5

Part 4: The following questions ask about how your nerve disorder of the hand(s) has affected your ability to take part in your daily work (including paid work, school work or housework) and recreational activities. Please circle one answer for each question.

	In *general*, over the past *week*	Very well	Well	Fairly well	Poorly	Very poorly
31	How well have you been able to manage the physical demands of your daily work?	1	2	3	4	5
32	How well have you been able to take part in recreational activities e.g. Hobbies or sport?	1	2	3	4	5

PLEASE PROVIDE THE DATE THAT YOU COMPLETED THE I-HAND SCALE HERE:	/	/ 2016

You have now reached the end of the questionnaire

Please check that you have answered all of the questions

THANK YOU for your time

For office use:

4

Quick-DASH

Participant Identification Number:	Baseline / Follow-up 1 / Follow-up 2

THE QuickDASH OUTCOME MEASURE

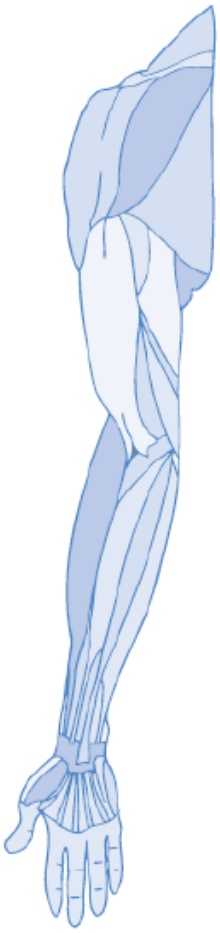
INSTRUCTIONS

This questionnaire asks about your symptoms as well as your ability to perform certain activities.

Please answer *every question*, based on your condition in the last week, by circling the appropriate number.

If you did not have the opportunity to perform an activity in the past week, please make your *best estimate* of which response would be the most accurate.

It doesn't matter which hand or arm you use to perform the activity; please answer based on your ability regardless of how you perform the task.



QuickDASH

Please rate your ability to do the following activities in the last week by circling the number below the appropriate response.

	NO DIFFICULTY	MILD DIFFICULTY	MODERATE DIFFICULTY	SEVERE DIFFICULTY	UNABLE
1. Open a tight or new jar.	1	2	3	4	5
2. Do heavy household chores (e.g., wash walls, floors).	1	2	3	4	5
3. Carry a shopping bag or briefcase.	1	2	3	4	5
4. Wash your back.	1	2	3	4	5
5. Use a knife to cut food.	1	2	3	4	5
6. Recreational activities in which you take some force or impact through your arm, shoulder or hand (e.g., golf, hammering, tennis, etc.).	1	2	3	4	5

	NOT AT ALL	SLIGHTLY	MODERATELY	QUITE A BIT	EXTREMELY
7. During the past week, *to what extent* has your arm, shoulder or hand problem interfered with your normal social activities with family, friends, neighbours or groups?	1	2	3	4	5

	NOT LIMITED AT ALL	SLIGHTLY LIMITED	MODERATELY LIMITED	VERY LIMITED	UNABLE
8. During the past week, were you limited in your work or other regular daily activities as a result of your arm, shoulder or hand problem?	1	2	3	4	5

Please rate the severity of the following symptoms in the last week. *(circle number)*	NONE	MILD	MODERATE	SEVERE	EXTREME
9. Arm, shoulder or hand pain.	1	2	3	4	5
10. Tingling (pins and needles) in your arm, shoulder or hand.	1	2	3	4	5

	NO DIFFICULTY	MILD DIFFICULTY	MODERATE DIFFICULTY	SEVERE DIFFICULTY	SO MUCH DIFFICULTY THAT I CAN'T SLEEP
11. During the past week, how much difficulty have you had sleeping because of the pain in your arm, shoulder or hand? *(circle number)*	1	2	3	4	5

PLEASE PROVIDE THE DATE THAT YOU COMPLETED THE QUICKDASH HERE: / / 2016

For office use:

Percentage of normal hand function form and global rating of change form

Percentage of Normal Hand Function and Global Rating of Change Form

Participant Identification Number:	Follow-up 2

Please answer part 1 and part 2 below

Part 1: Percentage of Normal Hand Function

Please read the following statement:

"A normal hand is one which is pain-free, with a full range of movement, normal strength, dexterity and sensation, and allows you to do what you feel your hand, if normal, should allow you to do. A normal hand is scored as 100 percent, while a completely useless hand is scored as 0 percent. Overall where would you rate your hand between 0 and 100 percent, at this present time"

