Development, validation, reliability and predictive capacity of neuro-motor recovery of the Acute Brain Injury Physiotherapy Assessment (ABIPA): a tool for physiotherapists during early management of people following Acquired Brain Injury (ABI).

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Declaration by Author

This thesis contains no material submitted towards the award of any other degree or diploma in any other tertiary institution.

No other person's work has been used without due acknowledgment in the main text of the thesis.

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Publications during candidature

Peer-reviewed publications

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Gesch, Janelle M., Low Choy, Nancy L., Weeks, Benjamin K., Steele, Michael. Kuys, Suzanne S. Strength and characteristics of the items of the Acute Brain Injury Physiotherapy Assessment (ABIPA) in people with an acquired brain injury: A factor analysis. (Submitted for review. Brain Injury, 2019)

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ABIPA - Acute Brain Injury Physiotherapy Assessment

Contributions by others to the manuscripts

The jointly authored studies included in this thesis are listed below. The PhD candidate was involved in all levels from initial concept to recruitment, data analysis and manuscript production. All work is original with contribution from the authors acknowledged. The PhD candidate was also primarily involved in dissemination of research at international, national and local conferences.

Study 1 - *Gesch, Janelle M.*, Low Choy, Nancy L., Weeks, Benjamin K., Passier, Leanne L., Nascimento, Margarida. Haines, Terrence P., Kuys, Suzanne S. Development and preliminary validation of the Acute Brain Injury Physiotherapy Assessment (ABIPA). Brain Impairment, 2014 15(2): 132-145 (Appendix 5).

Margarida Nascimento and Leanne Passier were responsible for the initial concept, item identification, expert panel review, patient recruitment and principal data acquisition for 15 % of the manuscript. Nancy Low Choy, Benjamin Weeks and Suzanne Kuys were responsible for manuscript review, data interpretation and critical revision (15%). Dr Terry Haines was responsible for assistance with the data analysis (10%). The PhD candidate was responsible for the remainder of the work (60%) including initial concept, item identification, study design, ethics applications, study co-ordination, patient recruitment, principal data acquisition, data analysis and interpretation, primary manuscript drafting, editing, appraisal, and critically reviewed the manuscript.

Study 2 - *Gesch, Janelle M*., Low Choy, Nancy L., Weeks, Benjamin K., Nascimento, Margarida., Steele, Michael., Kuys, Suzanne S. Inter and intra-tester reliability of the Acute Brain Injury Physiotherapy Assessment (ABIPA) in patients with acquired brain injury. Brain Injury, 2016 9: 1-8 (Appendix 6).

Margarida Nascimento contributed to concept, design, patient recruitment and video production for 15% of the manuscript. Professor Suzanne Kuys, Dr Benjamin Weeks and Professor Nancy Low Choy contributed to manuscript review, data interpretation and critical revision (20 %), with Dr Michael Steele responsible for assistance with data analysis, 5%. The PhD candidate was responsible for the remainder of the work, 60%, including initial concept, study design, ethics applications, study co-ordination and student supervision, patient recruitment, principal data acquisition, data management and cleaning, principal data analysis, interpretation, primary manuscript drafting, editing, appraisal, revisions and production, and approved manuscript.

Study 3 *Gesch, Janelle M*., Low Choy, Nancy L., Weeks, Benjamin K., Steele, Michael., Kuys, Suzanne S. Strength and characteristics of the items of the Acute Brain Injury Physiotherapy Assessment (ABIPA) in people with an acquired brain injury: A factor analysis (Appendix 7).

Professor Suzanne Kuys, Professor Nancy Low Choy and Dr Benjamin weeks contributed to initial concept, manuscript review, data interpretation and critical revision for 20% of the manuscript. Dr Michael Steel contributed to the data cleaning, initial analysis, data interpretation and manuscript drafts for 10% of the manuscript with the PhD candidate

responsible for the remainder of the work, 70%, including initial concept, study design, ethics applications, study co-ordination, data management and cleaning, principal data analysis, interpretation, primary manuscript drafting, editing, appraisal, revisions and production, and approved manuscript.

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Abstract

In the acute stages following ABI, when people are functionally dependent, a specific scale for physiotherapists to monitor incremental changes in neuro-motor function is needed. This thesis represents the development of the acute brain injury physiotherapy assessment (ABIPA), an outcome measure to fill this gap.

The first step in the development of the ABIPA was to identify items known to reflect acute neuro-motor impairments for inclusion in the measure and develop scoring criteria along with guidelines for the identified items (Study 1). The final items of the ABIPA were: upper limb and lower limb movement; overall muscle tone in each limb; head and trunk alignment in supine; head and trunk alignment in sitting; head and trunk control in sitting; and overall presentation. Once items were selected and scoring criteria established, the new outcome measure underwent psychometric testing. In Study 1 responsiveness and concurrent validity of the ABIPA were examined together with participants assessed at day 1, 3, 7 and at discharge through their acute hospital admission to capture clinical changes. Concurrent validity of the ABIPA was examined against other commonly used measures; specifically, the Glasgow Coma Scale (GCS), Clinical Outcomes Variable Scale (COVS) and Motor Assessment Scale (MAS). The ABIPA was found to be responsive to change demonstrating greater sensitivity to change (SRM = 0.83) when compared to other assessment measures (SRMs $\leq$ 0.77) during the early weeks following ABI. Additionally, the ABIPA demonstrated good concurrent validity with commonly used measures to assess acute brain injury, including the GCS (rho = 0.76, $p \leq 0.001$, COVS (rho = 0.82, $p \leq 0.001$) and MAS (rho = 0.66, $p \leq 0.001$).

Study 2 of this thesis investigated inter- and intra-tester reliability of physiotherapists using the ABIPA. An observational study using video-recorded ABIPA assessments of seven

people with moderate or severe ABI was undertaken with two cohorts of physiotherapists; trained and untrained. Trained physiotherapists attended two one-hour training sessions; an initial instructional session and then a practice session. The untrained physiotherapists were provided with the ABIPA guidelines. Participating physiotherapists scored the video recorded package of ABIPA assessments with intra-tester reliability examined by repeat screenings of the video recorded assessments a minimum of two weeks after the initial session.

A high level of inter-tester reliability ($\alpha \geq 0.9$) was demonstrated for both trained and untrained physiotherapists. Trained physiotherapists showed good to excellent internal consistency for total ABIPA score and for all individual items except for alignment of the trunk in supine ($\alpha = 0.4$). Similarly, untrained physiotherapists showed good to excellent internal consistency on the total ABIPA score and all individual items except for alignment of the trunk in supine ($\alpha = 0.09$) and alignment of the head in supine ($\alpha = 0.60$). For intra-tester reliability, substantial or perfect agreement was achieved for eight items (Weighted kappa $K_w \geq 0.6$), with moderate agreement reached for a further four items ($K_w = 0.4 - 0.6$), leaving three items (representing 20% of the scale) achieving fair agreement. Items with the lowest agreement were alignment of the head in supine ($K_w = 0.289$); alignment of the trunk in supine ($Kw = 0.387$) and tone left upper limb ($Kw = 0.366$). This was similar for both the trained and untrained physiotherapists.

Study 3 of the thesis investigated the underlying factor structure of the ABIPA using an exploratory factor analysis with principal axis factor extraction and varimax rotation. A four-factor solution with a simple structure (factor loadings ≥.30) that explained 69.6% of total variance was suggested. Factor one (*alignment and posture*) accounted for 36.6% of the variance while factor two (*tone*) explained 15.8%, factor three (*left side movement*) explained 9.6% and factor four (*right side movement*) accounted for 7.5%. Two items were identified

with the lowest loading with the four-factor solution, *alignment of the head in supine* loading to factor three at 0.358 and *alignment of the trunk in supine* loading to factor two at 0.405.

The final study of this thesis examined the association of the ABIPA with long term recovery following ABI by evaluating ABIPA scores at acute hospital admission and ABIPA scores at admission to rehabilitation against: length of stay in the acute hospital setting, length of stay in rehabilitation, discharge destination and secondary measures including the GCS, Mental Status Questionnaire, COVS, Coma Recovery Scale-Revised (CRS-R), Functional Independence Measure (FIM), Disability Rating Scale (DRS) and Carer Strain Index (CSI). ABIPA at acute hospital admission and rehabilitation were inversely related to acute, rehabilitation and total hospital length of stay ($rho \geq -.508$; $p \leq 0.044$). ABIPA at acute hospital admission demonstrated moderate to good correlations with ABIPA, FIM (motor) and COVS ($rho \geq 0.563$, $p \leq 0.023$) at long term follow up. ABIPA scores at rehabilitation admission demonstrated moderate to good correlations with GCS and MSQ ($rho \geq 0.564$, $p \leq 0.023$) and excellent correlations with ABIPA, FIM (motor) and COVS ($rho \geq 0.799$, $p \leq 0.001$). Overall the ABIPA showed moderate to good relationships with length of stay and long-term neuro-motor recovery from severe ABI.

This thesis demonstrates that a new outcome measure with strong psychometric properties has been developed for measurement of acute neuro-motor impairments following severe ABI. Further investigation is required to continue the development paradigm by removing outlying items, establishing a minimal clinically important difference and expanding participant numbers.

Abbreviations

ABI	Acquired brain injury
ABIEBR	Acquired Brain Injury Evidence Base Review
ABIPA	Acute brain injury physiotherapy assessment
ADL	Activities of daily living
AIHW	Australian Institute of Health and Welfare
ANOVA	Analysis of variance
AVM	Arteriovenous malformation
CSI	Carer Strain Index
CRS – R	Coma Recovery Scale-Revised
COSMIN	COnsensus based Standards for the selection of health Measurement Instruments
COVS	Clinical Outcomes Variable Scale
DRS	Disability Reliability Scale
FIM	Functional Independence Measure
FOUR	Full Outline of Unresponsiveness
GCS	Glasgow Coma Scale
GOS	Glasgow Outcome Scale
HREC	Human Research Ethics Committee
KMO	Kaiser-Meyer-Olkin
Kw	Weighted Kappa
LOS	Length of stay
MCA	Middle cerebral artery
MSQ	Mental Status Questionnaire
MVA	Motor vehicle accident

PTA	Post traumatic amnesia
QCAT	Queensland Civil and Administrative Tribunal
SRM	Standardised response mean
TBI	Traumatic brain injury

Chapter 1

Introduction

This chapter serves as an introduction to the thesis. It will present the research problem; research program aims and significance. An overview of the thesis will also be presented.

1.1 Objective, Aims and Scope of the Thesis

Each year in Australia approximately 28 000 adults sustain an acquired brain injury (ABI) (Helps, Henley, & Harrison, 2008). For between 5% and 8% of people with an ABI, these injuries are associated with long-lasting disability (AIHW, 2007; Fortune & Wen, 1999; Mortenson & Eng, 2003) and are classified as severe (Glasgow Coma Scale 3-8) (Teasdale & Jennet, 1974). ABI is now the leading cause of death in adults under 40 years old in developed countries, and is responsible for a large burden of disability among survivors together with economic and human costs to individuals and society (Gentleman, 2001; Goldstein, 1990; Jennett, 1996). In 2005, ABI in Australia was estimated to have a direct cost of hospital care of AUD$184 million (Helps et al., 2008; Moorin, Miller, & Hendrie, 2014). In 2008, the total estimated cost of ABI in Australia was $8.6 billion, with a lifetime cost of AUD$2.5 million per person with a moderate (GCS 9 -13) ABI and AUD$4.8 million for a person with a severe ABI (Moorin et al., 2014). A 7% increase from 2000 – 2004/5 (Helps et al., 2008) signals the potential for escalating health and welfare costs, with ABI recovery and subsequent rehabilitation and societal reintegration of high socioeconomic significance with new cases of moderate to severe ABI adding more than $2 billion in lifetime costs to the Australian healthcare system annually(Access Economics, 2009). It is a particularly important issue for the state of Queensland, which has the highest rate of traumatic brain injury associated hospital admissions of all states in Australia (AIHW, 2007; Fortune & Wen, 1999).

During the initial recovery from an ABI, people face a host of challenges requiring treatment from the multidisciplinary team. Although there is limited robust research evaluating the rehabilitation interventions for people with an ABI (New Zealand Guidelines Group, 2007; Teasell et al., 2007), the delivery of allied health interventions including physiotherapy

decreases length of inpatient stay, optimises neuro-motor function at discharge, and reduces overall level of disability (Chestnut, 1990; Gray, 2000; Hall & Cope, 1995; Turner-Stokes, Disler, Nair, & Wade, 2005; Zhu, Poon, Chetwyn, Chan, & Chan, 2007). Physiotherapy therefore is regarded as a key discipline for rehabilitation following ABI (Hellweg & Johannes, 2008; New Zealand Guidelines Group, 2007; Teasell et al., 2007) with a direct impact on outcomes for this population.

Increasing the amount of rehabilitation has resulted in improved functional outcomes and rates of recovery of personal independence in people with ABI (Cifu et al., 2003; Slade, Tennant, & Chamberlain, 2002; Spivack, Spettell, Ellis, & Ross, 1992; Turner-Stokes et al., 2005). Long term outcomes however are often based on retrospective analysis (Chua & Kong 2002; McNett, 2007; Pape et al., 2006) and there is limited research examining the impact of different modes of acute care (New Zealand Guidelines Group, 2007; Teasell et al., 2007) and a lack of research capturing the acute stage of recovery following severe ABI (Canedo, Grix, & Nicoletti, 2002; Shukla, Devi, & Agrawal, 2011; Teasdale & Jennet, 1974; Wright, Bushnik, & O'Hare, 2000). Despite emerging confirmation of the advantages of physiotherapy for management of people with ABI, a specific outcome measure to monitor changes in neuro-motor impairments during the acute stage following ABI is absent from the field.

Following an ABI, injury to a range of structures and systems within the brain will have multiple effects on cognition, communication, behaviour and physical abilities (Greenwood, 2003; Mazaux et al., 1997). The characteristics of resulting physical disabilities (or neuro-motor impairments) will depend on the location and the level of damage to the brain and is the focus of this thesis. Damage to neuro-motor function, the relationship of the nervous system to the musculoskeletal system, may be defined by reduced muscle power, sensory disturbances disrupting feedback and feed forward mechanisms, tonus disorder (spasticity)

and decreased co-ordination (Umphred, 2007). Each could result in disorganisation of motor control (Teasdale & Jennet, 1974). In the acute phase of care, people with severe ABI are often functionally dependent and a small amount of limb movement is often the best neuro-motor function observed (Turner-Stokes et al., 2005).

In ABI rehabilitation, outcome measures are needed to quantify neuro-motor function, determine the efficacy of therapeutic intervention, monitor the achievement of goals, and/or inform adjustments to individual rehabilitation programs (New Zealand Guidelines Group, 2007; Teasell et al., 2007; G. Zitnay et al., 2008). Well recognised assessment scales of neuro-motor function include the Clinical Outcomes Variable Scale (Seaby & Torrance, 1989), the Motor Assessment Scale (Carr, Shepherd, & Nordholm, 1985) and the Functional Independence Measure –Motor component (Kidd, Stewart, & Baldry, 1996). A systematic review conducted in 2012 (Laxe et al., 2012) identified the outcome measures most frequently used in brain injury research. The Functional Independence Measure was used in 50% of studies investigating brain injury, with the next most common being the Glasgow Outcome Scale (34%) (Weir et al., 2012) and the Disability Rating Scale (32%) (Neese et al., 2000). Of these measures, only the Disability Rating Scale captures neuro-motor impairments. Therefore, it seems reasonable to suggest that during the acute phase of care following severe ABI, there are few outcome measures available for assessment of neuro-motor impairments.

Several of the above-mentioned outcome measures such as the Clinical Outcome Variable Scale, the Motor Assessment Scale and the Functional Independence Measure assess neuro-motor tasks associated with activities of daily living such as wheelchair mobility, transfers, walking and upper limb motor skills. However, many people with moderate or severe ABI are not capable of performing these tasks in the earliest stage of recovery (Pilon, Sullivan, & Coulombes, 1995). Whilst valid and reliable for the assessment of neuro-motor impairments

as progress occurs, these measures are more relevant when dealing with the person who can actively participate in a range of functional tasks across the continuum of care (i.e. a more advanced stage of rehabilitation). Other recognised measures commonly used in the acute care setting include the Glasgow Coma Scale (Chieregato et al., 2010), and Full Outline of Unresponsiveness scale (Fischer et al., 2010). These scales also have been acknowledged by the brain injury specific outcome measure database, as evaluating consciousness, response to pain, cognitive function, behaviour, social participation, and functional movement (Wright et al., 2000). However, these scales fail to capture specific neuro-motor impairments in the acute stage of recovery following moderate to severe ABI that are important to physiotherapy management (Canedo et al., 2002; O'Dell et al., 1996; Pape et al., 2006; Teasdale & Jennet, 1974).

A specific outcome measure to assess acute changes in neuro-motor impairments remains absent and thus there is a need for a new measure to be developed to capture early neuro-motor recovery following ABI.

1.2 Overview of the thesis

The overall purpose of this research program is to develop and evaluate a new physiotherapy specific outcome measure for people who have sustained a moderate to severe brain injury – the Acute Brain Injury Physiotherapy Assessment (ABIPA). Four studies comprise this research program. Initially the items known to reflect acute neuro-motor impairment were identified in the literature for inclusion in the tool as part of Study 1. Once the items of the outcome measure were identified, psychometric properties of the ABIPA were examined. Firstly, responsiveness to change and concurrent validity of the outcome measure compared to other measures of neuro-motor impairment were investigated (Study 1). Reliability was investigated next with an examination of inter-tester and intra-tester reliability of the ABIPA

(Study 2). Study 3 utilised principal component analyses to understand the dimensions or factors included in the ABIPA and the relative contribution of the dimensions or factors were examined. Study 3 also determined how well the hypothesized factors explained the observed data and which items were supported for continued inclusion in the ABIPA. The final study included in this thesis investigated the association of ABIPA with long term recovery for people following ABI (Study 4).

For the first three studies included in this research program, the objectives were to:

1) Determine the neuro-motor categories (items) and scoring guidelines for the ABIPA, a new outcome measure that could be applied by physiotherapists in the acute stage of management for people following moderate to severe ABI;
2) Evaluate the responsiveness of the ABIPA to assess change compared to standard measures of consciousness and neuro-motor function following moderate to severe ABI;
3) Determine the concurrent validity of the ABIPA against standard measures of consciousness and neuro-motor function following moderate to severe ABI;
4) Determine the reliability of physiotherapists using the ABIPA; and
5) Examine the factors underpinning the ABIPA.

Once the psychometric properties of the tool were established, the final study of this thesis investigated the association of the ABIPA with long term recovery (Study 4). Specifically, Study 4 examined the association between ABIPA scores at acute hospital admission and rehabilitation admission and;

- Acute hospital length of stay;
- Length of stay in rehabilitation;

- Discharge destination; and
- Neuro-motor recovery and carer burden between 2 and 5 years post discharge from rehabilitation.

Overall this thesis comprises eight chapters. Following the introduction, a background chapter (Chapter 2) will address the common clinical presentation of the group identified as requiring a new assessment tool. Chapter 2 will also review currently available outcome measures and highlight the gap in the literature for acute neuro-motor outcome measures. The background chapter will also discuss the current evidence around the characteristics required when considering new outcome measure development. Chapter 3 will detail the methods for all studies and Chapters 4-7 will present each of the four studies included in this research program generated to develop and evaluate the new outcome measure (ABIPA). The final chapter (Chapter 8) will include an overall discussion, conclusions, limitations and future direction for research and clinical practice.

Chapter 2

Background

This chapter will provide a rationale for the research program by outlining the aetiology of acquired brain injury and the common clinical presentations of this population, highlighting the common neuro-motor impairments. It will also discuss the most common assessment scales in ABI rehabilitation, highlighting the absence of a specific outcome measure which covers neuro-motor impairments relevant to the early stages of recovery of people with moderate to severe ABI.

2.1 Aetiology of ABI

In Australia, acquired brain injury has been defined as any damage to the brain that occurs after birth, with common causes including trauma, infection, hypoxia or conditions such as stroke (Fortune & Wen, 1999). ABI encompasses traumatic and non-traumatic aetiologies (Table 2.1). Traumatic brain injury (TBI) is defined as "an acute brain injury resulting from mechanical energy to the head from external physical force" (World Health Organization, 2002). Non-traumatic injuries may include cerebral concussion, brain contusions, subarachnoid haemorrhages or other acquired problems. An ABI by definition results in a deterioration in physical, cognitive, emotional and independent functioning and for the purpose of this research program, these impairments are enduring (AIHW, 2007).

Table 2.1 Definition of acquired brain injury (ABI)

Included in ABI definition	Excluded from ABI definition
Traumatic causes • Motor vehicle accidents • Assaults • Sport injuries • Falls • Gunshot wounds	**Congenital and developmental problems** • Developmental delay • Cerebral palsy • Autism • Down's syndrome • Spina bifida with hydrocephalus • Muscular dystrophy
Non-traumatic causes • Subarachnoid haemorrhage (non-focal) • Intracerebral haemorrhage (focal) • Cerebrovascular accident (i.e. stroke) • Anoxia • Meningitis • Encephalitis/encephalopathy (viral, bacterial, drug, hepatic) • Tumours (benign/meningioma only) • Malignant/metastatic tumours	**Progressive processes** • Dementia • Alzheimer's disease • Multiple sclerosis • Parkinson's disease • Pick's disease • Amyotrophic lateral sclerosis • Huntington's disease

(Fary, Baguley, & Cameron, 2003)

Several criteria are used to establish a clinical diagnosis of ABI. For such a diagnosis, people must present with at least one of the following:

- a period of decreased consciousness or loss of consciousness;
- the presence of post-traumatic amnesia; and/or
- other neurological anomalies, such as focal neurological signs, seizure and/or intracranial lesions.
  (Menon, Schwab, Wright, & Maas, 2010)

Such presenting signs and symptoms cannot be due to alcohol or drug ingestion or because of medications. Additionally, these signs and symptoms cannot be the result of treatment for other injuries (e.g. systemic injuries, facial injuries or intubation), or caused by other issues such as co-existing medical or psychological conditions (Fortune & Wen, 1999; Menon et al., 2010).

Non-traumatic causes of ABI include tumours, a lack of oxygen or anoxia, focal brain lesions, aneurysm, vascular malformations, and infections of the brain such as meningitis (AIHW, 2007; Fary et al., 2003). Figure 2.1 outlines the incidence of acquired brain injury in Australia (per 1,000 of the population) by age group and gender.

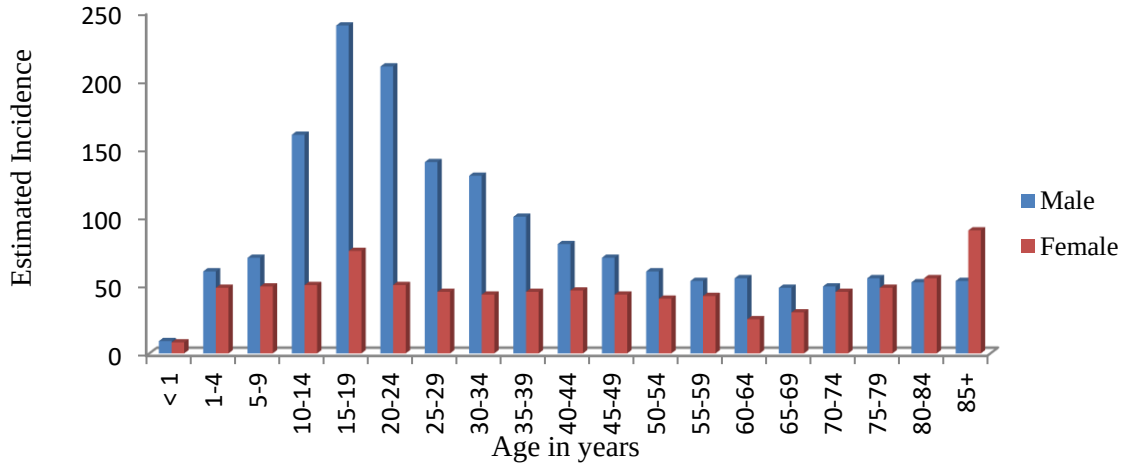

Figure 2.1 Incidence of Acquired Brain injury in Australia (per 1,000 of the population) by age group and gender (AIHW, 2007)

Peak incidence of ABI is among young males constituting a large subgroup (Fortune & Wen, 1999; Tate, McDonald, & Lulham, 1998). Males are three times more likely than females to suffer an ABI. Additionally, adults aged between 15 and 25 years old comprise 40% of survivors of ABI (AIHW, 2007; Fortune & Wen, 1999).

Severe traumatic brain injuries are for the majority (64%) of cases the result of road accidents involving for example: drivers, passengers, pedestrians, motor bikes or cyclists. The remainder of people with severe TBI are due to other causes such as assaults, falls, sport or recreation injuries and gunshot injuries (Fortune & Wen, 1999; Greenwald et al., 2015; Tate et al., 1998). Figure 2.2 outlines the mechanism of injury of TBI incidence in Australia. Table 2.2 outlines Australian data for number of TBI cases in Australia.

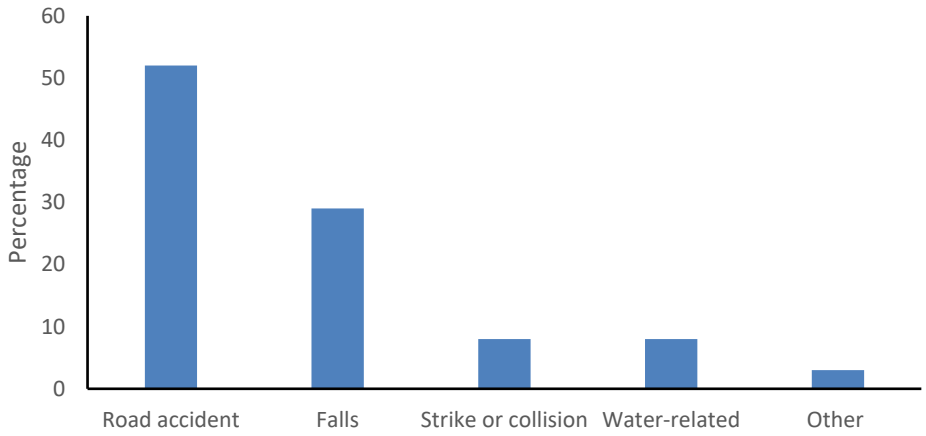

Figure 2.2 Incidence of traumatic brain injury by mechanism of injury in Australia, 2006-2007(AIHW, 2007; Helps et al., 2008)

Table 2.2 Number of TBI cases in Australia in 2008 according to severity and gender

	Number of TBI cases per year		
	Male	**Female**	**Total**
Moderate	1026	467	1493
Severe	688	313	1001
Total	1714	780	2493

When classifying the severity of ABI the Glasgow Coma Scale (GCS) and Post-Traumatic Amnesia (PTA) scale are two reliable indicators of acute brain injury severity (Sherer, Struchen, Yablon, Wang, & Nick, 2008). Both the GCS and PTA are discussed in detail in Section 2.4 Physiotherapy management of people following ABI

Physiotherapy following ABI aims to provide high quality patient centred clinical services to empower people with ABI to achieve their maximum potential and quality of life. Physiotherapists provide treatment to manage the patient's physical impairments and activity limitations resulting from the ABI, associated injuries (e.g. orthopaedic problems such as fractures or ligament damage) and those limitations resulting from long periods of inactivity or rest (Hellweg & Johannes, 2008; Synnot et al., 2017). Such impairments and activity limitations can relate to posture, balance, coordination, strength, endurance, and body sensation and perception (e.g., inability to determine the location, nature, or intensity of a stimulus applied to the body)(Allison, 1999).

Evidence supports the effectiveness of physiotherapy management with people following an ABI to improve the quality of movement, posture and balance (Tolfts & Stiller, 1997). Treatment may include:

- Management of abnormal movement patterns (Tolfts & Stiller, 1997).

- Maintenance of range of motion through positioning, passive stretches and movement facilitation, splinting and serial casting (Mortenson & Eng, 2003).
- Ensuring that limbs are positioned to prevent damage to joints & soft tissue
- Retraining balance and dynamic skills (Allison, 1999).
- Management of visual and vestibular problems (Herdman, 2014).
- Retraining quality movement in standing and sitting
- Gait retraining and progression of mobility (Eng, Rowe, & McLaren, 2002)
- Patient and relative/carer education of their condition (Dismuke, Walker, & Egede, 2015)
- Training in safe transfer techniques (French et al., 2010).

2.5 Assessment of consciousness and injury severity. Determining ABI severity often guides medical management and prognosis for recovery. Table 2.3 demonstrates the accepted classification system and for this thesis people with moderate to severe brain injuries will be considered.

Table 2.3 Classification of brain injury severity according to Glasgow Coma Scale score

Severity category	Initial Glasgow Coma scale
Mild	12-15
Moderate	9-11
Severe	3-8

(Fary et al., 2003)

2.2 Impairments following an ABI

An ABI may result in injury to a range of structures and systems within the brain potentially affecting cognition, communication, behaviour and neuro-motor abilities (Mazaux et al.,

1997). The manner and severity of the brain injury is a key determinant of the level of severity of the resulting disability. Other factors, such as concomitant injuries, associated medical issues, social and personal factors can also influence the resulting disability. Brain function is critical for every aspect of a persons' physical, sensory, cognitive, behavioural and social functioning. Measurement of function after brain injury is therefore challenging, due to the varying array and complexity of presentations and continuing problems that may occur following brain injury (Krefting, Warren, & Grace, 1992).

Physical disability is common following ABI with four out of every five people with an ABI presenting with a physical disability (AIHW, 2007). Approximately 42% of people with an ABI experience a psychological disability, 39% a sensory or communication disability and 29% an intellectual disability (AIHW, 2007). The next section will briefly describe the common cognitive, communication and behavioural impairments commonly associated with an ABI. A more detailed description is beyond the scope of this thesis. A detailed description of neuro-motor impairments will then be explained, as these are the focus of the thesis.

2.2.1 Cognitive function

Cognitive function may be affected following an ABI resulting in difficulties with thinking processes - such as attention, problem solving, learning, memory and language. 'Higher level' thinking processes can also be affected and may continue as long-term problems. For example planning, decision making and abstract reasoning skills are higher level thinking processes which may be affected following an ABI, and are likely to affect the ability to manage day-to-day tasks independently (Cicerone et al., 2011; Greenwood, 2003; Kennedy et al., 2008). Cognition has also been associated with level of functioning throughout the rehabilitation process (Neese et al., 2000) and correlates strongly with other measures of function following rehabilitation (Cullen & Weisz, 2011; Hanks et al., 2008).

2.2.2 Communication

Communication impairments are common following an ABI and include difficulties with word finding (dysphasia) (Olver, Ponsford, & Curran, 1996), muscle control (dysarthria) (Goozee, Murdoch, Theodoros, & Stokes, 2000), muscle co-ordination (dyspraxia) (Jaeger, Hertrich, Stattrop, Schönle, & Ackermann, 2000) as well as difficulties with non-verbal and pragmatic or social communication (Snow, Douglas, & Ponsford, 1997). Social communication difficulties may present as difficulty initiating conversation, getting stuck on a topic (perseveration) and going off the topic without finishing the idea (tangential thinking). Other problems may include: poor eye contact, an inability to take turns, interrupting others and talking too much (Angeleri et al., 2008; Bosco, Parola, Sacco, Zettin, & Angeleri, 2017; Douglas, 2010; Greenwood, 2003). The persistent nature of these communication difficulties have been reported previously (Snow et al., 1997) and represent a long term disability for people following ABI (Ponsford et al., 2014).

2.2.3 Behaviour

An ABI often results in a multitude of changes that affect behaviour, often resulting in increased irritability and decreased anger control (Kim, Manes, Kosier, Baruah, & R0binson, 1999), changes in sleep patterns (Zuzuárregui, Bickart, & Kutscher, 2018), reduced self-control, reduced insight and increased fatigue and tiredness (Olver et al., 1996; Zinno & Ponsford, 2006). Following an ABI, people can be easily distracted and may be resistant to assistance from carers or support staff (Lance, 1976; Rosenthal, Griffith, Bond, & Miller, 1990; Tateno, Jorge, & Robinson, 2003).

2.3 Neuro-motor impairments

Neuro-motor impairments following ABI can be varied, since the area of damage post-injury can be dispersed throughout many areas of the central nervous system (Teasdale & Jennet,

1974). For the studies in this research program, neuro-motor impairments range from paralysis of individual muscles to generalised difficulties in planning and co-ordinating complex movements.

The observed functional disabilities, as a result of neuro-motor impairments may be related to movement with muscle changes of strength and length, tonus disorder (spasticity) and co-ordination impairments resulting in and contributing to disorganisation of motor control and a decrease in postural control (Teasdale & Jennet, 1974). These neuro-motor impairments form a major part of the construct that underpins this research program and will be discussed further. All parts of the brain participate directly and indirectly in the control of purposeful movement and therefore people with ABI may present with specific motor impairments as outlined below but are very likely to present with multiple impairments.

2.3.1 Muscle strength

Muscle strength is defined as the observable attempt of an individual to produce a voluntary action or movement (Schmidt & Wrisberg, 2000). In the severe ABI population, this active or spontaneous movement is not always present, or the movement observed may not be purposeful or functional. In fact, functional motor activities such as wheelchair mobility, transfers, walking and upper limb fine motor skills, while important, are activities that most people with severe ABI are not capable of performing in the earliest stage of recovery. Reduced muscle strength may be due to multiple factors including as a direct result of the brain injury itself causing reduced muscle activation or as a secondary consequence such as disuse, particularly if the person has had a prolonged hospital length of stay (Bloomfield, 1997; Ferrando, Lane, Stuart, Davis-Street, & Wolfe, 1996) .

2.3.2 Contracture

Muscle length and connective tissue properties may change following ABI due to adaptive changes as a result of reduced muscle strength or the immobilisation of a muscle or joint in a shortened position (Marshall et al., 2007; Rosenthal et al., 1990). Muscles may alter their characteristic properties with changes in motor unit recruitment and changes in muscle length-tension relationships (Thompson, 1996) as a result of decreased movement (Bloomfield, 1997; Dos Santos et al., 2016). Normal neuro-motor performance is not possible when muscles are shortened as the adaptation can have an adverse effect on force generation and control of the biomechanical relationships between body segments (Thompson, 1996; Umphred, 2007).

2.3.3 Muscle tone

Tone is the resistance felt when a muscle is passively stretched or lengthened (Rosenthal et al., 1990). Many therapists hold the view that altered muscle tone underlies or accentuates other motor impairments (Anderson, Bhimani, Henly, & Stoddard, 2011; Bobath, 1990). Abnormal muscle tone can take on two forms: hypotonic or reduced tone (i.e. no resistance to movement) and hypertonic referring to increased muscle tone (Rosenthal et al., 1990).

The most common presentation of increased muscle tone observed in people following a severe ABI is spasticity. Spasticity is defined as an "increase in the velocity-dependent stiffness of a muscle" (Lance, 1976) and collectively refers to a host of neuro-motor over activity syndromes stemming from upper motor neuron damage (Crooks, Zumsteg, & Bell, 2007). For people with more severe acquired brain injuries, altered tone tends to develop earlier and more aggressively. Additionally, similar presentations are associated with hypoxic ischemic brain injury and autonomic dysfunction commonly associated with severe brain injuries (Zafonte, Elovic, & Lombard, 2004). Spasticity has been suggested to occur in up to

50% of people with TBI (Synnot et al., 2017) though this is difficult to determine due to inconsistencies in defining and measuring spasticity. Spasticity can influence movement performance and contribute to contracture, reduced range of motion and joint stiffness (Ada, O'Dwyer, & O'Neill, 2006).

2.3.4 Co-ordination of muscle activity

Reduced co-ordination is commonly referred to as the inability to selectively isolate and coordinate muscle activity when performing a movement (Allison, 1999; Canning, Ada, Adams, & O'Dwyer, 2004; Freund & Stetts, 2013). Neuro-motor function is reliant on coordination of movement or dexterity as well as muscle strength. It can however be challenging to assess movement coordination in muscles with limited strength. Movement coordination or dexterity has been shown to significantly contribute to neuro-motor function in people with stroke (Allison, 1999; Canning et al., 2004; Freund & Stetts, 2013).

In people with reduced coordination, there is an inability to selectivity recruit and combine muscle activity to move according to the environmental and task demands and may present as clumsiness. In people with severe brain injuries this can present with abnormal limb positioning, difficulties achieving balance and decreased control as the body changes positions (Rosenthal et al., 1990).

2.3.5 Postural alignment

Sensory disturbances interrupting feedback and feed forward mechanisms may also be apparent following ABI. Injury to the cervical afferents may affect the cervical-ocular reflexes, effecting the ability to signal normal alignment of the head over the trunk, or the ability to move the head to permit visual orientation to the environment (Allison, 1999). This somatosensory impairment reduces the ability to perceive the location of body segments in relation to each other (alignment) and the location of the body in relation to the base of

support (balance) (Young & Young, 1997). The trauma involved may also impair input from visual and vestibular afferents and their transmission into the central nervous system which may also contribute to the reduced ability to align to the vertical (Herdman, 2014).

The motor cortex is thought to contain two distinct systems for motor control; one for small precise movements particularly involving distal musculature and a second for postural stabilization and control (Rossi, Triggs, & Eisenschenk, 1999). This latter system contributes to the ability to use muscle activity to maintain body position in space and has implications when damaged for the awareness of body position, response of the body to gravity and response of the body to positional changes following an ABI.

These impairments may act collectively and result in poor alignment of the head, trunk and limbs as well as interfere with motor control during the performance of motor tasks. During the acute stage of recovery following an ABI, it is therefore important to be able to assess and monitor the effect of these impairments on alignment and movement.

2.3.6 Summary

A range of deficits and in particularly neuro-motor impairments are observed in people following moderate to severe ABI. Several assessment measures available for use following ABI monitor the severity of the injury by measuring the level of consciousness and physical recovery of the individual. A review of the assessment measures commonly used to assess consciousness and injury severity is provided in the next section. Additionally, tools to assess neuro-motor recovery will be explored for their capacity to monitor the specific impairments in neuro-motor control that occur during the early stages following severe ABI.

2.4 Physiotherapy management of people following ABI

Physiotherapy following ABI aims to provide high quality patient centred clinical services to empower people with ABI to achieve their maximum potential and quality of life. Physiotherapists provide treatment to manage the patient's physical impairments and activity limitations resulting from the ABI, associated injuries (e.g. orthopaedic problems such as fractures or ligament damage) and those limitations resulting from long periods of inactivity or rest (Hellweg & Johannes, 2008; Synnot et al., 2017). Such impairments and activity limitations can relate to posture, balance, coordination, strength, endurance, and body sensation and perception (e.g., inability to determine the location, nature, or intensity of a stimulus applied to the body)(Allison, 1999).

Evidence supports the effectiveness of physiotherapy management with people following an ABI to improve the quality of movement, posture and balance (Tolfts & Stiller, 1997). Treatment may include:

- Management of abnormal movement patterns (Tolfts & Stiller, 1997).
- Maintenance of range of motion through positioning, passive stretches and movement facilitation, splinting and serial casting (Mortenson & Eng, 2003).
- Ensuring that limbs are positioned to prevent damage to joints & soft tissue
- Retraining balance and dynamic skills (Allison, 1999).
- Management of visual and vestibular problems (Herdman, 2014).
- Retraining quality movement in standing and sitting
- Gait retraining and progression of mobility (Eng, Rowe, & McLaren, 2002)
- Patient and relative/carer education of their condition (Dismuke, Walker, & Egede, 2015)
- Training in safe transfer techniques (French et al., 2010).

2.5 Assessment of consciousness and injury severity

In the acute care phase following severe ABI few scales are available to measure neuro-motor impairments. The most commonly used scales with people following ABI predominately measure impairments such as consciousness, cognitive function, behaviour, social participation, and functional limitations; as acknowledged by the brain injury specific outcome measure database (Wright et al., 2000). Outcome measures commonly used in the acute care phase of recovery for people with ABI include the Glasgow Coma Scale (McNett, 2007), the Coma Recovery Scale (O'Dell et al., 1996), the Full Outline of Unresponsiveness (Fischer et al., 2010), Post Traumatic Amnesia scale (Marosszeky, Ryan, Shores, Batchelor, & Marosszeky, 1998) and the Ranchos Los Amigos Scale. These will be briefly outlined below.

2.5.1 Glasgow Coma Scale

The Glasgow Coma Scale (GCS) (McNett, 2007; Teasdale & Jennet, 1974) is a standardised system widely used for people with altered consciousness. The GCS is used in the early stages of recovery following ABI to measure responsiveness by evaluating a person's verbal, eye opening and motor response. Scores range from 3 to 15, with low scores indicating a lower level of responsiveness. The GCS can also be used to assess the degree of brain injury. Scores between 3 and 8 indicate a severe ABI; while scores between 9 and 13 indicate a moderate ABI; and mild ABI is attributed to GCS scores of 14 and 15 (Teasdale & Jennet, 1974).

Furthermore, the GCS is considered by medical specialists to be the most important factor influencing the decision to intubate a patient, choice of sedation and outcome prediction (Chieregato et al., 2010). The GCS however, does not address specific physical functional changes that are of primary interest in physiotherapy, such as motor performance, muscle

tone and head and trunk alignment (Chieregato et al., 2010; McNett, 2007). The GCS provides information about a person's state of arousal following a coma, not their physical function.

An extension of this measure, the Glasgow Outcome Scale and Glasgow Outcome Scale extended examine how the brain injury affects function and social outcome (Teasdale, Pettigrew, Wilson, Murray, & Jennett, 1998). These tools however are not intended to provide details regarding specific impairments that present after ABI (Weir et al., 2012; Wilson, Pettigrew, & Teasdale, 1998). Traditionally, this scale is scored following a short unstructured interview with questions reviewing independence both at home, and outside the home including work or employment status. The Glasgow Outcome Scale is primarily used to group people following an ABI according to broad disability and handicap outcome categories (Wilson et al., 1998). The four categories are vegetative state, severe disability, moderate disability and good recovery (Jennett, Snoek, Bond, & Brooks, 1981).

2.5.2 Full Outline of Unresponsiveness scale

A more recent scale, the Full Outline of Unresponsiveness (FOUR) scale (Fischer et al., 2010), was developed to address limitations with the GCS including use on people unable to make a verbal response, inconsistent inter-tester reliability (Gill, Martens, Lynch, Salih, & Green, 2007) and inability to assess brainstem reflexes. The FOUR has been shown to provide more detailed information regarding neurological function than the GCS in people with low levels of responsiveness and is considered to be superior to the GCS (Gorji, Gorji, & Hosseini, 2015; Stead et al., 2009; Wijdicks, Bamlet, Maramattom, Manno, & McClelland, 2005).

This scale consists of four items. The first two, eye response and motor response have been drawn from the GCS. Brainstem reflexes and respiration pattern are additional items included

in the FOUR. Each item is scored on a five-point scale, from 0 to 4, with low scores indicating a worse response. Scoring is similar to the GCS for the first two items (eye response, motor response) and scoring for brainstem reflexes is as follows (Fischer et al., 2010):

4 = pupil and corneal reflexes present

3 = one pupil wide and fixed

2 = pupil or corneal reflexes absent

1 = pupil and corneal reflexes absent

0 = absent pupil, corneal, and cough reflex

The FOUR score does not include a verbal response. Respiration pattern replaces the verbal response item included in the GCS and is scored (Fischer et al., 2010) as follows:

4 = not intubated, regular breathing pattern

3 = not intubated, Cheyne-Stokes breathing pattern

2 = not intubated, irregular breathing

1 = breathes above ventilator rate

0 = breathes at ventilator rate or apnoea

The FOUR scale, however, is not specific to physiotherapy and monitors aspects of a person's consciousness that are more basic than the physical and functional neuro-motor changes required to be assessed by a physiotherapist in the acute stage of recovery following an ABI.

2.5.3 Post Traumatic Amnesia scale

Classifying severity of brain injury in the initial period of recovery is generally defined by the GCS; however in the longer term severity is often measured using the Post Traumatic

Amnesia (PTA) scale (Shores, Marosszeky, Sandanam, & Batchelor, 1986; Zafonte et al., 2004). Post-traumatic amnesia refers to the period following ABI during which continuous memories are unable to be established (Marosszeky et al., 1998).

The PTA scale consists of 12 questions presented to the individual daily assessing orientation to name, place and time as well as short and long-term memory. Table 2.4 outlines the relationship between PTA score duration and severity of brain injury. PTA is a timed measure, recorded in days from the initial injury until the 12 questions are answered correctly for three consecutive days. If PTA is experienced for longer than 6 months, people are deemed to have ongoing memory problems. Like the GCS and FOUR, the PTA scale although widely used in assessing severity, gives no direction to neuro-motor impairments.

Table 2.4. Severity classification due to post-traumatic amnesia (PTA)

Severity classification	**Duration of post traumatic amnesia**
Very mild	Less than 5 minutes
Mild	5 to 60 minutes
Moderate	1 to 24 hours
Severe	1 to 7 days
Very severe	1 to 4 weeks
Extremely severe	More than 4 weeks
Ongoing memory problems	More than 6 months

(Marosszeky et al., 1998)

2.5.4 Ranchos Los Amigos

The Ranchos Los Amigos Levels of cognitive functioning scale was developed as a global index to describe awareness, behavioural competence and environmental interaction (Timmons, Gasquoine, & Scibak, 1987; Zafonte et al., 1996). It provides a description of behaviour and monitors recovery through eight stages of cognitive dysfunction (Hagen, 2001) and is designed for use throughout the initial recovery period following an ABI. The Ranchos Los Amigos scale comprises eight levels; level 1 represents the lowest level of function where a person demonstrates no response to external stimuli. As cognitive and behavioural performance improves individuals are scored higher on the scale. The original scale was modified to be suitable for use with people with higher levels of recovery following ABI.

All the scales included in this section, common measures of consciousness and indicators of injury severity, provide little or no measure of neuro- motor impairments.

2.6 Assessment of neuro-motor impairments

Physiotherapists are primarily interested in neuro-motor impairments following an ABI. A number of outcome measures are available for use by physiotherapists working with people following an ABI such as the Clinical Outcomes Variable Scale (COVS) (Seaby & Torrance, 1989), Motor Assessment Scale (MAS) (Carr, Shepherd, & Nordholm, 1985), Functional Independence Measure (FIM) (Kidd et al., 1996) and Disability Rating Scale (DRS) (Neese et al., 2000). These outcome measures assess functional motor skills such as bed mobility, transfers, wheelchair mobility, walking and upper limb function including fine motor skills. However, the activities included in these tools are too advanced for most people with a severe ABI and cannot be attempted in the earliest stage of recovery (Pilon et al., 1995).

Measures such as the Berg Balance Scale (Berg, 1987; Berg, Wood-Dauphinee, Williams, & Maki, 1992; Blum & Korner-Bitensky, 2008) and Community Balance and Mobility Scale

would be considered to be more suitable for people with balance and mobility difficulties (Inness et al., 2011); common activity limitations associated with people with an ABI. However, the specific investigation of balance limitations and tools associated with the measure of balance limitations in people with an ABI is not the focus of this thesis.

Whilst valid and reliable for the assessment of neuro-motor function, it will become clear that commonly used scales such as those identified are more applicable for people with mild to moderate brain injuries. They are best suited to when the person has sufficiently progressed and is able to take part in the successive stages of rehabilitation required by most people following a severe ABI**.**

2.6.1 Clinical Outcomes Variable Scale

The COVS (Seaby & Torrance, 1989) comprises 13 motor tasks commonly retrained by physiotherapists including rolling from side to side in bed, moving from supine to sitting over the edge of the bed, sitting balance, standing up, walking, transferring to and from the bed and floor surfaces as well as wheelchair skills. Each motor task is scored from 1 to 7 with higher scores reflecting more independence and total scores ranging from 13 to 91.
The COVS has established psychometric properties in a range of populations requiring rehabilitation including people with stroke and spinal cord injury (Barker, Amsters, Kendall, Pershouse, & Haines, 2007; Salter, Teasell, Foley, & Jutai, 2007). In people with ABI, the COVS has demonstrated high to very high inter-tester and intra-tester reliability across a range of severity levels (Low Choy, Kuys, Richards, & Isles, 2002).

2.6.2 Motor Assessment Scale

The MAS was developed to measure functional movement recovery in people following stroke (Carr, Shepherd, & Nordholm, 1985; Dean & Mackay, 1992; Shukla et al., 2011). The MAS comprises eight motor tasks including supine to side lying, supine to sitting, balanced

sitting, sit to stand, walking, upper arm function, hand movements and advanced hand activities. Motor tasks are scored on a seven-point rating scale, from 0 to 6. Higher scores indicate better function such as a greater level of independence, better quality of movement or being able to complete more complex tasks.

The MAS has high concurrent validity and high inter-tester reliability (Carr, Shepherd, & Nordholm, 1985; Loewen & Anderson, 1988; Poole & Whitney, 1988). Additionally, the MAS is effective in measuring functional movement recovery and is sensitive to change in people following stroke (English, Hillier, Stiller, & Warden-Flood, 2006; Loewen & Anderson, 1990) and able to predict a discharge destination of home (Brauer, Bew, Kuys, Lynch, & Morrison, 2008). No studies were found that specifically investigated the MAS in people following ABI.

2.6.3 Functional Independence Measure

The FIM (Hall & Johnstone, 1994) is one of the most widely used measures of activities of daily living, during inpatient rehabilitation. Certainly, this is the case for studies investigating people with brain injury with 50% of all studies identified in a systematic review conducted in 2012 using this measure (Laxe et al., 2012). The FIM comprises 18 items each measuring a range of activities of daily living including self-care, bladder and bowel function, transfers, mobility, communication, and social cognition. Items are scored on a seven-point scale with a minimum score of 1 indicating complete assistance required and a maximum score of 7 indicating complete independence. Items can be grouped to form two domains with one reflective of motor function (FIM-Motor, 13 items, total score 91) and the second reflective of cognitive function (FIM-Cognitive, 5 items, total score 35). Combining domains to form the total score; scores range from 18 (complete dependence) to 126 (complete independence) (Linacre, Heinemann, Wright, Granger, & Hamilton, 1994).

The FIM has been shown to have sound psychometric properties as demonstrated by a systematic review conducted in 2013 (Turner-Stokes & Siegert, 2013). The FIM was developed for use during inpatient rehabilitation to quantify the level of disability (Linacre et al., 1994) and help inform the need for care services. The FIM does not measure activity or participation components important for determining burden of an injury or illness following initial rehabilitation completion. Additionally, the FIM has been identified as having some limitations for use in brain injured populations such as not including behavioural and psychosocial impairments, but nevertheless is widely used when these constructs are not being assessed (Hall & Johnstone, 1994).

The Functional Assessment Measure has been combined with the FIM to address these limitations and has been tested in the brain injury population (Turner-Stokes, Nyein, Turner-Stokes, & Gatehouse, 1999). The Functional Assessment Measure has established reliability and validity (Donaghy & Wass, 1998) for adults with severe brain injury, but was not collected in the clinical setting for this thesis. The FIM has also been shown to have a ceiling effect with some limitations in assessing change after discharge from rehabilitation (Coster, Haley, & Jette, 2006; Hall et al., 1996) and in assessing day therapy outcomes in people with TBI (Seel, Wright, Wallace, Newman, & Dennis, 2007). As the focus of this thesis is the neuro-motor impairments of people in the acute stage of recovery following ABI, the FIM will be used as an outcome measure.

2.6.4 Disability Rating Scale

The DRS was initially developed to assess people with an ABI in the rehabilitation phase of recovery. The scale comprises eight items which are grouped into four categories (Neese et al., 2000). Items include eye opening, communication ability, motor response, feeding, toileting, grooming, level of functioning and employability (Shukla et al., 2011). The four resulting categories are: awareness and responsiveness, cognitive ability for self-care

activities, dependence on others, and psychosocial adaptability (Rappaport, 2005). The scale is scored from 0 to 29 with 0 indicating no disability and the maximum score of 29 representing a profound disabled state.

The DRS has been found to have good inter-rater reliability (Neese et al., 2000) and validity against other ABI specific disability and physiological scales (Hall & Johnstone, 1994). Additionally, the DRS has been shown to have predictive validity, both for acute hospital length of stay and discharge functional state (Eliason & Topp, 1984; Gouvier, Blanton, LaPorte, & Nepomuceno, 1987). Furthermore, the DRS has been shown to be able to differentiate between people who received rehabilitation interventions and those who did not (Fryer & Haffey, 1987).

The DRS appears to be a popular outcome measure for use with people with an ABI, with good psychometric properties including sensitivity, reliability and ease of administration (either self-administered or via an interview of the person or care-giver) (Shukla et al., 2011). However, DRS is not well suited to people with very severe impairments (Hall, Hamilton, Gordon, & Zasler, 1993; Hall et al., 1996) assessing only general functional change (Hall & Johnstone, 1994).

2.6.5 Summary

The outcome measures reviewed in this section assess consciousness, injury severity and/or certain stages of neuro-motor recovery. None of the measures effectively capture changes in physical function and neuro-motor impairments that occur in the acute stage of recovery following ABI (Canedo et al., 2002; O'Dell et al., 1996; Pape et al., 2006; Teasdale & Jennet, 1974).

The International Classification of Functioning, Disability and Health (ICF) (Koskinen et al., 2011; Mittrach et al., 2008) provides a universal reference framework that can be used to classify outcome measures as:

- Focusing on impairments of neurological or cognitive functions,
- Focusing on activity limitations or
- Focusing on participation in society

Table 2.5 outlines the outcome measures commonly used in assessment of people with ABI and relevant ICF construct.

The availability of an outcome measure that can monitor incremental changes in neuro-motor impairments more effectively than functional motor scales and holds associations with long term outcome and care burden would be particularly helpful to clinical practice. Prognostic studies are crucial as important information can be provided to clinicians to guide resource use and clinical decision making including choice of appropriate treatment strategies as well as inform service delivery options such as rehabilitation intervention programs (Altman, 2001).

Table 2.5 Presents the outcome measures discussed in this thesis classified according to ICF category and the construct /items each outcome measures evaluates

Outcome measures in TBI recovery	ICF category	Construct / items
Berg balance Scale (Berg, 1987; Berg et al., 1992; Blum & Korner-Bitensky, 2008).	Activity limitations Participation	Balance and mobility difficulties
Clinical Outcomes Variable Scale (Seaby & Torrance, 1989).	Activity limitations	Functional movement recovery- predominantly motor tasks
Coma Recovery Scale-Revised (O'Dell et al., 1996).	Impairments	Auditory, visual, motor, oral motor, communication and arousal functions
Community Balance and Mobility Scale (Inness et al., 2011).	Activity limitations Participation	Balance and mobility difficulties
Disability Reliability Scale (Neese et al., 2000).	Impairments Activity limitations	Awareness and responsiveness, cognitive ability for self-care activities, dependence on others, and psychosocial adaptability
Functional Independence Measure (Kidd et al., 1996).	Activity limitations Participation	Activities of daily living in two domains – motor function and cognitive function
Functional Assessment Measure (Donaghy & Wass, 1998).	Activity limitations Participation	Extension of FIM including behavioural and psychosocial impairments
Full Outline of Unresponsiveness (Fischer et al.,	Impairment	Level of Responsiveness /Consciousness

Outcome measures in TBI recovery	ICF category	Construct / items
2010).		
Glasgow Coma Scale (McNett, 2007; Teasdale & Jennet, 1974).	Impairment	Level of Responsiveness /Consciousness
Glasgow Outcome Scale (Teasdale et al., 1998).	Activity limitations Participation	Function and social outcome
Motor Assessment Scale (Carr, Shepherd, & Nordholm, 1985).	Activity limitations	Functional movement recovery- predominantly motor tasks
Post-traumatic amnesia (Marosszeky et al., 1998).	Impairment	Cognition / Classification of severity
Ranchos Los Amigos Scale (Timmons et al., 1987).	Impairment	Behaviour and cognitive dysfunction

The lack of a suitable outcome measure for physiotherapists to assess and monitor early neuro-motor impairments following moderate to severe ABI impacts on clinicians' ability to objectively assess the effectiveness of interventions, convey changes in a people's condition with other team members and advocate for a people to have an opportunity for further rehabilitation rather than be discharged into long-term care. Such a tool would ideally also have some association with acute care length of stay, discharge destination and long-term neuro-motor recovery. It may also be reasonable to suggest that such a tool may demonstrate better usefulness in the early stages of recovery following a moderate or severe ABI compared to other measures commonly used in this population. Lack of such a measure presents a significant barrier to the advancement of research and evidence-based practice in the early stages of rehabilitation for this complex and challenging clinical population.

To address this deficit in the literature, a series of studies were proposed. This thesis will present the development of a new assessment measure – the Acute Brain Injury Physiotherapy Assessment (ABIPA). The studies included in this thesis outline the selection of items for inclusion in the measure, investigate selected psychometric properties and investigate the relationship of the ABIPA score to functional long-term outcomes of people who have sustained a moderate to severe ABI. The next section of this chapter will outline considerations required when developing a new outcome measure.

2.7 Outcome measure development

One of first choices clinicians will make if interested in documenting patient progress is determining which measuring instrument or outcome measure to use (Portney & Watkins, 2000). For some patient presentations there is a clearly defined or commonly used assessment scale – for others the answer is not as simple. When unable to find a suitable outcome measure for a specific purpose, in this case, to measure the neuro-motor changes

observed by physiotherapists in the early stages of recovery following a moderate to severe ABI, the development of a new measure may be indicated.

Current evidence can direct the requirements when developing new outcome measure. This section will review the requirements and the procedure for the development of a new outcome measure and the following chapter (Chapter 3) will describe how the requirements were applied to the development of the ABIPA.

2.7.1 A new outcome measure

Development of a new outcome measure generally arises from an unanswered clinical question or an inability to find in the literature a scale to measure a specific presentation. In choosing an outcome measure, the most important consideration is the research question of interest (Tilley, 2012). For the purposes of this research program, the research question being posed is *Can neuro-motor impairments in the acute stages following a severe ABI be measured?* There is limited vigorous research evaluating rehabilitation interventions in the ABI population (New Zealand Guidelines Group, 2007; Teasell et al., 2007) and there is limited information to evaluate the impact of diverse types of acute care treatment on prognosis (New Zealand Guidelines Group, 2007; Teasell et al., 2007). The outcome measures reviewed earlier in this chapter (Sections 2.4 and 2.5) fail to capture the specific incremental neuro-motor changes in the acute stage of recovery significant to physiotherapy management following moderate to severe ABI (Canedo et al., 2002; O'Dell et al., 1996; Pape et al., 2006; Teasdale & Jennet, 1974).

In this population, physiotherapy management includes assessment of tone, spontaneous and voluntary movements, postural status or equilibrium reactions, passive range of motion and reflexes and ability to sit and transfer (Herdman, 2014; New Zealand Guidelines Group, 2007; Teasdale & Jennet, 1974). The significance of each item to recovery following severe

ABI is discussed further in Chapter 4 (Charness, 1986; Duncan, 1990; Laxe et al., 2012; Mayo, Sullivan, & Swaine, 1991; Pilon et al., 1995; Swaine, Sullivan, & Sicotte, 1994; Walker & Pickett, 2007).

One of the requirements for a new assessment measure is that it needs to be evidence based (Holmbeck & Devine, 2009). That is, all steps involved in the development and testing of a new outcome measure need to be informed by evidence and be investigated as rigorously as possible. Holmbeck & Devine (2009) developed a checklist of criteria when developing new measures; including establishing a scientific need of the measure. Additionally, an assessment measure should demonstrate content validity specific for the construct, context and purpose of the measure, and provide validity above and beyond other similar measures (Holmbeck & Devine, 2009).

As early as 1954, Meehl argued that at least three steps are required when determining the construct validity of a measure (Meehl, 1954). The first step involves conceptualisation of the theoretical construct to be measured including any interrelated theoretical concepts. The second step involves the development of techniques or items to measure the identified theoretical constructs with the third and last step involving evaluating the techniques or items across a range of applications in the desired context (Meehl, 1954).

More recently a consensus checklist of criteria for evaluating the methodological quality of studies investigating psychometric properties of health measures was developed; the COnsensus-based Standards for the selection of health Measurement INstruments or COSMIN (Mokkink et al., 2006).

In addition to construct validity the COSMIN checklist states a well-established outcome measure will have many of the following psychometric properties: (a) internal consistency, (b) reliability, (c) content validity (including face validity), (d) criterion-related validity, (e)

responsiveness (f) interpretability / clinical relevance (Mokkink et al., 2012). When considering all these points an outline for outcome measure development emerges.

2.7.2 Conceptualisation

As part of the initial steps of outcome measure development it is important to clearly understand the specific construct and theoretical context that is being targeted (Mokkink et al., 2012). Known as conceptualisation this clearly defines what the outcome measure will and will not assess. Recovery from ABI is multifaceted and there is no limit to the number of constructs that could be represented in a new outcome measure. For example, the new outcome measure may be aiming to assess memory loss, cognition changes, behaviour changes, neuro-motor changes or any combination of these constructs. Outcome measures can also be developed at all levels of the recovery continuum, from acute to rehabilitation, discharge and community integration. A vital issue to be determined in the initial developmental stage of an assessment measure is the scope or range of the target construct. In the development of the ABIPA, the construct or what was to be measured was clearly defined as acute recovery of neuro-motor impairments following an ABI.

Once the construct is defined, it is then important to develop the assessment items that will underpin the outcome measure. It is recommended that the available literature is consulted when choosing which assessment items to include in the measure, sampling all content that is relevant to the target construct (Clark & Watson, 1995; Comrey, 1988; Kline, 1986). Item identification and selection are expanded in Section 3.4.1.1.

2.7.3 Psychometric properties

Once an outcome measure is established it is important to investigate the psychometric properties to help guide ongoing development of the outcome measure. Responsiveness,

validity and reliability are considered important characteristics of a well-established outcome measure.

2.7.3.1 Responsiveness

Following conceptualisation and development of the initial assessment format it is necessary to determine responsiveness. The responsiveness of an assessment tool refers to the ability of the assessment to detect variation over time in the chosen construct (Mokkink et al., 2012). In other words, does the score change in proportion to the change in a persons' status and remain stable if the person is unchanged (Portney & Watkins, 2000).

2.7.3.2 Validity

Validity refers to the degree to which an outcome measure evaluates what it is intended to evaluate (Portney & Watkins, 2000) and may also compare the relationships between the new measure and established measures. Construct, content and criterion validity offer the background behind the decisions of item inclusion and can examine the degree to which the outcome measure is evaluating the chosen construct. Construct validity is "the degree to which a test measures what it claims to be measuring." Researchers generally establish the construct validity of a measure by correlating it with a number of other measures and argue from the pattern of correlations that the measures are associated in theoretically predictable ways (Clark & Watson, 1995). Content validity refers to the extent to which a measure represents all facets of a given construct and finally two types of criterion validity are available, concurrent validity and predictive validity. Criterion validity is generally accepted as the extent to which a measure is related to an outcome (Portney & Watkins, 2000).

Another common approach to construct validation is a factor analysis (Portney & Watkins, 2000). A crucial role in assessing the validity of outcome measures is achieved with a factor analysis (Clark & Watson, 1995). Construct validity cannot however be inferred from a

single set of observations, whether these measure factor structure, correlations with other measures, differentiation between selected groups, or hypothesized changes over time. A series of examinations are required to begin the process of identifying the construct that underlies a measure (Clark & Watson, 1995). As the scale development process unfolds each of these will be discussed throughout the proceeding chapters.

2.7.3.3 Reliability

Reliability of an outcome measure specifies the error that may exist and the degree to which the measurement is free of random chance (McDowell, 2006), or the extent to which a measurement is consistent with repeated applications (Portney & Watkins, 2000). If similar results are produced under uniform conditions, a measure is said to have high reliability. Scores that are highly reliable are accurate, reproducible, and consistent from one testing session to another (Mokkink et al., 2012). Reliability of a measure can be determined via inter-tester and intra-tester reliability and internal consistency (Portney & Watkins, 2000).

2.7.3.4 Interpretability / clinical relevance

Interpretability is not considered a psychometric property, but it is an important requirement for the suitability of an instrument in research or clinical practice and is included in the COSMIN checklist (Mokkink et al., 2012). Interpretability is the degree to which qualitative meaning can be assigned to the measure - that is, the clinical interpretation and application of the measure's raw scores or change scores. Clinical relevance is independent from the statistical significance of a measure and can be influenced by multiple factors including the population, clinicians' knowledge, and resources available.

Regarded as important criteria for the development of a new outcome measure each of the psychometric properties and the statistical tests chosen are expanded further in the following chapter.

Chapter 3

Methods

Health care management requires the ability to assess the efficacy of therapeutic interventions, to monitor the achievement of goals and/or inform adjustments to individual programmes (New Zealand Guidelines Group, 2007; Teasell et al., 2007; G. Zitnay et al., 2008). This is commonly achieved by using outcome measures. Current evidence can direct towards the accepted criteria required when considering the development of a new assessment measure. This methods chapter will outline how the accepted criteria for development of a valid and reliable outcome measure informed the program of research of four studies included in this thesis. Key elements of study methodology including design, participant recruitment and selection criteria, procedures and data analysis for each study will be presented. Additionally, ethical considerations pertaining to the participant group being studied, those with moderate to severe ABI will also be discussed.

3.1 Design

Study 1 was undertaken in two parts. Initially a systematic approach to a literature review was undertaken to confirm the absence of an outcome measure to assess the early neuro-motor impairments in the ABI population. This review also identified items for consideration when measuring incremental changes in neuro-motor impairments associated with the early recovery of people following moderate to severe ABI. The findings of the literature review were explored using an expert panel to select the items for inclusion in the ABIPA. The second part of Study 1was a prospective cohort study of a sample of convenience of people admitted to the neurosurgical unit at Princess Alexandra Hospital, Brisbane. The second part of Study1 investigated the responsiveness of the newly formed ABIPA to changes in the acute stages of recovery following ABI and its concurrent validity to other assessment tools validated for use with this population.

Study 2 was an observational study using video recorded assessments of patient presentations to determine inter- and intra-tester reliability of physiotherapists using the ABIPA. Study 3 involved a secondary analysis using an exploratory maximum likelihood factor analysis to establish the factorial structure of the ABIPA. In Study 4, a prospective longitudinal follow up design was used to investigate the association of the ABIPA outcome measure with long term recovery and carer burden.

3.2 Participants

Two participant groups were recruited for the studies in this thesis; people with an ABI participated in all four studies, while physiotherapists working with people with ABI were only involved in the first two studies.

3.2.1 People with an ABI

All studies in this research program involved people who had recently been diagnosed with either a moderate (GCS 9-12) or severe (GCS 3-8) ABI. A convenience sample was recruited of people admitted to either the acute neurosurgical ward or brain injury rehabilitation unit of a tertiary public hospital in Brisbane, Queensland, Australia. The setting will be described in further detail in Section 3.3. Inclusion and exclusion criteria for participants were consistent for the four studies comprising this research program.

To be eligible for inclusion people admitted to acute hospital care needed to:

- be diagnosed with a moderate (GCS 9-12) or severe (GCS 3-8) ABI or a grade four or five subarachnoid haemorrhage;
- be medically stable (i.e. had been discharged from intensive care);
- be aged between 16 and 60 years;
- have no major musculoskeletal or orthopaedic disorders either pre-existing or because of their injury that influenced neuro-motor recovery (e.g. amputation or fracture); and
- have no previous neurological conditions (e.g. stroke or Parkinson disease) that may impact on neuro-motor recovery

People with an ABI were excluded if they were:

- not medically stable;
- scored more than 12 on the GCS; or
- awaiting clipping of an aneurysm

3.2.2 Physiotherapists

Physiotherapists were participants in the first two studies of this program of research. An expert panel of experienced physiotherapists working in the field of neurological rehabilitation with between 10 and 20 years' experience in ABI, were recruited to Study 1. This panel, through consensus, and a literature frequency analysis informed ABIPA item selection and established content validity of the included items. Additionally, the expert panel developed detailed assessment guidelines to conduct and score the ABIPA.

In Study 2, two groups of physiotherapists working in the field of neurological rehabilitation were required. Physiotherapists were recruited as samples of convenience and were eligible to participate if they worked in the acute neurosurgical unit, brain injury rehabilitation unit or rehabilitation unit at the same tertiary referral public facility.

The first group of physiotherapists underwent training with the ABIPA guidelines while the second group received no training. For both groups, demographic details of participating physiotherapists collected included age, gender, years working as a physiotherapist, and time spent working specifically with neurological patients.

3.3 Setting

All studies in this research program were conducted in the one tertiary referral public facility, the Princess Alexandra Hospital, in Brisbane, Queensland, Australia. This hospital is the largest tertiary hospital in Metro South Hospital and Health Service of Queensland Health and provided services to 1.5 million people in 2016 – 2017. Participants for the four studies were recruited from the acute neurosurgical ward and the brain injury rehabilitation unit of this facility.

The acute neurosurgical ward comprises an eight-bed high dependency unit and twenty-eight bed ward that admits both neurosurgical and neurology patient groups. Patients can be referred to the ward from throughout the state of Queensland and northern New South Wales. The ward is serviced by a multidisciplinary team comprising medical consultants, junior and senior house doctors, nursing staff and all allied health disciplines. All patients are referred for physiotherapy and receive care from all health care disciplines as required by clinical presentation. The multidisciplinary team determine the appropriate acute care discharge destination with people generally waiting between 1 to 5 weeks to obtain a bed in the state-wide specialised brain injury unit, co-located at the same facility. At times acute neurosurgical ward patients may return to their referring hospital and health district awaiting a rehabilitation bed in the specialised brain injury unit.

The brain injury rehabilitation unit is a tertiary level state-wide service that operates under the Division of Rehabilitation, Princess Alexandra Hospital within the Metro South Hospital Health Service District of Queensland Health. This unit provides specialised inpatient brain injury rehabilitation health services for Queensland adults aged 16 to 70 years of age with an ABI. The brain injury rehabilitation unit is the only specialised unit for people recovering from an ABI in Queensland and has aproximately160 admissions annually with 50% from traumatic injuries.

The brain injury unit is staffed by a multidisciplinary team specialised in ABI management including physiotherapists, occupational therapists, speech pathologists, social workers, neuropsychologists, pharmacists, podiatrists and medical teams. The aim of the rehabilitation programme is to improve the physical, cognitive and behavioural functioning of patients by promoting increased levels of independence and integration back into the community. Patients are seen by all allied health disciplines five days a week with coverage from physiotherapy on the weekend as required for cardio respiratory interventions. Goal directed

therapy programs typically involve daily sessions between 60 and 90 minutes for physiotherapy.

The multidisciplinary team benchmark for length of stay, functional change, functional outcome and discharge destination with the Australian rehabilitation outcome centre database. The Australian rehabilitation outcome centre national benchmarking system (Simmonds, 2018), produces information on the efficacy of rehabilitation interventions, develops clinical and management information reports, provides education and training and certification in the use of the Functional Independence Measure and other outcome measures, provides annual reports summarising Australasian rehabilitation data and develops research proposals (Simmonds & Stevermuer, 2007).

3.4 Procedure

Detailed descriptions of the procedures associated with each study will be discussed in turn.

3.4.1 Study 1

An initial literature search was undertaken to identify outcome measures used in the ABI population. From this review, commonly used outcome measures were identified and reviewed to determine the ability of these measures to capture the incremental changes in neuro-motor impairments in the acute stage of recovery relevant for physiotherapy management following severe ABI (Canedo et al., 2002; O'Dell et al., 1996; Pape et al., 2006; Teasdale & Jennet, 1974).

Additionally, the brain injury outcome measure database (Wright et al., 2000) was examined. This database is specific to measures used for people with a brain injury and outcome measures typically used during the acute stage of recovery following ABI were highlighted. Documented assessment measures of neuro-motor impairments used specifically by

physiotherapists were also identified and investigated for the potential to assess the desired construct - incremental changes in neuro-motor impairments following an ABI.

3.4.1.1 Item identification and selection

A variety of approaches can be utilised to identify and select items that would underpin a new assessment measure. It is recommended that the available literature is consulted when choosing which assessment items to include in the measure (Clark & Watson, 1995; Comrey, 1988; Kline, 1986) to ensure that all relevant content to the target construct are identified.

A relevant item to be included in a new outcome measure is one that is appropriate to the population for whom the outcome measure is intended (Mokkink et al., 2012); in this case, physiotherapists working with those following moderate to severe ABI. Therefore, for the purposes of this research program, items need to represent relevant impairments that a physiotherapist would measure.

A variety of other methods may be used to develop this initial comprehensive list of items to be considered for inclusion in a new outcome measure. Some studies support the use of an expert consensus panel of experienced clinicians, using surveys or focus groups (De Morton, Davidson, & Keating, 2008; Haines et al., 2007; Tyson et al., 2008; Williams, Robertson, Greenwood, Goldie, & Morris, 2005), while other methods to identify items rely on the literature alone. It is also feasible that item identification may be driven by the lack of a specific item included in other outcome measures. Potential items may also be identified based on the limitations or ceiling effects of other outcome measures (Hall et al., 1996).

Once the potential list of items has been identified there are several approaches available for reaching consensus of the items to be included in a new outcome measure. The aim of a consensus approach is to determine the extent to which experts or lay people agree. Table 3.1 summarises the characteristics of various consensus methods. Three of the most common

methods for reaching consensus being the Delphi method (Dalkey & Helmer, 1963), Nominal group technique (Delbecq & Van de Ven, 1971) and Consensus conferences (Fink, Kosecoff, Chassin, & Brook, 1984; Fretheim, Schünemann, & Oxman, 2006).

Table 3.1 Characteristics of various consensus development methods

Consensus development method	**Mailed questionnaires**	**Private decisions elicited**	**Formal feedback of group choices**	**Face-to-face contact**	**Interaction structured**	**Aggregation method**
Informal	No	No	No	Yes	No	Implicit
Delphi method	Yes	Yes	Yes	No	Yes	Explicit
Nominal group technique	No	Yes	Yes	Yes	Yes	Implicit
RAND version	Yes	Yes	Yes	Yes	Yes	Explicit
Consensus development conference	No	No	No	Yes	No	Implicit
Other methods						
Staticised group	No	Yes	No	No	-	Explicit
Social judgement analysis	No	Yes	Yes	Yes	No	Implicit
Structured discussion	No	No	No	Yes	Yes	Implicit

(Murphy, 1998)

As demonstrated in Table 3.1 the main differences between the various methods is the use of mailed questionnaires, the privacy of the decision process and the presence of any feedback mechanism to the participants. Consensus development conferences are different in that they provided a public forum for discussion of the chosen topic (Fink et al., 1984). For the aggregation method, implicit methods generally are examples of a majority vote whereas the

explicit methods involve statistical analysis to come to a consensus (Murphy, 1998). It is generally agreed that consensus development uses available information, either scientific data or the shared knowledge of the participants, to come to an agreement on the proposed question (Fink et al., 1984; Murphy, 1998).

No one method is supported by the literature over the others, with most new measures employing a combination of the above to generate an initial list or potential list of items for inclusion (Streiner, 2015). It is generally accepted though that the initial collection of items should be broad and more comprehensive than the accepted theoretical view of the target construct with the initial pool including content that either broadens or deepens the core construct (Clark & Watson, 1995).

Study 1 identified items for consideration for inclusion in the ABIPA. To do this, two processes were undertaken. First a literature search of relevant databases was completed. Databases reviewed included Cochrane, Pedro, PubMed, Medline, Cinahl, Embase, COMBI (Centre for Outcome Measurement in Brain Injury) and ABIEBR (Acquired Brain Injury Evidence Based Review). The second process of item selection involved an expert consensus panel of experienced physiotherapists. The initial literature review identified items with a frequency analysis identifying the most commonly assessed items to incorporate in a measure of neuro-motor impairment for severe ABI (Table 4.1). In consultation with the expert panel of experienced physiotherapists, several items were identified as important to consider with items not represented in other outcome measures also identified. Items identified for inclusion from a frequency analysis were spontaneous and voluntary movements, tone, passive range of motion and reflexes and postural status or equilibrium reactions. Items will be identified in more detail in Chapter 4.

3.4.1.2 Item scoring

Once items had been identified and selected, the next step of the process in the development of the ABIPA was to consider how the items would be scored. This was done by considering the scoring systems of common validated tools measuring similar constructs. Items were mostly observational; requiring clinician judgement to score. As this judgement was qualitative, using experienced clinicians' clinical judgement has been suggested as the best method of scoring or classifying the observational data into measurable dimensions (Gutman, 2004; Guyatt, Krishner, & Jaeschke, 1992; Hagerty, 2002).

Retrieved articles from the literature review related to each ABIPA item were examined to inform the scoring range. For example, the item most closely related to movement return was compared to the most commonly accepted motor function impairment measures. Motor impairment measures commonly used include the manual muscle test (Harms-ringdahl, 1993), movement recovery scale (Sodring, Bantz-Holter, Ljunggren, & Wytter, 1995) and the Motricity Index (Demeurisse, Demol, & Roboye, 1980). All these measures use either a five or six- point scale.

Muscle tone was identified as an item for inclusion in the ABIPA with several items covering this construct. Two measures are commonly used to assess muscle tone in ABI populations; the Modified Ashworth Scale (Ansari, Haghdi, Moammeri, & Jalaie, 2006; Pomeroy et al., 2000) and the Tardieu scale (Tardieu et al., 1957). Both measures use a six- point scale.

Several ABIPA items assess alignment, including alignment of the head and trunk in supine and alignment of the head and trunk in sitting. For these items, the cardinal planes of movement (i.e. sagittal, coronal and horizontal) were considered as well as whether the body was fully aligned or not able to be assessed. As a result, a four-point scale was developed.

From the range of outcome measures identified by the literature review, the scoring used for these measures, and that items were observational or qualitative in nature, the expert panel of experienced clinicians identified the dimensions considered clinically important to develop the scoring criteria of the ABIPA. Three experienced (10years +) clinical physiotherapists working within the Neuroscience Unit (comprising the acute neurosurgical ward and brain injury rehabilitation unit), Princess Alexandra Hospital applied the current measure and scoring system across multiple ABI patient presentations. These single case pilot studies identified ambiguous distinctions between levels, which were able to be clarified; developed the dimensions that were considered clinically significant and allowed the clinicians to ensure all patient presentations were covered.

3.4.1.3 Psychometric testing

Following item identification the next step in developing a new outcome measure is to perform conceptual and psychometric analysis to identify relevant, strongly related items for continued inclusion in the new outcome measure (Clark & Watson, 1995). Additionally, it is important to identify weak, unrelated items that should be removed from the emerging outcome measure (Clark & Watson, 1995). A well-established assessment measure will have many of the following; responsiveness, content validity (including face validity), construct validity, criterion-related validity, internal consistency, reliability and interpretability or clinical relevance (Mokkink et al., 2012). In the development of a new outcome measure it is important then to test these psychometric properties with each one detailed in the following sections.

It is also essential to show that the chosen items are evaluating the chosen construct. In the case of the ABIPA, does the outcome measure assess neuro-motor impairments in the acute stages following an ABI. To address this, Study 1 examined the responsiveness for measuring

change and concurrent validity of the ABIPA in the acute stages of neuro-motor recovery. Section 3.4 Data analysis will outline the choice of statistical methods.

The potential for observational bias is another important concern in experimental studies (Portney & Watkins, 2000). Two assessors were therefore involved at each assessment time point and randomly allocated to concurrently assess the patients. This deliberate strategy would reduce the time burden for these highly dependent people at this stage of their rehabilitation. Assessors completed either the new ABIPA assessment (assessor 1) or the two selected comparator outcome measures of neuro-motor function (assessor 2). With random assignment each assessor had an equal chance to be assigned to assess the ABIPA, providing confidence that systematic observational bias would be minimised due to each assessors' individual attributes (Portney & Watkins, 2000).

The ABIPA was performed using a standardised procedure as outlined in Study 1 (Chapter 4).

3.4.2 Study 2

Study 2 investigated inter- and intra-tester reliability using the ABIPA. Investigating reliability using a measure of neuro-motor impairments relies on repeated patient performance within a single testing session to determine inter-tester reliability or repeated patient performance over at least two testing sessions to determine intra-tester reliability. However, there is the potential for a persons' presentation to vary across brief periods of time, especially for people with moderate to severe ABI during the acute stages of recovery following ABI (Stuss, Pogue, Buckle, & Bonder, 1994). Additionally, people with ABI may become agitated if assessed by multiple assessors, suffer from fatigue or respond poorly to extended periods of handling (Zinno & Ponsford, 2006). Therefore, repeat assessments were considered to not be appropriate for this population.

3.4.2.1 Video assessment development

For Study 2, assessments were videorecorded to investigate reliability of the ABIPA. The use of videorecorded assessments alleviated the need for repeat patient performances for both inter-tester and for intra-tester reliability and removed the burden of multiple assessors. Video recorded assessments also removed any within-subject variability from the ABIPA assessment (Swaine & Sullivan, 1999). Videorecorded assessments have been used to investigate reliability in outcome measures in people with ABI undergoing rehabilitation (Kierkegaard & Tollbäck, 2005; Low Choy et al., 2002; Subramanian, Lourenco, Chilingaryan, Sveistrup, & Levin, 2013; Swaine & Sullivan, 1996), investigate reliability of musculoskeletal screening tests (Weeks, Carty, & Horan, 2012), facilitate assessments of gait (McGinley, Goldie, Greenwood, & Olney, 2003; Williams, Robertson, Greenwood, Goldie, & Morris, 2006), to assess motor development (Pomeroy, Pramanik, Sykes, Richards, & Hill, 2003), and evaluate training of undergraduate physiotherapy students (Ada, Canning, Dean, & Moore, 2004). Thus, post hoc ratings of videorecorded assessments presented a practical and viable method of determining reliability of the ABIPA for people with ABI.

Video recordings were created for seven people with moderate or severe ABI which were used for investigating reliability of the ABIPA. All videos were recorded according to a prior determined format and sequence with the same order of assessment of items recorded. Table 3.2 outlines the positions, movement, order and views captured during the ABIPA assessments. Following completion, the videorecorded assessments were de-identified and randomised by someone not involved in the reliability testing. Randomisation was completed to ensure participating physiotherapists were scoring assessments of people with varying neuro-motor abilities and that the assessments did not follow any predetermined pattern. Video guidelines and recording procedures were developed and pilot tested with physiotherapy students from a local university.

Table 3.2 Key positions, movements and views captured with patients participating in the development of the ABIPA

ABIPA item	**Video recording views**
Resting position of person lying in bed	*Resting position* of the person lying in bed was videorecorded from the foot of bed.
Head and trunk alignment	Views of the head and trunk from above and from the side were recorded for *head alignment and trunk alignment*. The therapist was filmed palpating each patient's rib cage with views from the foot of the bed and from the side.
Muscle tone in upper and lower limbs	Each limb was recorded being moved three times while the therapist gave a brief 'verbal account'* of their observations to interpret *overall muscle tone.*
Movement in upper and lower limb	*Upper and lower limb movement* was recorded as the therapist asked the patient to move, assessing each limb individually. Camera views captured the assessment from the side with additional zoom for notable movements (flickers of muscle activity).
Examination of *head and trunk control in sitting*.	The final view captured, the patient in a sitting position with views of the head and trunk from the side, back, and front included to show the degree of support required to maintain this position.

*Dialogue was recorded from the assessing physiotherapist to indicate 'overall muscle tone´ and 'movement' to maximise authenticity for therapists observing the video recorded performances

3.4.2.2 Physiotherapist training

Two groups of physiotherapists, both samples of convenience were involved in Study 2. The first group underwent training on use of the ABIPA to score patient performances prior to

viewing and scoring the videorecorded performances of the patients. The second group of participating physiotherapists were provided with the ABIPA guidelines but were not provided with any training or coaching prior to viewing and scoring the package of ABIPA assessments.

The provision of training to provide knowledge and familiarity prior to the administration of an outcome measure has been previously found in the literature (Ada et al., 2004; Baer, Smith, Rowe, & Masterton, 2003). As the ABIPA was a new measure initially it was considered that it was important to ensure that clinicians were familiar with the concepts and items included in the outcome measure; particularly if aiming to ensure the measure is administered consistently and reliably. High inter-tester and intra-tester reliability in outcome measures without training would suggest that this is not always necessary (Donaghy & Wass, 1998; Fischer et al., 2010; Hall et al., 1993; Loewen & Anderson, 1988; Seaby & Torrance, 1989).

It is also reasonable when developing a new outcome measure to determine if the tool can be administered without the need for training. If the measure can be reliably administered without the need for formal training, this may be of benefit for future implementation into clinical practice. Full details of the training procedure are described in Chapter 5.

3.4.3 Study 3

Study 3 investigated the factorial structure of the ABIPA. The procedure for Study 3 differed from the previous studies in this thesis, in that previously collected data were used for comparison and an exploratory approach to data analysis was undertaken (Portney & Watkins, 2000). The aim of Study 3 was to examine the structure within the items included in the ABIPA, determine the nature of the relationships between each item, and examine how the items correlated and what factors were represented under the initial construct. Study 3

therefore investigated the underlying structure of the ABIPA by means of factor analysis including maximum likelihood extraction.

Initially, the data sample was examined to determine if a sufficient number of ABIPA assessments were available for analysis and a correlation matrix interpreted to determine if a factor model was appropriate. Factor analysis has some competing techniques such as cluster analysis or multidimensional scaling (Hurley et al., 1997; Pett, Lackey, & Sullivan, 2003). The interpretation of the correlation matrix of Study 3 has shown that these methods were not recommended. Multidimensional scaling and cluster analysis have no ability to recognize multiple relationships amongst items, since the correlations are treated merely as generic "similarity measures" rather than as correlations (Gorsuch, 1983). The decisions around factor analysis will be examined further in Section 4.4.

3.4.4 Study 4

Study 4 investigated the association of the ABIPA with long-term recovery and carer burden. A database was created with records retrieved for people admitted to the participating facility with moderate or severe ABI, who had previously participated in Study 1 and 2 and were assessed with the ABIPA during an acute hospital admission. Patients identified from hospital databases were sent a letter of invitation at their last known address seeking their participation in a one-off physiotherapy assessment. A follow up phone call confirmed receipt of the letter and determined an interest and willingness to participate in the study.

Once participants had been identified and consent obtained, demographic data were collected from medical charts using a standardised collection form and included age (years), gender, diagnosis, length of acute admission, length of rehabilitation stay, usual place of residence at time of admission and discharge destination. Pre-injury measures of education and

employment were also collected. The evidence of change to living status, post-injury rehabilitation, evidence of behavioural problems and carer burden were also collected.

A follow up appointment was organised with participants' primary carer (if required) to collect outcome data required for longitudinal comparison. The ABIPA together with a collection of secondary measures were recorded. Chapter 7 will provide further details.

3.5 Data analysis

In determining the statistical analyses to be included in this thesis, consideration was given to the type of data provided by the ABIPA and the participant group being measured. The ABIPA is a scale which yielded categorical, nonparametric data. The planned data analysis for the studies in this thesis are detailed in this section.

A further consideration is the sample size required to use the statistical test. With the anticipated small sample size for Study 1, 2 and 4, it was directive to which statistical approach would be the best fit. The final consideration is whether or not the participants are representative of a single group that will change in the same manner (homogeneous) or change differently from each other (heterogeneous) (De Yébenes Prous, Rodríguez Salvanés, & Carmona Ortells, 2008). This section will discuss the choice of statistical methods, for this research program, with Table 3.3 identifying the statistical methods used in each study. To assist with clarity data analysis associated with each study will be discussed in turn.

Table 3.3 Summary of statistical methods used in this research program

Study	Statistical method utilised	Purpose
1	Standardised response means (SRM)	Measure change over time
	Spearman's rho correlation	Measure if there is an association between measures
2	Cronbach's alpha	Determine agreement of scores between assessors; is a measure of inter-rater reliability
	Cohen's weighted Kappa (K_w)	Determine agreement between scores by the same assessor (intra-tester reliability).
3	Kaiser-Meyer-Olkin (KMO)	Measure of sampling adequacy
	Bartlett's test of sphericity	Assess if the correlation matrix was an identity matrix, and therefore the factor model was appropriate
	Factor analysis	Undertaken to reveal the underlying structure and strength of ABIPA items
		Unidimensional - refers to outcome measure with only one dimension measuring a single ability or construct. To determine all items, measure changes to neuro-motor impairments.
4	Spearman's rho correlation	Measure if there is an association between measures at different time points

3.5.1 Study 1

3.5.1.1 Responsiveness of the ABIPA to change

It is generally accepted that there are two aspects of responsiveness. Internal responsiveness or the ability to measure change over time and external responsiveness the extent to which a change in a measure reflects a change in health status (Husted, Cook, Farewell, & Gladman, 2000). Responsiveness was investigated to show that the ABIPA measured change in the

construct of interest; that is, changes in acute neuro-motor impairments for people following moderate to severe ABI. Internal responsiveness was the focus of Study 1.

In Study 1, the choice of statistical analysis was the standardised response mean (SRM) to compare change over time (internal responsiveness) with the ABIPA compared to other commonly used measures. Internal responsiveness is determined using a distribution-based approach to determine change over time. The most common approaches being t-test, analysis of variance and measures of effect size (De Yébenes Prous et al., 2008).