Percentage of Normal Hand Function	%

Part 2: Global Rating of Change

Please tick ✓ one box only. Since you last completed the I-HaND Scale 3 months ago do you think that your overall hand function has improved, is the same or worse?

improved	much the same	worse than before
☐	☐	☐

PLEASE PROVIDE THE DATE THAT YOU COMPLETED THIS FORM HERE: / / 2016

For office use:

Appendix 5.2 Contents of the participant information pack for phase 3

REC Reference: 14/NE/1087

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PARTICIPANT INFORMATION SHEET – PHASE 3

The Hand Nerve Disorders Study –

'The HaND Study'

You are invited to take part in a doctoral research study. Before making a decision it is important for you to understand what taking part involves and why the study is being done. Please take your time to read through this information, discuss it with others or feel free to get in touch if you have any questions. Our contact details are given at the end of this document.

What is the purpose of the study?

Nerve disorders of the hand can have a significant impact on a person's ability to carry out daily life tasks. Patients who sustain a nerve injury often require surgery or rehabilitation to help regain their independence. To evaluate the effectiveness of such treatments, patients are often asked to complete questionnaires. There are currently no questionnaires that look specifically at the impact of a nerve injury on hand function and activities of daily living. The overall aim of this research study therefore aims to develop such a questionnaire. We have completed the first stages of this project by developing a draft questionnaire. The final stage of the project will involve a series of tests to determine how well the questionnaire measures what it is supposed to, how consistent it is over time and how sensitive it is in detecting patient improvement over time.

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

You have been approached as you are receiving, or have received treatment for your nerve disorder at the Norfolk and Norwich University Hospital (NNUH). We would like you to test our new questionnaire which asks about the impact of a nerve disorder affecting your hand(s).

Do I have to take part?

Participation in this study is voluntary and it is entirely up to you to decide whether or not you want to take part. Discuss it with friends and family if you like, and ask any questions you may have before

making a decision. You are free to leave the study at any time, you do not have to give a reason and this will not affect any current or future treatment for your condition.

What will happen if I agree to take part?

If you agree to take part, we ask you to complete the enclosed questionnaire and demographic form. We will also require you to complete a similar hand questionnaire at this time. Each questionnaire should take between 5 – 10 minutes to complete. On completion we ask that you return the questionnaires to us by post in the prepaid envelope included. Within two weeks you will be posted out the new questionnaire to complete and return to us again. You will be sent the questionnaire again in three months and asked to complete and return it for the final time. The questionnaire will be kept in a secure place at the UEA. No personal information (e.g. name, address) will be stored with it. It will be accessed only by members of the research team.

What are the possible benefits of taking part?

There are no direct benefits to taking part in the overall study. However, you will be helping us to develop a questionnaire which can be used to assess the results of treatment in the future and which is relevant to patients with a nerve disorder affecting the hand(s).

What are the possible risks and disadvantages involved in taking part?

There are no risks associated with this study. Completing each questionnaire will take approximately 10-20 minutes of your time.

Will my taking part in the study be kept confidential?

Yes, we will follow ethical and legal best practice and all information you provide us will be treated in confidence. Results will be published in a doctoral thesis, scientific peer reviewed journals and presented at meetings or conferences. These reports will not contain any names and we will ensure that individuals cannot be identified from details in the reports or study results. If you desire we will provide you with a summary of the results of the study.

Will my GP be informed of my involvement in the study?

We will inform your GP of your involvement in the study.

How do I raise concerns or make a complaint?

If you have concerns about any aspect of this project, you can speak to Mark Ashwood - Chief investigator or Dr Christina Jerosch-Herold – Primary supervisor who will do their best to answer any queries. If you remain unhappy and wish to make a formal complaint, please contact Professor Valerie Lattimer, Head of the School of Health Sciences on 01603 59 7247 or through the normal NHS complaints procedure by contacting your local hospital switchboard.

REC Reference: 14/NE/1087

Who is organising and funding the project?

The chief investigator is a qualified occupational therapist and is carrying out this research as part of his doctoral degree. It is funded by the University of East Anglia.

Who has reviewed this study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your safety, rights, wellbeing and dignity. This study has been reviewed and approved by the York Research Ethics Committee (Ref: 14/NE/1087).

Yes, I would like to take part in the study – what do I need to do now?

If you wish to take part:-

1. Complete the enclosed questionnaires.
2. Complete the demographic information form.
3. Return these documents along with the medical information form (completed by your therapist) in the stamped addressed envelope provided within one week.

I am not sure about taking part – where can I get further information?

We would be very happy to answer any questions you may have. Please contact Mark Ashwood, the chief investigator.

Contact information:

Chief investigator: Mark Ashwood

Telephone 01603 593093 email: M.Ashwood@uea.ac.uk

OR

Primary supervisor: Dr Christina Jerosch-Herold

Telephone: 01603 593316 email: C.Jerosch-Herold@uea.ac.uk

Thank you for taking the time to read this information

NNUH PIS 3 /Version 3.1 / 11.09.2015

Centre Number: 01
REC Reference: 14/NE/1087
Patient Identification Number for this study:

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Norfolk and Norwich University Hospitals NHS
NHS Foundation Trust

University of East Anglia

PATIENT CONSENT FORM – PHASE 3

The Hand Nerve Disorders Study –

'The HaND Study'

Name of Researcher: Mr Mark Ashwood

Please initial all boxes

1. I confirm that I have read and understand the information sheet dated 11.09.2015 (version 3.1) 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 understand that relevant sections of my medical notes and data collected during the study may be looked at by individuals from the Norfolk and Norwich University Hospital (NNUH), from regulatory authorities or from the NHS Trust, where it is relevant to my taking part in this research. I give permission for these individuals to have access to my records. ☐
4. I agree to my GP being informed of my participation in the study. ☐
5. I agree to take part in the above study. ☐

Name of participant	Date	Signature
Name of person taking consent	Date	Signature

Appendix 5.3 Patient identification centre approvals

Royal Free London NHS
NHS Foundation Trust
Royal Free Hospital
Pond Street
Ground Floor, Room 649/1
London
NW3 2QG

www.royalfree.nhs.uk

Switchboard: 020 7794 0500 EXT: 33211
Fax: 020 7830 2468
Direct line: 020 7317 7558
Generic email: rf.randd@nhs.net

Mrs Nikki Burr
Royal Free London NHS Foundation Trust
Royal Free Hospital
Lead Hand Therapist
Plastic Surgery - Hand Therapy Unit 1st Floor

Date: Tuesday, 8 December 2015

Dear Mrs Burr

RFH RD no:	9637 (Please quote in all correspondence)
REC Ref:	14/NE/1087
IRAS ID:	155734
Title:	Development and Validation of a Patient-Reported Outcome Measure (PROM) for Peripheral Nerve Disorders of the Hand

I am writing to confirm that Royal Free London NHS Foundation Trust agrees to act as Participant Identification Centre (PIC) in the above study.

The PIC as defined by the NIHR CSP Operating Guidelines, version 4.0 dated September 2009.

"Participant identification Centres are not considered to be research sites, which are defined as organisations responsible for participant-related research procedures specified in the protocol, including recruitment and informed consent.

The NHS Organisation responsible for the Participant Identification Centre is expected to review the request to refer patients (including any resource implication and other issues such as data protection) and agree to this in the form of an agreement letter. It is the site that conducts the protocol-driven procedures that is responsible for providing indemnity for the research activity, not the NHS Organisation responsible for the PIC_4

Yours sincerely

Dr Adele Fielding
Director of Research and Development
Royal Free London NHS Foundation Trust

St George's University of London

St George's University Hospitals NHS
NHS Foundation Trust

St George's Joint Research & Enterprise Office (JREO)
Ground Floor, Hunter Wing, St George's University of London,
Cranmer Terrace, Tooting, London SW17 0RE

Direct Line: 020 8266 6488
Email: nazzouzi@sgul.ac.uk

22/01/2016

Ms Megan Blakeway
Clinical Specialist - Hand Therapy
St George's University Hospitals NHS Foundation Trust
Blackshaw Road
Tooting
London
SW17 0QT

Dear Ms Megan Blakeway

PROJECT TITLE:	Development and validation of a patient-reported outcome measure (PROM) for peripheral nerve disorders of the hand
REC Reference:	14/NE/1087
JRO Reference:	PIC15.0014
CSP Reference:	n/a
UKCRN Reference:	n/a
Sponsor:	University of East Anglia
PIC Site	St George's University Hospitals NHS Foundation Trust
Chief Investigator (CI):	Mr Mark Ashwood

Thank you for providing us with documentation regarding this study. The JREO has no objection to St George's University Hospitals NHS Foundation Trust being used as a Participant Identification Centre for the above study.