If considering a distribution based approach a repeated t-test or analysis of variance (ANOVA) design has been suggested as the analysis of choice (Altman, 2006). However, use of a t-test or ANOVA requires statistical assumptions such as normally distributed and parametric data (Portney & Watkins, 2000) along with the assumption that the change is due to treatment (Husted et al., 2000). For the purpose of this research program the t-test and ANOVA were considered to not be appropriate statistical tests.

Using an effect size statistical analysis is generally considered preferable for determining change as group variability is considered. Determining effect size index provides information on the size of the change relative to the standard deviation of the initial measure; however, it is difficult to differentiate between the change in scores and change in variability of the initial measure (De Yébenes Prous et al., 2008). When using an effect size index an anchor-based approach, Guyatts' responsiveness index or standardised response mean may be considered to measure change over time.

An anchor based approach uses an anchor such as a secondary measure or clinically meaningful marker to determine a minimally clinical important difference and is more commonly used after an intervention (Eurich, Johnson, Reid, & Spertus, 2006). Secondary measures included as a correlation between the change scores is often considered the

preferred method for comparing change in an outcome measures (Terwee, F., Wiersinga, Prummel, & Bossuyt, 2003). Guyatt's responsiveness index calculates the minimally clinical important difference or smallest difference between the two test points that represent a meaningful benefit to the participant group.

To determine responsiveness of the ABIPA and comparator measures, standardised response mean analysis was selected as the appropriate analysis method. Standardised response mean (SRM) was defined as the mean change in score between the first assessment and the comparison assessment, divided by the standard deviation of the individual changes in scores (Portney & Watkins, 2000). Standardised response mean analysis does not depend on the sample size, a potential issue in this research program (Husted et al., 2000) and takes into account the variability of the change score (De Yébenes Prous et al., 2008).

The greater the responsiveness to change, the higher the SRM, whereby a value of >0.8 is considered a large effect, >0.5 as a moderate effect and 0.2 as a small effect (Cohen, 1977). By calculating the SRM at day 3, day 7 and discharge, change over time from admission was able to be measured.

3.4.1.2 Construct validity

Construct validity of the ABIPA was examined by determining the relationship between the ABIPA and validated and reliable assessment tools for people with an ABI. The ABIPA was compared to the GCS, COVS and MAS by calculating the Spearman's rho correlation coefficient to examine construct validity. Spearman's rho also provided information regarding the association between these measures. That is, were the measures assessing the same construct of acute neuro-motor impairments following ABI. A high correlation would support the use of the ABIPA for measuring change across the acute stages of recovery.

Spearman's rank-order correlation was considered the appropriate statistical test as data were non-parametric (De Yébenes Prous et al., 2008; Ottenbacher & Tomchek, 1993; Portney & Watkins, 2000). Spearman's is also recommended when a direct relationship (monotonic) exists between the variables; one variable increases while the other variable increases or decreases, but not necessarily in a linear fashion. Once calculated the Spearman's coefficient is represented as *rho* and will be between +1 to -1. A calculated score of zero indicates no relationship between the variables and the closer the score to zero the weaker the relationship (Portney & Watkins, 2000).

3.5.2 Study 2

Study 2 examined the consistency of scoring the ABIPA items. Inter-tester reliability, similarity of scores recorded by different therapists and intra-tester reliability, similarity of scores recorded if the same therapist scored the same patient was examined. As all items measure the same construct, the ABIPA achieves one of the assumptions required to analyse reliability by calculating Cronbach's alpha (Gadermann, Guhn, & Zumbo, 2012) the most commonly applied statistical measure for internal consistency (Portney & Watkins, 2000). Cronbach's alpha was used to determine consistency of scores between assessors – a measure of inter-tester reliability (Cohen, 1977) for each item and for the total ABIPA score. High Cronbach alpha scores indicate a high reliability which means that the assessment is reproducible over time, in different settings and by different assessors (Zapf, Castell, Morawietz, & Karch, 2016).

To examine intra-tester reliability Cohen's weighted Kappa (K_w) statistic was selected to determine agreement between scores by the same assessor. As the ABIPA tool yielded categorical data, reliability should be assessed by a measure of agreement. Perhaps the simplest form of agreement is percentage agreement. However, determining percentage agreement on a score does not take into account any agreement that might occur by random

chance (Portney & Watkins, 2000). The Kappa statistic takes into account the possibility of chance agreement (Ottenbacher & Tomchek, 1993). The weighted Kappa is appropriate to use when an ordinal scale comprises a number of categories (Portney & Watkins, 2000). Scoring for individual ABIPA items uses a four to six-point scale; with the full ABIPA scored out of a maximum of 60. The weighted Kappa is therefore the appropriate statistical analysis for examining intra-tester reliability for each individual ABIPA item as well as the total ABIPA score. Interclass correlation co-efficient was not considered as data were not ordinal or interval in nature (Ottenbacher & Tomchek, 1993; Portney & Watkins, 2000).

3.5.3 Study 3

For Study 3, the 15-item ABIPA was examined by means of factor analysis including maximum likelihood extraction to establish a correlation matrix. It is recommended that an exploratory factor analysis be used when the number of factors that will explain the relationships between items is not known (Gorsuch, 1983; Pett et al., 2003; Tabachnick, 2014). Exploratory factor analysis analyses the interrelationships among the items and explains these items in terms of a smaller number of underlying factors. In contrast confirmatory factor analysis is more appropriate when a relationship is already believed to be present (Jackson, Gillaspy, & Purc-Stephenson, 2009). Other tests such as t-test or ANOVA are more useful to analyse differences between groups not their interrelationship (Pett et al., 2003).

One of the assumptions required for exploratory factor analysis is a large same size (Pett et al., 2003) Therefore the Kaiser-Meyer-Olkin (KMO) measure of sampling adequacy was used to test if the available sample was sufficient. Specifically the KMO determined whether the correlations among the items were small and Bartlett's test of sphericity was interpreted to assess if the correlation matrix was an identity matrix, and therefore the factor model was

appropriate (Ho, 2006). The KMO measure of sampling adequacy showed that the sample was able to be analysed into factors.

A secondary decision is required to establish a reasonable estimate of the relationship that may exist between items and this can be achieved with either a Principle component analysis or the more classical approach of a common factor analysis (Pett et al., 2003). Common factor analysis approaches include principle axis factoring, alpha factoring, image factoring, unweighted and generalised least squares and maximum likelihood methods. Further discussion of all these approaches is beyond the scope of this thesis.

For Study 3 a principle axis factor extraction with maximum likelihood and varimax rotation was the analysis of choice. To ensure internal consistency of component outcome measures, 0.30 or higher was selected as the criterion of significance for the factor loading, with loading of items below this level not included in the analysis (Tabachnick, 2014).

3.5.4 Study 4

As previously identified, analysis of the ABIPA is ideally undertaken using non-parametric analyses due to the data type (nonparametric and monotonic) and sample size. In Study 4 ABIPA scores at acute and rehabilitation admission were examined for their relationship with length of stay, discharge destination and long-term outcomes. Spearman's rho correlation coefficients were calculated for this analysis. Logistic and multiple regression analyses were not appropriate due to the data extracted and were not considered for use. Spearman rho coefficients greater than 0.75 were considered good to excellent, while rho coefficients between 0.50 and 0.75 were moderate to good (Portney & Watkins, 2000).

3.6 Ethical considerations

The primary aim of this research was to develop a tool to measure neuro-motor impairments in the acute stages following an ABI. Due to the nature of the participants included in this research program (i.e. people with moderate to severe ABI) and the timing of their assessments (i.e. acute stages of recovery) there were ethical implications and aspects of the consent process that needed consideration. Not least, was accounting for those participants who were agitated and restless and who had language, cognition or behaviour difficulties that would influence the assessment process. It was also necessary to consider those participants, who due to their injury may have a reduced capacity to consent.

The above considerations identify this cohort as a vulnerable group of participants who may not make decisions for themselves, requiring a power of attorney or legal guardian to act on their behalf. As part of the ethical process, an application was submitted to the Queensland Civil and Administrative Tribunal (QCAT) for approval to conduct clinical research under the guardianship and administration Act 2000. QCAT determined that due to the nature of assessment that underpins this research their approval was not required and that the approval of family members, next of kin or guardians was sufficient (Appendix 4).

Consent forms and explanatory statements were therefore created for both the people with an ABI able to give consent and a second consent and explanatory statement for family members or legal guardians as required. The overall risk to these participants was calculated as minimal, with the assessment considered to be no more than a standard physiotherapy treatment session, which would typically be provided during their stay in hospital.

For all studies, ethical approval was granted by the Human Research Ethics Committee of the recruiting hospital, Princess Alexandra Hospital. As the research program progressed, amendments were required, and further institutions included resulting in multiple ethical

approvals. Table 3.4 outlines the approving institutions and application numbers associated with each study in this thesis.

Table 3.4 Institutional ethical approval for each study contained in the thesis.

Study	**Ethical approval granted**	**HREC no.**
1	Princess Alexandra Hospital	HREC/04/QPAH/30.
2	Princess Alexandra Hospital	HREC/04/QPAH/30.
	Griffith University	GU Ref No. PES/28/12 HREC
	Bond University	RO-889A
3.	Princess Alexandra Hospital	HREC/04/QPAH/30
	Griffith University	GU Ref No. PES/28/12 HREC
4.	Princess Alexandra Hospital	HREC/13/QPAH/314
	Griffith University	GU Ref No. PES/28/12 HREC

The initial ethical approval was obtained by the candidate as a clinician working at the Princess Alexandra Hospital. This approval was amended to include Griffith University following candidate enrolment into a Master of Philosophy program. Further approval was required from Bond University, Gold Coast as physiotherapy internship students were associated with pilot testing of the video recordings for reliability testing (Study 2). No further ethical approvals were required as all data collection had been completed prior to the transfer to the Doctoral program at ACU. All ethical approvals are included in Appendices 2 and 3.

3.6.1 Informed consent

In Study 1, consent related primarily to the assessment process with participants consenting that as part of the study, two senior members of the physiotherapy team would assess them using the newly developed ABIPA. Participants also consented to assessment using previously validated physiotherapy assessment tools (i.e. GCS, COVS and MAS).

For Study 2, consent was given by participants to be assessed by an experienced physiotherapist from the Princess Alexandra Hospital using the ABIPA tool. Consent was also given to allow the session to be videorecorded for future viewing by a group of physiotherapists and to have the results collected and analysed by the researchers to help determine the reliability of the ABIPA.

Physiotherapist participants in Study 2 consented to attend two informative education sessions on the use of the ABIPA tool and to attend video viewing sessions in which they would be required to use the ABIPA tool to assess people with an ABI. Physiotherapist participants also consented to have the data collected and analysed by the researchers to help determine the inter- and intra-tester reliability of the ABIPA.

As Study 3 was an analysis of data collected under the already existing ethical approvals no additional consent forms or explanatory statements were required.

In Study 4, participants were initially invited to participate in the research program looking at long -term outcomes following an ABI, via a letter mailed to their last known address. They or their substitute decision maker were then contacted via phone to confirm receipt of the letter, discuss the research program, answer questions and gain verbal consent to attend an assessment session. Participants agreed to allow the research team access to their medical records to collect a history of their hospital admission/s relevant to their initial injury and any management including rehabilitation if relevant. Participants agreed to attend an assessment

session of approximately 2 hours at the participating facility, or other appropriate facility and be assessed with the ABIPA, FIM and DRS assessment forms and to answer a questionnaire regarding their current level of function, social interaction and mental health. Parking support was provided as needed.

With the above considerations for both participant groups and research protocols all studies in this research program were conducted with ethical approval and adhering to Helsinki consent and research requirements (World Medical Association, 2013) and the Australian Code for Responsible Conduct of Research (National Health and Medical Research Council, 2018).

The following four chapters will report on the findings of the four studies conducted as part of this research program.

Chapter 4

Study 1: Development and preliminary validation of the Acute Brain Injury Physiotherapy Assessment (ABIPA).

The following chapter is based on a peer-reviewed submission published in Brain Impairment (Appendix 5). The bibliographic details are:

Gesch, Janelle M., Low Choy, Nancy L., Weeks, Benjamin K., Passier, Leanne L., Nascimento, Margarida. Haines, Terrence P., Kuys, Suzanne S. Development and preliminary validation of the Acute Brain Injury Physiotherapy Assessment (ABIPA). Brain Impairment, 2014 15(2): 132-145.

Abstract

Background: For people with a severe brain injury no objective physiotherapy assessment tool is currently available for use in the acute stage of recovery that is responsive to the incremental changes in neuro-motor impairments.

Objective: This study aims to identify items reflective of neuro-motor impairments and scoring criteria for the Acute Brain Injury Physiotherapy Assessment (ABIPA) and determine responsiveness to change and concurrent validity against accepted standard measures of consciousness and physical function in adults following severe brain injury.

Methods: A literature search was conducted and an expert consensus panel of experienced clinical physiotherapists informed item selection, established content validity and developed practical assessment guidelines. The ABIPA was investigated for responsiveness to change and concurrent validity against the Glasgow Coma Scale (GCS), Clinical Outcome Variable Scale (COVS) and Motor Assessment Scale (MAS).

Results: Eleven people (9 males; cohort 41; SD18 years) with moderate or severe brain injury were recruited. Participants were assessed at Day 1, 3, 7 and then weekly until discharge. At Day 3, the ABIPA showed the greatest responsiveness to change (SRM > 0.83) compared to other measures (SRMs ≤ 0.77). Change in neuro-motor impairments was demonstrated by all measures at discharge. The ABIPA demonstrated good to excellent correlations with the GCS (rho > 0.76, $p \leq 0.001$), COVS (rho > 0.82, $p \leq 0.001$) and MAS (rho > 0.66, $p \leq 0.001$).

Conclusion: The ABIPA is a valid tool and is responsive to change for detecting incremental changes in neuro-motor impairments after acute severe brain injury.

4.1 Introduction

During recovery from severe ABI, people face several challenges requiring interventions from many different professionals. Physiotherapy is considered to be a key discipline for rehabilitation following ABI (Hellweg & Johannes, 2008; New Zealand Guidelines Group, 2007; Teasell et al., 2007; Tolfts & Stiller, 1997). Although there is limited robust research evaluating rehabilitation interventions in the ABI population (New Zealand Guidelines Group, 2007; Teasell et al., 2007; G. Zitnay et al., 2008) the delivery of allied health interventions including physiotherapy has been shown to reduce length of inpatient stay, optimise motor function at discharge and decrease overall disability (Chestnut, 1990; Gray, 2000; Hall & Cope, 1995; Turner-Stokes, Disler, Nair, & Wade, 2003; Zhu et al., 2007).

The brain injury specific outcome measure database (Wright et al., 2000) highlights that scales typically used during the acute stages of recovery evaluate consciousness, cognitive function, behaviour, social participation, and functional limitations. However, these scales fail to capture the incremental changes in neuro-motor impairments in the early stages of recovery important to physiotherapy management following severe ABI (Canedo et al., 2002; O'Dell et al., 1996; Pape et al., 2006; Teasdale & Jennet, 1974). A specific outcome measure to monitor acute incremental changes in neuro-motor function during the acute stages following severe ABI when people are functionally dependent remains conspicuously absent from the field.

A recent systematic review (Laxe et al., 2012) identified the most common outcome measures used in brain injury research as the FIM (50%), Glasgow Outcome Scale (34%) and DRS (32%). Some well- known outcome measures of neuro-motor function used specifically by physiotherapists include the Clinical Outcomes Variable Scale (COVS) (Seaby & Torrance, 1989), Motor Assessment Scale (MAS) (Carr, Shepherd, Nordholm, & Lynne,

1985) and Functional Independence Measure – Motor component (FIM-motor) (Kidd et al., 1996). These outcome measures monitor key motor tasks such as walking, transfers, wheelchair mobility, and fine motor upper limb skills, but most patients with severe ABI are not capable of attempting these tasks in the earliest stage of recovery (Pilon et al., 1995). A new outcome measure that captures acute changes in neuro-motor impairments following severe ABI is required.

A cohort of experienced physiotherapists from Princess Alexandra Hospital aspired to develop an outcome measure suitable for measuring incremental neuro-motor impairments during the acute stage following severe ABI. The goal was to develop a quantitative assessment measure, informed by empirical evidence that would be sensitive to change and include the key items required to portray the incremental changes in neuro-motor impairments that underpin physiotherapy assessment for the severely brain injured.

Study 1 of this thesis comprised two parts. Part A involved the identification of items to measure incremental changes in neuro-motor impairments that may be associated with the acute physiotherapy management of people following severe ABI – that is, identify the content of the ABIPA. Part B investigated the responsiveness of the ABIPA to measure change in neuro-motor impairments in the acute stages of recovery following severe ABI as a first step in determining concurrent validity of the tool for use in the clinical setting.

Thus, the aims of Study 1 were:

1) To identify the items and develop scoring guidelines for the ABIPA, a new outcome measure that could be used by physiotherapists to assess neuro-motor impairments of people in the acute stages following severe ABI;

2) To evaluate the responsiveness to change of the ABIPA to a measure of consciousness (GCS) and measures of neuro-motor function (COVS, MAS); and

3) To establish concurrent validity of the ABIPA with these tools at initial and discharge assessments in the acute hospital setting.

4.2 Methods

4.2.1 PART A: ABIPA Development – Item Selection

4.2.1.1 Search strategy

A systematic approach to a literature review and an expert consensus panel of experienced clinical physiotherapists was employed to inform item selection, address content validity and establish practical assessment guidelines. A literature search was undertaken of relevant databases including Cochrane, Pedro, PubMed, Medline, CINAHL, Embase, COMBI (Centre for Outcome Measurement in Brain Injury) and ABIEBR (Acquired Brain Injury Evidence Based Review). Search terms included “brain injury or head injury or CVA or stroke or cerebrovascular accident “AND "physical therapy or physiotherapy” AND "outcome assessment or outcome measure" AND “motor recovery”. Search limits of human, English language and age related 19 years+ were used. Studies were included if participants were in the acute phase of recovery following moderate or severe ABI (GCS < 12). All study types including meta-analysis studies, systematic reviews and practical guidelines were included. Studies were excluded if the focus was on spinal injury or other neurological diseases such as multiple sclerosis or Parkinson’s disease; if community based; or high-level function or mobility was being measured. Studies were also excluded if treatment focused; investigating the chronic phase of recovery; pharmacological studies; or focused on cognitive or psychosocial interventions; or were conference proceedings; or were unavailable in full text.

Figure 4.1 shows the flow chart for the search strategy. Initial searches yielded 2023 articles. A total of 1564 articles from databases and a further 459 from the Acquired Brain Injury Evidence Base Review (ABIEBR) were retrieved. Excluded, based on title and abstract were studies such as those dealing with cognition, behaviour, community focus, long term outcomes, mild injury and pharmacological studies. One hundred and seventeen articles (n = 117) were recovered for full text review from the database search and 127 articles from ABIEBR.

Following removal of duplicates one hundred and fifty-nine (n = 159) articles were then collected into manuscripts outlining frequently used outcomes measures (n = 128) and those articles that concentrated on item identification required for measuring neuro-motor impairments in ABI (n = 31). Of the articles outlining frequently used outcomes measures, those measures that were reported less than 3 times or were related to a specific body part such as the upper limb (n = 39) were removed from further analysis. Reference lists of articles that concentrated on item identification were further examined to ensure any relevant publications were not overlooked and eight more studies (n = 8) were included; resulting in a total of 39 articles to be included for item identification relevant to measuring neuro-motor impairments.

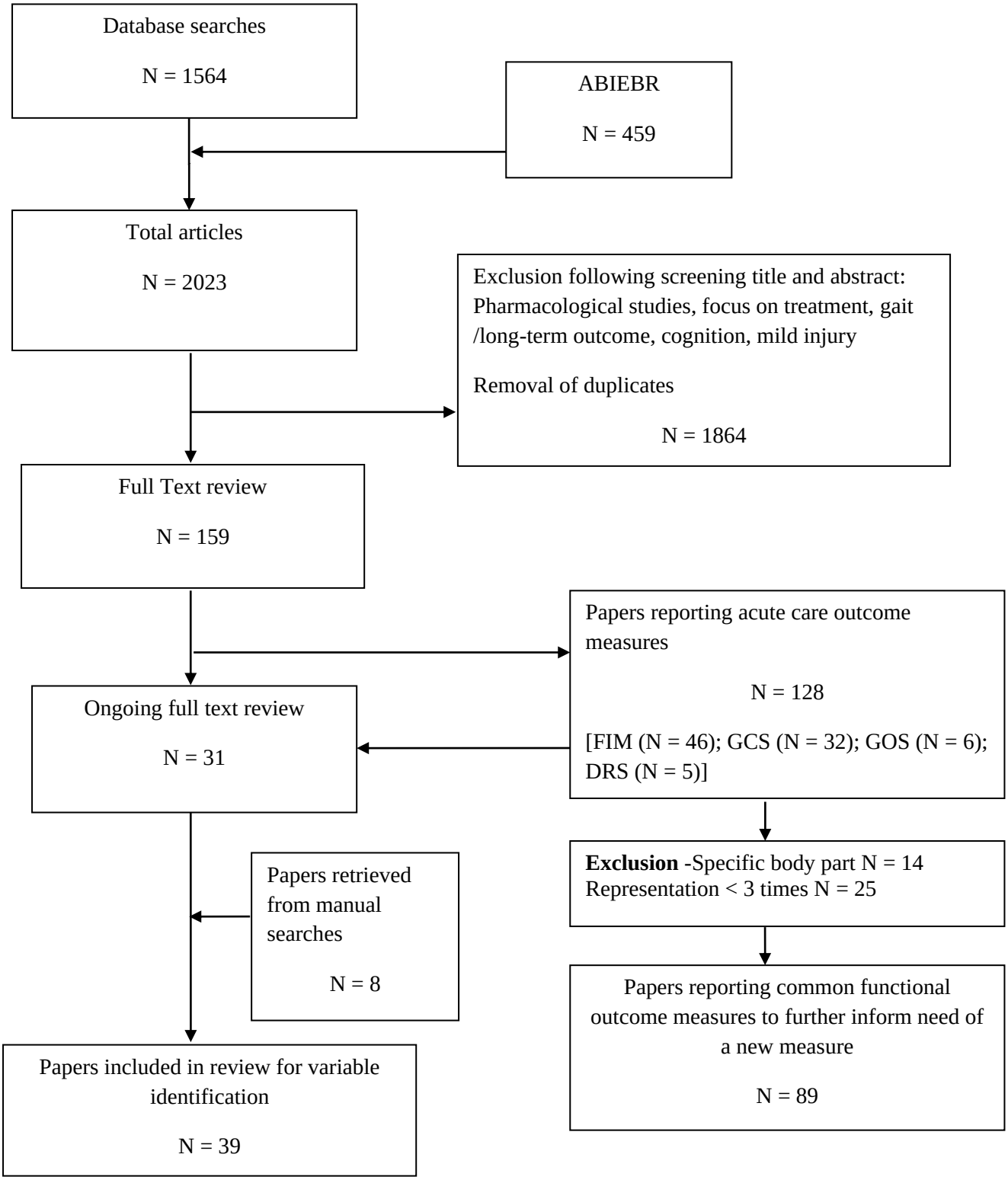

Figure 4.1 PRISMA diagram for manuscript identification.

Abbreviations: ABIEBR, Acquired Brain Injury Evidence Base Review; DRS, Disability Rating Scale; FIM, Functional Independence Measure; GCS, Glasgow Coma Scale; GOS, Glasgow Outcome Scale

4.2.1.2 Data extraction

Data were obtained from all articles related to frequently used outcome measures, identifying the component variables of the measures and items identified as important for measurement of neuro-motor impairments in the ABI population. The most frequently reported outcome measures in the retrieved articles were the FIM or Functional Assessment Measure (n = 46), GCS (n = 32), GOS (n = 6) and DRS (n = 5). This finding is supported by previous studies reviewing frequently used outcome measure in ABI (Crooks et al., 2007; Haigh et al., 2001; Laxe et al., 2012; Pollock, Morris, Wijck, Coupar, & Langhorne, 2011; Shukla et al., 2011). Commonly used in the acute care setting, the GCS was selected as an accepted validated outcome measure for comparison with the ABIPA. The FIM was not selected due to its prime use as a rehabilitation measure (Nichol et al., 2011) and this research program was interested in the acute care setting. In addition, well known physiotherapy assessment outcome measures of neuro-motor function, the COVS (Seaby & Torrance, 1989) and MAS (Carr, Shepherd, & Nordholm, 1985) were also selected as comparative measures.

To identify common items measuring neuro-motor function, the 39 studies retrieved were reviewed by an expert consensus panel of three experienced clinical physiotherapists working within the Neuroscience Unit, Princess Alexandra Hospital. Further studies were removed if the items identified only included injury severity, age, cultural background and ethnicity, systemic insults and medical complications. Studies were also removed if the focus was on level of disability (inability to perform) and functional activities such as transfers. Fourteen studies (n = 14) remained that identified neuro-motor items.

The most important items for inclusion in a measure of neuro-motor impairment following severe ABI were identified with a frequency analysis. The items were tone (93%), spontaneous and voluntary movements (71%), postural status or equilibrium reactions (64%),

passive range of motion (29%) and reflexes (43%) (Table 4.1). Evaluated as being ‘extremely important’ or ‘very important’ items requiring inclusion were passive range of motion, spontaneous movements and postural status (Mayo et al., 1991; Pilon et al., 1995; Swaine et al., 1994; Walker & Pickett, 2007). Additional items identified as important to measure included postural control and ‘tolerance to vertical’ and the ability to sit unsupported (Pilon et al., 1995) along with muscle tone, voluntary movements, range of motion, equilibrium reactions and transfers (Charness, 1986; Duncan, 1990; Laxe et al., 2012; Mittrach et al., 2008; Nelson, 1984; Swaine & Sullivan, 1996, 1999).

The identified items were grouped under similar categories and became items of muscle power, muscle tone, body alignment and maintaining body position. The final items of the ABIPA were: upper limb and lower limb movement, overall muscle tone in each limb, head and trunk alignment in supine, head and trunk alignment in sitting, head and trunk control in sitting and overall presentation.

Table 4.1 Neuro-motor items identified from retrieved articles

	PROM	Voluntary Movement	Postural status/ Equilibrium reactions	Sit unsupported	Muscle tone	Sensation	Coordination	Reflexes	Transfers
Swaine and Sullivan (1994)	X	X	X		X	X	X	X	X
Duncan (1990)	X	X	X		X			X	X
Charness (1986)	X	X	X		X			X	X
Nelson (1984)	X	X	X		X			X	X
Swaine and Sullivan (1996)			X	X	X				X
Swaine and Sullivan (1999)				X	X				X
Pollock (2011)	X	X	X		X				
Walker (2007)		X	X		X		X		
Laxe (2012)		X			X			X	
Mayo (1991)		X	X		X		X	X	
Pilon (1995)	X	X	X		X			X	
Mittach (2008)		X	X		X				X
Tolfts (1997)		X	X		X			X	
New Zealand Guidelines Group (2007)		X	X		X	X			

4.2.1.3 Scoring the ABIPA

The evidence supporting outcome measure development, as well as the scoring systems of commonly used validated tools were considered to determine the scoring for the ABIPA outcome measure. Scoring the final items of the ABIPA required clinical judgement of the assessor as the data to be scored was observational or qualitative in nature. The best method of scoring qualitative data in an outcome measure format has been suggested as mapping the observational data into measurable dimensions using experienced clinicians' clinical judgement (Gutman, 2004; Guyatt et al., 1992; Hagerty, 2002).

In addition, the retrieved articles relevant to each ABIPA item were further examined to inform a scoring technique relevant to each item. For example, for the first item, upper and lower limb movement; common motor function measures included the manual muscle test (Harms-ringdahl, 1993), movement recovery scale (Sodring et al., 1995) and the Motricity Index (Demeurisse et al., 1980). For these measures, either a five or six- point scale was used. The Modified Ashworth Scale (Ansari et al., 2006; Pomeroy et al., 2000) and the Tardieu scale (Tardieu et al., 1957) are two widely used clinical measures for upper and lower limb muscle tone. Both are rated using a six-point scale. For the remaining items of alignment and control, consideration was given to the cardinal planes of movement (i.e. sagittal, coronal and horizontal) and whether the head or trunk was fully aligned or not able to be assessed. Considering the range of outcome measures supported by the literature, the experienced clinicians developed the dimensions that were considered clinically significant. A series of single case pilot studies clarified the dimension and a five-point scale emerged. Scores for each item range from 0 to 4 with low scores representing poorer function and a score of 4 representing best function (Hagerty, 2002). The ABIPA outcome measure, its items and scoring are set out in Table 4.2. The guidelines for ABIPA administration are set out in Section 4.2.2.3.1.

Table 4.2 Description and scoring of the ABIPA

ABIPA Item	0	1	2	3	4	Score		Item Total
Movement 1. UL R) and L) 2. LL R) and L)	No active movement	Mass patterns or reflexive movement	Some movement or flickers.	Active movement through ≥ 1/4 ROM.	Normal movement, but may be weak or agitated	R) UL LL L) UL LL	/4 /4 /4 /4	/ 16
Muscle Tone 1. UL R) and L) 2. LL R) and L)	Rigid, or limb is flaccid.	Difficulty with passive movement, PROM reduced	Marked increase in muscle tone through ROM, full PROM available	Slight increase, catches or minimal resistance, including patient resisting	Normal muscle tone	R) UL LL L) UL LL	/4 /4 /4 /4	/16
Head and trunk alignment 1. Supine 2. Sitting	Patient is fixed in a position, or alignment is unable to be assessed.	Alignment is lost in all three planes	Alignment is lost in any two planes	Alignment is lost in one plane.	Alignment in all three planes is in the midline position	Supine, head Supine, trunk Sitting, head Sitting, trunk	/4 /4 /4 /4	/16
Control 1.Head 2. Trunk	Unable to hold position, patient completely dependent	Able to hold any position for 1 seconds	Able to hold any position for 5 seconds	Able to hold in any position 10 seconds	Able to hold in midline 10 seconds	Control, head Control, trunk	/4 /4	/ 8
Overall presentation	Bilateral hemiparesis +/– spasticity - all four limbs involved.	Hemiplegia - one side of body affected, no movement present, may have spastic or flaccid limbs	Hemiparesis - weakness of one side of body	Monoplegia - no or abnormal movement in one limb, may be spastic or flaccid	Monoparesis - weakness in one limb			/ 4
						ABIPA TOTAL		**/ 60**

4.2.2 PART B: Responsiveness of the ABIPA to Change and Concurrent Validity

4.2.2.1 Design

In the second part of Study 2, the ABIPA was examined for responsiveness to change in the acute stages of recovery following an ABI. Other assessment tools currently in use with this population were also investigated to establish concurrent validity. A sample of convenience of people admitted to the neurosurgical unit at Princess Alexandra Hospital were included in a prospective cohort study. Assessments were conducted on people throughout their acute hospital stay, until they were discharged or showed a variation in scores on two other commonly used outcome measures of neuro-motor function (COVS and MAS).

4.2.2.2 Participants

The neurosurgical unit is based in a tertiary referral hospital, Brisbane, Queensland, with state-wide admissions from Queensland and northern New South Wales. The unit contains 36 beds and is staffed by a multidisciplinary team including physiotherapists, speech pathologists, social workers, occupational therapists, neuropsychologists and a medical team.

People were included in the study if they were aged between 16 and 60 years, had recently suffered either a moderate (GCS 9-12) or severe (GCS 3-8) ABI or a grade four or five subarachnoid haemorrhage and were medically stable (i.e. had been discharged from intensive care). People were excluded if they had major musculoskeletal disorders that may impact on movement return (e.g. amputation or fracture) or if there were any residual impairments from previous neurological insult or conditions (e.g. previous stroke or Parkinson disease). People not deemed medically stable or who were awaiting clipping of an aneurysm were also excluded.

Ethical clearance was obtained from two institutional HRECs and the study was supported by the Medical Director of the neurosurgical unit. Informed consent was obtained from the next of kin or legal guardian as required.

4.2.2.3 Procedure

Participants were assessed during their acute hospital admission. The first assessment took place on the first week-day post admission to the neurosurgical unit. The second assessment occurred on day three following admission. Subsequent assessments occurred at Day 7 post neurosurgical unit admission then at weekly intervals until the patient showed a change in scores on the two selected outcome measures of motor function - COVS and the MAS. Assessments took place at approximately the same time of day.

The presence of a tracheostomy and weaning status, GCS and any changes to relevant medications were recorded at each assessment. Assessors were randomly allocated to concurrently assess the participants using either the ABIPA or selected other measures (COVS and MAS) and were blinded to each other's scores. People with a moderate or severe ABI were assessed using the ABIPA. ABIPA items were assessed in a consistent order for all participants commencing with resting alignment in bed (supine), general tone and movement before assisting the patient into sitting as described in the guidelines (Appendix 1).

4.2.2.3.1 Guidelines for ABIPA

The ABIPA is designed for patients in the acute phase after a severe brain injury. It is a global assessment based on observation, which considers overall patterns. The scale can be used with patients who are unable to follow commands or have cognitive impairments.

Alignment in Supine

Resting alignment of the patient's head and trunk is observed from the bedside. The patient is then placed in a midline position with a single pillow and allowed to settle before assessing

alignment which is graded for obvious deviations from midline. Trunk alignment observations are confirmed by palpation.

4. Aligned in all three planes, midline position
3. Alignment is lost in one plane; sagittal, coronal or transverse
2. Alignment is lost in any two planes
1. Alignment is lost in all three planes
0. Patient is fixed in a position, or alignment is unable to be assessed (for example due to medical equipment, positioning, and orthopaedic injuries)

General Tone

This subscale considers only the presence or absence of tone and not its source. Joints are moved through passive range of motion three times then graded on the worst score (for repetition of PROM, or joint).

4. Normal muscle tone
3. Slight increase, catches or minimal resistance, including patient resisting
2. More marked increase in muscle tone through ROM, full PROM available
1. Difficulty with passive movement due to tone, PROM reduced
0. Rigid in flexion or extension, or limb is flaccid.

Movement Scale

This subscale looks for active movement, whether normal and selective or pathologic. All four limbs are assessed individually by:

Looking: Patient is observed for any spontaneous movement including reflexive, patterned or selective movement.

Asking: Patient is asked to move the limb in any way possible.

Positioning: Place the patient's limb in a mid-range position and note any muscle activity or holding ability.

Feeling: Move the limb through range noting any active involvement.

Complete all components of the assessment and grade on completion unless the patient scores 4 in which case assessment of that limb is concluded.

4. Movement appears normal but may be weak or agitated.
3. Some active movement felt, anywhere in ROM for > ¼ ROM
2. Some active movement evident or flickers at any point in range
1. Movement in mass patterns of flexion or extension, or reflexive movement
0. No active movement

Control Scale

The control subscale requires the patient to be sitting on a firm surface with feet supported. The ability to hold or maintain this position with normal or abnormal muscle activity is assessed and timed using a stopwatch. For head control, the trunk should be fully supported midline.

4. Able to hold in midline 10 seconds
3. Able to hold in any position 10 seconds
2. Able to hold any position for 5 seconds
1. Able to hold any position for 1 seconds
0. Unable to hold position, no active involvement, patient completely dependent and falls unless supported

Note: Score head and trunk = 0: if for any reason the patient is unable to achieve sitting, for example medical limitations, safety, or concomitant injuries

Alignment in Sitting

Alignment in sitting is rated using the same scale as alignment in supine. The patient should be sitting on a firm surface with feet supported. For head alignment have the trunk fully supported in midline, take the head to midline and release as able. For patients constantly moving, repeat three times and rate on the worst alignment.

Note:

Score head and trunk = 0: if for any reason the patient is unable to achieve sitting, for example medical limitations, safety, or concomitant injuries

Score head = 0: if patient does not have any head control (as per control scale)

Score trunk = 0: if patient requires maximum assistance to maintain sitting

Posture

Overall posture is rated based on the completed assessment of tone, movement, alignment and control.

4. Monoparesis - weakness in one limb
3. Monoplegia - no or abnormal movement in one limb, may be spastic or flaccid
2. Hemiparesis - weakness of one side of body
1. Hemiplegia - one side of body affected, no movement present in one side, may have spastic or flaccid limbs
0. Bilateral hemiparesis +/– spasticity - all four limbs involved

4.2.2.4 Measures

The standardised procedure and scoring of the ABIPA is outlined in the guidelines and Table 4.2. On initial approach to the bedside the resting alignment of the patient's head and trunk was observed. The patient was then placed in a supine position with a single pillow under their head and allowed to settle. Head alignment was observed, scoring for obvious

deviations from the midline, noting rotation, lateral flexion and flexion. Trunk alignment was assessed with observations confirmed by palpation. The therapist observed lateral trunk angle, rib height, iliac crest height and compared equal presentation for both right and left sides. The shoulder girdle, pelvis alignment and lumbar lordosis were also observed, and then overall alignment scored.

Muscle tone and movement was assessed first for the upper limbs and then for the lower limbs. Initially the presence of any spontaneous movement (including reflexive, patterned or selective movement) was observed. Each major muscle group of the upper limb and lower limb was moved through passive range of motion three times to assess muscle tone and determine a score using the ABIPA outcome measure. The lowest score from the major muscle groups for each limb was recorded as the overall score for that limb.

Active movement was assessed for each of the four limbs individually. The patient was asked to move the limb as able and then the patient's limb was positioned in mid-range and any muscle activity or ability to hold the position recorded. Finally, the limb was moved through range for the major joints noting any active movement. The highest score was then recorded as movement for that limb.

Head and trunk control was assessed in sitting with the patient sitting on a firm surface with feet supported. This relates to the active movement of the trunk and head and is defined as the ability to maintain a position in space with some muscle activity, normal or abnormal. To assess head control, the trunk was fully supported in the midline while the head was placed in the upright position, head support was then removed. Trunk control was assessed in the same manner, with the trunk placed in the midline and hand support then removed. If the patient was unable to sit (e.g. medical limitations, safety, or concomitant injuries), the head and trunk were scored as 0.

Alignment in sitting was assessed using the same scale and procedure as alignment in supine. Head alignment was assessed by positioning the head and trunk in the midline and while fully supporting the trunk, the quality of head alignment in the upright position was assessed. Trunk alignment was assessed in the same manner – position the trunk and then remove support. The best alignment achieved for both head and trunk was scored. For patients who were constantly moving, the movement was repeated three times. A score of 0 was recorded: if the patient was unable to sit (e.g. medical limitations, safety, or concomitant injuries); if the patient did not have any head or trunk control (as per control scale); or if the patient required maximum assistance to sit. Finally, overall presentation was scored.

As part of the assessment procedure three comparative measures were performed: GCS (Chieregato et al., 2010; McNett, 2007), COVS (Seaby & Torrance, 1989) and MAS (Carr, Shepherd, Nordholm, et al., 1985).

4.3 Data Analysis

Each outcome measure was scored according to standard criteria and the items for each outcome measure were totalled. At each assessment point from admission to discharge descriptive statistics including mean (standard deviation), median (range) and frequency were generated for all outcome measures. To determine responsiveness to change for all measures at Day 3, 7 and discharge standardised response means (SRM) were calculated. This would show the mean change in score between the first assessment and the comparison assessment, divided by the standard deviation of the individual changes in scores (Portney & Watkins, 2000). The higher the SRM the greater the responsiveness to change, whereby a value of >0.8 is considered a large effect, >0.5 as moderate effect and 0.2 as a small effect (Cohen, 1977).

To investigate the concurrent validity of the ABIPA compared to the GCS, COVS and MAS a Spearman's rho correlation coefficient was calculated. Admission and discharge scores

were analysed separately with comparisons made between Day 1 scores with Day 3, Day 7, and discharge scores. Discharge data were the last assessment recorded for each participant. Rho coefficients greater than 0.75 were considered good to excellent, with rho coefficients between 0.50 and 0.75 considered to be moderate to good (Portney & Watkins, 2000).

4.4 Results

4.4.1 Participants

Eleven patients (aged 41 years SD18) were recruited to this study. Participant characteristics are included in Table 4.4 In total, 57 assessments were completed for the eleven participants Three participants were assessed over three data points (Days 1, 3 and 7) and were discharged from the study at day seven as they had achieved changes in the scores on the validated functional assessment measures (COVS and MAS).

4.4.2 Responsiveness to change

Table 4.4 illustrates the standardised response means (SRM) from initial assessment for all outcome measures at Day 3, Day 7 and on discharge from the acute ward. At Day 3, the ABIPA showed the greatest responsiveness to change (SRM > 0.83) compared to the other functional measures (SRMs < 0.55), although the GCS was similar (SRM = 0.77). By Day 7, the GCS demonstrated the greatest responsiveness to change while the ABIPA was higher than the other measures (SRMs < 0.87). At discharge all outcome measures showed good responsiveness to change (SRMs > 0.9) with the strongest score demonstrated by the GCS followed by the ABIPA and the MAS. The responsiveness of the MAS and COVS was consistently low to moderate on Day 3 of the assessments and continued to be lower than the ABIPA on Day 7. The total COVS was also lower at discharge with the MAS showing a similar SRM as the ABIPA by discharge.

Table 4.3 Participant characteristics

Participant	Age (years)	Gender	Diagnosis	Mechanism of injury	Time since injury (days)	GCS at admission
1	24	M	Intraventricular bleed / diffuse axonal injury	High speed MVA / multi-trauma	14	6
2	17	M	Intracerebral haemorrhage	MVA	20	5
3	58	F	Anterior cerebral aneurysm	Collapse at home	13	5
4	62	M	Intracerebral haemorrhage	Collapse at home	9	7
5	21	M	Intracerebral haemorrhage	Drug overdose	10	10
6	69	F	Subarachnoid haemorrhage	Trauma	9	3
7	51	M	Intracerebral haemorrhage	Hypertensive bleed	12	6
8	49	M	Subarachnoid haemorrhage	Collapse	30	3
9	30	M	Subdural haemorrhage	Assault	16	3
10	42	M	Subdural haemorrhage	Assault	8	7
11	26	M	Diffuse axonal injury	Trauma-MVA	13	4

Abbreviations: F, Female; M, Male; GCS, Glasgow Coma Scale; MVA, motor vehicle accident

Table 4.4 Standardised response means (SRM) from initial assessment for all outcome measures

Outcome measure	SRM Day 3	SRM Day 7	SRM Discharge
GCS	0.77	1.76	2.25
ABIPA	0.83	1.2	1.95
COVS	0.40	0.68	0.91
MAS	0.55	0.87	1.94

Abbreviations: ABIPA, Acquired Brain Injury Physiotherapy Assessment; COVS, Clinical Outcome Variable Scale; GCS, Glasgow Coma Scale; MAS, Motor Assessment Scale; SRM, Standardised Response Mean.

4.4.3 Concurrent validity of ABIPA

Table 4.5 illustrates admission and discharge scores on all outcome measures for all participants. For all assessments (n = 57) the ABIPA demonstrated good to excellent correlations with the GCS (rho > 0.76, $p \leq 0.001$), COVS (rho > 0 .82, $p \leq 0.001$) and MAS (rho > 0.66, $p \leq 0.001$). The investigation of concurrent validity at specific assessment points - such as Day 1, 3 and 7 – showed that the ABIPA was moderately associated with all outcome measures across the first week at admission to the acute neuroscience ward (rho > 0.53, $p \leq 0.001$) whereas at discharge, the associations were higher (rho > 0.72, $p \leq 0.001$).

Table 4.5 Admission and discharge scores for all outcome measures (n = 11)

Participant	Day 1				Discharge			
	GCS (/15)	ABIPA (/60)	COVS (/91)	MAS (/21)	GCS (/15)	ABIPA (/60)	COVS (/91)	MAS (/21)
1	9	22	13	1	14	45	31	12
2	8	27	17	1	N/A	48	22	5
3	8	22	13	0	10	18	14	4
4	7	19	13	0	11	41	18	6
5	10	34	13	0	12	53	36	10
6	4	6	13	0	5	11	13	0
7	7	30	14	0	10	48	22	8
8	9	16	13	0	14	41	20	9
9	9	27	14	0	14	53	65	6
10	7	30	14	1	12	55	37	8
11	6	18	13	0	12	44	20	5

Abbreviations: ABIPA, Acquired Brain Injury Physiotherapy Assessment; COVS, Clinical Outcome Variable Outcome measure; GCS, Glasgow Coma Scale; MAS, Motor Assessment Scale; N/A, not available.

4.5 Discussion

The aims of this first study of the thesis were to describe the development of the ABIPA, examine its responsiveness to change against other common measures and establish its concurrent validity with other common assessment tools. The ABIPA score holds a strong positive relationship with GCS score, the current standard measure of acute brain injury, and shows a greater responsiveness to change when compared to other assessment measures during the acute recovery stage following moderate to severe ABI.