During the identification of potential participants you should ensure compliance with the Data Protection Act 1998 and all other current and relevant statutory guidance and legislation.

Please contact the JREO if you require any further guidance or information on any matter mentioned above.

Yours sincerely

Ms Nadia Azzouzi
On behalf of SGHT
Joint Research and Enterprise Office

Chelsea and Westminster Hospital NHS
NHS Foundation Trust

Department of Research and Development
Research Delivery Team Office
Unit G3, Harbour Yard
Chelsea Harbour
London
SW10 0XD

21 December 2015

Dr Sarah Mee
Chelsea and Westminster Hospital NHS Foundation Trust

Dear Dr Sarah,

Notification of NHS Permission (R&D Approval)

Version: Participant Identification Centre (PIC)

Study title: Development and Validation of a Patient-Reported Outcome Measure (PROM) for Peripheral Nerve Disorders of the Hand
IRAS reference: 155734
REC reference: 14/NE/1087
Local reference: CW15.145

I am pleased to inform you that the department of research and development review of the above project is now complete, and Chelsea and Westminster Hospital NHS Foundation Trust has agreed to act as a Participant Identification Centre (PIC) for the above study. The documents reviewed are as follows:

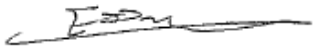
Document	Version	Date
REC Favourable Opinion Letter		28 July 2014
REC Favourable Opinion Letter	substantial amendment	18 September 2015
R&D Form	155734/849640/14/816	22 September 2015
Participant Information Sheet	3.1	11 September 2015
Consent Form	2.2	11 September 2015
GP Letter	1.1	31 July 2014
Protocol	3.0	10 September 2015
Clinical Record Form	1.2	02 September 2015

Please note that while the Trust retains the responsibility for the healthcare of the participants outside the research, it does not provide indemnity for any of the research activities associated with the above project.

The duration of this agreement to act as a PIC extends to the date specified in the R&D Form. Please let us know should you wish to extend the duration of your project. Also please be reminded that you must notify us of any amendments and the study closure.

I wish you well in your research. Please do not hesitate to contact us should you need any guidance or assistance.

Yours sincerely



Dr Essam Ramhamadany
Assistant Director of Research and Development
Chelsea and Westminster Hospital NHS Foundation Trust

cc: Mark Ashwood, Chief Investigator,M.Ashwood@uea.ac.uk
Dr Christina Jerosch-Herold, Sponsor Contact, c.Jerosch-Herold@uea.ac.uk
Dr Sarah Mee, Local collaborator, sarah.mee@chelwest.nhs.uk

Joint Research Management Office
Queen Mary Innovation Centre
5 Walden Street
London
E1 2EF

Tel: 020 7882 7260
Fax: 020 7882 7276
Email: Sponsorsrep@bartshealth.nhs.uk

FINAL PIC APPROVAL
(Participant Identification Centre)

10th February 2016

Niall Fitzpatrick
Outpatient Therapies
Royal London Hospital
Whitechapel
E1 1BB

Dear Niall,

Protocol: **Development and Validation of a Patient Reported Outcome Measure (PROM) for Peripheral Nerve Disorders of the Hand**

REC Ref: **14/NE/1087**

I am pleased to inform you that the Joint Research Management Office for Barts Health NHS Trust and Queen Mary University of London, has granted research governance approval for the above study based on the evidence described in the IRAS application form and the supporting documents.

I note that the only involvement for Barts Health NHS Trust is as a Participant Identification Centre and therefore the Chief investigator's organisation should arrange for appropriate indemnity cover against any negligence that may occur during the course of your project.

Please note that all research within the NHS is subject to the Research Governance Framework for Health and Social Care, 2005. If you are unfamiliar with the standards contained in this document, or the BH and QMUL policies that reinforce them, you can obtain details from the Joint Research Management Office or go to: http://www.dh.gov.uk/en/Publicationsandstatistics/Publications/PublicationsPolicyAndGuidance/DH_4108962

You must stay in touch with the Joint Research Management Office during the course of the research project, in particular:

- If there is a change of Local Collaborator
- When the project finishes

We wish you all the best with your research, and if you need any help or assistance during its course, please do not hesitate to contact the Office.

Yours sincerely

Gerry Leonard, Head of Research Resources

Copy to: Mark Ashwood (CI)

Dear Mrs Kirkham

Re: IRAS 155734. Confirmation of Capacity and Capability at UHSM (University of South Manchester NHS Foundation Trust) – PIC Site
Full Study Title: Development and Validation of a Patient-Reported Outcome Measure (PROM) for Peripheral Nerve Disorders of the Hand
UHSM R&D Ref: 2016BP001

This email confirms that UHSM has the capacity and capability to act as a Participant Identifying Centre (PIC) site for the above referenced study.