The mechanism for determining construct validity of an outcome measure was to compare it with outcome measures that measure similar, related constructs. In this study, the ABIPA was compared with the GCS (a measure of responsiveness), the COVS (a measure of functional independence) and MAS (a measure of motor recovery). The strong relationship between scores of these instruments supports the high construct validity of the ABIPA.

The ABIPA had the highest level of responsiveness to change when comparing scores Day 1 to Day 3 after admission to the neurosurgical ward. Between Day 1 and Day 7, GCS and ABIPA continued to have higher responsiveness to change than the COVS and MAS. Further, a statistically significant difference in responsiveness to change between ABIPA and COVS, GCS and MAS and COVS was found. The ABIPA was able to detect change much earlier than the other functional neuro-motor outcome measures for any given patient. This is an important finding as physiotherapists must make decisions regarding suitability for rehabilitation very early in a patient's acute hospital stay. If such decisions are based on COVS and MAS alone, it would be difficult to advocate objectively for the patient as the existing outcome measures are not detecting change during the immediate period after ABI. As the ABIPA continues to show high responsiveness to change during the stages of acute hospital care it makes an attractive tool for clinical use.

To date, there is no specific outcome measure to monitor acute incremental changes in a patient's neuro-motor impairments across the acute period of care, for those with severe brain impairment following ABI. The majority of outcome measures focus on the patient's level of consciousness, cognitive functions, behaviour, social participation and functional limitations (Wright, Bushnik & O, Hare, 2000). The absence of an appropriate outcome measure for this patient population significantly impacts on clinicians' ability to objectively assess the effectiveness of interventions, communicate changes in a patient's condition with other team members and advocate for patients (Altman, 2001). It is also a significant barrier to the advancement of research and evidence-based practice in the early stages of rehabilitation for this complex and challenging clinical population.

No outcome measures were located that specifically monitored neuro-motor impairments in the acute stages of recovery, which is the focus of physiotherapy management following severe ABI (Canedo et al., 2002; O'Dell et al., 1996; Pape et al., 2006; Teasdale & Jennet, 1974). The ABIPA was found to be a valid measure of change in neuro-motor impairments following severe brain injury, producing scores that were responsive to change.

4.6 Limitations

A key challenge was recruiting an adequate number of participants for the study. The number of severe brain injuries each year is relatively low and as motor vehicle accidents account for a large percentage, often patients have concomitant orthopaedic injuries and thus, had to be excluded. There were only 11 participants in the initial sample and 8 participants following the third assessment. Difficulties were encountered in assessing those people who were agitated and restless, who have reasonable movement but whose communication, cognition or behaviour was such that they made it exceedingly difficult to accurately assess.

The participant cohort suffered predominately severe ABI (GCS 3-8), with only one patient representative of the moderate brain injury (GCS 9-12) population. This limits the ability to generalise the outcome measure and would suggest the need for further study of a broader cohort following ABI.

4.7 Conclusion

This study verifies the concurrent validity of the ABIPA and demonstrates its high responsiveness to change against other common measures used for ABI patients. It is now necessary to test the reliability of assessors using the tool and involve multiple assessors to further investigate the inter-tester and intra-tester reliability of the instrument.

Chapter 5

Study 2: Inter and intra-tester reliability of the Acute Brain Injury Physiotherapy Assessment (ABIPA) in patients with acquired brain injury.

The following chapter is based on a peer-reviewed submission published in Brain Injury (Appendix 6). The bibliographic details are:

Gesch, Janelle M., Low Choy, Nancy L., Weeks, Benjamin K., Nascimento, Margarida, Steele, Michael, Kuys, Suzanne S. Inter and intra-tester reliability of the Acute Brain Injury Physiotherapy Assessment (ABIPA) in patients with acquired brain injury. Brain Injury, 2016 9: 1-8.

Abstract:

Background: The Acute Brain Injury Physiotherapy Assessment (ABIPA) is a new outcome measure with face validity and responsiveness to change in the acute stages of neuro-motor recovery after Acquired Brain Injury. Reliability of physiotherapists scoring the tool has not been established.

Objective: Determine inter- and intra-tester reliability of physiotherapists using the ABIPA.

Methods: Observational study using video-recorded assessments of patient performance (n = 7) was undertaken with two cohorts of physiotherapists: those receiving training and those provided with guidelines only to administer the ABIPA.

Results: Thirty physiotherapists were recruited, 83% female, average 8.5 SD8.5 years' experience as physiotherapists and 3.2 SD4.9 years' experience in neurological rehabilitation. Twenty-three (77%) physiotherapists received training. Across all physiotherapists (n = 30), inter-tester reliability was excellent ($\alpha \geq 0.9$) for total ABIPA score. All individual items, except trunk alignment in supine ($\alpha = 0.5$), showed excellent or good internal consistency ($\alpha \geq 0.7$). For intra-tester reliability, substantial or perfect agreement was achieved for eight items (Weighted kappa $K_w \geq 0.6$), moderate agreement was achieved for four items ($K_w = 0.4 - 0.6$), and three items achieved fair agreement (alignment head supine: $K_w = 0.289$; alignment trunk supine: $K_w = 0.387$; tone left upper limb: $K_w = 0.366$). Both trained physiotherapists and untrained physiotherapists demonstrated similar inter-tester and intra-tester reliability.

Conclusion: Physiotherapists are highly consistent scoring the ABIPA but several items need revision to improve intra-tester reliability. High inter-tester and intra-tester reliability was achieved regardless of whether training had been undertaken.

5.1 Introduction

It has previously been identified that more extensive research is required into the validity and reliability of outcome measures to improve patient care in people with a moderate to severe ABI (New Zealand Guidelines Group, 2007; Teasell et al., 2007; G. Zitnay et al., 2008). The ABIPA has been introduced in the previous chapters as a new physiotherapy outcome measure specifically developed for assessing people who present with a moderate or severe brain injury (Chapter 4). It combines the assessment of tone, head and body alignment, muscle strength and control and in the acute setting, is a practical method of monitoring patient progress. Chapter 4 established concurrent validity of the ABIPA and demonstrated sensitivity to change in the acute stages of neuro-motor recovery following ABI. For the ABIPA to be used with confidence in the clinical context by multiple assessors' additional psychometric properties need to be established. This chapter will investigate the inter- and intra-tester reliability of the ABIPA for physiotherapists in the acute stages of neuro-motor recovery following moderate to severe ABI.

When investigating the reliability of instruments during the early stages of recovery following ABI, the characteristics of the target population need to be considered. For people following moderate to severe ABI, clinical presentation may vary across short periods of time (Stuss et al., 1994; Swaine & Sullivan, 1996). This population may also present with increasing agitation, confusion and an inability to follow commands (Nott, Chapparo, & Baguley, 2006; Silva et al., 2012).

Furthermore, this population may suffer from fatigue or respond poorly to additional handling. If concurrent assessments are performed in the one session by multiple assessors, people following a moderate to severe ABI may be easily distracted (Borgaro, Baker, Wethe, Prigatano, & Kwasnica, 2005; Swaine & Sullivan, 1996; Zinno & Ponsford, 2006). Another

consideration is that the target population may present with an increase in behavioural symptoms or cognitive impairments and therefore respond poorly to the complexity of assessments (Belmont, Agar, & Azouvi, 2009). The changing clinical presentations impose a major constraint on the investigation of instrument reliability and suggest that determining inter-tester reliability through repeat patient assessments is difficult for this population.

An alternative to assess reliability is the use of videorecorded assessments. Videorecorded assessments alleviate the need for repeated assessments and limit the burden of multiple concurrent assessors, effectively eliminating within-subject variability from the analysis (Swaine & Sullivan, 1999). Therefore, rating videorecorded performances of people following an ABI presents a viable and practical method of determining reliability of the ABIPA.

5.2 Aims

The primary aim of this study was to determine the inter- and intra-tester reliability of physiotherapists scoring the ABIPA. A secondary aim was to determine if reliability of physiotherapy assessors improved when training was provided compared to using instructional guidelines to assist with the application of the ABIPA.

5.3 Method

5.3.1 Study design

An observational study design using video recorded assessments of people following a severe ABI was used to determine inter- and intra-tester reliability of physiotherapists using the ABIPA. Physiotherapy participants were recruited into two groups; those who were provided with instructional guidelines and those who received training in use of the ABIPA tool prior to viewing the videorecorded assessments. Ethical clearance was granted from Princess Alexandra Hospital Human research ethic committee (HREC) and Griffith

University (HREC) (Appendix 2). Informed consent was obtained from all participants including legal guardians or next of kin as required.

5.3.2 Participants

Two groups of participants were recruited: people with an ABI and physiotherapists working in the field of neurological rehabilitation. People with moderate or severe brain injury were recruited as a sample of convenience for the first group. Patients admitted to either the acute neurosurgical ward or brain injury rehabilitation unit of a tertiary public hospital in Brisbane, Queensland, Australia and recently diagnosed with either a moderate (GCS 9-12) or severe (GCS 3-8) ABI or a grade four or five subarachnoid haemorrhage were included in this study. Criteria for inclusion were people less than 60 years old, medically stable (i.e. had been discharged from intensive care) and with no major musculoskeletal disorders (e.g. amputation or fracture) or previous neurological conditions (e.g. stroke or Parkinson disease) that may impact on the quality of movement recovery. Those deemed not medically stable or who were awaiting clipping of an aneurysm were excluded. Everyone who consented to be part of the study was videorecorded during a single session with a physiotherapist who scored the patients' performance for each of the ABIPA items.

The second group of participants recruited were physiotherapists, who were eligible to participate if they were working in the acute neurosurgical unit, brain injury rehabilitation unit or rehabilitation unit at the same tertiary referral public facility. Physiotherapists were recruited in two groups as samples of convenience. The first group underwent training on use of the ABIPA to score patient performances prior to viewing and scoring the videorecorded performances of the patients. The second group was provided with the ABIPA scoring guidelines (Appendix 2), prior to viewing and scoring the videorecorded performances. Demographic details of the participating physiotherapists were collected including gender,

years working as a physiotherapist, and time spent working specifically with neurological patients.

5.4 Procedure

5.4.1 Production of the ABIPA video recording package

Video recordings were produced for seven patients with moderate or severe ABI. Patients were assessed with the ABIPA by an experienced neurological physiotherapist. Video guidelines were developed to ensure all videos were similar in their assessment procedure, format and sequence of ABIPA items assessed. The same order of assessment was recorded and multiple views, for example, from the side and the front, as described in Chapter 3.

The initial video guidelines and recording procedure was developed and trialled in a pilot study undertaken with physiotherapy students from Bond University. Results of this pilot study revealed that while overall reliability was high (Cronbach alpha $\alpha = 0.989$) some items performed less strongly. Items showing less reliability were the head and trunk alignment items in sitting and supine ($\alpha = 0.661 – 0.789$) and the tone assessment items ($\alpha = .719 – 0.880$). The video recording procedure was adjusted to include longer viewing time of positions, increased viewing angles and identification of markings for the alignment assessments and the addition of verbal cues to capture the essence of 'muscle tone and movement' components of the ABIPA assessment. These elements are normally evaluated by a physiotherapist using their sense of touch. Without the addition of word descriptors, physiotherapists viewing the performances found it more difficult to score the items of tone and movement based only on visual observation. Using this format, all participating patients were assessed using the ABIPA.

5.4.2 Reliability testing

To establish inter-tester reliability of the ABIPA, participating physiotherapists viewed and scored the video recording of the ABIPA assessment being carried out with the selected patients. Video recordings were viewed and scored by two groups of physiotherapists recruited sequentially; the first group who were trained and the second who were provided with written ABIPA scoring guidelines only.

The first group of participating physiotherapists attended two one-hour training sessions: an initial instructional session and then a practice session before completing their scoring session within one week of being instructed. The ABIPA and guidelines were presented and discussed and then a trial assessment on a selected video recorded patient assessment was completed during the two training sessions. The video recording of the selected patient used in the training process, was not included in the actual test session. Physiotherapists were encouraged to seek clarification about any assessment terms and all questions were answered. Within one week of training, participating physiotherapists scored the video recorded packages of ABIPA assessment. The second group of participating physiotherapists were provided with the ABIPA guidelines but were not provided with any training or coaching prior to viewing and scoring the *ABIPA package of assessments*.

During the test sessions, each group followed the same format with multiple assessors viewing the video recordings simultaneously on a projected screen and scoring the performance of each assessment item using the ABIPA assessment sheet and guidelines (Appendix 1). At the completion of each video recorded patient assessment, individual score sheets from each physiotherapist were collected and placed in a sealed envelope for future analysis. Physiotherapists were blinded to each other's scores. This process continued until all video assessments had been reviewed and scored by each physiotherapist. Intra-tester

reliability was examined by repeat screenings of patient video recorded assessments by available physiotherapists; a minimum of two weeks following the initial recording session.

5.5 Data analysis

All data were analysed using SPSS Software v.24 (IBM, Chicago, USA) or GraphPad Software. Descriptive statistics were generated for demographic profiles and characteristics of the two groups of participants. To determine consistency of scores between assessors Cronbach's alpha, a measure of inter-rater reliability (Cohen, 1977), was calculated for each item and for total ABIPA score. Cohen's weighted Kappa (K_w) statistic was selected to determine agreement between categorical scores by the same assessor (intra-tester reliability). Percentage agreement was also calculated for intra-tester reliability with a significance level set at $p < 0.05$.

5.6 Results

The characteristics of the participating patients in the video recordings informing the *ABIPA Package* are presented in Table 5.1. Of the seven participants, five (70%) were male with an average age of 29.0 SD13.9 years. Over 50% were diagnosed with a diffuse axonal injury, while the next most common diagnosis was subdural haematoma.

Thirty physiotherapists were recruited to the study, with 23 forming the trained group and seven (7) in the second group using the guidelines to score the video-recorded assessment (untrained). Of these, 26 (19 trained and 7 untrained) participated in the intra-tester reliability study. Physiotherapist characteristics are presented in Table 5.2.

Table 5.1 Participant characteristics.

Participant	Age (Years)	Gender	GCS (0-15)	Mechanism of Injury	Clinical presentation / Diagnosis
1	19	Male	3	MVA- Single vehicle rollover	Hypoxic brain injury with epidural haematoma and subdural haematoma
2	30	Male	6	Assault	Diffuse axonal injury and subdural haematoma
3	56	Male	3	AVM + Aneurysm	Diffuse axonal injury and subdural haematoma
4	45	Male	10	MVA	Frontal Parietal contusions and subdural haematoma
5	23	Female	4	Fall from 3rd storey balcony	Diffuse axonal injury, subdural/subarachnoid haematoma with petechial intra-parenchymal haemorrhages
6	20	Female	5	Infection	Hypoxic brain injury secondary to endocarditis
7	16	Male	6	MVA	Diffuse axonal injury

Abbreviations: AVM, Arteriovenous malformation; GCS, Glasgow Coma Scale; MVA, Motor vehicle accident

.

Table 5.2 Physiotherapist characteristics

	Trained physiotherapists		**Untrained physiotherapists**		**All**
	Inter-tester (n = 23)	**Intra-tester (n = 19)**	**Inter-tester (n = 7)**	**Intra-tester (n = 7)**	**(n = 30)**
Gender, males: n (%)	3 (13)	2 (10)	2 (29)	2 (29)	5 (17)
Years registered: mean (SD)	9.3 (9.3)	9.3 (9.3)	4.7 (4.2)	4.7 (4.2)	8.5 (8.5)
Years of neurological physiotherapy work: mean (SD)	3.7 (5)	3.0 (5.2)	1.6 (1.6)	1.6 (1.6)	3.2 (4.9)

5.6.1 Inter-tester reliability

Table 5.3 presents internal consistency of ABIPA scores for each item based on Cronbach's alpha, where $\alpha \geq 0.9$ is *excellent*, $\alpha = 0.7$ - 0.9 is *good* , $\alpha = 0.6 – 0.7$ is *acceptable* and $\alpha \leq 0.6$ is *poor* (Cohen, 1977). Across all physiotherapists (n = 30), inter-tester reliability was excellent ($\alpha = 0.90$) for total ABIPA score. All individual items, except for trunk alignment in supine, showed excellent or good internal consistency. The movement item showed the highest consistency ($\alpha > 0.90$) for right and left upper and lower limbs for all physiotherapists.

Table 5.3 Internal consistency (Cronbach's alpha) for individual ABIPA items and total ABIPA score for trained and untrained assessors

Items	Alpha (All)	Alpha (Trained)	Alpha (Un-trained)
Alignment head Supine	0.880	0.846	0.600
Alignment trunk supine	0.540	0.420	0.097
Tone right upper limb	0.917	0.701	0.952
Tone left upper limb	0.881	0.721	0.827
Tone right lower limb	0.951	0.881	0.932
Tone left upper limb	0.970	0.939	0.935
Movement right upper limb	0.996	0.994	0.989
Movement left upper limb	0.978	0.972	0.938
Movement right lower limb	0.994	0.992	0.982
Movement left lower limb	0.988	0.976	0.983
Control head	0.988	0.990	0.934
Control trunk	0.999	0.999	0.992
Alignment head sitting	0.967	0.944	0.921
Alignment trunk sitting	0.968	0.960	0.862
Posture	0.978	0.950	0.978
Total	0.995	0.993	0.987

Trained physiotherapists showed good or excellent internal consistency for total ABIPA score and for all individual items except for alignment of the trunk in supine (α = 0.40). Similarly, untrained physiotherapists demonstrated good-to-excellent internal consistency on total ABIPA score and all individual items except for alignment of the trunk in supine (α = 0.09) and alignment of the head in supine (α = 0.60).

5.6.2 Intra-tester reliability

Table 5.4 presents the weighted Kappa statistic (K_w) and percentage agreement for trained (n = 19) and untrained (n = 7) physiotherapists. The weighted Kappa statistic yields a quantitative measure of the magnitude of agreement between observers (Viera & Garrett, 2005) and determines the consistency with which physiotherapists scored the ABIPA items. The weighted Kappa agreement was interpreted as 0.21– 0.40 *fair* agreement, 0.41–0.60 *moderate* agreement, 0.61–0.80 *substantial* agreement and 0.81–0.99 almost *perfect* agreement (Viera & Garrett, 2005).

When considering all physiotherapists, substantial or perfect agreement was achieved for eight items, with moderate agreement reached for a further four items, leaving three items, 20% of the outcome measure, achieving fair agreement. The items with the lowest agreement were alignment head supine, alignment trunk supine and tone in the left upper limb were similar for both the trained and untrained participants.

Table 5.4 Weighted Kappa statistic and percentage agreement for individual ABIPA items for physiotherapy assessors

ABIPA Item	All Physiotherapists n = 30		Trained n = 19		Untrained n = 7	
	Weighted kappa	**Percentage agreement**	**Weighted kappa**	**Percentage agreement**	**Weighted kappa**	**Percentage agreement**
Alignment head supine	0.289	41.5	0.361	43.5	0.029	35.7
Alignment trunk supine	0.387	48.1	0.313	46.1	0.481	53.5
Tone right upper limb	0.530	71.7	0.503	73.0	0.610	67.8
Tone left upper limb	0.366	73.5	0.279	73.0	0.530	75.0
Tone right lower limb	0.676	72.6	0.647	73.0	0.727	71.4
Tone left upper limb	0.520	76.4	0.329	78.2	0.662	71.4
Movement right upper limb	0.839	78.3	0.831	79.4	0.840	75.0
Movement left upper limb	0.721	68.8	0.742	70.5	0.635	64.2
Movement right lower limb	0.685	69.7	0.780	74.3	0.819	78.5
Movement left lower limb	0.560	62.2	0.478	60.2	0.709	67.8
Control head	0.722	66.0	0.698	66.6	0.744	64.2
Control trunk	0.881	91.5	0.913	93.5	0.793	85.7
Alignment head sitting	0.559	49.0	0.536	48.7	0.569	50.0
Alignment trunk sitting	0.660	75.4	0.725	79.4	0.460	64.2
Posture	0.726	89.6	0.676	84.8	1.00	100

5.7 Discussion

Study 2 investigated the inter- and intra-tester reliability of physiotherapists scoring using the ABIPA and the findings demonstrated that physiotherapists have a high level of consistency when scoring the video recorded package of ABIPA assessments. Study 2 also demonstrated that physiotherapists achieved a high level of consistency when scoring the video-recorded package of ABIPA assessments without training and independently using the scoring guidelines.

The consistency of scoring between assessors did vary across items, suggesting that some items were more challenging to score than others. High inter-tester and intra-tester reliability was demonstrated across several items including tone right lower limb, movement of the right and left upper and lower limb, control of the head and trunk, alignment trunk sitting and posture. Items with the lowest inter-tester and intra-tester reliability were the assessment of head and trunk alignment in supine. This might reflect a limitation of two-dimensional video in accurately representing patient position. In fact, previous studies have reported difficulties in visually assessing alignment (Fedorak, Ashworth, Marshall, & Paull, 2003; Passier, Nasciemento, Gesch, & Haines, 2010) and may suggest that these particular items are better evaluated in a live performance assessment or may require visual markers when viewed via video recording. The items assessing alignment require further investigation.

Three items demonstrated high inter-tester reliability ($n = 30$ with $\alpha \geq 0.9$), but with only fair intra-tester reliability ($K_w \leq 0.4$). These items were alignment of the head in supine, alignment of the trunk in supine and tone in the left upper limb. These results are not easily explained. This unexpected finding may be partially due to familiarity with the assessment tool. Experience with the assessment guidelines may have influenced the second viewing with the physiotherapists thinking more about how they were scoring the performance and a

higher acceptance of the descriptors used to rate each item, resulting in different scores (Baer et al., 2003). Regardless, a similar trend across individual items was observed for both intra-tester and inter-tester reliability. Items of alignment of head and trunk in supine were the worst overall performers, for both inter-tester and intra-tester analyses. Clearly these items require further investigation for continued inclusion in the ABIPA with a factor or Rasch analysis indicated to guide revision of item content of the ABIPA (Belvedere & de Morton, 2010).

As the ABIPA is a new tool, training was initially provided to the first group of participating physiotherapists. It was anticipated that training was required to ensure that clinicians were familiar with the concepts and items included in the tool as well as illustrate how the scoring process was to be used. Training would optimise consistency and accuracy of ABIPA scores. However, the participating physiotherapists who did not receive training had comparable inter-tester reliability (Ada et al., 2004; Baer et al., 2003). Although the trained physiotherapists had higher Cronbach alpha scores than the untrained physiotherapists on ten of the 15 items, scoring the ABIPA achieved excellent to good consistency in both groups. The two overall lowest scoring items, head and trunk alignment in supine, also had low levels of agreement across the two groups. When comparing intra-tester reliability for the trained and untrained physiotherapists, it is notable that the untrained physiotherapists recorded higher weighted Kappa scores on 11 ABIPA items and for six items the difference was large enough to change the level of agreement. Overall though, when both inter- and intra-tester reliability results are considered, training does not appear to be necessary to achieve reliability when using the ABIPA. This suggests that clinicians can independently use the guidelines to prepare for application of the ABIPA into clinical practice. This would be a time efficient method for inducting new staff members to an acute neuroscience setting where the tool has an application in monitoring early signs of motor recovery after ABI.

Another consideration is the clinical experience of physiotherapists using the ABIPA. Previous studies have found assessment tools reliable across different experience levels (Baer et al., 2003; Carr, Shepherd, Nordholm, et al., 1985). However untrained physiotherapists had less than half the number of years of experience in neurological physiotherapy when compared to the trained physiotherapists in this group. This discrepancy makes it difficult to interpret the reliability findings based on training alone and other factors such as curriculum content related to preparation of graduate physiotherapists and training in observation of posture and movement may need to be considered.

5.8 Limitations

This study has several limitations. Firstly, a small sample of only seven patient videos after ABI was included, which limited the patient performances scored. As this population is difficult to assess, obtaining suitable patients without complications, who could be consented by next of kin, to participate and tolerate assessments, was challenging (Whyte, 2002). The sample did represent a variety of GCS levels and functional levels and was representative of the mostly male ABI population. A cross sample of ages was also represented. The sample of physiotherapists recruited may also have influenced our findings. Fewer untrained physiotherapists were recruited with only seven participating in the reliability analysis. It was anticipated that both groups would have similar numbers of participants; but a similar number of untrained physiotherapists could not be recruited. Additionally, physiotherapist experience may have also influenced the results with a range between one and twenty-one years of experience in neurological physiotherapy. Previous studies have shown that this limitation does not influence results (Baer et al., 2003; Kuys & Brauer, 2006).

The limitations of two-dimensional video assessment have also been highlighted as a possible contributor to poor inter- and intra-tester reliability for the alignment items (Pomeroy et al.,

2003; Wiles, Newcombe, Fuller, Jones, & Price, 2003). There are disadvantages associated with observational assessments, such as the apparent loss of clinical fidelity (i.e. assessors cannot 'feel' the patient's response) (Pomeroy et al., 2003). Nonetheless, videorecorded performances have been used to investigate reliability in patients with ABI undergoing rehabilitation (Kierkegaard & Tollbäck, 2005; Low Choy et al., 2002; Subramanian et al., 2013; Swaine & Sullivan, 1996). Such videorecorded performances can be viewed by different assessors to establish inter-rater reliability and at a later time interval by the same assessors to determine intra-rater reliability (Low Choy et al., 2002). It is unclear if, an assessment of a live performance may have resulted in different findings. This may need to be considered despite the challenges that this may involve for people after ABI (Belmont et al., 2009; Stuss et al., 1994; Zinno & Ponsford, 2006).

5.9 Conclusion

The complexity of the neuro-motor impairments experienced by those surviving ABI has stimulated multiple efforts within the physiotherapy discipline to develop more precise tools to monitor progress and outcomes in the acute stages of recovery after ABI. A measure with sound psychometric properties is indispensable for use in clinical practice and research. The ABIPA has shown a high level of inter-tester reliability for most items but requires further investigation of specific items to address the issues identified in relation to the intra-tester reliability.

Chapter 6

Study 3: Strength and characteristics of the items of the Acute Brain Injury Physiotherapy Assessment (ABIPA) in people with an acquired brain injury: A factor analysis.

The following chapter represents Study 3 of this thesis. This study has been prepared for peer-reviewed submission to Brain Injury, 2019 (Appendix 7).

Gesch, Janelle M., Low Choy, Nancy L., Weeks, Benjamin K., Steele, Michael, Kuys, Suzanne S. Strength and characteristics of the items of the Acute Brain Injury Physiotherapy Assessment (ABIPA) in people with an acquired brain injury: A factor analysis.

Abstract

Background: Investigation of the structure and dimensionality of the Acute Brain Injury Physiotherapy Assessment is required to examine if revision is possible with several items identified as having poor inter-tester and intra-tester reliability.

*Objective***:** To investigate the underlying factor structure of the Acute Brain Injury Physiotherapy Assessment (ABIPA).

Methods: Exploratory factor analysis with principal axis factor extraction and varimax rotation of ABIPA assessments conducted between 2005 and 2009 of adults diagnosed with moderate (GCS 9-12) or severe (GCS 3-8) brain injury admitted to an acute neurosciences ward and brain injury rehabilitation unit.

Results: Exploratory factor analysis suggested a four-factor solution with a simple structure (factor loadings ≥ 0.30) that explained 69.6% of total variance. Factor one accounted for 36.6% of the variance while factor two explained 15.8%, factor three 9.6% and factor four accounted for 7.5%. Two items were identified with the lowest loading with the four-factor solution, *Alignment of the head in supine* loading to factor three at 0.358 and *alignment of the trunk in supine* loading to factor two at 0.405.

Conclusions: Exploratory factor analysis indicates that a four-factor model provides the best fit for ABIPA items**.** Two items, *alignment of the head in supine* and *alignment of the trunk in supine* were the lowest loading items and should be further investigated.

6.1 Introduction

For those requiring rehabilitation after ABI, outcome measures are needed to assess the effectiveness of therapeutic interventions, monitor the achievement of goals, adjust individual rehabilitation programmes, and compare the performance of individual rehabilitation centres (New Zealand Guidelines Group, 2007; Teasell et al., 2007; G. Zitnay et al., 2008). Research has shown support for early physiotherapy intervention, with rehabilitation that begins in the acute phase improving the functional outcome of people with severe ABI (Andelic et al., 2012). There is limited research however, regarding outcome measures able to capture the acute stages of recovery following severe ABI (Canedo et al., 2002; Shukla et al., 2011; Teasdale & Jennet, 1974; Wright et al., 2000).

The ABIPA is an assessment tool designed to measure acute neuro-motor impairments in people with moderate to severe ABI. The ABIPA is a 15-item outcome measurement tool with five subscales; movement, muscle tone, head and trunk alignment in both supine and sitting, and overall position. Each item is scored using a 5-point (0 – 4) scale, with higher scores indicating more independent movement.

Prior investigations have demonstrated concurrent validity of the ABIPA with relevant assessments of consciousness and neuro-motor performance as well as being responsive to change over a 7-day period (Chapter 4). Additionally, inter-tester reliability of the ABIPA was excellent and intra-tester reliability varied from substantial to fair agreement (Chapter 5). As part of the ongoing development of the new assessment measure further investigation is warranted to examine other psychometric properties that would justify the inclusion or exclusion of ABIPA items.

A factor analysis was chosen to reveal the underlying structure and strength of the ABIPA items, determine the potential for item rationalisation and suggest if simplification or

reduction of the number of items influences the information communicated when using the ABIPA. Furthermore, it would be important to examine each subscale item of the ABIPA for any relationship, explore the dimensionality or number of factors underpinning the overall assessment and examine the relative contribution of each chosen item. A factor analysis would identify the expected connections between items (Hurley et al., 1997). It is assumed that similar items would correlate to some degree (Ho, 2006) with those items loading on one factor. For example, four ABIPA items relate to tone measurement. It is reasonable to suggest that these items would be highly associated. The role of factor analysis, therefore, is to highlight the relationship between items, report them as independent factors (Ho, 2006), and potentially create a smaller number of items. Using this premise a four-factor solution is hypothesised – one factor each for tone, for all items assessing movement, for all items assessing alignment and posture, and the last factor for control and overall presentation.

Thus, the aim of this analysis was to examine the factor structure of the ABIPA in a sample of people with ABI and to establish how many factors are needed to explain the pattern of relationships among the ABIPA items. Each item of the ABIPA will be examined for any relationship and thereby establish unique variance or agreement of items onto a single factor. The dimensionality or number of factors underpinning the overall assessment will then be explored and the relative contribution of each factor and the chosen items they represent, to the overall assessment will be examined.

6.2 Method

6.2.1 Study design

A secondary analysis was performed on previously collected ABIPA assessments from Studies 1- 3. The assessments were examined using an exploratory maximum likelihood factor analysis. Factor loadings were considered if greater than 0.3 and initial factors

extracted (Tabachnick, 2014). The factors identified were then examined to see how they corresponded to the ABIPA items initially chosen.

6.2.2 Participants

Psychometric characteristics of the ABIPA were analysed from a cohort of patients, with assessments collected between 2005 and 2009. In brief, participants were included with moderate (GCS 9-12) or severe (GCS 3-8) brain injury admitted to either the acute neurosurgical ward (36 beds) or the brain injury rehabilitation unit (26 beds) of a tertiary (large metropolitan) public hospital in Brisbane, Queensland, Australia. To be eligible, patients needed to be medically stable (i.e. had been discharged from intensive care) and be between 16 and 60 years of age. Patients were excluded if they had major musculoskeletal disorders that may impact on movement return (e.g. amputation or fracture) or if there were any residual impairments from previous neurological insult or conditions (e.g. previous stroke or Parkinson disease). Patients with subarachnoid haemorrhage who were awaiting clipping of an aneurysm or those not deemed medically stable were also excluded.

Ethical clearance was obtained from two institutional human ethics committees and the study was supported by the medical director of the neurosurgical unit (Appendix 2). Informed consent was obtained from the next of kin or legal guardian as required.

6.2.3 Analysis

The 15-item ABIPA was examined by means of factor analysis including maximum likelihood extraction using SPSS Software v24 (IBM, Chicago, USA) to establish a correlation matrix. The Kaiser-Meyer-Olkin (KMO) measure of sampling adequacy tested whether the correlations among the items were small and Bartlett's test of sphericity was interpreted to assess if the correlation matrix was an identity matrix, and therefore the factor model was appropriate (Ho, 2006). To ensure internal consistency of component scales, 0.30

or higher was selected as the criterion of significance for the factor loading, with loading of items below this level not included in the analysis (Tabachnick, 2014). Following a principal axis factor extraction, the matrix was rotated to obtain independent factors (varimax rotation). Clearly defined and interpretable factors were then identified. The amount of variance represented by a factor is explained by an eigenvalue, with an eigenvalue of 1 representing the variance captured by a single item. The plotting of these values onto a scree plot was used to identify the optimum number of factors to be extracted before the unique variance began to dominate the common variance structure (Tabachnick, 2014) and allowed a secondary method to determine the number of factors to retain. The factors were extracted that explained the greatest percentage of variance. A secondary analysis was performed to examine if a reduced number of factors could explain a similar variance percentage. Variance and factorial structure were then examined with reference to the patients' clinical picture and ABIPA items, and further refinement of ABIPA items considered.

6.3 Results

A total of 155 assessments were included in the factor analysis with varimax rotation of the 15 items of the ABIPA. Assessments were only included if all items were present and had been scored using the ABIPA scale. Assessments were analysed from a cohort of patients (n = 30), collected between 2005 and 2009 at the participating facility. Multiple assessments across different time points were anticipated and included for the same patient. Participants had an average age of 33 years and were predominantly male (90%). GCS at admission showed that 67% of participants experienced severe injuries (GCS 3-8) and 33% were classified as moderate brain injury (GCS 9-13). When examining the mechanism of injury 66% were traumatic with the remainder from seizures, post surgery and drug overdoses. An examination of the KMO measure of sampling adequacy suggested that the sample was factorable (KMO = 0.799).

6.3.1 Exploratory factor analysis

Table 6.1 represents the results of an orthogonal rotation with maximum likelihood extraction. When loadings less than 0.30 were excluded, the analysis yielded a four-factor solution with a simple structure that explained 69.6% of the total variance. Examination of the scree plot also supported a four-factor model as being sufficient to represent the data set.

Table 6.1: Factor loading by rotated factor matrix with shading depicting the highest Eigenvalue.

ABIPA items	**Factor**			
	1	**2**	**3**	**4**
Alignment head supine	.188	.178	***.358***	.139
Alignment trunk supine	-.072	***.405***	.199	.055
Tone right upper limb	.144	***.598***	.031	.381
Tone left upper limb	.086	***.614***	.273	-.045
Tone right lower limb	.218	***.735***	.024	.078
Tone left upper limb	.047	***.781***	.161	-.130
Movement right upper limb	.407	-.044	.228	***.853***
Movement left upper limb	.235	.206	***.606***	.145
Movement right lower limb	.424	.160	.318	***.741***
Movement left lower limb	.158	.227	***.952***	.129
Control head	***.663***	-.074	.174	.361
Control trunk	***.726***	.094	.409	.119
Alignment head sitting	***.542***	.037	-.041	.296
Alignment trunk sitting	***.767***	.135	.184	.097
Posture	***.608***	.359	.235	.168

Extraction method: Maximum likelihood. Rotation method: Varimax with Kaiser/normalization.

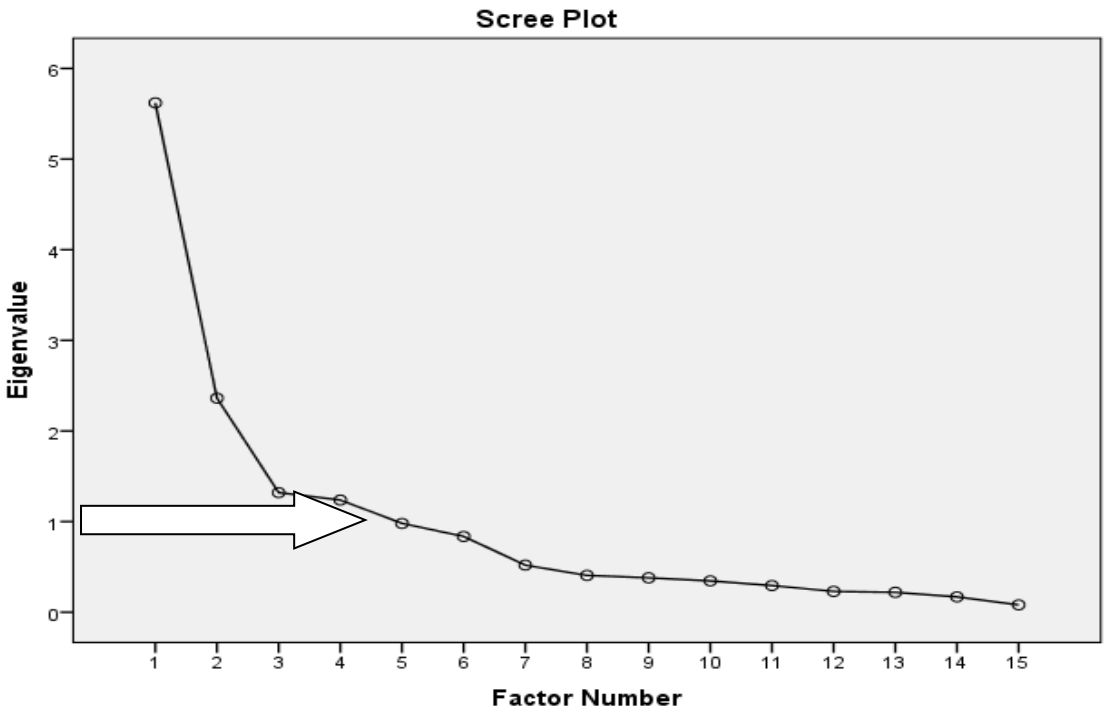

Figure 6.1 Scree plot representation of factor solution

The plotting of the eigenvalues onto a scree plot was used to identify the optimum number of factors to be extracted before the unique variance began to dominate the common variance structure (Tabachnick, 2014). When reviewing the scree plot and the individual eigenvalues, five items loaded onto factor one and included items relating to head and trunk alignment and control in the sitting position. This factor was labelled “alignment and posture”. Five items loaded onto a second factor related to tone in the upper and lower limb. This factor was labelled “tone”. Three items loaded onto factor three and two items loaded onto factor four with the movement items relating to the left and right limbs splitting across two factors – factor three loaded for left side movement and factor four loaded for right side movement.

The four identified factors accounted for 69.6% of the total variance. Factor one accounts for 36.6% of the variance, factor two explains 15.8%, factor three 9.6% and factor four accounts for 7.5%. The fifth factor recorded an Eigenvalue of only 0.97 and was below the accepted value of 1 representing unique variance and therefore no further factors were included.

To test if all four factors were required a secondary analysis was performed. It was proposed that the items associated with the fourth factor and the lowest loaded factor be removed. Factor three and factor four both represented the items of movement and it was hypothesised that potentially reducing them to one factor would not change the overall variance represented by the assessment tool. By removing the right upper limb and right lower limb movement items to restrict the analysis to three factors, only 50% of the variance could be accounted for. Table 6.2 illustrates the restricted (three factor) rotated factor matrix analysis.

Table 6.2: Rotated factor matrix with restricted analysis with shading depicting the highest Eigenvalue.

	Factor		
ABIPA Item	**1**	**2**	**3**
Alignment head supine	.142	***.243***	.242
Alignment trunk supine	-.079	***.417***	.133
Tone right upper limb	.341	***.575***	.088
Tone left upper limb	.099	***.655***	.003
Tone right lower limb	.455	***.655***	-.022
Tone left upper limb	.089	***.730***	-.196
Movement right upper limb	***.310***	.237	.249
Movement left upper limb	***.487***	.190	.125
Movement right lower limb	.387	-.158	***.774***
Movement left lower limb	***.993***	-.038	.098
Control head	.121	.031	***.829***
Control trunk	***.675***	.072	.341
Alignment head sitting	***.546***	.388	.278

Extraction method: Maximum likelihood.

Rotation method: Varimax with Kaiser normalization.

6.4 Discussion

As part of measurement development and to further examine the psychometric properties of the ABIPA, a factor analysis was undertaken to reveal the underlying structure and strength of ABIPA items. The analysis suggested a four-factor solution with a simple structure (factor loadings ≥0.30) that explained 69.6% of total variance. When the analysis was restricted to three factors, only 50% of the variance could be explained.

The four factors initially extracted were “alignment and posture”, “tone”, “left sided movement “and “right sided movement”. The first factor “alignment and posture” included the items of control of head and trunk, alignment of head and trunk in sitting and posture. These items have previously been identified as important items for inclusion when assessing neuro-motor impairments (Pilon et al., 1995). It seems reasonable to group these items in a single category in that all are assessing the position of the body in space.

The second factor “tone” grouped the items of muscle tone in upper and lower limbs and alignment of the trunk in supine. Tone or spasticity is defined as an increase in the velocity dependent stiffness of a muscle (Lance, 1976) and collectively refers to a host of motor over activity syndromes stemming from upper motor neuron damage (Crooks et al., 2007). Some therapists hold the view that altered muscle tone underlies or accentuates other motor impairments (Anderson et al., 2011; Bobath, 1990), while those with more severe brain injuries tend to develop earlier and more aggressive forms of altered tone (Marshall et al., 2007; Zafonte et al., 2004). The literature also supports muscle tone as an important item in the evaluation of ABI recovery (Charness, 1986; Duncan, 1990; Laxe et al., 2012; Mittrach et al., 2008; Swaine et al., 1994) and therefore this factor could be anticipated as one of the underlying factors for inclusion in an assessment of neuro-motor impairments post moderate to severe ABI.

The inclusion of alignment of the trunk in supine in factor two is not, however, as easily understood, especially considering that alignment of the head in supine, loads onto factor three. As with the alignment items of head and trunk in sitting (factor one), it might be expected that the alignment items of head and trunk in supine would load to the same factor; although it is not uncommon for factor analysis models to include factors with occasional unusual item loadings (Barth & Martin, 2005).

Another consideration could be made on the strength at which an item loads to a factor. Alignment of the head in supine loads to factor three at 0.358 and alignment of the trunk in supine loads to factor two at 0.405. Both are above the 0.30 criterion for load strength (Tabachnick, 2014), but perhaps identify that the alignment items in supine are poorly associated to one particular factor. Previous studies have also reported difficulties in assessing alignment (Fedorak et al., 2003). Assessing alignment in a patient group that may be agitated and restless and whose language, cognition or behaviour may influence the assessment of alignment may offer some explanation as to the difficulty associated with assessing alignment and therefore where that item may load. This difficulty with loading is also illustrated when looking at the items related to movement. The items for left side movement loaded to factor three, while the items for right side movement loaded to factor four. In people with moderate or severe ABI active or spontaneous movement is not always present or the movement observed may not be purposeful or functional (Greenwald et al., 2015; Turner-Stokes et al., 2005), but it would be reasonable to expect that all movement items would load to the same factor. The differential factor loading between sides may have occurred due to the presentation of the people assessed. People following brain injury may have weakness in only one side, weakness in only one limb, or a combination of weakness in all limbs (AIHW, 2007; Teasdale & Jennet, 1974). When trying to assess the different movement recovery patterns observed in people with brain injury, this result suggests that

loading on to different factors may be the best way to account for all possible presentations. When considering the implications for clinical use, representation of both left and right side is an important consideration when measuring outcomes in this patient group.

These factor discrepancies suggested further examination of the factor structure. The reduction in factors however, to a three-factor model, explained only 50% of the variance, suggesting that the four-factor solution was a better representation of the structure underlying the ABIPA items. There are no universal guidelines for the threshold of variance, but it is generally accepted practice to extract those factors that account for the highest percentage of variance until the factor only accounts for a small proportion of the variance (i.e. less than 5 per cent). When there is uncertainty about the number of factors to retain, authors are recommended to retain too many rather than too few (Gorsuch, 1983). Therefore, any further investigation of the ABIPA will focus on the four-factor solution.

6.5 Limitations

A potential limitation of this study was the sample size. People with an ABI often have behaviour or cognition impairments which will exclude them from participating and can make recruiting to formal studies difficult. The inclusion of multiple assessments across different time points for the same person may also have influenced the results. The analysis with the Kaiser-Meyer-Olkin (KMO) measure of sampling adequacy showed that the sample was able to be analysed into factors. This analyses of sample size could have been strengthened by commenting on the ratio of participants to variables, with a ratio of 5:1 accepted in other manuscripts (Norris & Lecavalier, 2010). When comparing the number of participants (155) to the number of variables (15) a ratio of 10:1 supports the assumption from the KMO analysis that the sample size is adequate for this analysis.