We agree to start this study on 12.07.16.

If you wish to discuss further, please do not hesitate to contact me.

Kind regards

Karen

Karen Rhodes
Clinical Trials Manager
First Floor
NIHR Building
Wythenshawe Hospital
Southmoor Road
Manchester
M23 9QZ

☎: 0161 291 5768

Appendix 5.4 Tables of transformed I-HaND total scores

Raw total scores	Transformed scores (%)
32	0
33	0.78
34	1.56
35	2.34
36	3.13
37	3.91
38	4.69
39	5.47
40	6.25
41	7.03
42	7.81
43	8.59
44	9.38
45	10.16
46	10.94
47	11.72
48	12.50
49	13.28
50	14.06
51	14.84
52	15.63
53	16.41
54	17.19
55	17.97
56	18.75
57	19.53
58	20.31
59	21.09
60	21.88
61	22.66
62	23.44
63	24.22
64	25.00
65	25.78
66	26.56
67	27.34
68	28.13
69	28.91
70	29.69
71	30.47
72	31.25
73	32.03
74	32.81

Raw total scores	Transformed scores (%)
75	33.59
76	34.38
77	35.16
78	35.94
79	36.72
80	37.50
81	38.28
82	39.06
83	39.84
84	40.63
85	41.41
86	42.19
87	42.97
88	43.75
89	44.53
90	45.31
91	46.09
92	46.88
93	47.66
94	48.44
95	49.22
96	50.00
97	50.78
98	51.56
99	52.34
100	53.13
101	53.91
102	54.69
103	55.47
104	56.25
105	57.03
106	57.81
107	58.59
108	59.38
109	60.16
110	60.94
111	61.72
112	62.50
113	63.28
114	64.06
115	64.84
116	65.63
117	66.41

Raw total scores	Transformed scores (%)
118	67.19
119	67.97
120	68.75
121	69.53
122	70.31
123	71.09
124	71.88
125	72.66
126	73.44
127	74.22
128	75.00
129	75.78
130	76.56
131	77.34
132	78.13
133	78.91
134	79.69
135	80.47
136	81.25
137	82.03
138	82.81
139	83.59
140	84.38
141	85.16
142	85.94
143	86.72
144	87.50
145	88.28
146	89.06
147	89.84
148	90.63
149	91.41
150	92.19
151	92.97
152	93.75
153	94.53
154	95.31
155	96.09
156	96.88
157	97.66
158	98.44
159	99.22
160	100.00

Appendix 5.5 Distribution of the individual items (data collected using version 2 of the I-HaND Scale)

	N		Mean	Std. Deviation	Variance	Skewness	Kurtosis
	Valid	Missing					
Q1	131	1	3.11	1.17	1.37	-0.21	-0.74
Q2	131	1	2.82	1.17	1.36	0.14	-0.93
Q3	130	2	3.19	1.28	1.65	-0.08	-1.18
Q4	130	2	3.29	1.25	1.56	-0.31	-1.01
Q5	132	0	3.61	1.28	1.63	-0.70	-0.53
Q6	131	0	3.27	1.30	1.69	-0.36	-0.93
Q7	132	0	3.09	1.11	1.23	-0.15	-0.62
Q8	130	2	2.93	1.31	1.71	-0.04	-1.08
Q9	132	0	2.23	1.37	1.89	0.78	-0.59
Q10	130	0	2.76	1.08	1.18	0.23	-0.47
Q11	131	1	3.24	1.31	1.72	-0.22	-1.08
Q12	131	1	2.01	1.21	1.47	0.99	0.04
Q13	131	2	2.98	1.42	2.02	-0.01	-1.22
Q14	130	2	3.13	1.43	2.04	-0.15	-1.26
Q15	131	1	2.78	1.43	2.05	0.09	-1.33
Q16	132	0	2.84	1.23	1.51	0.06	-0.84
Q17	132	0	2.18	1.11	1.23	0.58	-0.62
Q18	132	0	2.86	1.28	1.65	0.06	-1.23
Q19	131	1	2.12	1.25	1.57	0.77	-0.65
Q20	129	3	2.94	1.44	2.06	0.00	-1.35
Q21	132	0	2.8	1.45	2.10	0.18	-1.33
Q22	130	2	3.44	1.25	1.57	-0.35	-0.93
Q23	132	0	2.31	1.28	1.64	0.60	-0.78
Q24	132	0	2.97	1.37	1.88	-0.09	-1.22
Q25	131	1	2.47	1.20	1.44	0.49	-0.65
Q26	132	0	2.75	1.29	1.67	0.18	-1.07
Q27	132	0	2.2	1.17	1.37	0.63	-0.58
Q28	130	2	2.32	1.16	1.35	0.60	-0.44
Q29	131	1	3.11	1.40	1.96	0.08	-1.33
Q30	132	1	2.88	1.28	1.63	-0.10	-1.26
Q31	131	1	3.04	1.29	1.67	0.06	-0.93
Q32	130	2	3.47	1.25	1.55	-0.37	-0.78

Appendix 5.6 item-fit statistics (data collected using version 2 of the I-HaND Scale)

item	Location	SE	Fit residual	Chi-Sq	Prob	F-stat	Prob
1	-0.33	0.12	-1.38	7.05	0.13	2.32	0.06
2	0.08	0.11	0.04	0.48	0.98	0.18	0.95
3	-0.61	0.10	2.37	7.61	0.11	1.03	0.39
4	-0.68	0.11	0.01	3.87	0.42	1.15	0.34
5	-0.95	0.11	**5.24**	1.34	0.85	0.42	0.79
6	-0.47	0.10	**4.70**	40.15	0.00	5.90	0.00
7	-0.40	0.12	0.28	0.93	0.92	0.26	0.90
8	-0.08	0.10	**3.06**	7.10	0.13	1.33	0.26
9	0.53	0.09	**3.30**	28.09	0.00	3.65	0.01
10	0.00	0.12	-0.26	19.73	0.00	6.01	0.00
11	-0.62	0.10	-0.55	4.85	0.30	1.43	0.23
12	1.02	0.11	0.40	6.33	0.18	1.40	0.24
13	-0.19	0.09	**3.61**	47.87	0.00	5.75	0.00
14	-0.35	0.09	**3.48**	36.68	0.00	5.91	0.00
15	0.10	0.09	2.37	13.19	0.01	1.97	0.10
16	0.05	0.11	-1.45	5.30	0.26	1.80	0.13
17	1.58	0.12	**-2.62**	15.84	0.00	7.90	0.00
18	0.00	0.10	-0.92	5.05	0.28	1.38	0.25
19	1.06	0.11	-1.32	7.80	0.10	2.85	0.03
20	-0.10	0.10	-1.43	3.50	0.48	1.39	0.24
21	0.02	0.10	-1.08	7.53	0.11	2.23	0.07
22	-1.02	0.11	-1.84	17.12	0.00	6.88	0.00
23	0.75	0.10	-0.53	3.57	0.47	1.06	0.38
24	-0.12	0.10	-0.48	3.65	0.46	0.89	0.47
25	0.60	0.11	**-2.76**	16.73	0.00	8.19	0.00
26	0.14	0.10	-1.11	5.94	0.20	1.87	0.12
27	1.00	0.11	0.70	6.21	0.18	1.39	0.24
28	0.76	0.11	-0.04	2.32	0.68	0.53	0.72
29	-0.52	0.10	1.16	9.31	0.05	2.12	0.08
30	0.18	0.10	2.13	1.40	0.84	0.31	0.87
31	-0.38	0.10	-1.78	5.99	0.20	2.17	0.08
32	-1.05	0.11	-2.47	11.16	0.02	4.50	0.00
Ideal values			**< ± 2.5**		**>0.05**		**>0.05**

Appendix 5.7 Mean inter-item residual correlations (data collected using version 2 of the I-HaND Scale)

Mean inter- item correlations of residuals exceeding 0.3 (part 1)