The factor retention criteria could have been more clearly identified at the beginning of this analysis. The minimum level to be reached for an item to be included in a factor was identified at 0.30, but no minimum number of items to load onto one factor was established (Hayton, Allen, & Scarpello, 2004). Previous studies have also suggested the use of parallel analysis, to determine the number of factors to retain (Hayton et al., 2004). If the retention method was pre-established this would have allowed us to be more transparent with the choice of factors and strengthened the reasoning behind our decision to retain the four-factor solution. The representation of the rotated factor matrix, the analysis of both three- and four-factor structure, scree plot, Eigenvalue analysis and clinical significance does however support the result of retaining the four-factor solution.

Once the four-factor solution was identified a question arises as to whether the subscale items or the total ABIPA score best represent the chosen construct. Factor analysis has highlighted the relationship between items and reported them as independent factors but further investigation is required of the summed ABIPA score. This study is limited in the ability to explore the total ABIPA score and further investigation between the subscale items and the combined ABIPA score is required.

6.6 Conclusion

As part of the ongoing refinement of a new assessment tool a further examination of the psychometric properties underlying ABIPA item selection was undertaken. Exploratory factor analysis showed that the ABIPA items loaded onto four factors (factor loadings ≥0.30) explaining 69.6% of total variance. The four factors of - “alignment and posture”, “tone”, “left movement” and “right movement” best represent the pattern of relationships among the ABIPA items. Further work to examine the predictive capacity of the ABIPA will help determine if all items continue to be included in the overall structure of the ABIPA assessment.

Chapter 7

Study 4: The association of ABIPA score with long term recovery for people following ABI.

The following chapter represents Study 4 of this thesis. Although the previous studies have identified considerations for refinements of the ABIPA, this last study of the thesis investigates the association of ABIPA scores taken at acute hospital and acute rehabilitation admission with hospital length of stay and long-term recovery. It is anticipated that this preliminary investigation into long term associations of the ABIPA would further inform future refinements.

Abstract

Background: The Acute Brain Injury Physiotherapy Assessment (ABIPA) has demonstrated sound psychometric properties of validity and inter- and intra-tester reliability. It would be useful for physiotherapists to be able to determine if ABIPA performance was associated with hospital length of stay, long term recovery and carer burden following ABI.

Objective: To determine the association of the ABIPA with hospital length of stay, long term recovery and carer burden following ABI.

Methods: A longitudinal follow up study was conducted of people with moderate or severe ABI assessed using the ABIPA at admission to acute care at a tertiary facility. ABIPA scores at admission to acute care admission and rehabilitation were evaluated against: length of stay in the acute hospital setting, in rehabilitation and total hospital length of stay and discharge destination. Additionally, ABIPA scores were examined for association with secondary measures of consciousness (Glascow Coma Scale; GCS), orientation (Mental Status Questionnaire), neuro-motor recovery (Clinical Outcome Variable Scale; COVS), Coma Recovery Scale-Revised (CRS-R), Functional Independence Measure (FIM), Disability Rating Scale (DRS) and Carer Strain Index (CSI).

Results: ABIPA at acute care admission and rehabilitation were inversely related to acute, rehabilitation and total hospital length of stay. ABIPA scores at acute admission demonstrated moderate to good correlations with secondary measures of ABIPA, FIM (motor) and COVS ($rho > 0.508$, $p \leq 0.05$) at long term follow up. ABIPA scores at rehabilitation admission demonstrated moderate to good correlations with secondary measures of GCS and MSQ ($rho > 0.564$, $p \leq 0.05$) and excellent correlations with ABIPA, FIM (motor) and COVS ($rho > 0.802$, $p \leq 0.001$).

Conclusion: The ABIPA shows moderate to good relationships with length of stay and long-term neuro-motor recovery from severe ABI.

7.1 Introduction

For young adults, under 40 years of age, ABI is the leading cause of death in developed countries contributing to high burden of disability among survivors (Goldstein, 1990; Jennett, 1996). Rehabilitation and subsequent long-term care needs post-ABI is of socioeconomic significance. Therefore, rehabilitation effectiveness for improving all outcomes of people with moderate to severe ABI, including physical, cognitive, psychosocial, and functional outcomes is important (Lippert-Grüner, Lefering, & Svestkova, 2007; Shiel, 2001; Williams, Robertson, & Greenwood, 2004).

The rehabilitation process following moderate to severe ABI is characterized by three phases: acute care rehabilitation, sub-acute inpatient rehabilitation ideally in specialised settings, and community-based rehabilitation (Mazaux & Richer, 1998). Commencing rehabilitation within acute care hospital settings for those after severe ABI can improve potential for recovery and optimise outcomes (Khan, Khan, & Feyz, 2002). Early commencement of rehabilitation is therefore regarded as essential. Delays in the commencement of comprehensive rehabilitation, even small delays, can negatively impact functional outcomes in people following a moderate to severe ABI (Tepas et al., 2009). A scale to monitor early incremental changes in neuro-motor impairments, inform treatment and support the need for ongoing rehabilitation has been absent from the field. Clinical decision making regarding ongoing care for people following moderate to severe ABI such as transfer to sub-acute rehabilitation or long-term care facilities is therefore difficult to support without an objective measure (Altman, 2001). The substantial cost of providing services means such decisions have important implications for health service budgets. Therefore any ability to determine

functional recovery is an important factor in planning and utilising rehabilitation resources in clinical practice (Fang et al., 2003).

Variables related to long term outcome after moderate to severe brain injury have had some investigation. A systematic review of variables impacting return to work in adults following ABI grouped variables into three predictor domains. These domains conceptualize the recovery process after ABI and are therefore relevant to broad outcomes following ABI (Nightingale, Soo, & Tate, 2007). The domains and examples of variables included in each domain are provided below:

- pre-injury: demographic variables such as age, sex and education; psychological history, geographical living location, employment and income,
- injury: severity and neurological signs, and
- post injury: functional and neuropsychological status, and discharge destination.

Across the three domains, approximately 240 individual variables were identified in the systematic review (Nightingale et al., 2007); although the range of variables considered in each domain varied widely. Most commonly considered in the scientific literature is the pre-injury domain (Nightingale et al., 2007); with pre injury variables (Steyerberg et al., 2008; Stokes, 2011) as well as post injury variables (Cuthbert et al., 2011; Lingsma, Roozenbeek, Steyerberg, Murray, & Maas, 2010; Lippert-Grüner et al., 2007; Mazaux et al., 1997; Utomo, Gabbe, Simpson, & Cameron, 2009) investigated extensively. It is clear from the systematic review (Nightingale et al., 2007) that there is a lack of consensus regarding a minimum data set of variables associated with long term outcome following severe ABI.

Interestingly, in almost half of the studies included in the systematic review (25/55, 45%) early post injury neuro-motor variables were not considered (Nightingale et al., 2007). This is

in contrast with earlier work indicating that neuro-motor outcomes such as active movement, alignment, muscle tone and control were considered extremely important for evaluation in the early stages of rehabilitation following ABI (Charness, 1986; Duncan, 1990; Pilon et al., 1995; Swaine et al., 1994). Additionally, such variables have not been investigated for their association with long-term recovery or care burden. The availability of an outcome measure that is not only sensitive to change but is also associated with long-term outcome and carer burden would be valuable to clinical practice.

7.2 Aims

The aims of Study 4 were to determine the long-term association of the ABIPA by investigating the relationship between ABIPA scores at acute admission and ABIPA scores at admission to rehabilitation to:

- length of stay in the acute hospital setting,
- length of stay in rehabilitation, overall length of stay and discharge destination, and
- neuro-motor recovery and carer burden between 2 and 5 years post discharge from rehabilitation.

7.3 Method

7.3.1 Study Design

A longitudinal follow up study investigated the association of the ABIPA with long-term recovery and carer burden. Two groups of people with an ABI were included; those at two years post initial injury and those at five years post injury. Institutional Human Research Ethics Committees provided ethical clearance for the conduct of the study (Appendix 3) and informed consent was obtained from all participants or legal guardians or next of kin as required prior to the commencement of data collection.

7.3.2 Participants

People with a diagnosis of moderate to severe brain injury (GCS 3 – 11) who had been admitted to the Princess Alexandra Hospital, Neurosurgical unit, Brisbane, Australia and had been discharged to home or residential care two and five years previously were contacted and invited to participate in this study. All patients had been originally assessed using the GCS and ABIPA with scores recorded during their inpatient admission. Specific inclusion and exclusion criteria were unchanged from previous studies in this thesis. That is, participants had to be less than 60 years old, medically stable with no major musculoskeletal disorders or previous neurological conditions. Patients with moderate to severe brain injury who were not medically stable or who presented with an aneurysm requiring clipping were excluded.

7.3.3 Recruitment

Patients identified from hospital databases as previously assessed using the ABIPA were sent a postal letter invitation at their last known address to participate in a longitudinal study. A follow up phone call from the lead researcher confirmed receipt of the letter and determined their consent to participate in the study.

Once consent to participate had been determined, arrangements were made to see the participants at a location of their convenience with their main carer present if assistance was required for daily activities. Participants attended a once only appointment for approximately 2 hours in which all outcome measures were assessed.

7.3.4 Procedure

A database was created with medical records retrieved for people admitted with moderate to severe ABI, who were assessed with the ABIPA during an acute hospital admission. Demographic data were collected using a standardised collection form and included age

(years), gender, diagnosis, length of acute admission, length of rehabilitation, usual place of residence and discharge destination. At the mutually agreed appointment, all outcome assessments required for this study were completed. The ABIPA was administered together with the secondary measures including the GCS, Mental Status Questionnaire (MSQ), COVS, Coma Recovery Scale-Revised (CRS-R), Functional Independence Measure (FIM), Disability Rating Scale (DRS) and Carer Strain Index (CSI). Measures were selected based on those used previously within this thesis and to assess outcomes of interest of consciousness (GCS), orientation (MSQ), neuro-motor recovery (ABIPA, COVS, CRS-R, FIM, DRS) and carer burden.

7.3.5 Measures

The ABIPA was the primary measure of this study; measuring neuro-motor impairments at acute admission and rehabilitation admission. As previously presented in the preceding chapters the ABIPA is a 15-item tool developed for assessing people following a moderate to severe ABI. ABIPA items include upper limb and lower limb movement, overall muscle tone in each limb, head and trunk alignment in supine, head and trunk alignment in sitting, head and trunk control in sitting, and overall position. Items are scored 0 – 4 with lower scores representing less recovery of neuro-motor function. This is the first study to investigate if the ABIPA has any relationship with long-term outcomes.

Secondary measures will be discussed further and expanded to explore any previously established properties with long-term outcomes.

7.3.5.1 Glasgow Coma Scale

The GCS evaluates the best verbal response, eye opening and motor response. Scores range from 3 to 15 with low scores representing a poor response (Teasdale & Jennet, 1974). The GCS is widely used for patients with an altered level of consciousness and represents a

standardised tool to assess the severity of brain impairment (McNett, 2007). The severity of brain impairment using the GCS has generally been considered the best clinical predicator of long term outcome (Formisano et al., 2004; Hall, Cope, & Rappaport, 1985).

7.3.5.2 Mental Status Questionnaire

The Mental Status Questionnaire (MSQ) provides a brief, objective and quantitative measurement of cognitive functioning and consists of ten questions including an assessment of orientation to time and place, remote memory and general knowledge. The number of errors are counted, with a score of zero representing no errors and the maximum score (Kahn, Goldfarb, Pollack, & Peck, 1960). Previous studies have investigated the association of the MSQ with long- term outcome (De Guise et al., 2013) demonstrating a strong relationship with long-term disability.

7.3.5.3 Clinical Outcome Variable Scale

The COVS is a 13-item measure of neuro-motor function (Seaby & Torrance, 1989). Items and scoring have previously been discussed in Chapter 2. The COVS has been shown to predict length of hospital stay and discharge destination in the stroke population (Ekstrand, Ringsberg, & Pessah-Rasmussen, 2008).

7.3.5.4 Coma Recovery Scale-Revised

The Coma Recovery Scale was initially developed in the 1990s (Giacino, Kezmarsky, DeLuca, & Cicerone, 1991), and revised in 2004 (Giacino, Kalmar, & Whyte, 2004).

The Coma Recovery Scale-Revised (CRS-R) is designed for the diagnosis, prognosis and treatment planning of individuals in a vegetative or minimally conscious state. It comprises six subscales assessing auditory, visual, motor, oral motor, communication and arousal functions with scores ranging from 0-2 to 0-6 (Giacino & Kalmar, 2005; Gollega et al., 2015)

to represent an individual's ability to respond to stimulation. The CRS-R has demonstrated reliability and validity (Wilde et al., 2010) with total scores ranging between 0 to 23. Higher CRS-R scores at admission have shown an association with better outcomes at discharge (Giacino et al., 1991; Portaccio et al., 2018a, 2018b) with its strength lying in the diagnostic value of identifying minimally conscious and vegetative state.

7.3.5.5 Functional Independence Measure

For monitoring progress during post-acute inpatient rehabilitation the FIM (Hall & Johnstone, 1994; Kidd et al., 1996) is the most commonly used measure of functional ability. As previously described, FIM items are scored on a 7-point scale reflecting the level of independence in the task. The two domains represent motor function (8 items, total score 91) and cognitive function (5 items, total score 35). Domains are added, yielding a total score between 18 (complete dependence) and 126 (complete independence).

Total FIM scores have shown strong correlations with COVS scores at rehabilitation admission (rho = 0.823) and discharge (rho = 0.771). Additionally admission total FIM scores have demonstrated a strong negative correlation with rehabilitation length of stay (rho = -0.69) (Salter, Jutai, Foley, & Teasell, 2010); that is, higher FIM scores are associated with a shorter length of stay. FIM has also demonstrated strong associations with discharge function, with the motor domain a stronger predictor of LOS than the cognitive domain (Heinemann, Linacre, Wright, Hamilton, & Granger, 1994). The FIM has also been shown to be a predictor of the need for ongoing therapy (Seel et al., 2007).

7.3.5.6 Disability Rating Scale

The DRS (Neese et al., 2000) comprises eight areas of functioning across four categories: consciousness (eye opening, communication ability and motor response), cognitive ability for

self-care activities (feeding, toileting and grooming), level of function and employability. The DRS is valid, reliable and sensitive to change (Gouvier et al., 1987; Malec, Hammond, Giacino, Whyte, & Wright, 2012; Rappaport, Herrero-Backe, & Winterfield, 1989).

The DRS has demonstrated predictive validity; able to predict acute hospital length of stay and functional state at discharge (Eliason & Topp, 1984; Gouvier et al., 1987; Rao & Kilgore, 1992; Whyte et al., 2005). In addition, the DRS has been shown to be able to differentiate between people who received rehabilitation interventions and those who did not (Fryer & Haffey, 1987). Furthermore, DRS scores at hospital discharge have been shown to have some relationship with carer burden and physical dependency (McCauley, Hannay, & Swank, 2001). The DRS has also been shown to be an effective scale to track progress across the course of functional recovery (Shukla et al., 2011).

7.3.5.7 Carer burden - Caregiver Strain Index

The Caregiver Strain Index (CSI) (Robinson, 1983) is a 13-item tool that measures strain related to care provision with the following domains: employment, financial, social and time (Portney & Watkins, 2000; Sullivan, 2004). Good internal consistency of the CSI has been demonstrated (Post, Festen, van de Port, & Visser-Meily, 2007; Thornton & Travis, 2003; Whalen & Buchholz, 2009). The questions are in a yes/no format with positive responses to seven or more items indicating a greater level of strain and have been shown to correlate with the physical and emotional health of the caregiver. High caregiver burden has been associated with caring for a person with more severe disability (Manskow et al., 2015).

CSI may also be influenced by the 60% of people who report ongoing cognition, behavioural and emotional problems up to two years post initial injury (Ponsford, Olver, & Curran, 1995; Schalén, Hansson, Nordstrom, & Nordström, 1994).

7.4 Data analysis

All data were analysed using SPSS Software v.25 (IBM, Chicago, USA). Descriptive statistics were used to describe the demographic profiles and characteristics of the two participant groups (two year follow up and five year follow up). An initial analysis (independent t test or non-parametric equivalent) was used to investigate differences between the two participant groups to determine if data pooling were appropriate.

Spearman's rho correlation coefficient was calculated to investigate the relationship between ABIPA scores at acute and rehabilitation admission with length of stay in acute care, rehabilitation and total length of stay. A further analysis was undertaken to determine an association with secondary measures collected at long-term follow up including; GCS, MSQ, ABIPA, FIM (total, motor and cognition), COVS, CRS, DRS and CSI. Spearman rho coefficients greater than 0.75 were considered good to excellent, while rho coefficients between 0.50 and 0.75 were moderate to good (Portney & Watkins, 2000).

7.5 Results

7.5.1 Participants

A total of 46 people with ABI were originally identified as having been assessed with the ABIPA during an acute hospital admission and appropriate to be contacted for follow up assessments. Fifteen (33%) were lost to follow up; seven were deceased and eight were not able to be contacted. Nine (20%) declined being involved in the current study. Five had moved out of state and one did not attend agreed appointment times, leaving a total of 16 participants to be assessed on long-term recovery. Participant characteristics are presented in Table 7.1. Of the 16 participants, seven were in the two year follow up group and nine were in the five year follow up group. All but one participant was male and 50% (n = 8) were diagnosed with traumatic injuries.

Table 7.1 Participant characteristics

Participant	Age at time of injury (years)	Diagnosis	Mechanism of injury	GCS at admission	Acute Length of stay (days)	Gender	Time since injury (months)	Discharge destination
Two year follow up								
1	56	Atraumatic subdural haematoma, Subarachnoid haemorrhage	Multi-trauma	10	25	M	29	Previous residence
2	42	Traumatic subarachnoid haemorrhage Intracerebral haemorrhage, diffuse axonal injury	Pedestrian vs. car, multi-trauma	4	28	M	28	Previous residence
3	17	Traumatic brain injury depressed skull #, R frontal subarachnoid haemorrhage	MVA	4	46	M	28	Previous residence
4	21	Traumatic brain injury / extradural haemorrhage, intraventricular bleed, complex base of skull #	Skateboard accident	8	59	M	24	Previous residence
5	63	L) Subdural haemorrhage	Collapse at home	4	51	M	25	Transfer to hospital
6	59	Atraumatic Gr 4 subarachnoid haemorrhage, posterior communicating artery aneurysm	Seizure	9	76	M	25	Previous residence.

Participant	Age at time of injury (years)	Diagnosis	Mechanism of injury	GCS at admission	Acute Length of stay (days)	Gender	Time since injury (months)	Discharge destination
7	22	Traumatic subarachnoid haemorrhage, R parietal subdural haemorrhage, diffuse axonal injury	T- Boned with prolonged extrication	3	158	M	30	Extended rehabilitation facility
Five year follow up								
1	26	Severe TBI with diffuse axonal injury, cerebral oedema, degloving to R) upper arm	MVA	4	50	M	100	Previous residence
2	18	Mid cranial fossa haematoma, cerebral oedema w/ midline shift, skull #	MVA	3	297	M	67	Previous residence
3	57	Subarachnoid haemorrhage, bilateral subdural haematoma, diffuse axonal injury, linear skull #	Head impinged between horse and concrete wall	9	37	M	76	Previous residence
4	17	Right intraventricular haemorrhage and basal ganglia, multiple diffuse petechial haemorrhages, diffuse axonal injury	MVA	6	66	M	110	Previous residence
5	17	Subarachnoid haemorrhage / diffuse axonal injury	High speed MVA - car vs. pole	3	53	M	59	Previous residence
6	32	Traumatic brain injury	MVA	4	174	M	78	Interhospital transfer

Participant	Age at time of injury (years)	Diagnosis	Mechanism of injury	GCS at admission	Acute Length of stay (days)	Gender	Time since injury (months)	Discharge destination
7	49	Shearing injury with frontal contusions and petechial haemorrhages /subarachnoid haemorrhage and cortical contusions /diffuse axonal injury.	Fall from a horse	3	118	F	57	Previous residence
8	44	Restricted diffusion MCA territory / L frontal lobe	Post-surgical infarct	14	53	M	62	Previous residence
9	16	Multiple haemorrhages / midbrain / brainstem, contusion R lung, /diffuse axonal injury	High speed MVA	3	188	M	57	Previous residence

Abbreviations; AVM, Arteriovenous malformation; GCS, Glasgow Coma Scale; GR, grade; L, left; MVA, Motor vehicle accident; MCA, Middle cerebral artery; R, right; #, fracture

7.5.2 Length of stay and discharge destination

Table 7.2 presents the Spearman rho correlations between ABIPA scores at acute admission, ABIPA scores at rehabilitation admission and length of stay in acute care, rehabilitation, total length of stay and discharge destination. Discharge destination was differentiated and coded for analysis with acute hospital transfer, continuing to another hospital for rehabilitation, interim care or nursing home placement and returning to previous place of residence.

When considering length of stay, ABIPA scores at acute admission had at least moderate to good negative correlation with acute length of stay, rehabilitation length of stay and total length of stay (rho > 0.508, $p \leq 0.044$). ABIPA scores at rehabilitation admission correlated negatively with length of stay in rehabilitation (rho = -0.675, p = 0.004) and total length of stay (rho = -0.669, p = 0.005). There was no correlation between ABIPA scores at acute admission (rho = 0.014, p = 0.96) or ABIPA scores at rehabilitation admission (rho = -0.304, p = 0.250) with discharge destination.

Table 7.2 Spearman rho correlations of ABIPA scores at acute and rehabilitation admission with length of stay and discharge destination.

Spearman Rho				
	ABIPA score at acute admission	**P value**	**ABIPA score at rehabilitation admission**	**P value**
Length of stay				
- acute care	-.508	0.044	-.590	0.016
- rehabilitation	-.775	<0.001	-.675	0.004
- total (acute + rehabilitation)	-.849	<0.001	-.669	0.005
Discharge destination	-.014	0.960	-.304	0.252

7.5.3 Neuro-motor recovery and carer burden

Table 7.3 presents Spearman rho correlations between ABIPA scores at acute admission, ABIPA scores at rehabilitation admission and the secondary measures; GCS, MSQ, ABIPA, FIM (total, motor and cognition), COVS, CRS, DRS and CSI.

Table 7.3. Spearman rho correlations of ABIPA scores at acute and rehabilitation admission with secondary measures.

	Spearman Rho			
	ABIPA score at acute admission	**P value**	**ABIPA score at rehabilitation admission**	**P value**
GCS	.332	0.209	**.617**	0.011
MSQ	.392	0.133	**.564**	0.023
ABIPA	**.646**	0.007	**.802**	0.000
FIM (Total)	.400	0.125	**.719**	0.002
FIM (Motor)	**.688**	0.003	**.806**	<0.001
FIM (Cognition)	-.055	0.840	.373	0.155
COVS	**.563**	0.023	**.799**	<0.001
Coma recovery scale	.256	0.338	.**581**	0.018
Disability rating scale	-.374	0.154	**-.812**	<0.001
Carer strain index	.412	0.112	.037	0.892

Abbreviations: ABIPA, Acute Brain Injury Physiotherapy assessment; FIM, Functional Independent Measure; COVS, Clinical Outcomes Variable Scale.
GCS, Glasgow Coma Scale; MSQ, Mental Status Questionnaire;

ABIPA scores at acute admission demonstrated moderate to good correlation with ABIPA scored at long-term follow up, FIM (motor) and COVS (rho > 0.563, $p \leq 0.023$). ABIPA scores at acute admission did not correlate with FIM (cognition) (rho = -0.055, p = 0.84),

Coma recovery scale (rho = -0.256, p = 0.338), Disability rating scale (rho = -0.375, p = 0.154) or Carer strain index (rho = 0.412, p = 0.112).

ABIPA scores at rehabilitation admission demonstrated moderate to good correlation with GCS and MSQ (rho > 0.564, $p \leq 0.023$) and excellent correlations with ABIPA, FIM (motor) and COVS (rho > 0.802, $p \leq 0.001$). No correlation was found between ABIPA scores at rehabilitation admission and FIM (cognition) (rho = -0.373, p = 0.155), and Carer strain index (rho = 0.0.37, p = 0.892).

7.6 Discussion

The ABIPA was initially developed to facilitate physiotherapy assessment of acute recovery of neuro-motor impairments following an ABI. While ABIPA reliability, validity and responsiveness to change have been previously established, its association with long-term recovery had not been examined. The aim of this work, therefore, was to determine the association of the ABIPA for long-term recovery following ABI.

Of the initially identified potential participant group more than 50% were lost to this follow up study. While this proportion may seem high, some studies suggest poor follow up rates may be an inherent characteristic of studies of people following an ABI (Corrigan et al., 2003; Krellman et al., 2014). An initial inability to contact people is a major restriction to participation in long term research in the ABI population (Corrigan et al., 2003) with loss due to mortality previously reported up to 50% for people following a brain injury (Olver et al., 1996).

When a disproportional representation of the target population is recruited, a bias can occur from the study sample. This is especially common following ABI as generally only participants who received rehabilitation are followed (Corrigan et al., 2003). The participant group for Study 4, as a convenience sample were all previously patients of the brain injury

rehabilitation unit of the participating facility, the Princess Alexandra Hospital and the majority had been discharged to their previous residence with support from family. Recruitment bias may be influenced by marital status, residence at injury, ethnic group and education (Krellman et al., 2014). Such bias limits the validity of the results and suggests that results from the current study be interpreted with this consideration.

ABIPA scores at acute admission and rehabilitation appeared to have some relationship with length of stay; acute care, rehabilitation and overall length of stay. Higher ABIPA scores, and therefore less disability, regardless of whether this was scored at acute or rehabilitation admission were associated with a shorter length of stay. Although not unexpected, it is nevertheless pleasing to see that higher ABIPA scores are reflective of shorter length of stay in hospital, both in acute care and rehabilitation. ABIPA scores at acute admission mostly had stronger correlations with length of stay, particularly for rehabilitation and total length of stay than ABIPA scores at rehabilitation admission. This finding was somewhat unexpected, as there are likely a myriad of other considerations that could impact on an acute admission length of stay. Factors such as medical changes, concomitant injuries, deterioration and availability of a transfer destination may impact on acute admission length of stay (Olver et al., 1996). It is possible the admission ABIPA scores may have the potential to guide individual service decisions and resource allocation by identifying those people who may benefit from further rehabilitation.

Discharge destination however correlated poorly for both ABIPA at acute admission and ABIPA at rehabilitation admission. This finding was perhaps not unexpected considering the participant sample of this study. Thirteen (81%) participants were discharged from rehabilitation back to their home environments, two participants transferred to referring hospitals, and only one participant discharged to an extended rehabilitation facility. This may have biased the strength of correlation and further investigation with a larger sample size with

more widely distributed discharge destinations is required. It is also anticipated that other factors such as family support, available resources and support services could affect the discharge destination and these have not been accounted for in this study (Corrigan et al., 2003).

Long-term neuro-motor recovery is a key aim of rehabilitation following ABI. Having some ability to identify those patients with rehabilitation and long-term neuro-motor recovery potential would be valuable to clinicians. ABIPA scores at acute admission demonstrated moderate to good correlation with well-known measures of neuro-motor impairment, the FIM (motor) and COVS. ABIPA scores at rehabilitation admission appeared to demonstrate a stronger relationship with long-term neuro-motor recovery as indicated by good to excellent correlations with FIM motor and total scores, DRS and COVS follow up measures. Similarly, good to excellent correlations were also found between ABIPA scores in hospital with follow up ABIPA scores. Such strong associations are again pleasing to see as all are measuring neuro-motor impairments. Each of these measures have neuro-motor components and a good correlation is further encouragement that the ABIPA is measuring the construct demonstrated initially in Study 1. Neuro-motor score and limb movement have also previously been found to be associated strongly with functional outcome (Kamal, Agrawal, & Pandey, 2016; Langhammer & Stanghelle, 2006).

It was a little surprising that ABIPA scores at acute admission were not associated with GCS or MSQ but ABIPA scores at rehabilitation admission were. In Study 2 of this thesis, good association between ABIPA scores throughout the acute admission with GCS were demonstrated. The MSQ is a measure generally based on questions of orientation, so it would be reasonable to suggest that higher ABIPA scores representing better neuro-motor function, may also be related to better orientation and arousal. Previously a high association between

the MSQ and FIM (De Guise et al., 2013) has been demonstrated. Further investigation of reasons underpinning these findings is required.

Conversely those scales with limited neuro-motor items would be expected to not correlate well with the ABIPA. This is shown with poor correlations of ABIPA at rehabilitation admission to FIM (cognition) and Carer strain index. It could be argued that the Carer strain index would be influenced by the level of functional disability and by association the neuro-motor recovery, but previous studies have also shown that Caregiver anxiety was not related to level of disability (Bergquist, Bennett, Gouvier, & Novack, 1991) and neuro-motor impairments correlated poorly with quality of life (Langhammer & Stanghelle, 2006).

7.7 Limitations

Limitations of this study will affect the extent to which results can be generalised. Participant numbers in the follow up group represented a small sample which characterised poorly defined distribution of discharge destinations. When examining national datasets it is however representative of the ABI population with the majority of ABI units showing between 70% - 80% of people discharge to home environments (Chiavaroli et al., 2016; Simmonds, 2018). Using a sample of convenience, the participants had all received rehabilitation at the treating tertiary hospital, with no representation of people who did not receive ongoing rehabilitation or received rehabilitation at another facility.

Another consideration is the previously published limitations of the measures chosen as secondary measures. The FIM has previously been criticised for a ceiling effect, becoming insensitive to the changes in the person with a brain injury once in the community (Seel et al., 2007; Turner-Stokes & Siegert, 2013). This may limit the strength of the correlation with the FIM at long-term follow up. However, participants in the current study had not reached the

ceiling of any of the included measures and therefore it is reasonable to suggest that the included measures would still be able to demonstrate neuro-motor recovery.

7.8 Conclusion

The ABIPA had good to excellent correlation with acute, rehabilitation and total hospital length of stay and long-term neuro-motor recovery for this group of patients following moderate to severe ABI. These findings likely reflect similarities in elements of neuro-motor function captured by the various measures and highlight the value of the ABIPA beyond the acute stages. These results could also support the use of functional status measures in the development of rehabilitation resource use models. The availability of an outcome measure that is not only sensitive to change but is also associated with long-term outcome and carer burden would be valuable to clinical practice.

Chapter 8

Discussion and conclusion

The field of ABI continues to increase the current evidence base regarding ABI management with reliable and valid measures essential to the progress of any scientific field (Johnston & Keith, 1993). This research program outlining the initial development of a new assessment measure was motivated by a clinical need identified for people following moderate to severe brain injury. During acute stages following ABI, when patients are functionally dependent, a specific scale to monitor acute incremental changes in neuro-motor function was absent.

This thesis aimed to develop a tool to fill this gap. As part of the initial steps of outcome measure development it was important to understand the specific construct and theoretical context that was being targeted (Mokkink et al., 2012). Recovery from ABI is multifaceted and there is no limit to the number of constructs that could be represented in a new outcome measure. For example, the new outcome measure may be aiming to assess memory loss, cognition changes, behaviour changes, neuro-motor changes or any combination of these constructs. Outcome measures can also be developed at all levels of the recovery continuum, from acute to rehabilitation, discharge and community integration. A vital issue to be determined in the initial developmental stage of an assessment measure is the scope of the target construct. In the development of the ABIPA, the construct or what was to be measured was clearly defined as acute recovery of neuro-motor impairments following an ABI.

It was intended that the new outcome measure be responsive to change and possess content validity. The next step was to identify the items able to reflect acute neuro-motor impairments and to develop guidelines for the administration and scoring of the new measure, the ABIPA. Once established the new outcome measure underwent psychometric testing to determine responsiveness to change and concurrent validity against accepted standard

measures of consciousness and neuro-motor impairment in the severe brain injury population. As with any tool, it was necessary to establish the reliability of physiotherapists using the tool and further investigate the underlying structure.

This chapter presents a summary of the findings of the four studies undertaken within this thesis to develop a valid and reliable outcome measure to measure acute neuro-motor impairments for people recovering from a moderate to severe ABI. Results of each study will be discussed, and clinical implications, strengths and limitations of the thesis will be presented. Discussion and suggestions for clinical practice and further research will conclude this thesis.

8.1 Summary of findings

When an outcome measure demonstrates utility in clinical settings, is sensitive to change in the desired population, and provides incremental validity above and beyond other similar measures (Holmbeck & Devine, 2009) it is based in evidence. When referring to the accepted checklists for outcome measurement development (Mokkink et al., 2012) the overall scores for each measurement property in the ABIPA are summarised in Table 8.1.

Table 8.1 Summary of ABIPA results for psychometric properties

Requirement for outcome development	**Result**
Internal consistency	Good
Reliability Inter-rater / Intra-rater	Good to excellent for most items
Content validity / Face validity	Good
Criterion related validity	Good to excellent
Responsiveness	Good to excellent
Interpretability / Clinical relevance	Continuing

8.1.1 Study 1

The development of the ABIPA arose from an unanswered clinical question. Experienced physiotherapists working within the neurosurgical unit at a tertiary referral hospital were challenged to articulate the early improvements observed in people recovering from a severe ABI. The outcome measures in current use did not capture these acute neuro-motor changes. Study 1 began as a search for an outcome measure that would capture this change. A systematic review (Laxe, Tschiesner, Zasler, Lopez-Blazquez, Tormos & Bernabeu, 2012) identified the most frequent outcome measures in brain injury research as the FIM, Glasgow Outcome Scale and DRS. Of these, only the DRS incorporates neuro-motor function as variables or items within the scale. In the acute stages following severe ABI, few scales, including the DRS, can assess incremental changes in neuro-motor function that may occur at this time. Other scales typically used during this stage evaluate consciousness, cognitive function, behaviour, social participation, and functional limitations (Wright et al.2000), but not neuro–motor impairments.

When no appropriate assessment tool was found a cohort of experienced physiotherapists from Princess Alexandra Hospital, Brain Injury Rehabilitation Unit (BIRU) sought to develop an outcome measure suitable for measuring incremental neuro-motor impairments during the acute stage following severe ABI. Using the knowledge gained from the initial search, further information was gathered to support the items that would be used to create the new assessment, the ABIPA.

8.1.1.1 Identification and scoring of items reflecting acute neuro-motor impairments

The aims of Study 1 were to describe the development of the ABIPA, identify the items and scoring criteria for the ABIPA, compare the responsiveness to change of the ABIPA to a

measure of consciousness (GCS) and measures of motor function (COVS and MAS) and determine the concurrent validity of the ABIPA with these tools at initial and discharge assessments in the acute hospital setting. The ABIPA informed by empirical evidence should be responsive to change and incorporate the important items required to capture the incremental changes in neuro-motor impairments that underpin a physiotherapy assessment for the moderate to severely brain injured. The final items of the ABIPA resulting from a systematic approach to a literature review and frequency analysis described in detail in Study 1 were: upper limb and lower limb movement; overall muscle tone in each limb; head and trunk alignment in supine; head and trunk alignment in sitting; head and trunk control in sitting; and overall presentation (Appendix 1).

To inform the scoring of the items for inclusion in the ABIPA, scoring methods used in other scales suitable for this population were considered. Considering the range of scales supported by the literature, the experienced clinicians developed the dimensions that were considered clinically significant. A series of single case pilot studies clarified the dimension and a five-point scale emerged. Scores for each item range from 0 to 4 with low scores representing poorer function and a score of 4 representing best function (Hagerty, 2002).

8.1.1.2 Concurrent validity and responsiveness to change.

It was important to determine if the ABIPA was able to measure those acute neuro-motor changes that had first been identified as lacking measurement for those people in the early recovery phase of severe ABI. Construct validity and responsiveness to change of the ABIPA were determined through comparisons with scales that measured similar and related constructs commonly measured in this population. The ABIPA was compared with the GCS (a measure of responsiveness), the COVS (a measure of functional independence) and MAS (a measure of neuro-motor recovery). The strong relationship between scores of these instruments supports the high construct validity of the ABIPA.

The ABIPA showed the greatest responsiveness to change (SRM > 0.83) compared to the other measures (SRMs < 0.55) suggesting that the ABIPA was a valid tool for detecting incremental changes in neuro-motor impairments after severe brain injury. Overall, Study 1 established the concurrent validity of the ABIPA and demonstrated its high responsiveness to change against other common measures used for people recovering from a severe ABI during an acute admission. A statistically significant difference in responsiveness to change between ABIPA and COVS, GCS and MAS was also found. The ABIPA was able to detect change much earlier than the other functional motor scales for any given patient.

8.1.2 Study 2

Study 2 of this thesis examined the reliability of physiotherapists using the ABIPA to assess the acute stages of neuro-motor impairments in people following a moderate to severe ABI. Both inter- and intra-tester reliability were investigated to determine if the tool could be used with confidence in the clinical context by multiple assessors and by same assessors over time.

8.1.2.1 Reliability

As described in Chapter 5 inter-tester reliability for all physiotherapists (n = 30) was excellent ($\alpha \geq 0.9$) for total ABIPA score. All individual items, except trunk alignment in supine, showed excellent or good internal consistency ($\alpha \geq 0.7$). For intra-tester reliability, substantial or perfect agreement was achieved for eight items (Weighted kappa $K_w \geq 0.6$), moderate agreement for four items (K_w = 0.4 - 0.6), and three items achieved fair agreement (alignment head supine: alignment trunk supine: tone left upper limb).

The consistency of scoring between assessors varied across items, suggesting that some items were more challenging to score than others. The items with the lowest inter-tester and intra-tester reliability were the assessment of head and trunk alignment in supine. This might reflect a limitation of two-dimensional video in accurately representing patient position. In

fact, previous studies have reported difficulties in the visual assessment of alignment (Fedorak et al., 2003; Passier et al., 2010) and may suggest that these particular items are better evaluated in a live performance assessment or require visual markers when viewed via video recording. The items assessing alignment require further investigation.

Three items demonstrated high inter-tester reliability (n = 30 with $\alpha \geq 0.9$), but with only fair intra-tester reliability ($K_w \leq 0.4$). These results are not easily explained. This unexpected finding may be partially due to familiarity with the assessment tool. Regardless, a similar trend across individual items was observed for both intra-tester and inter-tester reliability. Items of alignment of head and trunk in supine were the worst overall performers, for both inter-tester and intra-tester analysis. These items require further investigation for continued inclusion in the ABIPA with a factor or Rasch analysis indicated to guide the revision of item content of the ABIPA (Belvedere & de Morton, 2010).

8.1.2.2 Influence of training

As the ABIPA is a new tool, Study 2 of this thesis also investigated if training was required to accurately administer the ABIPA. Two groups of physiotherapists participated in Study 2, those that received training and those that did not. Video training packages as described in Chapter 5 were initially provided to the first group of participating physiotherapists. Physiotherapists who did not receive training had comparable inter-tester reliability results as those who did receive training, with both groups achieving excellent to good consistency. Overall though, when both inter- and intra-tester reliability results are considered, training did not appear to be necessary to achieve reliability when using the ABIPA. This suggests that clinicians can independently use the ABIPA video package and guidelines to prepare for application of the ABIPA into clinical practice. This would be a time efficient method for

inducting new staff members to an acute neuroscience setting where the tool has an application in monitoring acute signs of neuro-motor impairments after ABI.

8.1.3 Study 3

Study 3 further examined the psychometric properties of the ABIPA, undertaking a factor analysis to reveal the underlying structure and strength of ABIPA items.

A factor analysis was chosen to determine the potential for item rationalisation and suggest if simplification or reduction of the number of items influences the clinical information communicated when using the ABIPA. Exploration of the dimensionality or number of factors underpinning the overall assessment and examining the relative contribution of each factor and the chosen items represented within a factor, to the overall assessment will strengthen the inclusion of items chosen in Study 1.

The analysis suggested a four-factor solution with a simple structure (factor loadings ≥ 0.30) that explained 69.6% of total variance of the ABIPA scores. The four factors initially extracted were “alignment and posture”, “tone”, “left sided movement” and “right sided movement”. The first factor “alignment and posture” included the items of control of head and trunk, alignment of head and trunk in sitting and posture.

The second factor “tone” grouped the items of muscle tone in upper and lower limbs and alignment of the trunk in supine. The literature also supports muscle tone as an important item in the evaluation process of ABI recovery (Charness, 1986; Duncan, 1990; Laxe et al., 2012; Mittrach et al., 2008; Swaine et al., 1994) and therefore this factor could be anticipated as one of the underlying factors for inclusion in an assessment of neuro-motor recovery in people with moderate to severe ABI. In the process of outcome tool development, it is reassuring that the factor structure is also supported by the initial literature review in Study 1

that identified the items relevant to be included in a measure of acute neuro-motor impairments.

The third and fourth factors “left sided movement” and “right sided movement” both related to movement, loaded onto different factors. In people with moderate or severe ABI active or spontaneous movement is not always present or the movement observed may not be purposeful or functional (Greenwald et al., 2015; Turner-Stokes et al., 2005), but it would be reasonable to expect that all movement items would load to the same factor. The differential factor loading between sides may have occurred due to the presentation of the people assessed. People following brain injury may have weakness in only one side, weakness in only one limb, or a combination of weakness in all limbs (AIHW, 2007; Teasdale & Jennet, 1974). When trying to assess the different movement recovery patterns observed in people with brain injury, this result suggests that loading on to different factors may be the best way to account for all possible presentations. When considering the implications for clinical use, representation of both left and right side is an important consideration when measuring outcomes in this patient group.

Items identified from Study 2 with the lowest inter-tester and intra-tester reliability - alignment of head and trunk in supine also loaded differently when considering the factor solution described above. Alignment of the trunk in supine loaded to factor two, tone, and alignment of the head in supine, loaded onto factor three and is not as easily explained. It might be expected that the alignment items of head and trunk in supine would load to the same factor; although it is not uncommon for factor analysis models to include factors with occasional unusual item loadings (Barth & Martin, 2005).

Another consideration could be made on the strength at which an item loads to a particular factor. Alignment of the head in supine loaded to factor three at 0.358 and alignment of the

trunk in supine loaded to factor two at 0.405 (Chapter 6). Both are above the 0.30 criterion for load strength (Tabachnick, 2014), but perhaps identify that the alignment items in supine are poorly associated with any one particular factor. . Difficulties in assessing alignment has been reported previously (Fedorak et al., 2003). Assessing alignment in a patient group that may be agitated and restless and whose language, cognition or behaviour may influence the assessment of alignment may offer some explanation as to the difficulty associated with assessing alignment and therefore where that item may load.

These factor discrepancies suggested further examination of the factor structure was required. The reduction in factors however, to a three-factor model, explained only 50% of the variance, suggesting that the four-factor solution was a better representation of the structure underlying the ABIPA items. There are no universal guidelines for the threshold of variance, but it is generally accepted practice to extract those factors that account for the highest percentage of variance until the factor only accounts for a small proportion of the variance (i.e. less than 5 per cent). When there is uncertainty about the number of factors to retain, authors are recommended to retain too many rather than too few (Gorsuch, 1983); therefore the four-factor model was retained.

8.1.4 Study 4

Available evidence is often based on retrospective analysis when evaluating long-term outcomes (Chua & Kong 2002; McNett, 2007; Pape et al., 2006) and there is little data to determine the impact of different types of acute care intervention on prognosis (New Zealand Guidelines Group, 2007; Teasell et al., 2007). The fourth study in this thesis examined the association of the ABIPA with long-term outcome and care burden.

Initial ABIPA scores collected at admission to acute care and admission to rehabilitation were examined for an association with acute admission, rehabilitation admission, and total

length of stay as well as discharge destination. Additionally, secondary measures of consciousness (GCS), orientation (MSQ), neuro-motor impairments (ABIPA, COVS, CRS, DRS, FIM) and Carer strain index, were collected to examine long-term outcomes for 16 people following an ABI; at two year follow up for seven participants and 5 years follow up for nine participants. Data were pooled for both groups for all outcomes.

8.1.4.1 Length of stay and discharge destination

ABIPA scores at acute admission and ABIPA at rehabilitation both demonstrated at least moderate to good negative correlation with length of stay in acute, rehabilitation and total length of stay ($rho > 0.508$, $p \leq 0.04$). A higher ABIPA score indicating less disability was associated with a shorter length of stay, which is not unexpected. Discharge destination however did not correlate with either ABIPA score at acute or rehabilitation admission ($rho > -0.675$, $p \leq 0.004$).

8.1.4.2 Neuro-motor recovery and carer burden

ABIPA scores at acute admission demonstrated moderate to good correlations with ABIPA scored at long-term follow up, FIM (motor) and COVS ($rho > 0.508$, $p \leq 0.05$). No relationship was observed with other secondary measures at long term follow up.