	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9	Q10	Q11	Q12
Q2	**0.43**											
Q3	-0.07	0.18										
Q4	**0.33**	**0.37**	0.22									
Q5	-0.02	0.00	-0.06	0.05								
Q6	-0.20	-0.07	0.19	-0.06	0.09							
Q7	-0.02	0.12	-0.07	-0.02	-0.06	-0.03						
Q8	-0.11	-0.13	-0.07	0.01	-0.05	-0.05	-0.15					
Q9	-0.15	-0.08	-0.05	-0.08	-0.08	0.04	-0.09	**0.44**				
Q10	-0.09	-0.07	0.14	0.10	-0.14	0.03	-0.09	0.07	0.03			
Q11	-0.13	-0.08	0.04	0.11	0.02	0.01	-0.09	0.16	-0.06	**0.43**		
Q12	0.01	0.02	0.00	-0.05	-0.16	0.11	-0.05	0.19	0.14	0.05	0.09	
Q13	-0.26	-0.07	0.20	-0.06	-0.02	**0.40**	-0.15	0.00	0.09	-0.01	-0.02	0.07
Q14	-0.25	-0.11	0.14	-0.10	-0.04	0.29	-0.07	0.11	**0.30**	-0.04	-0.05	0.21
Q15	-0.10	-0.16	-0.09	-0.02	-0.05	-0.06	-0.16	-0.03	0.03	0.31	**0.34**	-0.07
Q16	0.15	0.14	-0.15	0.06	-0.13	-0.26	-0.09	-0.07	-0.15	0.00	0.02	-0.14
Q17	0.04	-0.07	-0.22	-0.12	-0.12	-0.31	0.02	-0.12	-0.24	0.04	-0.02	-0.12
Q18	0.04	-0.01	-0.07	-0.10	-0.12	-0.20	0.29	-0.08	-0.02	-0.14	-0.17	-0.15
Q19	-0.09	-0.20	-0.19	-0.21	-0.02	-0.19	0.14	-0.11	-0.06	-0.17	-0.22	-0.17
Q20	0.11	-0.03	-0.14	-0.13	-0.06	-0.04	0.12	-0.16	-0.10	-0.36	-0.32	-0.12
Q21	0.22	0.03	-0.05	-0.22	-0.14	-0.17	0.09	-0.14	-0.03	-0.19	-0.32	-0.07
Q22	0.04	-0.15	-0.16	0.08	-0.01	-0.13	-0.08	-0.21	-0.29	0.05	-0.03	-0.14
Q23	-0.06	-0.10	-0.23	-0.05	0.06	-0.20	0.04	-0.20	-0.18	-0.04	-0.07	-0.12
Q24	-0.14	-0.03	-0.23	-0.19	0.03	-0.16	-0.09	-0.19	-0.12	-0.17	-0.02	-0.08
Q25	0.22	0.08	-0.17	-0.19	-0.18	-0.18	-0.05	-0.21	-0.23	-0.13	-0.22	-0.17
Q26	-0.03	-0.09	-0.29	-0.15	0.09	-0.18	-0.10	-0.26	-0.21	0.07	-0.21	-0.19
Q27	-0.02	-0.14	0.01	-0.15	-0.10	-0.12	0.08	-0.19	-0.06	-0.18	-0.18	-0.14
Q28	-0.01	-0.11	-0.16	-0.12	0.08	-0.21	0.00	-0.03	-0.14	-0.24	-0.16	-0.12
Q29	-0.11	-0.10	-0.01	-0.11	0.18	-0.17	-0.13	-0.20	-0.21	-0.02	-0.07	-0.09
Q30	-0.11	-0.13	0.14	-0.23	-0.12	-0.11	0.15	-0.07	-0.09	-0.24	-0.07	-0.08
Q31	0.10	-0.05	-0.23	0.05	-0.14	-0.26	-0.04	0.09	-0.06	0.00	0.09	-0.20
Q32	0.03	-0.10	-0.23	0.04	-0.05	-0.19	0.11	0.15	-0.15	0.04	0.08	-0.02

Mean inter- item correlations of residuals exceeding 0.3 (part 2)