ABIPA scores at rehabilitation admission appeared to have better associations with long term follow up with excellent correlations observed with all measures of neuro-motor recovery; ABIPA, FIM (motor), and COVS ($rho > 0.802$, $p \leq 0.001$). Interestingly ABIPA scores at rehabilitation admission also demonstrated moderate to good correlation with GCS and MSQ ($rho > 0.564$, $p \leq 0.023$). No correlation was found between ABIPA scores at rehabilitation admission and FIM (cognition) ($rho = -0.373$, $p = 0.155$) and Carer strain index ($rho = 0.0.37$, $p = 0.892$).

8.2 Clinical implications

To date, there is no specific scale to monitor acute incremental changes in a patient's physical condition across the acute period of care for those with severe brain impairment following ABI. The absence of an appropriate outcome measure for this patient population significantly impacts on clinicians' ability to objectively assess the effectiveness of interventions, communicate changes in a patient's condition with other team members and advocate for patients ongoing care. It is also a significant barrier to the advancement of research and evidence-based practice in the acute stages of rehabilitation for this complex and challenging clinical population.

The ABIPA was developed to start to fill this gap. This research program highlights a number of implications for clinicians working with this population including; measuring neuro-motor recovery in people following ABI; the availability of outcome measures with strong psychometric properties; clinical utility of the ABIPA; and the investigation of items considered important to assess in people following moderate to severe ABI. These will be expanded on below.

8.2.1 Measuring acute neuro-motor recovery in people with severe brain injury is possible

This research program illustrates that the ABIPA is able to quantify acute neuro-motor recovery in people with moderate to severe ABI. This is the first tool that has been specifically developed to capture this construct. For this population the majority of outcome measures focus on level of consciousness, cognitive functions, behaviour, social participation and functional limitations (Wright et al., 2000). Limited research investigates the impact of different models of acute care (Canedo et al., 2002; Shukla et al., 2011; Wright et al., 2000) due to a specific outcome measure being absent from the field.

By defining the initial construct – acute neuro-motor recovery in ABI – the clinical implications were always going to be highly-specific to this patient group. Many outcome measures tend to either assess an overall general presentation of a diagnostic group or look to define the specific impairment or disability (Tyson et al., 2008). The ABIPA was designed to assess a specific patient population; those with moderate to severe ABI and for whom current measures were not capturing the acute incremental changes of neuro-motor recovery.

8.2.2 Preliminary psychometric properties of the ABIPA have been established

Outcome measures must establish relevant psychometric properties before being applied in clinical practice. The psychometric properties investigated in this research program were identified using the COSMIN checklist for assessing methodological quality of measures of health status. An international panel of experts through a Delphi process identified these items as essential for health instruments (Mokkink et al., 2012).

The ABIPA was found to be able to measure responsiveness much earlier in recovery than other functional neuro-motor scales for people following moderate to severe ABI. This is an important finding as physiotherapists must make decisions regarding suitability for rehabilitation very early in a patient's acute hospital stay. As the existing scales do not detect change in the period immediately after ABI, for those with severs ABI, it is often difficult to advocate objectively for ongoing treatment and resources and justify further rehabilitation. Currently accepted evidence is that early access to specialist acute care and rehabilitation services improves outcomes; and that rehabilitation provided in specialised units result in better outcomes (Cullen 2003). The ABIPA can be influential in expediting such access.

Additionally, validity, reliability both inter-tester and intra-tester and internal consistency of the ABIPA has been demonstrated. The ABIPA demonstrated a strong relationship with the GCS, the current standard measure of acute brain injury, and with COVS and MAS, outcome

measures of neuro-motor recovery. Physiotherapists also showed a high level of consistency when assessing people following moderate to severe ABI, demonstrating that the assessments are reproducible over time, in different settings and by different assessors (Zapf et al., 2016). A measure with sound psychometric properties is indispensable for use in clinical practice and research. Further research is required into the subscale scores of each item and the overall score.

8.2.3 The ABIPA has clinical utility

A number of factors influence the translation of outcome measures into clinical practice. Clinical utility, the relevance and usefulness of an intervention in patient care, is a further consideration. Four factors have been suggested in defining clinical utility; appropriateness, accessibility, practicability and acceptability (Smart, 2006). Pragmatic aspects of using outcome measures in clinical practice should also be considered. Similarly, four factors have been identified to describe pragmatic criteria for clinical use; acceptability, respondent burden, administrative burden and (Auger, Demers, & Swaine, 2006). Tools with excellent clinical utility have been described as those able to be administered in less than 20 minutes, require equipment typically found in the clinic, are freely available and are easy to score (McCulloch et al., 2013). The underlying emphasis is on the practicality of administration of the tool. The ABIPA requires no specific equipment and is easily accessible with both guidelines and scoring format already published. The time required to perform any new outcome measure is highly relevant to busy clinicians (Van Peppen, Maissan, Van Genderen, Van Dolder, & Van Meeteren, 2008). Initial studies have shown the ABIPA can be administered within 20 minutes as it includes items considered to be part of usual physiotherapy assessment procedures. This also suggests the ABIPA is acceptable with low administrative burden. Therefore, the ABIPA is a practical and pragmatic outcome measure for the ABI population.

The ABIPA was developed initially by clinicians working within the ABI population. Factors such as the time and training required to be able to reliably administer the assessment were considered in the development of the tool along with resources and / or equipment required. When examining the format of an assessment tool the components are generally considered as training, clarity of instructions, simplicity of presentation and administration (Auger et al., 2006). Study 2 demonstrated that training was not required to reliably administer the ABIPA beyond the provision of guidelines and the assessment form. The high correlation between physiotherapists administering the tool also supports the clarity of the guidelines. This was an important finding. Being confident that the ABIPA can be used in clinical settings without training is important to facilitate the translation into clinical practice (Smart, 2006).

The versatility of where the assessment can be performed (i.e. bedside) will also influence how the outcome measure is incorporated into daily clinical practice. The literature review undertaken in Study 1 identified the items relevant to be included in a measure of acute neuro-motor recovery and the items were further supported for inclusion in an ABI outcome measure by the factor structure determined in Study 3. Both studies support the items in the ABIPA as part of usual ABI assessment and appropriate when considering clinical utility. Perhaps this is not surprising given this was the intent from the literature review. Additionally, all items in the ABIPA contribute to usual assessment of people with ABI (Hall & Johnstone, 1994). This further enhances the clinical utility of the ABIPA as administering the assessment requires no specific equipment or additional resources beyond what is current practice.

It has been suggested that another consideration for clinical utility is required cooperation and invasiveness (Auger et al., 2006). The initial need for the development of the outcome measure was due to the inability of the patient group to participate, follow instructions and

co-operate with the therapist. The identified construct of neuro-motor impairments in the acute ABI population defines the target patient group for the ABIPA, and removes the need for co-operation to be considered in the utility of the instrument. Similarly, invasiveness is not considered as the assessment is part of usual physiotherapy practice and therefore no more invasive than usual practice.

8.2.4 ABIPA is associated with length of stay and longer-term neuro-motor recovery

Trying to predict length of stay for those people with moderate to severe ABI or identify those likely to benefit from further rehabilitation is challenging (Tooth, McKenna, Goh, & Varghese, 2005). It has long been accepted that diagnosis alone is a poor predictor of potential outcome following ABI and therefore costing models accounting for functional status may be more beneficial to resource management (Heinemann et al., 1994). Despite the relatively low numbers of people suffering moderate to severe ABI (AIHW, 2007) there is a high socioeconomic cost associated with the care of this patient cohort; both in terms of acute hospital care as well as long-term care whether that be based in institutions or supported by family (Gentleman, 2001). These costs potentially increase the value of having an assessment measure that can provide further information around patient recovery. An outcome measure linked with both early responsiveness and associated with length of stay and long term neuro-motor recovery, as demonstrated in Studies 1 and 4, is likely to appeal to those responsible for resource delegation in the health system (Heinemann et al., 1994).

8.2.5 Alignment is difficult to measure

One important finding in the thesis was the low reliability for the items of alignment. Study 1 identified alignment as an important item for inclusion in a measure of neuro-motor impairment following ABI. In Study 2 however, the items with the lowest inter-tester and intra-tester reliability were the items for assessment of head and trunk alignment in supine. In

Study 3, alignment of head and trunk in supine loaded differently from the other alignment items. The loading of alignment of the trunk in supine to factor two, tone; and alignment of the head in supine to factor three are not easily explained.

The low reliability and factor distribution of the items of alignment could suggest that these items should be removed from the ABIPA. Such a proposal does however raise a clinical question. From a neurological perspective, alignment is not generally measured in any of the standard outcome measures for the ABI population, despite being identified as an important item for inclusion (Pilon et al., 1995). Previous studies have also reported difficulties in visually assessing alignment (Fedorak et al., 2003; Passier et al., 2010). Further investigation would be helpful to determine if removal of these items changes the responsiveness of the ABIPA and the association with long-term neuro-motor recovery. Or alternatively, from a clinical perspective is further investigation of how to measure alignment of people following ABI required. Ultimately, the purpose of an outcome measure is to monitor health status, detect changes, and be able to report on interventions. The availability of a measure to facilitate such objectives within the ABI population has high clinical value.

8.3 Limitations

Studies within the thesis have several limitations which are reported within their respective chapters. Limitations associated with the samples, the use of video recordings for the reliability assessment and long term follow up in this population, however, will be further discussed in this section.

8.3.1 Sample

Firstly, only a modest sample size was achieved for each of the four studies in the thesis. As this population is difficult to assess, obtaining suitable patients without complications, who

could consent themselves or be consented by next of kin, to participate and tolerate assessments, was challenging.

The number of participants available to be recruited for participation in the studies included in this thesis was a challenge for several reasons. Motor vehicle accidents are a main contributing reason for moderate to severe brain injury (AIHW, 2007) and therefore concomitant orthopaedic injuries are often present. Patients who presented with major musculoskeletal or orthopaedic injuries needed to be excluded as these might limit neuro-motor recovery and hence were a potential confounding variable. The removal of this patient group will limit the ability of the ABIPA to be generalised to this population without further research. Furthermore, difficulties were encountered evaluating people who were agitated and restless, who have reasonable movement but whose communication, cognition or behaviour. was such that they could not be included in this research program. Such difficulties have been acknowledged by others identifying that people with an ABI often have behavioural or cognitive impairments which exclude them from participating and can make recruiting to formal studies difficult (Whyte, 2002).

The number of people with severe brain injuries each year is relatively low which further limited the available participant pool. As such, patients with moderate brain injury were also recruited to try and expand the available participant pool. Despite this only one participant with a moderate brain injury was included in the first three studies of this research program and thus, the sample may not truly reflect the moderate-to-severe ABI range. All participants were recruited from a single site and availability was therefore limited by the admitted patient numbers. Nonetheless the samples did represent a variety of GCS levels, ages and functional levels and was representative of the mostly male ABI population.

In Study 2 two samples of physiotherapists were recruited; those who received training and those who did not. The untrained sample was smaller and represented a more inexperienced group of physiotherapists. Overall though, the sample of physiotherapists recruited to this study had more than eight years of experience as physiotherapists and more than three years working with neurological patients. This may not be representative of other rehabilitation facilities working with patients following severe ABI.

8.3.2 Use of video-recorded assessments

The use of two-dimensional video assessment in Study 2 may also be considered a limitation and one that has been highlighted as a possible contributor to poor inter- and intra-tester reliability for the alignment items (Pomeroy et al., 2003; Wiles et al., 2003). Additionally, there are disadvantages associated with observational assessments, such as the apparent loss of clinical fidelity (i.e. assessors cannot 'feel' the patient's response) (Pomeroy et al., 2003). Nonetheless, videorecorded performances have been used to investigate reliability in patients with ABI undergoing rehabilitation (Kierkegaard & Tollbäck, 2005; Low Choy et al., 2002; Subramanian et al., 2013; Swaine & Sullivan, 1996). Considering these limitations an assessment of a live performance may also need to be considered despite the challenges that this may involve for people after ABI (Belmont et al., 2009; Stuss et al., 1994; Zinno & Ponsford, 2006).

8.3.3 Loss to long-term follow-up

In Study 4 of this thesis, only approximately one-third of people identified who met the inclusion criteria were available for follow up. An initial inability to contact people restricted the potential for inclusion and has been shown to be a major restriction in long-term research in the ABI population (Corrigan et al., 2003). The reasons behind the inability to contact potential participants varied. A number of potential participants had died in the two to five year follow up period. The mortality rate previously reported following brain injury has been

as high as 50% (Olver et al., 1996); suggesting that the 15% deceased in Study 4 was not unreasonable. Other identified participants had moved and previous contact details were no longer valid. Previous studies have also identified poor follow up rates for people following ABI (Corrigan et al., 2003; Krellman et al., 2014) with most frequently associated variables including deterioration of motor function, violent injury aetiologies and changed residence from that at time of injury. Over 50% of the sample identified for Study 4 had experienced traumatic injuries. It was anticipated that a sufficient sample would be able to be recruited for Study 4 as all but one of the identified sample had supportive family and social supports identified during inpatient admissions. These findings further illustrate the challenges associated with supporting and managing people in the community following severe ABI, even for those with family and social supports.

8.4 Further research directions

The incidence of ABI worldwide is rising due to injuries associated with the increased use of motor vehicles, particularly in middle-income and low-income countries (Maas, Stocchetti, & Bullock, 2008) with evidence showing that epidemiological patterns of ABI are changing due to prevention strategies and health-care delivery (Roozenbeek, Maas, & Menon, 2013). There is a need for more epidemiological and clinical data associated with severe acquired brain injury, particularly regarding those of non-traumatic origin (Chiavaroli et al., 2016). There is certainly a role for an outcome measure able to measure the neuro-motor recovery in this population. Several issues arose during the studies in this thesis that warrant further attention and provide opportunities for further research.

8.4.1 Further psychometric testing

This thesis presents preliminary psychometric testing of the ABIPA. Further testing is required as well as consideration regarding items with poor inter-tester and intra-tester reliability. One possibility would be to remove items with poor reliability or those items that did not load onto any of the four factors from the ABIPA. Analyses could be repeated and even further additional data collected to determine if their removal influenced selected psychometric properties.

Few outcome measures in the ABI population include alignment as an item for measuring neuro-motor recovery, despite being identified as important for inclusion when measuring early neuro-motor recovery of people with severe brain injury (Pilon et al., 1995). Further research is required to determine if removal of these items changes responsiveness and other psychometric properties of the overall ABIPA and the association with long-term recovery that was shown in Study 4. Alternatively, from a clinical perspective, further investigation of how to measure alignment of people following ABI is required.

Other psychometric properties have been identified as important to assess in health instruments. Minimal clinical important difference is defined as “the smallest difference in score in the construct of interest which patients perceive as beneficial and which would mandate, in the absence of troublesome side effects a change in patient management” (Jaeschke, Singer, & Guyatt, 1990). The ideal method to determining minimal clinical important difference has yet to be determined (Altman, 2006; Copay, Subach, Glassman, Polly, & Schuler, 2007; Terwee et al., 2003) and should be part of further studies informing the development of the ABIPA.

8.4.2 Ongoing review of ABIPA items

For each of the studies in this thesis, analysis has largely considered only overall ABIPA scores. Responsiveness, validity and association with long term neuro-motor recovery has only been investigated using the total ABIPA scores.

This was a deliberate decision as it was determined in Study 1 through the literature review and expert panel that all items were important to consider when assessing early neuro-motor recovery in people with moderate to severe ABI. Reliability testing and factor analysis explored individual items. With both types of analyses identifying items with poor reliability and items that did not load onto factors; it is perhaps reasonable to suggest that some items appear to be more indicative of early neuro-motor recovery than others. It could be worthwhile to explore individual items or groups of items that loaded onto specific factors in terms of providing clinically meaningful information.

8.4.3 Dissemination of the ABIPA into physiotherapy clinical practice

The ABIPA was developed and tested in one tertiary facility in Queensland, Australia. The tool has been included as part of the outcome measures available for use by physiotherapists within this neurosurgical unit. Future plans to disseminate the measure once further psychometric testing has been completed are being considered.

The participating facility provides a state-wide service for management of moderate to severe brain injuries. The facility houses one of two neurosurgical units in Queensland along with the only brain injury rehabilitation unit. The current state-wide plan for ABI services introduces a revised state-wide service model to improve the quality of, and access to, brain injury rehabilitation services for adult Queenslanders across the continuum. The service model will provide specialised, post-acute inpatient and community services to adults across

multiple new step-down services across the state, expanding the potential to influence and collect data and develop multi-site research projects.

Establishing a state-wide database to collect ABI data would improve the understanding of the ABI population. Using the ABIPA as one of the recommended measures would help disseminate the use of the ABIPA across multiple health services. Dissemination would also have the potential for other benefits. The use of the ABIPA across all people admitted with ABI would potentially explore a larger sample and across more diverse patient presentations. Currently within Queensland, there are multiple changes around health care management and specifically for ABI services. For the Princess Alexandra Hospital, the first hospital in the southern hemisphere with an integrated electronic medical record, the possibilities of streamlining data collection and data extraction are countless. The potential to create a minimum data set of outcomes collected for ABI – including the ABIPA would create multiple research opportunities.

Once further psychometric testing has been completed a broader dissemination beyond the local facility and state of Queensland will be required. The ABIPA is freely available and is free to use. Additionally, it appears that the tool can be used with good reliability without the need for specific training. However, providing a resource for clinicians to confirm their scoring ability, particularly for physiotherapy students, junior clinicians, or clinicians with limited clinical experience in ABI could be useful. It is possible that an online platform could be created with video resources produced with all relevant consent, for clinicians to score. The creation of such a platform may also lend itself to being able to collect de-identified data of patients from anywhere in the world to help gain better understanding of not only the early neuro-motor recovery of those with moderate to severe ABI, but also potentially long-term recovery. Additionally, the ABIPA could also in the future be used to monitor the effect of interventions aimed at improving neuro-motor recovery of this patient group.

8.5 Conclusion

This thesis has contributed original, new information to neurological physiotherapy by creating a new assessment tool for measurement of acute neuro-motor recovery in the moderate and severe ABI population. With an available outcome measure, new research can now be generated, influencing treatment interventions, resource allocation and consideration for rehabilitation. With improved rehabilitation and improved outcomes there are also implications for reduced length of stay and decreased cost for the health services.

The association of the ABIPA with long-term recovery will also provide clinicians with an objective measure to guide discussions with other professionals and family in the acute stages of recovery. Ongoing research into the ABIPA would also be beneficial. The small sample size requires results to be considered with some caution. A larger multi-site study would help strengthen the findings.

Establishing the validity of a new outcome measure is an ongoing process requiring many studies across a range of patient groups and clinical settings. The findings of the studies in this thesis will guide rehabilitation teams to continue to improve clinical management and outcomes for individuals following severe and moderate ABI.

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List of Appendices

Appendix 1 – ABIPA Assessment form and Guidelines

ACUTE BRAIN INJURY PHYSIOTHERAPY ASSESSMENT (ABIPA)

Date: **Time:**

GCS: E V M

Medications: (Dose, time, frequency)

Comments:

SUPINE	Head	Trunk
Alignment		

	Upper Limb		Lower Limb	
	R	L	R	L
General Tone				
Movement				

SITTING	Head	Trunk
Control		
Alignment		

POSTURE	
BILATERAL HEMIPARESIS +/- SPASTICITY	0
HEMIPLEGIA	1
HEMIPARESIS	2
MONOPLEGIA	3
MONOPARESIS	4

Total Score: **/ 60**

ALIGNMENT SCALE
4. Aligned in all planes
3. Not aligned in one plane
2. Not aligned in two planes
1. Not aligned in three planes
0. Fixed position or unable to assess

GENERAL TONE SCALE
4. Normal muscle tone.
3. Slight increase, catch or minimal resistance
2. Marked increase in muscle tone, full PROM available
1. Difficulty moving through ROM, PROM reduced
0. Rigid in flexion or extension, or flaccid

MOVEMENT SCALE
4. Normal movement, but may be weak or agitated
3. Active movement through ≥ 1/4 ROM
2. Some movement or flickers
1. Moves in mass patterns or reflexive movement
0. No active movement

CONTROL SCALE
4. Holds in midline for 10 secs
3. Holds for in any position 10 sec
2. Hold for 5 sec
1. Hold for 1 sec
0. Unable to Hold

ABIPA guidelines

The ABIPA is designed for patients in the acute phase after a severe brain injury or subarachnoid haemorrhage. It is a global assessment based on observation, which considers overall patterns. The scale can be used with patients who are unable to follow commands or have cognitive deficits.

Alignment in supine

The resting alignment of the patient's head and trunk is observed from the bedside. The patient is then placed in a midline position with a single pillow and allowed to settle before assessing alignment which is graded for obvious deviations from midline. Trunk alignment observations are confirmed by palpation.

4. Aligned in all three planes, midline position
3. Alignment is lost in one plane, either sagittal, coronal or transverse
2. Alignment is lost in any two planes
1. Alignment is lost in all three planes
0. Patient is fixed in a position, or alignment is unable to be assessed (for example due to medical equipment, positioning, and orthopaedic injuries)

Movement scale

This subscale looks for active movement, whether normal and selective or pathologic. All four limbs are assessed individually by:

Looking: Patient is observed for any spontaneous movement including reflexive, patterned or selective movement.

Asking: Patient is asked to move the limb in any way possible.

Positioning: Place the patient's limb in a mid-range position and note any muscle activity or holding ability.

Feeling: Move the limb through range noting any active involvement.

Complete all components of the assessment and grade on completion unless the patient scores 4 in which case assessment of that limb is concluded.

4. Movement appears normal but may be weak or agitated.
3. Some active movement felt, anywhere in ROM for >= ¼ ROM
2. Some active movement evident or flickers at any point in range
1. Movement in mass patterns of flexion or extension, or reflexive movement
0. No active movement

General Tone

This subscale considers only the presence or absence of tone and not its source. Joints are moved through passive range of motion three times then graded on the worst score (for repetition of PROM, or joint).

4. Normal muscle tone
3. Slight increase, catches or minimal resistance, including patient resisting
2. More marked increase in muscle tone through ROM, full PROM available
1. Difficulty with passive movement due to tone, PROM reduced
0. Rigid in flexion or extension, or limb is flaccid.

Control Scale

The control subscale requires the patient to be sitting on a firm surface with feet supported. The ability to hold or maintain this position with normal or abnormal muscle activity is assessed and timed using a stopwatch. For head control, the trunk should be fully supported midline.

4. Able to hold in midline 10 seconds
3. Able to hold in any position 10 seconds
2. Able to hold any position for 5 seconds
1. Able to hold any position for 1 seconds
0. Unable to hold position, no active involvement, patient completely dependent and falls unless supported

Note: Score head and trunk = 0: if for any reason the patient is unable to achieve sitting, for example medical limitations, safety, or concomitant injuries

Alignment in sitting

Alignment in sitting is rated using the same scale as alignment in supine. The patient should be sitting on a firm surface with feet supported. For head alignment have the trunk fully supported in midline, take the head to midline and release as able. For patients constantly moving, repeat three times and rate on the worst alignment.

Note:

- Score head and trunk = 0: if for any reason the patient is unable to achieve sitting, for example medical limitations, safety, or concomitant injuries
- Score head = 0: if patient does not have any head control (as per control scale)
- Score trunk =0: if patient requires maximum assistance to maintain sitting

Posture

Overall posture is rated based on the completed assessment of tone, movement, alignment and control.

4. Monoparesis - weakness in one limb

3. Monoplegia - no or abnormal movement in one limb, may be spastic or flaccid

2. Hemiparesis - weakness of one side of body

1. Hemiplegia - one side of body affected, no movement present in one side, may have spastic or flaccid limbs

0. Bilateral hemiparesis +/– spasticity - all four limbs involved

Appendix 2 – Ethics Approvals Study 1, 2 and 3.

Princess Alexandra Hospital
Health Service District

Queensland Government

Queensland **Health**

Enquiries to: PAH Research Ethics Committee
Telephone: 07 3240-5856
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Facsimile: 07 3240-7667
Our Ref: KF
Date: 9 July 2004

Ms Janelle Gesch
Physiotherapist
Department of Physiotherapy
PRINCESS ALEXANDRA HOSPITAL

Dear Ms Gesch

re **Research Protocol: 2004/030**
"Validation of the Acute Brain Injury Physiotherapy Assessment"
-J Gesch, M Nascimento, L Passier

At the meeting of the Princess Alexandra Hospital Human Research Ethics Committee held on 2 March 2004, the Committee approved the above protocol. The Committee is constituted and operates in accordance with current NHMRC Guidelines.

If any substantial change is made to the protocol, this will need to be approved by the Committee. Submission of an amendment or extension to the protocol must give sufficient time and detail for formal consideration. The Committee must also be informed of any problems that arise during the course of the project which may have ethical implications. Serious adverse events must be notified to the Committee as soon as possible. If the study has not commenced within two years approval will lapse.

A NHMRC requirement is that all projects be reviewed annually. Accordingly, a short questionnaire will be sent to you every 12 months after initial approval and your assistance in completing and returning this promptly would be appreciated.

If this study involves the recruitment of patients from PAHHSD, it is my responsibility to remind you of your ongoing duty of care for all people recruited into clinical trials whilst public patients. All conditions and requirements regarding confidentiality of public information and patient privacy apply. You are therefore required to comply at all times with any applicable requirement of Australian Law including the Health Services Act and other relevant legislation, ethics obligations and guidelines which may be applicable to the PAHHSD from time to time (including, without limitation, any requirement in respect of the maintenance, preservation or destruction of patient records).

When the study involves patient contact, it is your responsibility as the principal investigator to notify the relevant consultant and request their approval.

A copy of this letter should be presented when required as official confirmation of the approval of the PAH Human Research Ethics Committee.

Yours sincerely

[redacted]

Deb Podbury
District Manager
PRINCESS ALEXANDRA HOSPITAL HUMAN RESARCH ETHICS COMMITTEE

Office	Postal	Phone	Fax
Princess Alexandra Hospital Health Service District	Ipswich Road Woolloongabba Q 4102	61 7 3240 2111	61 7 3240 5677

Amendment Study 1

Metro South
Human Research Ethics Committee

Enquiries to: Metro South Health Service District Human Research Ethics Committee
Phone: 07 3176 7672
Fax: 07 3176 7667
HREC Ref: HREC/04/QPAH/30
E-mail: PAH_Ethics_Research@health.qld.gov.au
Date: 28 Jan. 11

Ms Janelle Gesch
Physiotherapy Department
Princess Alexandra Hospital
Ipswich Road
Woolloongabba, 4102

HREC Reference number: HREC/04/QPAH/30
Project title: Validation Of The Acute Brain Injury Physiotherapy Assessment

On the 28 January 2011, the Chair of the Metro South Health Service District Human Research Ethics Committee noted and accepted the following:-

- Extension of study of till 31 January 2012.
- Addition of researcher, Master Degree Student – Ms Kristian Novak

The Metro South HREC is constituted and operates in accordance with the National Health and Medical Research Council's *"National Statement on Ethical Conduct in Human Research (2007), NHMRC and Universities Australia Australian Code for the Responsible Conduct of Research (2007)* and the "*CPMP/ICH Note for Guidance on Good Clinical Practice".*

It should be noted that all requirements of the original approval still apply.

A copy of this letter should be forwarded to your Research Governance Office(r).

If you have any queries please do not hesitate to contact the Human Research Ethics Committee office on +617 3176 7672.

Yours sincerely,

[redacted]

Dr Peng Tjun Choy
Manager Research Ethics
Metro South Health Service District
Human Research Ethics Committee
Centres for Health Research
Princess Alexandra Hospital

Griffith University Approval

Main_Document_2
GRIFFITH UNIVERSITY HUMAN RESEARCH ETHICS COMMITTEE

26-Nov-2012

Dear Ms Gesch

I write further to the additional information provided in relation to the conditional approval granted to your application for ethical clearance for your project "PR: Development, validation, reliability and predictive capacity of motor recovery of the Acquired Brain Injury Physiotherapy Assessment (ABIPA): a tool for physiotherapists during early management of people following Traumatic Brain Injury (TBI)." (GU Ref No: PES/28/12/HREC).

This is to confirm receipt of the remaining required information, assurances or amendments to this protocol.

Consequently, I reconfirm my earlier advice that you are authorised to immediately commence this research on this basis.

The standard conditions of approval attached to our previous correspondence about this protocol continue to apply.

Regards

Dr Gary Allen
Senior Policy Officer
Office for Research
Bray Centre, Nathan Campus
Griffith University
ph: +61 (0)7 3735 5585
fax: +61 (0)7 5552 9058
email: g.allen@griffith.edu.au
web:

Cc:

At this time all researchers are reminded that the Griffith University Code for the Responsible Conduct of Research provides guidance to researchers in areas such as conflict of interest, authorship, storage of data, & the training of research students.
You can find further information, resources and a link to the University's Code by visiting
http://www62.gu.edu.au/policylibrary.nsf/xupdatemonth/e7852d226231d2b44a25750c0062f457?opendocument
PRIVILEGED, PRIVATE AND CONFIDENTIAL
This email and any files transmitted with it are intended solely for the use of the addressee(s) and may contain information which is confidential or privileged. If you receive this email and you are not the addressee(s) [or responsible for delivery of the email to the addressee(s)], please disregard the contents of the email, delete the email and notify the author immediately

Appendix 3 – Ethics Approval Study 4

Metro South Health

Enquiries to: Metro South
Human Research Ethics Committee
Phone: 07 3443 8049
Fax: 07 3443 8003
HREC Ref: HREC/13/QPAH/314
E-mail: PAH_Ethics_Research@health.qld.gov.au

Ms Janelle Gesch
Clinical Team Leader
Physiotherapy Department
Princess Alexandra Hospital
199 Ipswich Road
Woolloongabba QLD 4102

Dear Ms Gesch

HREC Reference number: HREC/13/QPAH/314
Project Title: The association of Acquired Brain Injury Physiotherapy Assessment (ABIPA)scores with longterm outcomes for people acquired Brain Injury.

Thank you for submitting the above research protocol to the Metro South Human Research Ethics Committee for ethical and scientific review. This protocol was first considered by the Human Research Ethics Committee (HREC) at the meeting held on 4 June 2013.

You are reminded that this letter constitutes ethical approval only. You must not commence this research protocol at a site until separate authorisation from the Metro South Chief Executive or Delegate of that site has been obtained.

A copy of this approval must be submitted to the Research Governance Office(r)/Delegate of the relevant institution with a completed Site Specific Assessment (SSA) Form for authorisation from the Chief Executive or Delegate to conduct this research at the Princess Alexandra Hospital.

I am pleased to advise that the HREC has granted approval of this research protocol. The documents reviewed and approved include:

Document	Version	Date
• Letter of response (email)		
• Phone contact template		
• Participant Information Sheet - DCE Survey for Health Professionals - Qld	1	29 April 2013
• Participant Information Sheet/Consent Form - Non-Interventional Study	2	10 June 2013
• Consent Form	2	10 June 2013
• Form for Withdrawal of Participation	2	10 June 2013
• Participant Information Sheet/Consent Form - Person Responsible	2	10 June 2013
• Consent Form - Person Responsible	2	10 June 2013
• Form for Withdrawal of Participation - Person Responsible	2	10 June 2013

Please note the following conditions of approval:

1. The Principal Investigator will immediately report anything which might warrant review of ethical approval of the protocol in the specified format, including unforeseen events that might affect continued ethical acceptability of the protocol. Serious Adverse Events must be notified to the HREC as soon as possible. In addition the Investigator must provide a summary of the adverse events, in the specified format, including a comment as to suspected causality and whether changes are required to the Patient Information and Consent Form. In the case of Serious Adverse Events occurring at the local site, a full report is required from the Principal Investigator, including duration of treatment and outcome of the event.
2. Amendments to the research protocol which may affect the ongoing ethical acceptability of a protocol must be submitted to the HREC for review. Amendments should accompanied by all relevant updated documentation and a cover letter from the principal investigator, providing a brief description of the changes, the rationale for the changes, and their implications for the ongoing conduct of the study. Hard copies of the cover letter and all relevant updated documents, with *tracked changes*, must also be submitted to the HREC office as per standard HREC SOP. (Further advice on submitting amendments is available at http://www.health.qld.gov.au/ohmr/documents/researcher_userguide.pdf http://www.health.qld.gov.au/pahospital/research/amendments.asp
3. Amendments to the research protocol which only affect the ongoing site acceptability of the protocol are not required to be submitted to the HREC for review. These amendment requests should be submitted directly to the Research Governance Office/r.
4. Proposed amendments to the research protocol which may affect both the ethical acceptability and site suitability of the protocol must be submitted firstly to the HREC for review and, once HREC approval has been granted, then submitted to the Research Governance Office/r.
5. Amendments which do not affect either the ethical acceptability or site acceptability of the protocol (e.g. typographical errors) should be submitted electronically (track changes) and in hard copy (final clean copy) to the HREC Coordinator. These should include a cover letter from the Principal Investigator providing a brief description of the changes and the rationale for the changes, and accompanied by all relevant updated documents with tracked changes.
6. The HREC will be notified, giving reasons, if the protocol is discontinued at a site before the expected date of completion.
7. The Principal Investigator will provide at least, an annual report to the HREC on the anniversary of the approval and at completion of the study in the specified format.
8. If you require an extension for your study, please submit a request for an extension in writing outlining the reasons. Note: One of the criteria for granting an extension is the compliance with the approval's conditions including submission of progress reports.
9. Any research study that prospectively assigns human participants or groups of humans to one or more health-related interventions to evaluate the effects on health outcomes (WHO / ICMJE 2008 definition) should be registered, including early phase and late phase clinical trials (phases I-III) in patients or healthy volunteers (WHO Recommendation / ICMJE policy). If in doubt, registration is recommended. All studies must be registered prior to the study's inception, i.e. prospectively. http://www.anzctr.org.au/

   This HREC approval is valid for three (3) years from the date of this letter.

Should you have any queries about the HREC's consideration of your protocol please contact the Metro South HREC Office on 07 3443 8049.

Please note that the Metro South HREC is constituted and operates in accordance with the National Health and Medical Research Council's (NHMRC) *National Statement on Ethical Conduct in Human Research (2007), NHMRC and Universities Australia Australian Code for the Responsible Conduct of Research (2007)* and the *CPMP/ICH Note for Guidance on Good Clinical Practice*. Attached is the HREC Composition (Attachment I).

The HREC Terms of Reference, Standard Operating Procedures, membership and standard forms are available from the following websites:
http://www.health.qld.gov.au/pahospital/research/ethics.asp
http://www.health.qld.gov.au/ohmr/html/regu/regu_home.asp

Once authorisation to conduct the research has been granted, please complete the Commencement Form (Attached) and return to the Metro South Human Research Ethics Committee.

The Metro South HREC wishes you every success in your research.

Yours sincerely,

[redacted]

Professor Maher Gandhi
Chair
Metro South Hospital and Health Service
Human Research Ethics Committee (EC00167)
Centres for Health Research
Princess Alexandra Hospital

22/8/13

Ethics Study 4 Extension

Metro South Health

Enquiries to: Metro South
Human Research Ethics Committee
Phone: 07 3443 8049
Fax: 07 3443 8003
HREC Ref: «ProjectNo»
E-mail: Ethicsresearch.pah@health.qld.gov.au
Amendment AM01

Ms Janelle Gesch
Clinical Team Leader
Physiotherapy Department
Princess Alexandra Hospital
199 Ipswich Road
Woolloongabba QLD 4102

Dear Ms Gesch

HREC Reference number: HREC/13/QPAH/314
Project Title: The association of Acquired Brain Injury Physiotherapy Assessment (ABIPA)scores with longterm outcomes for people acquired Brain Injury.

The Office of the Metro South Human Research Ethics Committee noted and approved the following:-

Document	Version	Date
Notification of amendment/MSF49 form in respect to extension of ethical approval until 23 August 2017		28 July 2016

The Metro South Hospital and Health Service HREC is constituted and operates in accordance with the National Health and Medical Research Council's *"National Statement on Ethical Conduct in Human Research (2007), NHMRC and Universities Australia Australian Code for the Responsible Conduct of Research (2007)* and the "*CPMP/ICH Note for Guidance on Good Clinical Practice".*

This will be ratified by the HREC at its 4 October 2016 meeting.

Please provide a copy of this approval letter to the Research Governance Office.

It should be noted that all requirements of the original approval still apply. Please continue to provide at least annual progress reports until the study has been completed.

If you have any queries please do not hesitate to contact the Human Research Ethics Committee office on +617 3443 8049.

Yours sincerely,

[redacted]

A/Prof Scott Campbell
A/Chair
Metro South Hospital and Health Service
Human Research Ethics Committee (EC00167)
Centres for Health Research
Princess Alexandra Hospital
Woolloongabba QLD 4102

6/9/16

Queensland Government

Griffith University and Metro South agreement

Date:

Princess Alexandra Hospital
Centres for Health Research
Level 7 TRI
37 Kent St Woolloongabba QLD 4102

Background

A. The Griffith University ("GU") wishes to carry out a Project entitled: "**Research Protocol HREC/13/QPAH/314** "*The Association of the Acquired Brain Injury Physiotherapy Assessment tool (ABIPA) with Long-term Outcome for People Following a Brain Injury*" ("Project").

B. In order for GU to carry out the Project, GU wishes to enter into this agreement Metro South Hospital and Health Service (ABN 86 834 068 616) ("MSHHS").

Terms of Agreement

1. Conduct of Project

MSHHS agrees to permit GU to carry out the Project in accordance with Schedule 1.

2. Supply of Information

MSHHS undertakes to GU to supply GU, at GU's cost, such information which GU requests in writing from time to time concerning patients participating in the Project, provided that at all times the provision of any information by MSHHS to GU pursuant to this clause 4 shall be subject to:

(a) any required MSHHS Ethics Committee approvals;

(b) any required patient consents;

(c) compliance by MSHHS with any applicable requirements of Australian law including the Health Services Act, the Privacy Act and other relevant legislation, ethics obligations and guidelines which may be applicable to MSHHS from time to time (including, without limitation, any requirement in respect of the maintenance, preservation or destruction of patient records); and

(d) GU undertaking any administrative requirement (including but not limited to appropriate labelling and categorising of patient records or other records generated during the Project, which MSHHS may retain) which may increase the preservation time of records. All data pertaining to the Project will be stored by GU at its own risk.

3. Confidential Information and Publication

3.1 Each Party agrees that it will not disclose or publish in any manner any Confidential Information owned by the other Party without obtaining written consent from the owner. For the purposes of this clause, "Confidential Information" means all trade secrets and know-how, pre-existing intellectual property, financial information, patient data and other valuable information of whatever description and in whatever form that is not in the public forum, but excludes the interpretation, analysis and application of general information generally known to the public.

3.2 GU agrees to acknowledge the involvement of MSHHS in any published articles and publicity pertaining to the Project.

4. Indemnity

4.1 GU agrees to indemnify, defend and hold harmless MSHHS and its directors, trustees, governors, officers, researchers, employees contractors and agents (collectively the Indemnified Party) from and against any and all demand, claim, action suit, liability, loss, damage, cost or expense (including reasonable attorney's fees, court and other expenses of litigation) ("Claim") suffered by any Indemnified Party arising out of or in conjunction with third party claims relating to the conduct of the Project on MSHHS premises or using its facilities and staff except and to the extent that such Claim arises out of or in connection with the wilful misconduct or negligence of the Indemnified Party.

4.2 The liability of MSHHS, howsoever arising under this Agreement, is limited to the value of the fees paid by GU to MSHHS for the provision of the MSHHS Services.

4.3 The liability of a Party under this Agreement in respect of all consequential and indirect loss (including, but not limited to, loss of profits, loss of revenue and expectation loss) is excluded.

5. Warranties

GU warrants that the Project will be performed in compliance with:

(a) the principles of good scientific and clinical research practices;

(b) all applicable local, state and federal laws, legislation, regulations, rules, by-laws; and

(c) MSHHS Ethics Committee approvals and directions.

6. Intellectual Property

6.1 Any Intellectual Property developed by GU, and by MSHHS as a direct result of the provision of the MSHHS Services during the term of this Agreement will be owned by GU as at the date of creation.

6.2 For the purposes of this clause, "Intellectual Property" includes but is not limited to all inventions, discoveries, innovations, technical information and data, prototypes, processes, improvements, patent rights, circuitry, computer programs, drawings, plans, specifications, copyright, trade mark rights, design rights, plant variety rights and Confidential Information.

7. Termination

7.1 Breach: A Party may terminate this Agreement by notice in writing if another Party breaches this Agreement and fails to remedy the breach within 30 days of receipt of the written notice being given by the Party requiring the breach to be remedied.

7.2 Termination of this Agreement under clause 7.1 shall be without prejudice to the rights of any Party accrued under this Agreement prior to termination.

7.3 Safety: MSHHS may terminate this Agreement, with immediate effect, if in MSHHS's sole discretion MSHHS is of the reasonable opinion that the Project is not being conducted safely and patient well-being necessitates the termination of this Agreement.

7.4 Failure to Obtain Ethical Clearance: If GU is wholly or partially precluded from complying with its obligations under this Agreement by failure to obtain and maintain MSHHS Ethics Committee approvals, GU may by written notice to MSHHS terminate the Agreement, with immediate effect, without further liability for its failure to obtain and maintain such approvals.

7.5 Consequences of Termination: On termination of this Agreement, for any reason whatsoever, GU agrees to pay to MSHHS :

(a) all outstanding correctly rendered invoices; and

(b) any sums which are due to MSHHS which have not been invoiced as at the date of termination,

within seven (7) days of the date of termination.

7.6 Termination of Medical Procedures: On termination of this Agreement, for any reason whatsoever, each Party will cooperate with the other Party and do all things reasonably necessary to ensure an orderly and medically permissible termination of all procedures conducted in association the Project.

8. Force Majeure

8.1 Where a Party is unable, wholly or in part, by reason of an event or circumstance beyond the control of the Parties to carry out any of its obligations under this Agreement ("Force Majeure event"), and that Party:

(i) gives the other Party prompt notice of that the Force Majeure event including reasonable particulars, and, in so far as known, the probable extent to which it will be unable to perform or be delayed in performing its obligations; and

(ii) uses all reasonable diligence to remove the Force Majeure event as quickly as possible,

that obligation is suspended so far as it is affected by the Force Majeure event during the continuance of the Force Majeure event and that Party shall be allowed a reasonable extension of time to perform its obligations.

8.2 If, after 30 days, the Force Majeure event has not ceased, the Parties shall meet in good faith to discuss the situation and endeavour to achieve a mutually satisfactory resolution to the problem.

8.3 Where the Force Majeure event precludes a Party from performing its obligations that would materially affect the completion and/or the generation of the expected or likely results of the Agreement or the Force Majeure Event exceeds 90 days in duration the Parties may, after meeting in accordance with clause 8.2, unanimously decide to terminate the Agreement without liability to the other Party. Alternatively where the Parties unanimously agree that the Agreement is capable of completion the Parties may decide upon written agreement to elect to continue the Agreement in accordance with any agreed variations.

8.4 The requirement that any Force Majeure event must be removed with all reasonable diligence does not require the settlement of strikes, lockouts or other labour disputes or claims or demands by any government or third party on terms contrary to the wishes of the Party affected.

9. Dispute Resolution

9.1 A Party must not commence legal proceedings relating to this Agreement unless the Party wishing to commence proceedings has complied with this clause 9. However, this clause 9 will not apply where a Party seeks urgent interlocutory relief from a court.

9.2 The Parties will co-operate with each other and use their best endeavours to resolve by mutual agreement any differences between them and all other difficulties which may arise from time to time relating to this Agreement.

9.3 Any dispute arising between the Parties relating to the ownership of Intellectual Property which cannot be resolved between them will be finally determined by an expert determination undertaken at the shared expense of the Parties by:

(a) a licensed Patent Attorney agreed on by the Parties experienced in the relevant field; or, if the Parties are unable to agree;

(b) a licensed Patent Attorney appointed by the Australian President of the Licensing Executives Society.

9.4 The expert's determination under clause 9.3 is binding on all the Parties.

9.5 If a dispute arises between the Parties relating to or arising out of this Agreement other than one covered by clause 9.3 (the "Dispute") then:

(a) the Party alleging the Dispute must notify the existence and nature of the Dispute to the other Parties within 30 days of the dispute arising (the "Notification");

(b) upon receipt of a Notification the Parties must request the General Manager of Queensland Health and the Deputy-Vice Chancellor (Research) of GU or their respective nominees to resolve the Dispute;

(c) if the Dispute is not resolved as provided in clause 9.5(b) within 30 days of receipt of the Notification then any Party may refer the Dispute to mediation as provided in clause 9.5(d) and must do so before initiating proceedings in a court to resolve the Dispute;

(d) any Dispute which is referred to mediation must be referred to The Institute of Arbitrators and Mediators Australia ("IArbA") and be conducted in accordance with the Mediation Rules of IArbA; and

(e) if the Dispute is not resolved within 60 days of referral to IArbA any Party is free to initiate proceedings in a court in respect of the Dispute.

9.6 Compliance with the provisions of this clause 9 is a condition precedent to seeking relief in any court or tribunal in respect of the Dispute.

10. Equipment

GU will retain ownership of any equipment acquired in the course of the Project. GU agrees any GU or Project equipment which is kept on MSHHS premises shall for the duration of this Agreement be at GU's sole risk.

11. Facilities to be Returned to Original State

The area used by GU to conduct the Project must be returned to its original state at the completion of the Project at GU's cost, and supervised by MSHHS building and maintenance department.

12. Survival

The Parties agree that clauses 3, 4, 6, 9, 12 and 13 will survive termination of this Agreement.

13. Governing Law

This Agreement is governed by the laws of Queensland. The Parties agree to submit to the exclusive jurisdiction of the Courts exercising jurisdiction within Queensland.

14. Counterparts

This Agreement may be executed in any number of counterparts. All counterparts taken together will be taken to constitute one agreement.

15. Notices

GRIFFITH UNIVERSITY

Legal and Administrative matters:
Office for Research
Bray Centre (N54 1.24A)
Griffith University
170 Kessels Road
NATHAN QLD 4111
Phone: +61 7 3735 6545
Fax: +61 7 3735 7994
Email: researchgrants@griffith.edu.au

Project related matters:
Dr. Suzanne Kuys
School of Rehabilitation Sciences
Clinical Sciences 1 (G02) 1.21
School of Rehabilitation Sciences, Gold Coast campus, Griffith University, QLD 4222
Phone: +61 7 5552 7087
Fax: +61 7 5552 8674
Email: s.kuys@griffith.edu.au

MSHHS
Business Unit Manager
Centres for Health Research
Level 7, TRI
Princess Alexandra Hospital
37 Kent Street, Woolloongabba
Brisbane, QLD, Australia 4102
Tel: +61 7 3443 8050
Fax: +61 7 3443 8003
Email: PAH-Research@health.qld.gov.au

EXECUTED as an Agreement

Signed for and on behalf of **The Griffith University**

[redacted]

3/10/13

Dr. Vicki Pattemore
Director, Office for Research

Date

[redacted]

Witness

MARY WILKINSON

Name of Witness

Signed for and on behalf of **Metro South Hospital and Health Service**

Professor Ken Ho
Chair, Centres For Health Research
Metro South Health

[redacted]

Authorised Signatory

Date

Position

8/10/14

[redacted]

Witness

MARIA WOJCIECHOWSKI

Name of Witness

Appendix 4 - QCAT approval

QCAT

Queensland Civil and Administrative Tribunal

Our Reference: CRL020-13
Contact Name: Jodie Brownlee
Contact Number: 07 3234 1432
Facsimile: (07) 3221 9156

15 July 2014

Janelle Gesch
Physiotherapy Department
GARU
Princess Alexandra Hospital
Ipswich Road
WOOLLOONGABBA QLD 4107

Dear Ms Gesch

Case number: **CRL020-13**
Applicant: **Janelle Gesch**

Enclosed is the Tribunal's Order together with an Appeals Information Notice for your reference.

If you require any further information, please visit www.qcat.qld.gov.au.

Yours sincerely

[redacted]

Jodie Brownlee
Human Rights Senior Case Manager 2
Queensland Civil and Administrative Tribunal

QCAT

Queensland Civil and Administrative Tribunal

DECISION

Case number:	**CRL020-13**
Applicant:	**Janelle Gesch**
Before:	**Senior Member Endicott**
Date:	**30 June 2014**
Proceeding Type:	**On-Papers Hearing**

IT IS THE DECISION OF THE TRIBUNAL THAT:

1. The clinical trial "The Association of the Acquired Brain Injury Physiotherapy Assessment Tool (ABIPA) scores with long term outcomes for people with Acquired Brain Injury" is approved.

2. This approval remains current for three (3) years or until the expiry or revocation of ethics approval, whichever is sooner.

Signed

[redacted]

Senior Member Endicott
Queensland Civil and Administrative Tribunal

QUEENSLAND CIVIL AND ADMINISTRATIVE TRIBUNAL
CERTIFIED TRUE COPY
PRINCIPAL REGISTRAR

ARTICLE

Development and Preliminary Validation of the Acute Brain Injury Physiotherapy Assessment (ABIPA)

Janelle M. Gesch,[1] Nancy L. Low Choy,[2,3] Benjamin K. Weeks,[4] Leanne L. Passier,[1] Margarida Nascimento,[1] Terrence P. Haines,[1,5] and Suzanne S. Kuys[3,4]

[1] *Brain Injury Rehabilitation Unit, Physiotherapy Department, Princess Alexandra Hospital, Ipswich Road, Woolloongabba, Brisbane 4102, Australia*
[2] *Australian Catholic University, (McAuly Campus), Brisbane, Australia*
[3] *The Prince Charles Hospital, Brisbane, Australia*
[4] *Griffith Health Institute, Griffith University, Gold Coast, Australia*
[5] *Southern Physiotherapy Clinical School, Physiotherapy Department, Monash University, Melbourne, Australia*

Background and aims: For patients with a severe brain injury there is no objective physiotherapy assessment tool that is responsive to the incremental changes in motor recovery in the acute stage. The aims of this study were to identify the items of neuro-motor recovery and scoring criteria for the Acute Brain Injury Physiotherapy Assessment (ABIPA) and determine responsiveness to change and concurrent validity against accepted standard measures of consciousness and physical function in the severe brain injury population.
Method: The literature was searched and an expert consensus panel of experienced clinical physiotherapists informed item selection and developed practical assessment guidelines. The ABIPA was investigated for responsiveness to change and concurrent validity against the Glasgow Coma Scale (GCS), Clinical Outcome Variable Scale (COVS) and Motor Assessment Scale (MAS). Eleven patients (9 males; cohort 41 ± 18 years) with moderate/severe brain injury were recruited, and assessed on days 1, 3, 7 and then weekly until discharge.
Results: The ABIPA demonstrated good to excellent correlations overall with the GCS (rho > .76, $p \leq .001$), COVS (rho > .82, $p \leq .001$) and MAS (rho > 0.66, $p \leq .001$). On day 3, the ABIPA showed the greatest responsiveness to change (standardised response means (SRM) > .83) compared to other measures (SRMs < .77). At discharge all tools demonstrated change in neuro-motor recovery.
Conclusions: The ABIPA is a promising tool for detecting incremental changes in neuro-motor recovery early after severe brain injury.

Keywords: severe brain injuries, physiotherapy, assessment, rehabilitation, outcome measures

Introduction

In Australia, about 28,000 individuals of working age sustain an acquired brain injury (ABI) every year. Of these injuries, 5–8% are classified as severe (Glasgow Coma Scale score 3–8) (Teasdale & Jennet, 1974) and are associated with long-lasting or permanent disability (Fortune & Wen, 1999). Patients with severe ABI are typically functionally dependent and a small amount of limb movement is often the best motor ability observed during the acute phase of care (Turner-Stokes, Nair, Sedki, Disler, & Wade, 2005). During recovery such patients face a multitude of challenges, requiring treatment from many different disciplines. Physiotherapy is considered to be a key discipline for rehabilitation following ABI (Hellweg &

Address for correspondence: Janelle Gesch, Physiotherapy Department, Princess Alexandra Hospital, Ipswich Road, Woolloongabba, Brisbane 4102, Australia. E-mail: Janelle.Gesch@health.qld.gov.au

Johannes, 2008; New Zealand Guidelines Group, 2007; Teasell et al., 2007; Tolfts & Stiller, 1997). Although there is limited robust research evaluating rehabilitation interventions in the ABI population (New Zealand Guidelines Group, 2007; Teasell et al., 2007; Zitnay et al., 2008), the delivery of allied health interventions, including physiotherapy, has been shown to reduce length of inpatient stay, optimise motor function at discharge and decrease overall disability (Chestnut, 1990; Gray, 2000; Hall & Cope, 1995; Turner-Stokes et al., 2003; Zhu, Poon, Chan, & Chan, 2007). In fact, increasing the intensity of rehabilitation has resulted in accelerated rates of recovery of personal independence and improved physical outcomes (Cifu, Kreutzer, Kolakowsky-Hayner, Marwitz, & Englander, 2003; Slade, Tennant, & Chamberlain, 2002; Spivack, Spettell, Ellis, & Ross, 1992; Turner-Stokes et al., 2003). Despite emerging evidence for the benefits of physiotherapy for ABI management, a specific scale to monitor early incremental changes in neuro-motor function during the early stages following ABI, when patients are functionally dependent, remains absent from the field.

A recent systematic review (Laxe, Tschiesner, Zasler, López-Blazquez, Tormos, & Bernabeu, 2012) identified the most frequent outcome measures in brain injury research as the Functional Independence Measures (FIM) (50%), Glasgow Outcome Scale (34%) and Disability Rating Scale (DRS) (32%). Of these, only the DRS incorporates motor function as variables or items within the scale. In the acute stages following severe ABI, few scales, including the DRS, are capable of assessing incremental changes in neuro-motor function that may occur at this time. The brain-injury-specific outcome measure database (Wright, Bushnik, & O'Hare, 2000) highlights that scales typically in use during this stage evaluate consciousness, cognitive function, behaviour, social participation and functional limitations (Wright et al., 2000). However, these scales fail to capture the incremental changes in neuro-motor function in the early stages of recovery important to physiotherapy management following severe ABI (Canedo, Grix, & Nicoletti, 2002; O'Dell et al., 1996; Pape et al., 2006; Teasdale & Jennet, 1974).

Some well-known assessment scales of motor function used specifically by physiotherapists include the Clinical Outcome Variable Scale (COVS) (Seaby & Torrance, 1989), the Motor Assessment Scale (MAS) (Carr, Shepherd, & Nordholm, 1985) and the Functional Independence Measure–Motor component (FIM-motor) (Kidd, Stewart, & Baldry, 1996). These scales monitor important motor tasks such as walking, transfers, wheelchair mobility and fine motor upper limb skills, but most patients with severe ABI are not capable of attempting these tasks in the earliest stage of recovery (Pilon, Sullivan, & Coulombe, 1995). While valid and reliable for the assessment of patients' motor function, these scales are more applicable when dealing with the patient who is able to actively participate in practising a range of motor tasks at more advanced stages of rehabilitation. Other well-known scales commonly used in the acute care setting include the Glasgow Coma Scale (GCS) (Chieregato et al., 2010), Glasgow Outcome Scale (GOS) (Weir et al., 2012) and Full Outline of UnResponsiveness (FOUR) scale (Fischer et al., 2010). These tools provide a measure of consciousness or responsiveness in the early stages following severe ABI but do not address the potential for incremental changes in neuro-motor recovery relevant to physiotherapy, such as muscle tone, head and trunk alignment, sitting balance, posture and movement.

A new scale that captures early changes in neuro-motor recovery following severe ABI is required. Four experienced physiotherapists from Princess Alexandra Hospital, Brain Injury Rehabilitation Unit (BIRU) sought to develop an outcome measure suitable for measuring incremental neuromotor recovery during the early stage following severe ABI. The goal was to develop a quantitative assessment scale, informed by empirical evidence that would be responsive to change and incorporate the important items required to capture the incremental changes in neuro-motor recovery that underpin a physiotherapy assessment for the severely brain injured.

The study was undertaken in two parts. The first part involved the identification of relevant items to measure incremental changes in neuromotor recovery that may be associated with the early physiotherapy management of people following severe ABI – that is, it identified the content of the Acquired Brain Injury Physiotherapy Assessment (ABIPA). The second part investigated the responsiveness of the ABIPA to measure change in neuro-motor recovery in the early stages of recovery following severe ABI, as a first step in determining concurrent validity of the tool for use in the clinical setting. Thus, our aims were: (1) to identify the items and develop scoring criteria for the ABIPA, a new measurement scale that could be used by physiotherapists to assess neuro-motor recovery of people in the early stages following severe ABI; (2) to compare the responsiveness to change of the ABIPA to measures of motor function (COVS and MAS) and a measure of consciousness (GCS); and (3) to determine the concurrent validity of the ABIPA with these tools at initial and discharge assessments in the acute hospital setting.

Methods

PART A: ABIPA Development – Item Selection

Literature Search

In order to inform item selection and establish practical assessment guidelines, a systematic approach to a literature review and an expert consensus panel of experienced clinical physiotherapists was employed. A literature search was undertaken of relevant databases including Cochrane, Pedro, PubMed, Medline, Cinahl, Embase, COMBI (Centre for Outcome Measurement in Brain Injury) and ABIEBR (Acquired Brain Injury Evidence Based Review). Search terms included 'brain injury or head injury or CVA or stroke or cerebrovascular accident' AND 'physical therapy or physiotherapy' AND 'outcome assessment or outcome measure' AND 'motor recovery'. Search limits of human, English language and age-related 19 years+ were used. Studies were included if participants were in the acute phase of recovery following moderate or severe ABI (GCS < 12). All study types, including systematic reviews, meta-analysis studies and practical guidelines, were included. Studies were excluded if the focus was on spinal injury or other neurological diseases, such as Parkinson's disease or multiple sclerosis, if community based or if high-level function or mobility was being measured. Studies were also excluded if treatment focused, investigating the chronic phase of recovery, pharmacological studies, focused on cognitive or psychosocial interventions, if they were conference proceedings or were unavailable in full text.

The flow chart for the search strategy is shown in Figure 1. Initial searches yielded 2023 articles. A total of 1564 articles from databases and a further 459 from ABIEBR were retrieved. Excluded, based on title and abstract, were studies such as those dealing with behaviour, cognition, community focus, long-term outcomes, pharmacological studies or mild injury. One hundred and seventeen articles ($n = 117$) were retrieved for full-text review from the database search and 127 articles from ABIEBR.

Following removal of duplicates, 159 articles ($n = 159$) were then grouped into manuscripts outlining commonly used outcomes measures ($n = 128$) and those articles focusing on item identification required for measuring neuro-motor recovery in ABI ($n = 31$). Of the articles outlining commonly used outcomes measures, those measures that were reported less than three times or were related to a specific body part such as the upper limb ($n = 39$) were excluded from further analysis. Reference lists of articles focusing on item identification were further examined to ensure any relevant publications were not overlooked, and eight more studies ($n = 8$) were included; resulting in a total of 39 articles to be included for item identification relevant to measuring neuro-motor recovery.

Data Extraction

Data were extracted from all articles related to commonly used outcome measures, identifying the component variables of the common outcome measures and items identified as important for measurement of neuro-motor recovery in the ABI population. The most commonly reported outcome measures in the retrieved articles were the FIM or Functional Assessment Measure ($n = 46$), GCS ($n = 32$), GOS ($n = 6$) and DRS ($n = 5$). This finding is supported by previous studies reviewing commonly used outcome measures in ABI (Crooks, Zumsteg, & Bell, 2007; Haigh et al., 2001; Laxe et al., 2012; Pollock, Morris, Wijck, Coupar, & Langhorne, 2011; Shukla, Devi, & Agrawal, 2011). Of these, the GCS, commonly used in the acute care setting, was selected as an accepted validated outcome measure for comparison with the ABIPA. The FIM was not selected due to its use primarily as a rehabilitation measure (Nichol et al., 2011) and we were more interested in the acute care setting. In addition, well-known physiotherapy assessment scales of motor function, the COVS (Seaby & Torrance, 1989) and MAS (Carr et al., 1985), were also selected as comparison measures.

In order to identify common items to measure neuro-motor function, the 39 retrieved studies were then reviewed by an expert consensus panel of three experienced clinical physiotherapists working within the Neuroscience Unit, Princess Alexandra Hospital. Their task was to identify the items of neuro-motor recovery appropriate for inclusion in an ABI measurement scale that could be applied to those with a severe injury. Following full review of each manuscript, further studies were removed if the items identified only included age, ethnicity and cultural background, injury severity, systemic insults and medical complications. Studies were also removed if the focus was on level of disability (inability to perform) functional activities, such as transfers. Fourteen studies ($n = 14$) remained that identified neuro-motor items.

A frequency analysis identified the most important items for inclusion in a measure of neuro-motor impairment following severe ABI. The items were tone (93%), spontaneous and voluntary movements (71%), postural status/equilibrium reactions (64%), passive range of motion (29%) and reflexes (43%) (see Table 1). Passive range of

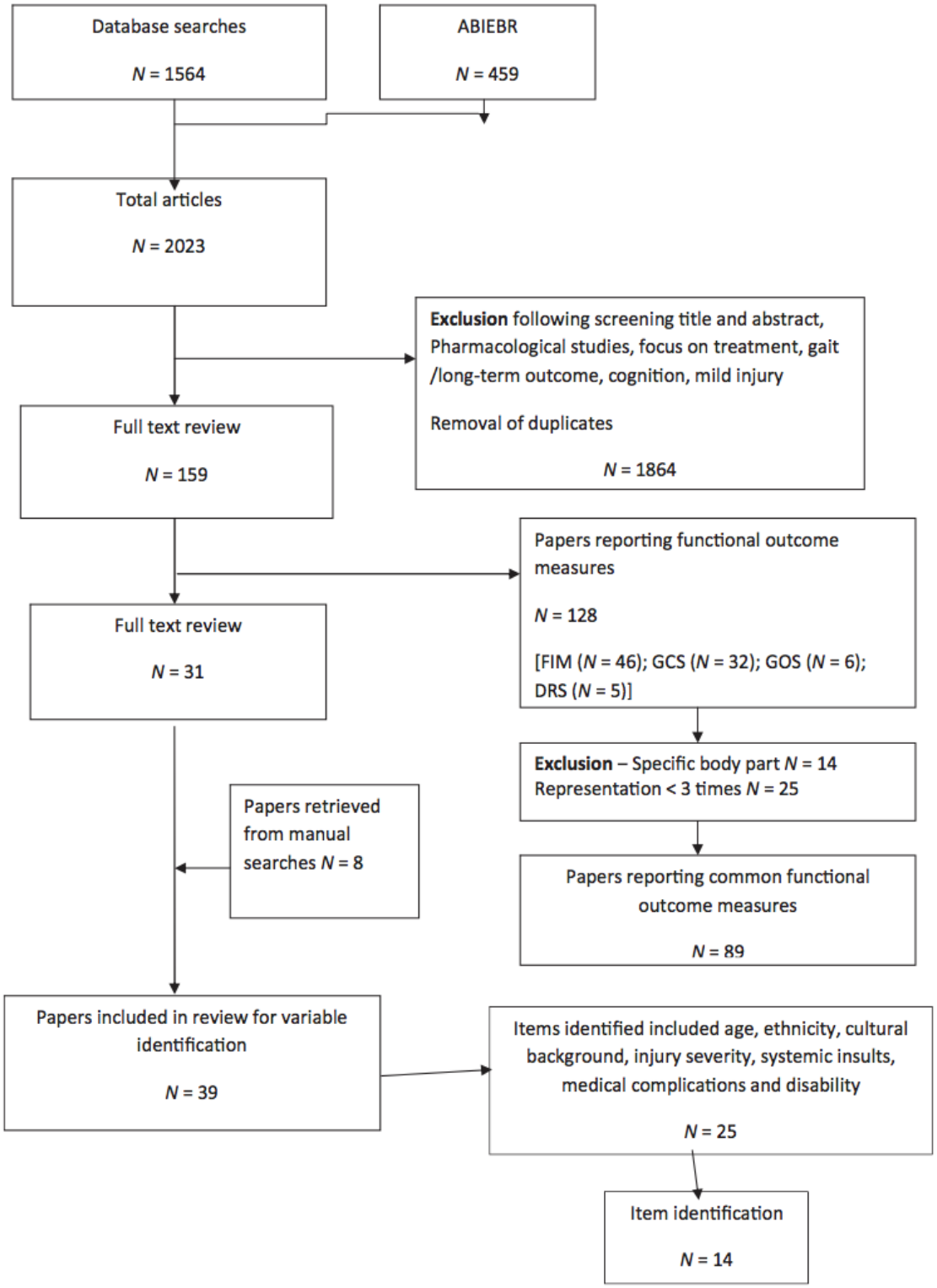

FIGURE 1
Flow diagram for manuscript identification.

TABLE 1
Neuro-motor Items Identified from Retrieved Articles

	PROM	Spontaneous or voluntary movement	Postural status/ equilibrium reactions	Sit unsupported	Muscle Muscle
Swaine et al. (1994)	X	X	X		X
Duncan (1990)	X	X	X		X
Charness (1986)	X	X	X		X
Nelson (1984)	X	X	X		X
Swaine and Sullivan (1996)			X	X	X
Swaine and Sullivan (1999)				X	X
Pollock et al. (2011)	X	X	X		X
Walker and Pickett (2007)		X	X		X
Laxe et al. (2012)		X			X
Mayo et al. (1991)		X	X		X
Pilon et al. (1995)	X	X	X		X
Mittach et al. (2008)		X	X		X
Tolfts and Stiller (1997)		X	X		X
New Zealand Guidelines Group (2007)		X	X		X

motion, spontaneous movements and postural status were rated as being 'extremely important' or 'very important' items, requiring evaluation (Mayo, Sullivan, & Swaine, 1991; Pilon et al., 1995; Swaine, Sullivan, & Sicotte, 1994; Walker & Pickett, 2007). Additional items identified as important to measure included the ability to sit unsupported, postural control and 'tolerance to vertical' (Pilon et al., 1995), along with muscle tone, voluntary movements, equilibrium reactions, transfers and range of motion (Charness, 1986; Duncan, 1990; Laxe et al., 2012; Mittrach et al., 2008; Nelson, 1984; Swaine & Sullivan, 1996, 1999).

The identified items were grouped under similar categories and became items of muscle power, muscle tone, body alignment and maintaining body position. Piloting of the tool was undertaken with a series of single case studies, with the definitions and procedures for a severe ABI scale explored, developed and refined to enhance the overall clarity of the scale. The final items of the Acquired Brain Injury Physiotherapy Assessment (ABIPA) determined by the expert panel of experienced clinical physiotherapists were: upper limb and lower limb movement, overall muscle tone in each limb, head and trunk alignment in supine, head and trunk alignment in sitting, head and trunk control in sitting and overall presentation.

Scoring

To determine the scoring for the ABIPA scale, the type of data, the evidence supporting scale development, as well as the scoring systems of commonly used validated tools were considered. Scoring these final items of the ABIPA required clinical judgement of the assessor as the data to be scored were observational or qualitative in nature. The best method of scoring qualitative data in a scale format has been suggested as mapping the observational data into measurable dimensions using experienced clinicians' clinical judgement (Hagerty, 2002; Guttman, 2004; Guyatt, Krishner, & Jaeschke, 1992).

In addition, the retrieved articles relevant to each ABIPA item were further examined to devise a scoring technique relevant to each item. For example, for the first item, upper and lower limb movement, common motor function impairment measures included the manual muscle test (Harms-ringdahl, 1993), movement recovery scale (Sodring, Bantz-Holter, Ljunggren, & Wytter, 1995) and the Motoricity Index (Demeurisse, Demol, & Roboye, 1980). For these measures, either a five- or six-point scale was used. Two of the more widely used clinical measures for upper and lower limb muscle tone are the Modified Ashworth Scale (Ansari, Haghdi, Moammeri, & Jalaie, 2006; Pomeroy et al., 2000) and the Tardieu scale (Tardieu et al., 1957). Both are rated using a six-point scale. For the remaining items – head and trunk alignment in sitting and supine, and head and trunk control in sitting – consideration was given to the cardinal planes of movement (i.e., sagittal, coronal and horizontal) and whether the head or trunk was fully aligned or not able to be assessed. Considering the range of scales supported by the literature, the experienced clinicians developed the dimensions that were considered clinically significant. A series of single-case pilot studies clarified the dimension and a five-point scale emerged. Scores for each item range from 0 to 4, with low scores representing poorer function and a score of 4 representing best function (Hagerty, 2002). The ABIPA scale, its items and scoring are set out in Table 2.

PART B: Responsiveness of the ABIPA to Change and Concurrent Validity

Design

Part B investigated the responsiveness of the ABIPA to changes in a patient in the early stages of recovery following an ABI. It also investigated its concurrent validity with other assessment tools currently in use with this population. To achieve this, a prospective cohort study was conducted using a sample of convenience of patients admitted to the neurosurgical unit at Princess Alexandra Hospital. Blinded assessments were conducted on patients throughout their acute hospital stay, until each patient was discharged or showed a change in scores on two other commonly used scales of motor function (COVS and MAS).

Participants

The neurosurgical unit is based in a tertiary referral hospital in Brisbane, Queensland, with statewide admissions covering Queensland and northern New South Wales. The unit is comprised of 36 beds and is staffed by a multidisciplinary team including physiotherapists, occupational therapists, speech pathologists, social workers, neuropsychologists and a medical team.

Patients were included in the study if they had recently suffered either a moderate (GCS 9–12) or severe (GCS 3–8) ABI or a grade four or five subarachnoid haemorrhage, were medically stable (i.e., had been discharged from intensive care) and were aged between 16 and 70 years. Patients were excluded if they had major musculoskeletal disorders that may impact on movement return

TABLE 2
Description and Scoring of the ABIPA

ABIPA Item	0	1	2	3	4
Movement 1. UL R) and L) 2. LL R) and L)	No active movement	Moves in mass patterns or reflexive movement	Some movement or flickers	Active movement through ≥ 1/4 ROM	Normal may agita
Muscle tone 1. UL R) and L) 2. LL R) and L)	Rigid in flexion or extension, or limb is flaccid	Difficulty with passive movement, PROM reduced	More marked increase in muscle tone through ROM, full PROM available	Slight increase, catches or minimal resistance, including patient resisting	Normal
Head and trunk alignment 1. Supine 2. Sitting	Patient is fixed in a position, or alignment is unable to be assessed	Alignment is lost in all three planes, sagittal, coronal and transverse	Alignment is lost in any two planes	Alignment is lost in one plane	Alignm plane midli
Control 1. Head 2. Trunk	Unable to hold position, no active involvement, patient completely dependent	Able to hold any position for 1 s	Able to hold any position for 5 s	Able to hold in any position 10 s	Able to 10 s
Overall presentation	Bilateral hemiparesis ± spasticity – all four limbs involved	Hemiplegia – one side of body affected, no movement present, may have spastic or flaccid limbs	Hemiparesis – weakness of one side of body	Monoplegia – no or abnormal movement in one limb, may be spastic or flaccid	Monop weak

(e.g., amputation or fracture) or if there were any residual deficits from previous neurological insult or conditions (e.g., previous stroke or Parkinson's disease). Patients with subarachnoid haemorrhage who were awaiting clipping of an aneurysm or those not deemed medically stable were also excluded.

Ethical clearance was obtained from the Metro South Human Resource Ethics Committee and Griffith University Human Resource Ethics Committee, and the study was supported by the Medical Director of the neurosurgical unit. Informed consent was obtained from the next of kin or legal guardian, as required.

Procedure

Participants were assessed throughout their acute hospital admission. The first assessment took place on the first weekday post admission to the neurosurgical unit. The second assessment occurred on day 3 following admission. Subsequent assessments occurred on day 7 post neurosurgical unit admission then at weekly intervals until the patient showed a change in scores on the two selected scales of motor function, COVS and MAS. Assessments took place at approximately the same time of day.

At each assessment, current GCS, presence of a tracheostomy and weaning status, along with any changes to relevant medications, were recorded. The GCS was included as a measure of consciousness with established responsiveness in the early stages following severe ABI.

Two assessors were involved in each participant assessment and all assessments were completed by one of three physiotherapists, each with 10–20 years of clinical experience in the management of ABI patients. Assessors were randomly allocated to concurrently assess the patients with either the ABIPA assessment or the COVS and MAS assessment, to minimise the time burden for these highly dependent patients at this stage of their rehabilitation. The GCS data were collected from ward assessments. Physiotherapist assessors were blinded to each other's scores, previous scores and were not involved in patient care in the neurosurgical unit. Participants were assessed using the ABIPA (Table 2), which included five items: movement of the limbs, general tone, head and trunk alignment in sitting and supine, head and trunk control in sitting, and overall presentation. ABIPA items were assessed in a consistent order for all participants, commencing with resting alignment in bed (supine) and movement and general tone before assisting the patient into sitting.

Measures

The ABIPA was conducted using a standardised procedure and scored as outlined in Table 2. On initial approach to the bedside the resting alignment of the patient's head and trunk was observed. The patient was then placed in a supine position with a single pillow under the head and allowed to settle. *Head alignment* was observed, scoring for obvious deviations from the midline, noting rotation, lateral flexion and flexion. *Trunk alignment* was assessed with observations confirmed by palpation. The therapist observed lateral trunk angle, rib height, iliac crest height and compared equal presentation for both right and left sides. The shoulder girdle, pelvis alignment and lumbar lordosis were also observed, and then overall alignment scored.

Muscle tone and movement were assessed first for the upper limbs and then for the lower limbs. Initially the presence of any spontaneous movement (including reflexive, patterned or selective movement) was observed. Each major muscle group of the upper limb and lower limb was moved through a passive range of motion three times to assess *muscle tone* and determine a score using the ABIPA scale. The lowest score from the major muscle groups for each limb was recorded as the overall score for that limb.

Active movement was assessed for each of the four limbs individually. The patient was asked to move the limb as able. The patient's limb was then positioned in mid-range and any muscle activity or ability to hold the position recorded. Finally, the limb was moved through range for the major joints, noting any active movement. The highest score was then recorded as movement for that limb.

Head and trunk *control* was assessed in sitting. This relates to the active movement of the trunk and head and is defined as the ability to maintain a position in space with some muscle activity, normal or abnormal. It was assessed with the patient sitting on a firm surface, with feet supported, and timed using a stopwatch. To assess *head control*, the trunk was fully supported in the midline while the head was placed in the upright position, head support was then removed. *Trunk control* was assessed in the same manner, with the trunk placed in the midline and hand support then removed. If the patient was unable to sit (e.g., medical limitations, safety or concomitant injuries), the head and trunk were scored as 0.

Alignment in sitting was assessed using the same scale and procedure as alignment in supine. *Head alignment* was assessed by positioning the head and trunk in the midline and while fully supporting the trunk, the quality of head alignment in the upright position was assessed. *Trunk*

alignment was assessed in the same manner – positioning the trunk and then removing support. The alignments achieved for both head and trunk were scored. For patients who were constantly moving, the movement was repeated three times and the best alignment achieved was scored. A score of 0 was recorded: if the patient was unable to sit (e.g., medical limitations, safety or concomitant injuries), if the patient did not have any head or trunk control (as per control scale) or if the patient required maximum assistance to sit.

Finally, overall presentation was scored on the completed assessment of tone, movement, alignment and control as per Table 2.

As part of the assessment procedure three comparative measures were conducted: the Glasgow Coma Scale (GCS) (Chieregato et al., 2010; McNett, 2007), the COVS (Seaby & Torrance, 1989) and the MAS (Carr et al., 1985). As a well-known measure of consciousness, the GCS evaluates a patient's best verbal response, eye opening and motor response during the early stages of recovery, with scores ranging from 3 to 15.The COVS has established clinometric properties in a range of patient populations (Barker, Amsters, Kendall, Pershouse, & Haines, 2007; Salter, Jutai, Foley, & Teasell, 2010) including ABI (Low Choy, Kuys, Richards, & Isles, 2002). It is scored using a seven-point scale across 13 domains, including rolling, transfers, sitting balance, wheelchair mobility and gait. Lower scores indicate greater dependence in each domain with total scores ranging from 13 to 91.

The MAS was developed to measure functional progression amongst people following stroke. It comprises a seven-point scale across eight domains: supine to side lying; supine to sitting; balanced sitting; sit to stand; walking; upper arm function; hand movements and advanced hand activities. The MAS has good reliability and validity (Poole & Whitney, 1988). For the purposes of this study, only the domains of sitting balance and upper arm function (left and right) were adopted, as they were domains represented in the ABIPA. Thus, the possible score range is 0–21.

Data Analysis

Each scale was scored according to standard criteria and the items for each scale were totalled. Descriptive statistics including mean (standard deviation), median (range) and frequency were generated for all scales at each assessment point from admission to discharge.

Standardised response means (SRM) were calculated to determine responsiveness to change for all measures on day 3, day 7 and discharge. The standard response mean is defined as the mean change in score between the first assessment and the comparison assessment, divided by the standard deviation of the individual changes in scores (Portney & Watkins, 2000). The higher the SRM, the greater the responsiveness to change, whereby a value of >.8 is considered a large effect, >.5 a moderate effect and one of .2 a small effect (Cohen, 1977).

A Spearman's rho correlation coefficient was calculated to investigate the concurrent validity of the ABIPA compared to the GCS, COVS and MAS. Admission and discharge scores were analysed separately. Comparisons were made between day 1 scores and day 3, day 7 and discharge. Discharge data were the last recorded for each participant. Rho coefficients greater than .75 were considered good to excellent, while those between .50 and .75 were considered moderate to good (Portney & Watkins, 2000).

Results

Participants

Eleven patients (mean age 41; *SD* 18 years) were recruited to this study. Participant characteristics are included in Table 3.

Three participants were assessed over three data points (days 1, 3 and 7). These patients were discharged from the study at day 7 as they had achieved changes in the scores on the validated motor assessment scales (COVS and MAS). The highest number of assessments that a participant received was nine. In total, 57 assessments were completed for the eleven participants. On three occasions GCS data were not available.

Responsiveness to Change

Table 4 illustrates the standardised response means (SRM) from initial assessment for all scales on day 3, day 7 and discharge from the acute ward to other rehabilitation settings or to home. On day 3, the ABIPA showed the greatest responsiveness to change (SRM > .83) compared to the other measures of motor function (SRMs <.55), although the GCS was similar (SRM = .77). By day 7, the GCS demonstrated the greatest responsiveness to change while the ABIPA was higher than the other measures (SRMs < .87). At discharge all scales showed good responsiveness to change (SRMs > .9), with the strongest score demonstrated by the GCS followed by the ABIPA and the selected MAS items. The responsiveness of the MAS and COVS was consistently low to moderate on day 3 of the assessments and continued to be lower than the ABIPA on day 7. The total COVS was also lower

TABLE 3
Participant Characteristics

Participant	Age (years)	Gender	Diagnosis	Mechanism of injury	Time since injury (days)	GCS at admission
1	24	M	Intraventricular bleed/ diffuse axonal injury	High speed MVA/ multi-trauma	14	6
2	17	M	Intracerebral haemorrhage	MVA	20	5
3	58	F	Anterior cerebral aneurysm	Collapse at home	13	5
4	62	M	Intracerebral haemorrhage	Collapse at home	9	7
5	21	M	Intracerebral haemorrhage	Drug overdose	10	10
6	69	F	Subarachnoid haemorrhage	Trauma	9	3
7	51	M	Intracerebral haemorrhage	Hypertensive bleed	12	6
8	49	M	Subarachnoid haemorrhage	Collapse	30	3
9	30	M	Subdural haemorrhage	Assault	16	3
10	42	M	Subdural haemorrhage	Assault	8	7
11	26	M	Diffuse axonal injury	Trauma– MVA	13	4

MVA, motor vehicle accident.

TABLE 4
Standardised Response Means (SRM) from Initial Assessment for all Scales

Scale	SRM day 3	SRM day 7	SRM discharge
GCS	0.77	1.76	2.25
ABIPA	0.83	1.2	1.95
COVS	0.40	0.68	0.91
MAS	0.55	0.87	1.94

GCS, Glasgow Coma Scale; ABIPA, Acquired Brain Injury Physiotherapy Assessment; COVS, Clinical Outcome Variable Scale; MAS, Motor Assessment Scale.

at discharge, with the MAS items showing a similar SRM as the ABIPA by discharge.

Concurrent Validity of ABIPA

Table 5 illustrates admission and discharge scores on all scales for all participants. Across all assessments ($n = 57$) the ABIPA demonstrated good to excellent correlations with the GCS (rho $> .76$, $p \leq .001$), COVS (rho $> .82$, $p \leq .001$) and MAS (rho $> .66$, $p \leq .001$). The investigation of concurrent validity at specific assessment points – such as day 1, 3 and 7 – showed that the ABIPA was moderately associated with all scales across the first week at admission to the acute neuroscience ward (rho $> .53$, $p \leq .001$), whereas at discharge the associations were higher (rho $> .72$, $p \leq .001$).

Figure 2 shows the mean ABIPA, COVS, GCS and MAS scores for all participants converted to a percentage of the total possible score for each scale over the 7-week period. Three participants had been discharged from the study by day 14 as they had improved sufficiently to be suitable for measurement using the COVS and MAS. Therefore, fewer participants, who demonstrated slower recovery and lower scores, were included at each time point following day 14. Dips at day 14 and day 42 in overall ABIPA scores (Figure 2) represent the loss of those patients who were discharged from the study. By day 42, nine participants demonstrated changes in scores on the other scales and were discharged.

Discussion

We have described the development of the ABIPA, examined its responsiveness to change against other common measures and established its concurrent validity with other common assessment tools. We found that the ABIPA score had a strong positive relationship with the GCS score, the current standard measure of early brain injury, and showed a greater responsiveness to change when compared to the COVS (a measure of motor function) and selected MAS Items (a measure of motor recovery of bed mobility and sitting ability). The results of this study indicate that the ABIPA could be used as a responsive measure of neuro-motor change across the early stages of recovery, providing physiotherapists with a useful tool to use at this stage following ABI.

The ABIPA had the highest level of responsiveness to change when comparing scores on day 1 to day 3 after admission to the neurosurgical

TABLE 5
Admission and Discharge Scores for all Scales ($n = 11$)

	Day 1				Discharge			
Participant	GCS (/15)	ABIPA (/60)	COVS (/91)	MAS (/21)	GCS (/15)	ABIPA (/60)	COVS (/91)	MAS (/21)
1	9	22	13	1	14	45	31	12
2	8	27	17	1	N/A	48	22	5
3	8	22	13	0	10	18	14	4
4	7	19	13	0	11	41	18	6
5	10	34	13	0	12	53	36	10
6	4	6	13	0	5	11	13	0
7	7	30	14	0	10	48	22	8
8	9	16	13	0	14	41	20	9
9	9	27	14	0	14	53	65	6
10	7	30	14	1	12	55	37	8
11	6	18	13	0	12	44	20	5

N/A, Not available.

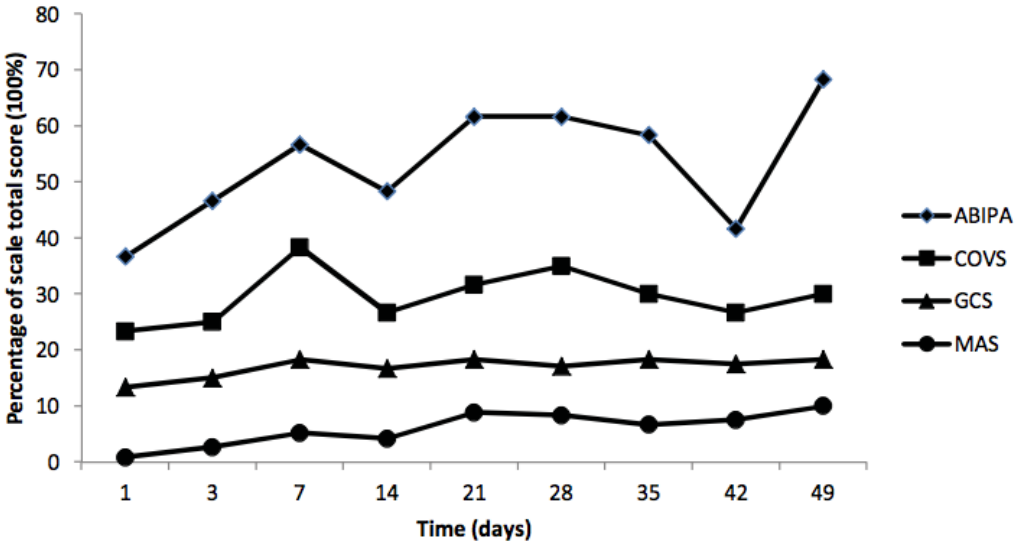

FIGURE 2
(Colour online) Mean ABIPA, COVS, GCS and MAS scores for all participants, converted to a percentage of the total possible score. ABIPA, Acquired Brain Injury Physiotherapy Assessment; COVS, Clinical Outcome Variable Scale; GCS, Glasgow Coma Scale; MAS, Motor Assessment Scale.

ward. Between day 1 and day 7, the GCS and the ABIPA continued to show higher responsiveness to change than the COVS and MAS. The ABIPA was able to detect change earlier than the other motor scales for any given patient. This is an important finding as physiotherapists must make decisions regarding suitability for rehabilitation very early in a patient's acute hospital stay. If such decisions are based on COVS and MAS alone, it would be difficult to advocate objectively for the patient as the existing scales may not detect change during the immediate period after ABI. As the ABIPA continues to show high responsiveness to change during the stages of acute hospital care, it is a promising tool for clinical use during early recovery.

To date, there is no specific scale to monitor early incremental changes in a patient's neuro-motor recovery across the acute period of care, for those with severe brain impairment following ABI. The majority of scales focus on the patient's level of consciousness, cognitive functions, behaviour, social participation and functional limitations (Wright et al., 2000). The absence of an appropriate outcome measure for this patient population significantly impacts on clinicians' ability to objectively assess the effectiveness of interventions, communicate changes in a patient's condition with other team members and advocate for patients. It is also a significant barrier to the advancement of research and evidence-based practice in the early stages of rehabilitation for this complex and challenging clinical population.

Available evidence is often based on retrospective analysis when evaluating long-term outcomes (Chua & Kong, 2002; McNett, 2007; Pape et al., 2006) and there is little data to determine the impact of different types of acute care intervention on prognosis (New Zealand Guidelines Group, 2007; Teasell et al., 2007). No scales were located that specifically monitored neuro-motor function in the early stages of recovery, which is the focus of physiotherapy management following severe ABI (Canedo et al., 2002; O'Dell et al., 1996; Pape et al., 2006; Teasdale & Jennet, 1974). We observed the ABIPA to be a responsive measure of change in neuro-motor function following severe brain injury.

Limitations

A key challenge was the recruitment of an adequate number of participants for the study. The number of patients admitted with severe brain injuries each year is relatively low and, as motor vehicle accidents account for a large percentage, often patients have concomitant orthopaedic injuries and, thus, have to be excluded. There were only 11 participants in the initial sample and eight participants following the third assessment. Three participants were excluded when they were able to achieve scores above the minimum on either the COVS or MAS and the flooring effect on these established measures no longer existed. In addition, we encountered difficulty in assessing those patients who were agitated and restless, who have reasonable movement but whose language, cognition or behaviour was such that they precluded accurate assessment. While this challenge is not unique to the ABIPA, it further limited our approach.

The participant cohort suffered predominately severe ABI (GCS 3–8), with only one patient representative of the moderate brain injury population (GCS 9–12). This limits the current generalisability of our results and suggests the need for further evaluation of the ABIPA in a broader cohort of participants with ABI. With a larger dataset, the factor structure of the ABIPA could be examined using factor analysis; while investigation of a more refined scoring approach and item generation could be pursued using Rasch analysis and Delphi Survey techniques.

Conclusion

This study has provided preliminary psychometric support for the utility of the ABIPA. It exhibits sound correlations with other measures, and scores during the acute phase show it is more responsive to change than other common measures of neuro-motor function. It is now necessary to test the reliability of assessors using the tool, and to involve multiple assessors to further investigate the test/re-test and intra- and inter-rater reliability of the instrument.

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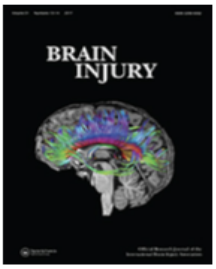
Appendix 6 – Study 2



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Inter- and intra-tester reliability of the acute brain injury physiotherapy assessment (ABIPA) in patients with acquired brain injury

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ABSTRACT

Background: The Acute Brain Injury Physiotherapy Assessment (ABIPA) is a new outcome measure with face validity and sensitivity to change in the early stages of neuromotor recovery after acquired brain injury (ABI). Reliability of physiotherapists using the tool has not been established.
Objective: Determine inter- and intra-tester reliability of physiotherapists using the ABIPA.
Methods: An observational study using video-recorded assessments of patient performance (n = 7) was undertaken with two cohorts of physiotherapists: those receiving training (n = 23) and those provided with guidelines only (n = 7) to administer the ABIPA.
Results: Across all physiotherapists (n = 30), inter-tester reliability was excellent (α ≥ 0.9) for total ABIPA score. All individual items, except trunk alignment in supine (α = 0.5), showed excellent or good internal consistency (α ≥ 0.7). For intra-tester reliability, substantial or perfect agreement was achieved for eight items (weighted Kappa K_w ≥ 0.6), moderate agreement for four items (K_w = 0.4–0.6) and three items achieved fair agreement (alignment head supine: K_w = 0.289; alignment trunk supine: Kw = 0.387 and tone left upper limb: K_w = 0.366).
Conclusion: Physiotherapists are highly consistent using the ABIPA but several items may need revision to improve intra-tester reliability.