	Q13	Q14	Q15	Q16	Q17	Q18	Q19	Q20	Q21	Q22	Q23	Q24
Q14	**0.54**											
Q15	-0.01	-0.01										
Q16	-0.24	-0.28	0.02									
Q17	-0.25	-0.33	-0.06	**0.31**								
Q18	-0.29	-0.19	-0.14	0.02	0.22							
Q19	-0.06	-0.16	-0.09	0.03	**0.35**	0.28						
Q20	-0.12	-0.16	-0.15	-0.01	0.12	0.12	**0.32**					
Q21	-0.22	-0.14	-0.08	0.05	0.09	0.13	0.14	**0.31**				
Q22	-0.18	-0.22	0.03	0.04	0.12	-0.09	0.10	0.09	0.15			
Q23	-0.32	-0.38	-0.07	-0.05	0.21	0.00	0.14	0.07	-0.02	0.20		
Q24	0.01	-0.13	0.01	0.05	0.02	-0.09	0.13	0.01	0.12	0.29	0.19	
Q25	-0.27	-0.27	-0.22	0.15	**0.35**	0.17	0.27	0.23	0.28	0.09	0.26	0.17
Q26	-0.28	-0.26	0.00	0.01	0.28	-0.05	0.07	0.00	0.09	0.24	0.45	0.14
Q27	-0.03	-0.06	-0.12	-0.02	-0.01	**0.43**	0.01	0.06	-0.06	-0.17	0.02	-0.11
Q28	-0.22	-0.09	-0.26	0.04	0.09	0.25	0.04	0.07	-0.04	-0.07	0.13	-0.14
Q29	-0.14	-0.22	0.05	0.03	0.10	-0.31	-0.03	-0.13	-0.08	0.21	0.24	0.06
Q30	-0.10	-0.03	-0.13	-0.10	-0.05	0.09	-0.07	0.00	-0.03	-0.09	0.04	-0.13
Q31	-0.26	-0.27	0.01	0.34	0.16	-0.01	-0.09	-0.11	-0.01	-0.05	0.01	0.06
Q32	-0.28	-0.18	-0.15	0.12	0.13	-0.08	-0.06	-0.02	0.01	-0.01	0.07	-0.04

Mean inter- item correlations of residuals exceeding 0.3 (part 3)

	Q25	Q26	Q27	Q28	Q29	Q30	Q31
Q26	0.25						
Q27	0.07	-0.10					
Q28	0.16	0.18	**0.37**				
Q29	-0.02	**0.45**	-0.11	-0.01			
Q30	-0.03	-0.06	**0.38**	**0.32**	0.16		
Q31	0.19	0.03	-0.14	0.04	0.14	-0.01	
Q32	0.12	0.10	-0.15	-0.03	0.09	-0.01	**0.49**

Appendix 5.8 Test-retest reliability for the overall I-HaND Scale (version 2) and for individual items

	Item		95% CI	
		ICC	Lower	Upper
1	How well did your hand(s) work?	0.89	0.82	0.94
2	The movement of your hand(s)	0.89	0.81	0.93
3	The sense of touch in your hand(s)	0.80	0.67	0.88
4	The strength in your hand(s)	0.79	0.66	0.88
5	I can't grip or pinch for very long without my hand getting tired	0.86	0.77	0.92
6	When I touch certain things it causes pins and needles or tingling	0.82	0.71	0.90
7	When I go to pick something up it falls out of my hand	0.82	0.70	0.89
8	Using my hand(s) can bring about strong emotions e.g. frustration, anger, sadness	0.87	0.78	0.92
9	I feel self-conscious if people look at my hand/arm	0.93	0.89	0.96
10	The pain or discomfort in my hand(s) has been	0.91	0.85	0.95
11	How often would you say that your pain or discomfort impacts on your daily routine?	0.87	0.78	0.92
12	I have hurt my hand and not realised it until later	0.88	0.79	0.93
13	My hand feels over sensitive when touched	0.86	0.76	0.91
14	I feel pain or discomfort when my hand is cold	0.91	0.85	0.95
15	It is difficult to get a good night's sleep because of the pain or discomfort in my hand/arm	0.92	0.87	0.95
16	How well have you been able to carry out your daily routine e.g. Getting ready, cooking, childcare etc.	0.87	0.79	0.93
17	Getting dressed or undressed	0.90	0.83	0.94
18	Doing up buttons	0.95	0.92	0.97
19	Putting toothpaste on a toothbrush	0.94	0.91	0.97
20	Cutting your nails	0.89	0.82	0.94
21	Cutting food using a knife & fork together	0.93	0.87	0.96
22	Opening lids of tight jars and bottles	0.88	0.80	0.93
23	Pouring from a kettle	0.84	0.73	0.90
24	Wringing out a cloth	0.90	0.84	0.94
25	Preparing a meal	0.82	0.70	0.89
26	Opening & closing heavy doors	0.90	0.83	0.94
27	Turning pages of a book, magazine or newspaper	0.91	0.85	0.95
28	Using electronic devices e.g. a remote control, mobile phone, tablet or computer	0.88	0.80	0.93
29	Carrying a heavy shopping bag	0.94	0.89	0.96
30	Handling small coins e.g. 5 pence or 1 pence	0.90	0.84	0.94
31	How well have you been able to manage the physical demands of your daily work?	0.90	0.83	0.94
32	How well have you been able to take part in recreational activities e.g. Hobbies or sport?	0.87	0.78	0.92
	I-HaND Scale total score	**0.97**	**0.94**	**0.98**