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Assessment; outcome measures; physiotherapy; rehabilitation; severe brain injury

Introduction

To improve patient care in people with an acquired brain injury (ABI), more extensive research is required on the validity and reliability of measures that are used to examine the physical outcomes of physiotherapy intervention [1–3]. The Acute Brain Injury Physiotherapy Assessment (ABIPA) is a new physiotherapy outcome measure specifically developed for assessing people who present with a moderate or severe brain injury (i.e. Glasgow Coma Score (GCS) less than 12) [4]. Used in the acute setting, it combines the assessment of muscle tone, head and body alignment, muscle strength and control, and is a practical method of monitoring patient progress daily or over longer periods of time. The ABIPA has been found to have face validity and is sensitive for measuring change in the early stages of neuromotor recovery [4] (Appendix 1). As part of next step of measure development, clinometric properties such as inter- and intra-tester reliability require investigation, so that the tool can be used with confidence in the clinical context by multiple assessors.

One issue associated with investigating reliability of instruments during the early stages of recovery following ABI is the potential for patient performance to vary across short periods of time [5,6]. Patients with a severe ABI frequently present with agitation, confusion and an inability to follow commands [7,8]. As these clinical signs may vary considerably in a short space of time, a major constraint is imposed on the investigation of instrument reliability in this population.

Furthermore, patients may be easily distracted by multiple assessors or suffer from fatigue and/or respond poorly to additional handling, if concurrent assessments are performed in the one session [6,9,10]. Patients with behavioural symptoms or cognitive deficits may also respond poorly to the complexity of assessments [11]. Determining inter-tester reliability through repeat patient assessments is therefore not appropriate for this patient population.

Post hoc ratings of video-recorded assessments present a practical alternative approach to determining reliability. Video-recorded assessments alleviate the need for repeated patient performances and limit the burden of multiple concurrent assessors, effectively eliminating within-subject variability from the analysis [12]. Further, videorecording a patient's resting position and motor behaviour during active movement controls for the observed performances between views by multiple assessors. Thus, post hoc ratings of video-recorded performances present a viable and practical method of investigating reliability of the ABIPA for patients with ABI.

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Aims

The primary aim of this study was to determine the inter- and intra-tester reliability of physiotherapists using the ABIPA. A secondary aim was to determine if reliability of physiotherapy assessors improved when training was provided compared to using instructional guidelines to assist with the application of the ABIPA.

Methods

Study design

An observational study design using video-recorded assessments of patient performance was used to determine inter- and intra-tester reliability of physiotherapists using the ABIPA. Two groups of physiotherapists were investigated: those who received training in use of the ABIPA tool and those who were provided with instructional guidelines prior to viewing the video-recorded assessments and using the tool to score the performances observed. Ethical clearance was obtained from all necessary institutional Human Research Ethics Committees. Informed consent was obtained from all participants including legal guardians or next of kin as required.

Participants

Two groups of participants were recruited: patients with an ABI and physiotherapists working in the field of neurological rehabilitation. The patient group consisted of a convenience sample of patients with moderate or severe brain injury admitted to either the acute neurosurgical ward (36 beds) or brain injury rehabilitation unit (26 beds) of a tertiary (large metropolitan) public hospital in Brisbane, Queensland, Australia. A multidisciplinary team including therapists, nursing staff and medical staff provided care for all patients.

Patients who had recently suffered either a moderate (GCS 9–12) or severe (GCS 3–8) ABI or a grade 4 or 5 subarachnoid haemorrhage were included in this study. To be eligible, patients had to be younger than 60 years, medically stable (i.e. had been discharged from intensive care) and with no major musculoskeletal disorders (e.g. amputation or fracture) or previous neurological conditions (e.g. stroke or Parkinson's disease) that may impact the quality of movement recovery. Those deemed not medically stable or who were awaiting clipping of an aneurysm were excluded. All patients who consented to be part of the study were video-recorded during a single session with a physiotherapist who scored the patients' performance for each of the ABIPA items.

The second group of participants recruited were physiotherapists, who were eligible to participate if they were working in the acute neurosurgical unit, brain injury rehabilitation unit or rehabilitation unit at the same tertiary referral public facility. Physiotherapists were recruited in two groups as samples of convenience. The first group underwent training on use of the ABIPA to score patient performances prior to viewing and scoring the video-recorded performances of the patients. The second group was provided with the ABIPA scoring guidelines (Appendix 2), prior to viewing and scoring the video-recorded performances. Demographic details of the participating physiotherapists were collected including age, gender, years working as a physiotherapist and time spent working specifically with neurological patients.

Procedure

Production of the ABIPA video-recording package

Video recordings were produced for seven patients with moderate or severe ABI. Patients were assessed by an experienced neurological physiotherapist, using the ABIPA. The ABIPA comprises 15 items including resting position, head and trunk alignment in supine, overall muscle tone in each limb, upper limb and lower limb movement and head and trunk control in sitting (Appendix 1). Each item is scored out of 4, with 0 representing no or poor performance and 4 representing normal or optimal performance, resulting in a maximum score of 60.

The initial video guidelines and the recording procedure were developed and trialled in a pilot study undertaken with physiotherapy students from Bond University. Results of this pilot study revealed that while overall reliability was high (Cronbach's alpha $\alpha = 0.989$), some items performed less strongly. Items showing less reliability were the head and trunk alignment items in sitting and supine ($\alpha = 0.661–0.789$) and the tone assessment items ($\alpha = 0.719–0.880$). The video-recording procedure was adjusted to include longer viewing time of positions, increased viewing angles and identification of markings for the alignment assessments, and the addition of verbal cues to capture the essence of 'muscle tone' components of the ABIPA assessment. These elements are normally evaluated by a physiotherapist using their sense of touch and without the addition of word descriptors; it was hypothesized that physiotherapists viewing the performances found it difficult to score these items based only on visual observation.

Video guidelines were developed to ensure all videos were similar in their assessment procedure, format and sequence of ABIPA items assessed. Video recordings were made of all content items of the ABIPA. The same order of assessment was recorded, and multiple views, for example, from the side and the front, as described in Table 1 were captured during the development of the ABIPA Package.

Using this format, all participating patients were assessed using the ABIPA by the same senior physiotherapist whose usual work setting was the brain injury rehabilitation unit at the facility. Patient assessments were video-recorded, de-identified and randomized, to ensure the performances of patients with varying neuromotor abilities were not sequenced or followed any predetermined pattern.

Reliability testing

To establish inter-tester reliability of the ABIPA, participating physiotherapists viewed and scored the video recording of the ABIPA assessment being carried out with the selected patients. Video recordings were viewed by two groups of physiotherapists recruited sequentially: the first group underwent training prior to viewing and scoring the video assessments, and the second were provided with written ABIPA scoring guidelines to review and score the recorded assessments (Appendix 2).

Table 1. Key positions, movements and views captured with patients participating in the development of the ABIPA.

Resting position of patient lying in bed	*Resting position* of the patient lying in bed was video-recorded from the foot of bed
Head and trunk alignment	Head alignment and trunk alignment were recorded with views of the head and trunk from above and from the side. The therapist was filmed palpating each patient's rib cage with views from the foot of the bed and from the side
Muscle tone in upper and lower limbs	To visualise and interpret *overall muscle tone*, each limb was recorded being moved three times, while the therapist gave a brief 'verbal account'* of their observations
Movement in upper limb and lower limb	*Upper and lower limb movement* was recorded as the therapist asked the patient to move, assessing each limb individually. Camera views captured the assessment from the side with additional zoom for notable movements (flickers of muscle activity)
Examination of head and trunk control in sitting.	The final view captured, the patient in a sitting position with views of the head and trunk from the side, back, and front included to show the degree of support required to maintain this position

*Dialogue was recorded from the assessing physiotherapist to indicate 'overall muscle tone' and 'movement' to maximize authenticity for therapists observing the video-recorded performances.

The first group of participating physiotherapists attended two 1-hour training sessions: an initial instructional session and then a practice session before completing their scoring session within 1 week of being instructed. During the two training sessions, the ABIPA and guidelines were presented and discussed, and then a trial assessment on a selected video-recorded patient assessment was completed. The video recording of the selected patient used in the training process was not included in the actual test session. Physiotherapists were encouraged to seek clarification about any assessment terms, and all questions were answered. Within 1 week of training, participating physiotherapists scored the video-recorded package of ABIPA assessments. The second group of participating physiotherapists were provided with the ABIPA guidelines, but were not provided with any training or coaching prior to viewing and scoring the *package of ABIPA assessments*.

During the test sessions, each group followed the same format with multiple assessors viewing the video recordings simultaneously on a projected screen and scoring the performance of each assessment item using the ABIPA assessment sheet and guidelines (Appendices 1 and 2). At the completion of each video-recorded patient assessment, individual score sheets from each physiotherapist were collected and placed in a sealed envelope for future analysis. Physiotherapists were blinded to each other's scores. This process continued until all video assessments had been reviewed and scored by each physiotherapist.

Intra-tester reliability was examined by repeat screenings of patient video-recorded assessments by available physiotherapists, a minimum of 2 weeks following the initial recording session. Each physiotherapist scored the ABIPA assessment, and the individual score sheets were placed in a sealed envelope for future analyses with the physiotherapists blinded to each other's scores.

Data analysis

All data were analysed using SPSS software v.24 (IBM, Chicago, USA) or GraphPad Software. Descriptive statistics were generated for demographic profiles and characteristics of the two groups of participants. Cronbach's alpha was used to determine consistency of scores between assessors – a measure of inter-rater reliability [13] for each item and for the total ABIPA score. As the ABIPA tool yielded categorical data, Cohen's weighted Kappa (K_w) statistic was selected to determine agreement between categorical scores by the same assessor (intra-tester reliability). Percentage agreement was also calculated for intra-tester reliability with a significance level set at $p < 0.05$.

Results

The characteristics of the participating patients in the video recordings informing the *ABIPA Package* are presented in Table 1. Of the seven participants, five (70%) were men with an average age of 29.0 ± 13.9 years. Over 50% were diagnosed with a diffuse axonal injury, while the next most common diagnosis was subdural haematoma (Table 2).

Table 2. Patient characteristics.

Participant	Age (years)	Gender	GCS (0–15)	Mechanism of injury	Clinical presentation/diagnosis
1	19	Male	3	MVA-single vehicle rollover	Hypoxic brain injury with epidural haematoma and subdural haematoma
2	30	Male	6	Assault	Diffuse axonal injury and subdural haematoma
3	56	Male	3	AVM + Aneurysm	Diffuse axonal injury and subdural haematoma
4	45	Male	10	MVA	Frontal Parietal contusions and subdural haematoma
5	23	Female	4	Fall from 3rd storey balcony	Diffuse axonal injury, subdural/subarachnoid haematoma with petechial intra-parenchymal haemorrhages
6	20	Female	5	Infection	Hypoxic brain injury secondary to endocarditis
7	16	Male	6	MVA	Diffuse axonal injury

AVM, arteriovenous malformation; GCS, Glasgow Coma Scale; MVA, motor vehicle accident.

Table 3. Physiotherapist characteristics.

	Trained physiotherapists		Untrained physiotherapists		
	Inter-tester (n = 23)	Intra-tester (n = 19)	Inter-tester (n = 7)	Intra-tester (n = 7)	All (n = 30)
Gender, males: n (%)	3 (13)	2 (10)	2 (29)	2 (29)	5 (17)
Years registered: mean ± SD	9.3 ± 9.3	9.3 ± 9.3	4.7 ± 4.2	4.7 ± 4.2	8.5 ± 8.5
Years of neurological physiotherapy work: mean ± SD	3.7 ± 5.0	3.9 ± 5.2	1.6 ± 1.6	1.6 ± 1.6	3.2 ± 4.9

Thirty physiotherapists were recruited to the study, with 23 forming the trained group and 7 in the second group using the guidelines to score the video-recorded assessment (untrained). Of these, 26 (19 trained and 7 untrained) participated in the intra-tester reliability study. Physiotherapist characteristics are presented in Table 3.

Inter-tester reliability

Table 4 presents the internal consistency of ABIPA scores for each item based on Cronbach's alpha, where $\alpha \geq 0.9$ is *excellent*, $\alpha = 0.7–0.9$ is *good*, $\alpha = 0.6–0.7$ is *acceptable* and $\alpha \leq 0.6$ is *poor* [13]. Across all physiotherapists (n = 30), inter-tester reliability was excellent ($\alpha = 0.995$) for the total ABIPA score. All individual items, except for trunk alignment in supine, showed excellent or good internal consistency. The movement item showed the highest consistency ($\alpha > 0.994$) for right and left upper and lower limbs for all therapists.

Trained physiotherapists showed good or excellent internal consistency for total ABIPA score and for all individual items except for alignment of the trunk in supine ($\alpha = 0.420$). Similarly, untrained physiotherapists demonstrated good-to-excellent internal consistency on the total ABIPA score and all individual items except for alignment of the trunk in supine ($\alpha = 0.097$) and alignment of the head in supine ($\alpha = 0.600$).

Table 4. Internal consistency (Cronbach's alpha) for individual ABIPA items and total ABIPA score for trained and untrained assessors.

Items	Alpha (all)	Alpha (trained)	Alpha (un-trained)
Alignment head supine	0.88	0.84	0.60
Alignment trunk supine	0.54	0.42	0.09
Tone right upper limb	0.91	0.70	0.95
Tone left upper limb	0.88	0.72	0.82
Tone right lower limb	0.95	0.88	0.93
Tone left upper limb	0.97	0.93	0.93
Movement right upper limb	0.99	0.99	0.98
Movement left upper limb	0.97	0.97	0.93
Movement right lower limb	0.99	0.99	0.98
Movement left lower limb	0.98	0.97	0.98
Control head	0.98	0.99	0.93
Control head	0.99	0.99	0.99
Alignment head sitting	0.96	0.94	0.92
Alignment trunk sitting	0.96	0.96	0.86
Posture	0.97	0.95	0.97
Total	0.99	0.99	0.98

Intra-tester reliability

Table 5 presents the weighted Kappa statistic (K_w) and percentage agreement for trained (n = 19) and untrained (n = 7) physiotherapists. The weighted Kappa statistic yields a quantitative measure of the magnitude of agreement between observers [14] and determines the consistency with which physiotherapists scored the ABIPA items. The weighted Kappa agreement was interpreted as 0.21– 0.40 *fair* agreement, 0.41–0.60 *moderate* agreement, 0.61–0.80 *substantial* agreement and 0.81–0.99 almost *perfect* agreement [14].

When considering all therapists, substantial or perfect agreement was achieved for eight items, with moderate agreement reached for a further four items, leaving three items, 20% of the scale, achieving fair agreement. The items with the lowest agreement were alignment head supine, alignment trunk supine and tone in the left upper limb. The agreement was similar for both the trained and untrained participants.

Discussion

As part of development of a new outcome measure, we investigated the inter- and intra-tester reliability of physiotherapists using the ABIPA. Our findings demonstrated that physiotherapists have a high level of consistency when scoring the video-recorded package of ABIPA assessments. We also demonstrated that independent use of the scoring guidelines without training also achieved a high level of consistency when physiotherapists scored the video-recorded package of ABIPA assessments.

The consistency of scoring between assessors did vary across items, suggesting that some items were more challenging to score than others. High inter-tester and intra-tester reliability was demonstrated across several items including tone right lower limb, movement of the right and left upper and lower limb, control of the head and trunk, and alignment trunk sitting and posture. Items with the lowest inter-tester and intra-tester reliability were the assessment of head and trunk alignment in supine. This might reflect a limitation of two-dimensional video in accurately representing patient position. In fact, previous studies have reported difficulties in visually assessing alignment [15,16] and may suggest that these particular items are better evaluated in a live

Table 5. Weighted Kappa statistic and percentage agreement for individual ABIPA items for physiotherapy assessors.

Variable	Weighted Kappa (all) n = 30	Percentage agreement	Weighted Kappa (trained) n = 19	Percentage agreement	Weighted Kappa (untrained) n = 7	Percentage agreement
Alignment head supine	0.28	41.50	0.36	43.50	0.02	35.70
Alignment trunk supine	0.38	48.10	0.31	46.10	0.48	53.50
Tone right upper limb	0.53	71.70	0.50	73.00	0.61	67.80
Tone left upper limb	0.36	73.50	0.27	73.00	0.53	75.00
Tone right lower limb	0.67	72.60	0.64	73.00	0.72	71.40
Tone left upper limb	0.52	76.40	0.32	78.20	0.66	71.40
Movement right upper limb	0.83	78.30	0.83	79.40	0.84	75.00
Movement left upper limb	0.72	68.80	0.74	70.50	0.63	64.20
Movement right lower limb	0.68	69.70	0.78	74.30	0.81	78.50
Movement left lower limb	0.56	62.20	0.47	60.20	0.70	67.80
Control head	0.72	66.00	0.69	66.60	0.74	64.20
Control trunk	0.88	91.50	0.91	93.50	0.79	85.70
Alignment head sitting	0.55	49.00	0.53	48.70	0.56	50.00
Alignment trunk sitting	0.66	75.40	0.72	79.40	0.46	64.20
Posture	0.72	89.60	0.67	84.80	1.00	1.00

performance assessment or may require visual markers when viewed via video recording. The items assessing alignment require further investigation.

Three items demonstrated high inter-tester reliability n = 30 with $\alpha \geq 0.9$, but with only fair intra-tester reliability $K_w \leq 0.4$. These results are not easily explained. This unexpected finding may be partially due to familiarity with the assessment tool. Experience with the assessment guidelines may have influenced the second viewing with the physiotherapists thinking more about how they were scoring the performance and a higher acceptance of the descriptors used to rate each item, resulting in different scores [17]. Regardless, a similar trend across individual items was observed for both intra-tester and inter-tester reliability. Items of alignment of head and trunk in supine were the worst overall performers, for both inter-tester and intra-tester analysis. Clearly, these items require further investigation for continued inclusion in the ABIPA with a factor or Rasch analysis indicated to guide the revision of item content of the ABIPA [18].

As the ABIPA is a new tool, training was initially provided to the first group of participating physiotherapists. It was anticipated that training may be required to ensure that clinicians were familiar with the concepts and items included in the tool as well as illustrate how the scoring process was to be used. We felt that training would optimize consistency and accuracy of ABIPA scores. However, the participating physiotherapists who did not receive training had comparable inter-tester reliability [17,19]. Although the trained physiotherapists had higher Cronbach's alpha scores than the untrained physiotherapists on 10 of the 15 items, both groups achieved good-to-excellent consistency. The two overall lowest scoring items, head and trunk alignment in supine, also had low levels of agreement across the two groups. When comparing intra-tester reliability for the trained and untrained physiotherapists, it is notable that the untrained physiotherapists recorded higher weighted Kappa scores on 11 ABIPA items, and for six items the difference was large enough to change the level of agreement. Overall though, when both inter- and intra-tester reliability results are considered, training does not appear to be necessary to achieve reliability when using the ABIPA. This suggests that clinicians are able to independently use the ABIPA with guidelines in clinical practice.

Another consideration is the clinical experience of physiotherapists using the ABIPA. Previous studies have found assessment tools reliable across different experience levels [17,20]. However, untrained physiotherapists had less than half the number of years of experience in neurological physiotherapy when compared to the trained physiotherapists in this group. This discrepancy makes it difficult to interpret the reliability findings on the basis of training alone, and other factors such as curriculum content related to preparation of graduate physiotherapists and training in observation of posture and movement may need to be considered.

In order to supplement visual observations, we included verbal cueing in the videos as a surrogate for the therapist's 'kinaesthetic' experience of tone assessment. It is possible that this approach may have influenced the overall reliability score. In fact, the Cronbach's alpha scores (inter-rater reliability) for tone items were amongst the lowest, with scores ranging between 0.881 and 0.970, while reliability for all other items (excluding alignment) was more robust with alpha scores between 0.967 and 0.999. Similarly, Kappa scores (intra-rater reliability) for the same items were also amongst the lowest when comparing all ABIPA items. Interestingly, these values are comparable to those obtained from the initial pilot studies. Although verbal cues were included in the video-recorded performance to improve reliability, our results suggest that the reliability of the items was largely unchanged with the addition of verbal cues. Given this challenge, further investigation, however, is required to determine if these items should remain in the ABIPA.

Limitations

This study has several limitations. First, a small sample size of only seven patient videos after ABI was included, which limited the patient performances scored. As this population is difficult to assess, obtaining suitable patients without complications, who could be consented by next of kin, to participate and tolerate assessments, was challenging. The sample did represent a variety of GCS and functional levels and was representative of the mostly male ABI population. A cross-sample of ages was also represented. The sample of physiotherapists recruited may also have influenced our findings. Fewer untrained physiotherapists were recruited with only seven participating in the reliability analysis. Additionally, physiotherapist's experience may have also influenced the results with a range between 1 and 21 years of experience in neurological physiotherapy. Previous studies have shown that this limitation does not influence results [17,21].

The limitations of two-dimensional video assessment have also been highlighted as a possible contributor to poor inter- and intra-tester reliability for the alignment items [22,23]. There are disadvantages associated with observational assessments, such as the apparent loss of clinical fidelity (i.e. assessors cannot 'feel' the patient's response) [24]. Nonetheless, video-recorded performances have been used to investigate reliability in patients with ABI undergoing rehabilitation [6,25–27], examine reliability of musculoskeletal screening tests [28], facilitate assessments of gait [29,30], assess motor development [23] and evaluate training of undergraduate physiotherapy students [19]. Such video-recorded performances can be viewed by different assessors to establish inter-rater reliability and at a later time interval by the same assessors to determine intra-rater reliability [25]. Considering these limitations of video recordings, an assessment of a live performance may need to be considered despite the challenges that this may involve for people after ABI [5,9,11].

Finally, the current lack of literature supporting the psychometric properties of the ABIPA should be acknowledged. Additional investigations are planned as part of the development of this measure. A factor analysis of the ABIPA is underway to investigate the underlying structure and strength of the ABIPA items, determine the potential for item rationalisation and demonstrate if a reduction in the number of items influences the utility of the tool [31]. Specifically, it will be

important to examine each subscale item of the ABIPA for any relationship, explore the dimensionality or number of factors underpinning the overall assessment and examine the relative contribution of each chosen item.

Conclusion

The complexity of the neuromotor deficits experienced by those surviving ABI has stimulated multiple efforts within the physiotherapy discipline to develop more precise tools to monitor progress and outcomes in the early stages of recovery after ABI. A measure with sound psychometric properties is indispensable for use in clinical practice and research. The ABIPA has shown a high level of inter-tester reliability for the majority of items, but requires further investigation of specific items to address the issues identified in relation to the intra-tester reliability.

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Declaration of interest

The authors report no conflicts of interest.

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Appendix 1. Description and scoring of the ABIPA

ABIPA item	0	1	2	3	4	Score	Item Total
Movement 1. UL R) and L) 2. LL R) and L)	No active movement	Moves in mass patterns or reflexive movement	Some movement or flickers	Active movement through ≥ 1/4 ROM	Normal movement, but may be weak or agitated	R) UL /4 LL /4 L) UL /4 LL /4	/16
Muscle tone 1. UL R) and L) 2. LL R) and L)	Rigid in flexion or extension, or limb is flaccid	Difficulty with passive movement, PROM reduced	More marked increase in muscle tone through ROM, full PROM available	Slight increase, catches or minimal resistance, induding patient resisting	Normal muscle tone	R) UL /4 LL /4 L) UL /4 LL /4	/16
Head and trunk alignment (1) Supine (2) Sitting	Patient is fixed in a position, or alignment is unable to be assessed	Alignment is lost in all three planes, sagittal, coronal and transverse	Alignment is lost in any two planes	Alignment is lost in one plane	Alignment in all three planes is in the midline position	Supine, head /4 Supine, trunk /4 Sitting, head /4 Sitting, trunk /4	/16
Control 1.Head 2. Trunk	Unable to hold position, no active involvement, patient completely dependent	Able to hold any position for 1 second	Able to hold any position for 5 seconds	Able to hold in any position 10 seconds	Able to hold in midline 10 seconds	Control, head /4 Control, trunk /4	/8
Overall presentation	Bilateral hemiparesis +/– spasticity – all four limbs involved	Hemiplegia – one side of body affected, no movement present, may have spastic or flaccid limbs	Hemiparesis – weakness of one side of body	Monoplegia – no or abnormal movement in one limb, may be spastic or flaccid	Monoparesis – weakness in one limb		/4
						ABIPA TOTAL	**/60**

Appendix 2. Guidelines

The ABIPA is designed for patients in the acute phase after a severe brain injury. It is a global assessment based on observation, which considers overall patterns. The scale can be used with patients who are unable to follow commands or have cognitive deficits.

1. Alignment in supine

The resting alignment of the patient's head and trunk is observed from the bedside. The patient is then placed in a midline position with a single pillow and allowed to settle before assessing alignment which is graded for obvious deviations from midline. Trunk alignment observations are confirmed by palpation.

4. Aligned in all three planes, midline position
3. Alignment is lost in one plane, sagittal, coronal or transverse
2. Alignment is lost in any two planes
1. Alignment is lost in all three planes
0. Patient is fixed in a position, or alignment is unable to be assessed (for example, due to medical equipment, positioning and orthopaedic injuries)

2. General tone

This subscale is based on the Modified Ashworth scale and considers only the presence or absence of tone and not its source. Joints are moved through passive range of motion three times then graded on the worst score (for repetition of PROM, or joint).

4. Normal muscle tone
3. Slight increase, catches or minimal resistance, including patient resisting
2. More marked increase in muscle tone through ROM, full PROM available
1. Difficulty with passive movement due to tone, PROM reduced
0. Rigid in flexion or extension, or limb is flaccid.

3. Movement scale

This subscale looks for active movement, whether normal and selective or pathologic. All four limbs are assessed individually by:

Looking: Patient is observed for any spontaneous movement including reflexive, patterned or selective movement.

Asking: Patient is asked to move the limb in any way possible.

Positioning: Place the patient's limb in a mid range position and note any muscle activity or holding ability.

Feeling: Move the limb through range noting any active involvement.

4. Movement appears normal, but may be weak or agitated.
3. Some active movement felt, anywhere in ROM for ≥ ¼ ROM
2. Some active movement evident or flickers at any point in range
1. Movement in mass patterns of flexion or extension, or reflexive movement
0. No active movement

4. Control scale

The control subscale requires the patient to be sitting on a firm surface with feet supported. The ability to hold or maintain this position with normal or abnormal muscle activity is assessed and timed using a stopwatch. For head control, the trunk should be fully supported midline.

4. Able to hold in midline 10 seconds
3. Able to hold in any position 10 seconds
2. Able to hold any position for 5 seconds
1. Able to hold any position for 1 second
0. Unable to hold position, no active involvement, patient completely dependent and falls unless supported

Note: Score head and trunk = 0: if for any reason the patient is unable to achieve sitting, for example, medical limitations, safety or concomitant injuries.

5. Alignment in sitting

Alignment in sitting is rated using the same scale as alignment in supine. The patient should be sitting on a firm surface with feet supported. For head alignment, have the trunk fully supported in midline, take the head to midline and release as able. For patients constantly moving, repeat three times and rate on the worst alignment.

Score head and trunk = 0: if for any reason the patient is unable to achieve sitting, for example medical limitations, safety or concomitant injuries

Score head = 0: if patient does not have any head control (as per control scale)

Score trunk =0: if patient requires maximum assistance to maintain sitting

6. Posture

Overall posture is rated based on the completed assessment of tone, movement, alignment and control.

4. Monoparesis – weakness in one limb
3. Monoplegia – no or abnormal movement in one limb, may be spastic or flaccid
2. Hemiparesis – weakness of one side of body
1. Hemiplegia – one side of body affected, no movement present in one side, may have spastic or flaccid limbs
0. Bilateral hemiparesis +/– spasticity – all four limbs involved

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Appendix 7 – Study 3

Running head: Acute Brain Injury Physiotherapy Assessment

Title: **Strength and characteristics of the items of the Acute Brain Injury Physiotherapy Assessment (ABIPA) in people with an acquired brain injury: A factor analysis.**

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Abstract

Objective: To investigate the underlying factor structure of the Acute Brain Injury Physiotherapy Assessment

Design: Exploratory factor analysis (EFA) with principal axis factor extraction and varimax rotation.

Setting: Acute Neurosciences ward and Brain Injury Rehabilitation Unit.

Participants: Adults diagnosed with moderate (GCS 9-15) or severe (GCS 3-8) brain injury, with assessments collated between 2005 and 2009.

Main outcome measure: Acute Brain Injury Physiotherapy assessment (ABIPA)

Results: Exploratory factor analysis suggested a four-factor solution with a simple structure (factor loadings ≥.30) that explained 69.6% of total variance. Factor one accounted for 36.6% of the variance while factor two explained 15.8%, factor three 9.6% and factor four accounted for 7.5%. Two items were identified with the lowest loading with the four-factor solution, *Alignment of the head in supine* loading to factor three at 0.358 and *alignment of the trunk in supine* loading to factor two at 0.405.

Conclusions: Exploratory factor analysis indicates that a four-factor model provides the best fit for ABIPA items**.** Two items, *alignment of the head in supine* and *alignment of the trunk in supine* were the lowest loading items and should be further investigated.

Key words: Assessment; Outcome measures; Physiotherapy; Rehabilitation; Severe Brain Injury

Introduction

For those requiring rehabilitation after acquired brain injury (ABI), outcome measures are needed to assess the effectiveness of therapeutic interventions, monitor the achievement of goals, adjust individual rehabilitation programmes, and compare the performance of individual units (New Zealand Guidelines Group, 2007; Teasell et al., 2007; G. A. Zitnay et al., 2008). Research has shown support for early physiotherapy intervention, with rehabilitation that begins in the acute phase improving the functional outcome of people with severe ABI (Andelic et al., 2012). There is limited research however, regarding outcome measures able to capture the early stages of recovery following severe ABI (Canedo et al., 2002; Shukla et al., 2011; G. Teasdale & B. Jennet, 1974; Wright et al., 2000). The available measures typically used by physiotherapists in this early stage of recovery following ABI evaluate functional limitations, consciousness, behaviour, cognitive function and social participation (Wright et al., 2000). Few, if any measures, are suitable for monitoring incremental changes in the specific neuro-motor problems of muscle tone, movement, head and trunk alignment, sitting balance and posture (Canedo et al., 2002; O'Dell et al., 1996; Pape et al., 2006; G. Teasdale & B. Jennet, 1974).

Our research group has developed an assessment tool designed to measure early neuro-motor recovery in people with moderate to severe ABI – the Acute Brain Injury Physiotherapy Assessment (ABIPA) (J. Gesch et al., 2014). The ABIPA is a 15-item outcome measurement tool with five subscales; movement, muscle tone, head and trunk alignment in both supine and sitting, and overall position (J. Gesch et al., 2014). Each item is scored using a 5-point (0 – 4) scale, with higher scores indicating more independent movement.

Prior investigations have demonstrated concurrent validity of the ABIPA with relevant assessments of neuro-motor performance and consciousness as well as being responsive to change over a 7-day period (J. Gesch et al., 2014). Additionally, inter-tester reliability of the ABIPA was excellent and intra-tester reliability varied from substantial to fair agreement(J. M. Gesch et al., 2017). As part of

the ongoing development of the new assessment scale further investigation is warranted to examine other psychometric properties that would justify the inclusion or exclusion of ABIPA items.

A factor analysis was chosen to reveal the underlying structure and strength of the ABIPA items, determine the potential for item rationalization and suggest if simplification or reduction of the number of items influences the information communicated when using the ABIPA. Furthermore, a factor analysis would identify the expected connections between items (Hurley et al., 1997). It is assumed that similar items would correlate to some degree (Ho, 2006) with those items loading on one factor. For example, four ABIPA items relate to tone measurement. It is reasonable to suggest that these items would be highly associated. The role of factor analysis, therefore, is to highlight the relationship between items, report them as independent factors (Ho, 2006), and potentially create a smaller number of items.

Thus, the aim of this analysis was to examine the factor structure of the ABIPA in a sample of people with ABI and to establish how many factors are needed to explain the pattern of relationships among the ABIPA items. We will examine each item of the ABIPA for any relationship and thereby establish unique variance or agreement of items onto a single factor. We will then explore the dimensionality or number of factors underpinning the overall assessment and examine the relative contribution of each factor and the chosen items they represent, to the overall assessment.

Method

Study Design

A secondary analysis was performed on previously collected ABIPA assessments (J. Gesch et al., 2014; J. M. Gesch et al., 2017). The assessments were examined using an exploratory maximum likelihood factor analysis. Factor loadings were considered if greater than 0.3 and initial factors extracted. The factors identified were then examined to see how they corresponded to the ABIPA items initially chosen.

Participants

Psychometric characteristics of the ABIPA were analysed from a cohort of patients, with assessments collected between 2005 and 2009 and reported in previous studies (J. Gesch et al., 2014; J. M. Gesch et al., 2017). In brief, participants were included with moderate (GCS 9-15) or severe (GCS 3-8) brain injury admitted to either the Acute Neurosurgical ward (36 beds) or the Brain Injury Rehabilitation Unit (BIRU) (26 beds) of a tertiary (large metropolitan) public hospital in Brisbane, Queensland, Australia. To be eligible, patients needed to be medically stable (i.e. had been discharged from intensive care) and be between 16 and 60 years of age. Patients were excluded if they had major musculoskeletal disorders that may impact on movement return (e.g. amputation or fracture) or if there were any residual deficits from previous neurological insult or conditions (e.g. previous stroke or Parkinson disease). Patients with subarachnoid haemorrhage who were awaiting clipping of an aneurysm or those not deemed medically stable were also excluded.

Ethical clearance was obtained from two institutional human ethics committees and the study was supported by the Medical Director of the neurosurgical unit. Informed consent was obtained from the next of kin or legal guardian as required.

Analysis

The 15-item ABIPA was examined by means of factor analysis including maximum likelihood extraction using SPSS Software v 23 (IBM, Chicago, USA) to establish a correlation matrix. The Kaiser-Meyer-Olkin (KMO) measure of sampling adequacy tested whether the correlations among the items were small and Bartlett's test of sphericity was interpreted to assess if the correlation matrix was an identity matrix, and therefore the factor model was appropriate (Ho, 2006). To ensure internal consistency of component scales, 0.30 or higher was selected as the criterion of significance for the factor loading, with loading of items below this level not included in the analysis (Tabachnick, 2014). Following a principal axis factor extraction, the matrix was rotated to obtain independent factors (varimax rotation). Clearly defined and interpretable factors were then identified. The amount of variance represented by a factor is explained by an eigenvalue, with an eigenvalue of 1 representing

the variance captured by a single item. The plotting of these values onto a scree plot was used to identify the optimum number of factors to be extracted before the unique variance began to dominate the common variance structure (Tabachnick, 2014) and allowed a secondary method to determine the number of factors to retain. We extracted the factors that explained the greatest percentage of variance. A secondary analysis was performed to examine if a reduced number of factors could explain a similar variance percentage. Variance and factorial structure was then examined with reference to the patients' clinical picture and ABIPA items, and further refinement of ABIPA items considered.

Results

A total of 155 assessments were included in the factor analysis with varimax rotation of the 15 items of the ABIPA. Assessments were only included if all items were present and had been scored using the ABIPA scale (J. Gesch et al., 2014; J. M. Gesch et al., 2017). An examination of the KMO measure of sampling adequacy suggested that the sample was factorable (KMO = 0.799).

Exploratory Factor Analysis

Table 1 represents the results of an orthogonal rotation with maximum likelihood extraction. When loadings less than 0.30 were excluded, the analysis yielded a four-factor solution with a simple structure that explained 69.6% of the total variance. Examination of the Scree plot also supported a four- factor model as being sufficient to represent the data set.

Table 1: Factor Loading by Rotated Factor Matrix

ABIPA items	Factor			
	1	2	3	4
Alignment head supine	.188	.178	***.358***	.139
Alignment trunk supine	-.072	***.405***	.199	.055
Tone R) upper limb	.144	***.598***	.031	.381
Tone L) upper limb	.086	***.614***	.273	-.045
Tone R) lower limb	.218	***.735***	.024	.078
Tone L) lower limb	.047	***.781***	.161	-.130
Movement R) upper limb	.407	-.044	.228	***.853***
Movement L) upper limb	.235	.206	***.606***	.145
Movement R) lower limb	.424	.160	.318	***.741***
Movement L) lower limb	.158	.227	***.952***	.129
Control head	***.663***	-.074	.174	.361
Control trunk	***.726***	.094	.409	.119
Alignment head sitting	***.542***	.037	-.041	.296
Alignment trunk sitting	***.767***	.135	.184	.097
Posture	***.608***	.359	.235	.168

Extraction method: Maximum likelihood. Rotation method: Varimax with Kaiser/normalization.

Five items loaded onto factor one and included items relating to head and trunk alignment and control in the sitting position. This factor was labelled, “alignment and posture”. Five items loaded onto a second factor related to tone in the upper and lower limb. This factor was labelled “tone”. Three items loaded onto factor three and two items loaded onto factor four with the movement items relating to the left and right limbs splitting across two factors – factor three loaded for left side movement and factor four loaded for right side movement.

The identified four factors accounted for 69.6% of the total variance. Factor one accounts for 36.6% of the variance, factor two explains 15.8%, factor three 9.6% and factor four accounts for 7.5%. The fifth factor recorded a Eigenvalue of only 0.97 and was below the accepted value of 1 representing unique variance and was therefore no further factors were include. To test if all four factors were required a secondary analysis was performed. It was proposed that the items associated with the fourth factor and the lowest loaded factor be removed. Factor three and factor four both represented the items of movement and it was hypothesised that potentially reducing them to one factor would not change the overall variance represented by the assessment tool. By removing the right upper limb and right lower limb movement items to restrict the analysis to three factors, only 50% of the variance could be accounted for. Table 2 illustrates the restricted (three factor) rotated factor matrix analysis.

Table 2: Rotated Factor Matrix with restricted analysis

	Factor		
	1	2	3
Alignment head supine	.142	***.243***	.242
Alignment trunk supine	-.079	***.417***	.133
Tone R) upper limb	.341	***.575***	.088
Tone L) upper limb	.099	***.655***	.003
Tone R) lower limb	.455	***.655***	-.022
Tone L) lower limb	.089	***.730***	-.196
Movement R) upper limb	***.310***	.237	.249
Movement L) upper limb	***.487***	.190	.125
Movement R) lower limb	.387	-.158	***.774***
Movement L) lower limb	***.993***	-.038	.098
Control head	.121	.031	***.829***
Control trunk	***.675***	.072	.341
Alignment Head sitting	***.546***	.388	.278

Extraction Method: Maximum Likelihood.

Rotation Method: Varimax with Kaiser Normalization.

Discussion

As part of measurement development and to further examine the psychometric properties of the ABIPA, a factor analysis was undertaken to reveal the underlying structure and strength of ABIPA items. The analysis suggested a four-factor solution with a simple structure (factor loadings ≥.30) that explained 69.6% of total variance. When the analysis was restricted to three factors, only 50% of the variance could be explained.

The four factors initially extracted were “alignment and posture”, “tone”, “left sided movement “and “right sided movement”. The first factor “alignment and posture” included the items of control of head and trunk, alignment of head and trunk in sitting and posture. These items have previously been identified as important items for inclusion when assessing neuro-motor recovery (Pilon et al., 1995). It seems reasonable to group these items in a single category in that all are assessing the position of the body in space.

The second factor “tone” grouped the items of muscle tone in upper and lower limbs and alignment of the trunk in supine. Tone or spasticity is defined as an increase in the velocity- dependent stiffness of a muscle (Lance, 1976) and collectively refers to a host of motor over activity syndromes stemming from upper motor neuron damage (Crooks et al., 2007). Some therapists hold the view that altered muscle tone underlies or accentuates other motor impairments (Anderson et al., 2011; Bobath, 1990), while those with more severe brain injuries tend to develop earlier and more aggressive forms of altered tone(Marshall et al., 2007; R. D. O. Zafonte, E. P. M. D. Elovic, & L. M. D. Lombard, 2004). The literature also supports muscle tone as an important item in the evaluation process of ABI recovery (Charness, 1986; Duncan, 1990; Laxe et al., 2012; Mittrach et al., 2008; B. R. Swaine, S. J.

Sullivan, & D. Sicotte, 1994) and therefore this factor could be anticipated as one of the underlying factors for inclusion in an assessment of neuro-motor recovery post moderate to severe ABI.

The inclusion of alignment of the trunk in supine in factor two is not, however, as easily understood, especially considering that alignment of the head in supine, loads onto factor three. As with the alignment items of head and trunk in sitting (factor one), one might expect that the alignment items of head and trunk in supine would load to the same factor; although it is not uncommon for factor analysis models to include factors with occasional unusual item loadings (Barth & Martin, 2005).

Another consideration could be made on the strength at which an item loads to a particular factor. Alignment of the head in supine loads to factor three at 0.358 and alignment of the trunk in supine loads to factor two at 0.405. Both are above the 0.30 criterion for load strength (Tabachnick, 2014), but perhaps identify that the alignment items in supine are poorly associated to one particular factor. Previously studies have also reported difficulties in assessing alignment (Fedorak et al., 2003). In particular, assessing alignment in a patient group that may be agitated and restless and whose language, cognition or behaviour may influence the assessment of alignment may offer some explanation as to the difficulty associated with assessing alignment and therefore where that item may load. This difficulty with loading is also illustrated when looking at the items related to movement. The items for left side movement loaded to factor three, while the items for right side movement loaded to factor four. In people with moderate or severe ABI active or spontaneous movement is not always present or the movement observed may not be purposeful or functional (Greenwald et al., 2015; Turner-Stokes et al., 2005) but it would be reasonable to expect that all movement items would load to the same factor. The differential factor loading between sides may have occurred due to the presentation of the people assessed. People following brain injury may have weakness in only one side, weakness in only one limb, or a combination of weakness in all limbs(AIHW, 2007; G. Teasdale & B. Jennet, 1974). When trying to assess the different movement recovery patterns observed in people with brain injury, this result suggests that loading on to different factors may be the best way to account for all possible presentations. When considering the implications for clinical use,

representation of both left and right side is an important consideration when measuring outcomes in this patient group.

These factor discrepancies suggested further examination of the factor structure. The reduction in factors however, to a three-factor model, explained only 50% of the variance, suggesting that the four-factor solution was a better representation of the structure underlying the ABIPA items. There are no universal guidelines for the threshold of variance, but it is generally accepted practice to extract those factors that account for the highest percentage of variance until the factor only accounts for a small proportion of the variance (i.e. less than 5 per cent). When there is uncertainty about the number of factors to retain, authors are recommended to retain too many rather than too few (Gorsuch, 1983). Therefore, any further investigation of the ABIPA will focus on the four-factor solution.

Limitations

A potential limitation of this study was the sample size. People with an ABI often have behaviour or cognition deficits which will exclude them from participating and can make recruiting to formal studies difficult. Our analysis with the Kaiser-Meyer-Olkin (KMO) measure of sampling adequacy, showed that the sample was able to be analysed into factors. We could have strengthened this analyses of sample size by commenting on the ratio of participants to variables, with a ratio of 5;1 accepted in other manuscripts (Norris & Lecavalier, 2010). When comparing the number of participants (155) to the number of variables (15) a ratio of 10:1 supports the assumption from the KMO analysis that the sample size is adequate for this analysis.

We also could have more clearly identified the factor retention criteria at the beginning of this analysis. The minimum level to be reached for an item to be included in a factor was identified at 0.30, but no minimum number of items to load onto one factor was established (Hayton et al., 2004). Previous studies have also suggested the use of parallel analysis, to determine the number of factors to retain(Hayton et al., 2004). If the retention method was pre-established this would have allowed us to be more transparent with the choice of factors and strengthened the reasoning behind our decision to retain the four-factor solution. The representation of the rotated factor matrix, the analysis of both

three and four factor structure, Scree plot, Eigenvalue analysis and clinical significance does however support the result of retaining the four-factor solution.

Conclusion

As part of our ongoing refinement of a new assessment tool we have further examined the psychometric properties underlying ABIPA item selection. Exploratory factor analysis showed that the ABIPA items loaded onto four factors (factor loadings ≥.30) explaining 69.6% of total variance. The four factors of - “alignment and posture”, “tone”, “left movement” and “right movement” best represent the pattern of relationships among the ABIPA items. Further work to examine the predictive capacity of the ABIPA will help determine if all items continue to be included in the overall structure of the ABIPA assessment.

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